Independent Assessment of FDA Device Review Process Management

Evaluations and Studies of Premarket Device Reviews under Medical Device User Fee Amendments (MDUFA) II/III for the Food and Drug Administration, Contract Number: HHSF223201010017B, Order No. 22313004

Deliverable 10: Final Report on Findings and Recommendations

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1.1. Introduction

Under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the Food and Drug Administration (FDA) was granted the authority to collect user fees from medical device manufacturers to support FDA activities aimed at expediting the availability of innovative new products. On July 9, 2012, Congress enacted the Medical Device User Fee Amendments of 2012 (MDUFA III) as part of Public Law 112-144, also known as the Food and Drug Administration Safety and Innovation Act (FDASIA), reauthorizing the FDA to collect user fees from medical device manufacturers. As part of its agreement with industry, the Agency committed to meet certain performance goals aimed at increasing the speed and efficiency of its premarket review programs and expediting the approval of safe and effective medical devices to market. To that end, FDA published the MDUFA III Commitment Letter, which outlines planned measures designed to increase the predictability and efficiency of the device review process.

Pursuant to the Performance Goals and Procedures adopted under MDUFA III, the FDA and the medical device industry agreed to an independent, comprehensive assessment of the medical device submission review process. The assessment would be performed in two phases and consist of a technical analysis, a management assessment, and overall program evaluation. This first phase involves the assessment of the medical device submission review processes, FDA management systems, IT infrastructure, workload management tools, reviewer training programs, and staff turnover. The second phase of the assessment would entail an evaluation of the progress made by FDA to implement recommendations resulting from the first phase of the assessment. The MDUFA III Commitment Letter specified that the first phase of the evaluation would provide findings on a set of priority recommendations (i.e., those likely to have a significant impact on review times) within six months of contract award, and final recommendations for the full evaluation within one year. On December 11, 2013, the FDA published four priority recommendations developed by Booz Allen for addressing key areas of concern identified by industry and FDA, which were intended to resolve issues that would otherwise impede the success of the MDUFA III review processes going forward.

This final report summarizes the methodologies, findings, and recommendations supporting Booz Allen's system-based approach in assessing whether FDA has the processes, practices, and resources in place to successfully meet MDUFA III requirements and improve the efficiency and review times for the medical device submission review process.

1.2. Study Overview

The key objectives of this task were to develop a set of recommendations with the potential to have a significant impact on MDUFA III review times for FDA to implement as resources permit. To achieve this objective, this assessment consisted of the following activities:

- Identify issues contributing to longer total time to decision (TTD) and determine whether these issues were effectively addressed by implementation of new MDUFA III processes
- Determine the extent to which quality management (QM) components were implemented in the design of major new MDUFA III processes

- Evaluate implementation of major new MDUFA III processes and their impact on submission outcomes
- Assess the quality and effectiveness of Center for Devices and Radiological Health (CDRH) reviewer training programs, including current policies and procedures, to ensure staff has the necessary skills to perform efficient and timely reviews
- Identify best practices to enhance employee retention and minimize staff turnover
- Assess whether IT systems and workload management tools effectively support a timely and efficient review process.

Booz Allen first identified and analyzed Medical Device User Fee Amendments 2007 (MDUFA II) review process issues through a review of external and internal documents and interviews to assess whether issues were addressed through FDA implementation of new MDUFA III processes or systems, or whether alternative steps were taken by FDA to address the issues. In our assessment of FDA management systems, we held interviews with FDA staff to evaluate the design of the MDUFA III review processes, using high-level industry-recognized quality management principles found in International Organization Standard for Quality Management Systems (ISO 9001:2008), FDA Staff Manual Guide (SMG) 2020, and the newly-created CDRH Quality Management Framework. For our assessment, we adapted and qualitatively evaluated only those components we determined as being meaningful to CDRH's premarket submission review process.

A hypothesis-driven approach was used to evaluate the impact of MDUFA III processes on review outcomes, with an emphasis on minimizing review times while promoting consistency, transparency and predictability. To perform this assessment, Booz Allen gathered and analyzed data from submissions received during the MDUFA III calendar year 2013 (M3 Received Cohort). To analyze review times between MDUFA III and MDUFA II processes, submissions received during fiscal year 2012 (M2 Received Cohort) were also analyzed. In addition, to assess the impact of specific MDUFA III process improvements, a smaller cohort of submissions (M3 Study Cohort) was also evaluated, which included 37 Premarket Notifications (510(k)s and 28 Premarket Applications (PMAs). We also performed a series of case studies on topic areas of particular concern to industry and FDA stakeholders to supplement our cohort analysis. Booz Allen conducted interviews and focus groups with CDRH management and a staff survey to understand the impact of these challenges on the review process.

In addition, the CDRH IT systems and reviewer training programs were characterized and assessed for gaps in efficiency and best practices. Our evaluation focused on five primary systems that support MDUFA III: CDRH Center Tracking System (CTS), Image2000+, DocMan, Center Ad Hoc Reporting System (CARS), and eCopy. In addition to hands-on use of these systems and review of system specific guides (i.e., Quick Guides, Cheat Sheets, Reference Guides), we conducted focus groups and interviews, and performed two surveys to gain insight into user experience and ascertain challenges with data system use.

Booz Allen also characterized the four CDRH training programs that were most pertinent to MDUFA III: Reviewer Certification Program (RCP), Leadership Enhancement and Development Program (LEAD), Experiential Learning Program (ELP), and Specialized Training Program (or Ad Hoc). We evaluated these programs against the industry standard for training evaluation (Kirkpatrick Model), training programs at the U.S. Patent and Trademark Office (USPTO), FDA's

Center for Drug Evaluation and Research (CDER), as well as industry best practices. Training modules provided during MDUFA III implementation, and later incorporated into RCP, were also evaluated to determine whether key process elements were built into training content.

1.3. Issues Analysis

Booz Allen identified and analyzed review process issues from the MDUFA II timeframe to assess whether FDA had taken steps to address the issues identified as either a MDUFA III provision (e.g., implementation of RTA process), FDA provision (e.g., development of guidance documents), other steps taken, or a potential gap. Issues identified from the MDUFA II timeframe were consolidated and yielded a list of 31 unique issues, which were organized into six categories: submission quality, communication between Sponsors and FDA, review tools, review decision-making, management oversight, and workload. Booz Allen's preliminary assessment revealed that FDA appeared to have taken steps in addressing 21 of the 31 issues identified, either through the development and implementation of new MDUFA III provisions, updated systems, processes for review staff, and/or guidance for industry. For each of the remaining 10 issues, FDA provided validation and documentation on actions taken. Booz Allen determined that 9 of the 10 remaining issues were addressed. One outstanding issue was identified as an opportunity for improvement and resulted in a priority recommendation: FDA lacked sufficient tools and metrics to assess the consistency of decision making across the premarket review program. Actions taken to address this issue could positively impact review times and help address industry needs for a more consistent review process.

1.4. Quality Management Assessment

Booz Allen performed a quality management (QM) assessment to evaluate the design of major new MDUFA III processes and systems for their potential to address the identified issues and for consistency with QM principles. We employed a quality assessment framework drawn from established quality management principles, consisting of five components, including: senior management oversight; resource management; lifecycle management via document management; lifecycle management through corrective and preventive actions (CAPA) and continuous process improvement; and system evaluation. Each component was assessed to examine the degree to which quality was incorporated in the development and implementation of MDUFA III processes and infrastructure.

Senior Management

We determined whether senior management had a mechanism to provide oversight of new process development, prioritization of quality activities, and analysis of quality data. Representatives from all levels of management participated to determine how each new MDUFA III process would be operationalized and assessed. Senior management monitors the implementation of the processes and reviews new issues as they arise through existing mechanisms. Each level of management from the Branch to the Center is accountable to ensure successful process implementation and to raise and resolve issues. However, this feedback loop is not formally documented, which can result in missed opportunities and ambiguity among different management levels to assume all of the necessary steps to see through all issues to resolution.

Resource Management

For the resource management component, we assessed the extent to which review staff has resources available to ensure an adequate understanding of how to execute new business processes and quality activities. However, reviewer workload was not evaluated in this assessment. A variety of informal and formal methods are available to help staff understand new and existing review practices, including weekly senior staff meetings among Division and Office level managers, premarket rounds to educate staff on the practical implications of program changes, and new reviewer training. However, most of the available methods rely on the initiative of review staff to participate and learn about review processes. Specifically, FDA does not deploy surveys or use metrics or other evaluative methods to assess whether staff has adequately understood programmatic changes.

Lifecycle Management: Document Management

We investigated the various document control IT systems (i.e., CTS, DocMan, Image2000+) for quality in process design, and found that CDRH employs various mechanisms for introducing quality into its document control and document management processes, such as methods to store submission review templates, reference guides, and collaborative review materials. Access controls are in place, and there are mechanisms to notify staff of document updates. However, management interviews confirmed that inconsistencies within document control elements detract from review performance. For example, staff does not consistently follow intended document management practices, which results in errors and inefficiencies when performing document searches.

Lifecycle Management: CAPA and CPI

The Office of Device Evaluation (ODE) has implemented a CAPA database and periodic CAPA meetings to track and resolve issues that impact multiple Divisions, such as updating guidance, resolving appeals, or developing SOPs to clarify submission review milestones. Office of In Vitro Diagnostics and Radiological Health (OIR) management holds regular meetings to resolve issues and coordinate with ODE as relevant; however, OIR does not have a CAPA database to track issues. ODE and OIR staff may raise non-CAPA (i.e. Division-specific) issues, but currently have no formal method to log, track, or prioritize non-CAPA issues, record issue resolution, or communicate feedback. Similarly, staff may originate areas for improvement on an ad hoc basis, however standard methods across both offices do not exist to log, review, and close out suggestions for process improvement.

System Evaluation

CDRH senior management diligently monitors and reports on submission status, and relies heavily on MDUFA goal milestones for evaluating progress and success. CDRH also performs periodic *ad hoc* audits on certain processes (e.g., RTA audit), as well as annual audits to ensure administrative compliance (e.g., 510(k) program). Review staff has noticed that for several submissions that did not meet their MDUFA goal dates, milestones were missed earlier in the process. As a result, staff now pays more attention to these indicators and sends reminders to Lead Reviewers of upcoming due dates based on CARS or CTS workload reports. While this mechanism may work to identify some submissions at risk for longer review times, more granular internal metrics are not currently used to ensure the quality and effectiveness of sub-processes (e.g., RTA or IR) within the larger submission review process.

1.5. Review Process Analysis

Analysis of Traditional 510(k) Submissions

MDUFA III implementation introduced several new processes to improve the efficiency and timeliness of reviews for 510(k) submissions, including Refuse to Accept (RTA), Substantive Interaction (SI) and MDUFA Interactive Review (IR). Booz Allen assessed each of these processes in addition to other integral processes such as communication practices and consult reviews to assess their impact on overall review time and identify potential opportunities for improvement. Key observations and findings are summarized by specific review processes below.

Total Time to Decision (TTD) and Total Submission Time (TST)

Overall review times of Traditional 510(k) submissions were analyzed using two key metrics in our analysis: Total Time to Decision (TTD) and Total Submission Time (TST). TTD is an established measure used by FDA and industry to assess MDUFA III review times, and reflects the time from when the review clock begins for an accepted submission to final decision.[1] In comparison, TST includes the days prior to acceptance from when the submission was first received by CDRH to the final decision.[2]Analysis of Traditional 510(k) submissions within the MDUFA II (M2) and MDUFA III (M3) Received Cohort revealed that TTD decreased from M2 to M3 Received Cohorts from 127 days to 115 days, respectively. This decrease in TTD was driven mostly by a decrease in Manufacturer (MFR) Days. Furthermore, we observed that submissions from the Office of Device Evaluation (ODE) tended to have longer TTD than submissions from the Office of In Vitro Diagnostics and Radiological Health (OIR) and this observation was consistent in both the M2 and M3 Received Cohorts. In contrast, TST increased from M2 to M3 Received Cohorts from 127 days to 137 days. In spite of this overall decrease, ODE showed an increase in TST while OIR showed a decrease. This difference in TST is primarily due to increased Manufacturer Days prior to acceptance in submissions from ODE.

RTA Analysis

Within the M3 Received Cohort, more than 50% of Traditional 510(k) submissions were rejected within the first RTA cycle. The average number of RTA cycles for Traditional 510(k) submissions within the M3 Received Cohort was 1.6, with submissions from ODE having on average more RTA cycles (1.7) than did submissions from OIR (1.2). We also observed that submissions with a greater number of RTA cycles were associated with longer TTD and TST. Deeper analysis of Traditional 510(k) submissions within the M3 Study Cohort revealed that more than 80% of submissions contained at least one missing or deficient element within the Administrative category of the RTA checklist. The specific elements within the RTA checklist that were most frequently identified as missing or deficient were the 510(k) summary, identification of prior submissions and inclusion of Standards Data Reports.

Substantive Interaction Analysis

A majority of submissions (61%) within the M3 Received Cohort received an Additional Information (AI) Request or Telephone Hold (TH) as an SI, while 20% received a Proceed

[1] The review clock begins on the date of receipt of the submission that enables the submission to be accepted.
[2] Days prior to acceptance includes the time for RTA review, which would include any industry and FDA time for which a submission has been rejected. Booz Allen analyzed TST to assess FDA and sponsor days spent on submission reviews; however, TST is not a measure used by FDA or industry to assess review time as part of its MDUFA III negotiated agreements.

Interactively (PI) decision and 19% received a Substantially Equivalent (SE) decision. As expected, putting a submission on hold as a result of an AI or TH was associated with longer TTD. Analysis of SI issues/deficiencies within the M3 Study Cohort revealed that the number of SI issues identified in a submission positively correlated with length of TTD. We also observed that, on average, submissions from ODE had more SI issues (8.8) than those from OIR (6.2). Among the submissions that received an AI or TH decision in the M3 Study Cohort, 70% (14 of 20) of submissions from ODE had Labeling and Device Description issues, while 100% (7 of 7) of submissions from OIR had deficiencies in Performance Characteristics.

MDUFA Decision Analysis

The rates of Not Substantially Equivalent (NSE) and SE decisions remained constant between the M2 and M3 Received Cohorts (83% for SE and 3% for NSEs, respectively). Approximately two-thirds (41 of 61) of all NSE decisions within the M3 Received Cohort were due to lack of performance data. Rates of withdrawn submissions increased 50% from M2 to M3 (4.8% to 7.2%, respectively). Analysis of withdrawn submissions from the M3 Received Cohort revealed that two-thirds were withdrawn during the MDUFA Interactive Review phase. Of these, 30% were withdrawn with 10 or fewer days remaining on the review clock. The most frequently cited rationale for withdrawals according to both CDRH review staff and industry representatives was the inability for applicants to provide adequate data to support an SE decision. Furthermore, CDRH review staff frequently cited the inability to resolve deficiencies within MDUFA timeframes as another reason for withdrawn submissions.

Communications Analysis

As stated in the Commitment Letter, interactions between FDA and Sponsors during the course of the submission review are critical for performing an efficient and timely review of medical device submissions. Evaluation of communication practices between submissions across Offices revealed that OIR had on average more communications with Sponsors throughout the course of the review (18.2) than ODE (13.1), which may be attributable to OIR management expectations for earlier communications between OIR review staff and Sponsors. Interestingly, this increase in overall communications for OIR submissions was also associated with shorter overall TTD. Further analysis within specific phases of the review process revealed that the average number of communications per submission was significantly greater during the Substantive Review phase for OIR (6.4) than ODE (2.4), while the average number of communications were comparable between Offices during all other phases of the review. Analysis of communications held during substantive review and the number of SI issues also demonstrated a slight inverse correlation between number of communications and number of SI issues identified, suggesting that increased communication during Substantive Review may lead to fewer SI issues identified.

Consults Analysis

Examination of Traditional 510(k) submissions in the M3 Study Cohort demonstrated that an increased number of consult requests per submission was associated with longer TTD. On average, 1.9 consults were requested for Traditional 510(k) submissions in the M3 Study Cohort, with ODE requesting 2 consults per submission and OIR requesting 1.6 consults per submission. Clinical consults were by far the most frequently requested consult discipline within the M3 Study Cohort.

Analysis of PMA submissions

PMA Original (PMAO), Panel-Track Supplement (PTS), 180-Day Supplement and Real Time Supplement (RTS) submissions were assessed to determine the impact of MDUFA III processes on overall review performance. Due to the limited number of PMA Original and Panel-Track Supplement submissions within the M3 Received Cohort, only a limited assessment of MDUFA III process improvements could be performed. Briefly, TTD for PMA Original submissions and Panel-Track Supplements was comparable between the M2 and M3 Received Cohort. In contrast, TTD for PMA 180-Day supplements decreased from the M2 Received Cohort to the M3 Received Cohort while TTD for PMA Real-Time Supplements increased from the M2 Received Cohort to the M3 Received Cohort. A thorough assessment of the impact of RTA processes on PMA Original and Panel-Track Supplements could not be performed due to the limited number of closed PMA Original and Panel-Track Supplements within the M3 Received Cohort. As expected, evaluation of SI processes from our M3 Study Cohort revealed that PMA Original and Panel-Track Supplements had on average a greater number of SI issues identified per submission (7.2) than PMA 180-Day Supplements (1.0). Furthermore, we observed a positive correlation between number of SI issues and length of TTD across the PMA submission types that require SI decisions. Clinical deficiencies represented the most commonly identified deficiency type among PMA Original and Panel-Track Supplements.

Analysis of the MDUFA review phase within the M3 Study Cohort revealed that more than 75% of all submission types were approved by the MDUFA Goal Date. Evaluation of communications among all PMA submission types within the M3 Study Cohort revealed no correlation between the number of communications and length of TTD, except for a small positive correlation observed for PMA 180-Day Supplements. However, similar to findings gleaned from our analysis of Traditional 510(k) submissions, the average number of communications held between FDA and Sponsors for OIR submissions was greater than for submissions from ODE for all PMA submission types. Analysis of consult requests for PMA submissions revealed that PMA Original and Panel-Track Supplement reviews were associated with more consults requested per submission (17.6) than 180-Day supplements (2.5) and Real Time Supplement reviews (0.8). In addition, Clinical and Statistics consults were the most frequently requested disciplines for PMA Original and Panel-Track Supplement submissions.

1.6. IT Infrastructure and Workload Assessment

Booz Allen analyzed five existing IT infrastructure and data systems to evaluate MDUFA III enhancements that support review staff work functions, workload management, and MDUFA III goals across the entire review process (e.g., Submission Receipt, Filing Review, End of Review):

- **eCopy**. Electronic submission system that validates submission requirements against program requirements
- **CTS**. Center document tracking tool for premarket submissions, with available links to Image2000+ and DocMan for enabling submission references; provides real-time submission review information to facilitate workload management
- **Image2000+**. Front end for official Documentum repository of industry submissions and review process artifacts
- **DocMan**. Document management system to provide central location for managing ongoing reviews
- **CARS**. Database of reviewer submissions that enables queries of workload reports.

During the course of our evaluation, we found that while reviewers were offered training prior to October 1, 2012, awareness and retention of knowledge regarding changes to specific review processes varied. For example, users reported uncertainty about which documents to store in DocMan, where to store them, and which work processes would be integrated with DocMan capabilities. In addition, although CTS modules were introduced to aid in managing goal dates and to identify submission review progress, some users reported that the new, multiple date fields were confusing. Our survey data indicated that 53% of respondents who identified themselves has having received training on CTS, Image2000+, and DocMan indicated that it eased review, while only 7% said it detracted from review. In contrast, only 12% of staff who identified themselves as not having received IT training indicated that IT systems eased their reviews, while 41% reported that IT systems detracted from the review process. These findings suggest that training has a significant impact on the perceived effectiveness of the new systems implemented.

Our analysis also uncovered inconsistencies within the structure and quality of eCopy submissions from industry, which often render them unsearchable or difficult to read. Focus group participants indicated that consistent applicant submission of searchable PDFs would enable more efficient reviews. Additionally, reviewers noted that applicant inclusion of bookmarks were beneficial for identifying important submission content, a practice not strongly emphasized in guidance for CDRH submissions but heavily promoted and articulated in detail in guidance documents of CDER submissions.

We also reviewed current tools and methodologies for managing and monitoring staff workload and resource use, including CARS, CTS MDUFA III Modules, and CTRS. While managers are meant to primarily utilize CARS and CTS in managing staff workload, our findings indicated that they primarily rely on CTS because it contains more accurate and real-time data. While CTS contains information on current submission assignments, the system does not have critical data for informing workload decisions, such as the number of submissions that a reviewer has on hold, or the number of Inter-Center Consults (ICCs) a reviewer may have. FDA staff interviews indicated that Lead Reviewers must manually enter ICC requests into CTS for tracking purposes since they are often initiated by CDER/Center for Biologics Evaluation and Research (CBER) through a hard-copy paper request and/or through e-mail. Accordingly, managers have created their own methods to assess workload by piecing together information from multiple data sources. A more comprehensive and uniform method of summarizing and visualizing each reviewer's current and evolving workload could help managers more efficiently use staff resources.

1.7. Assessment of Training Programs

Booz Allen characterized four formal training programs that support staff training on the medical device review process, including:

- **Reviewer Certification Program (RCP).** Mandatory new reviewer training program, which provides core reviewer skills and competencies
- **Leadership Enhancement and Development Program (LEAD).** Mandatory training program for all supervisors, which provides core leadership skills

- **Experiential Learning Program (ELP).** Voluntary training program in which reviewers visit industry sites to gain first-hand experience of new processes, procedures, and technologies
- **Ad Hoc Training.** Voluntary training to address just-in-time and new reviewer needs. Because this program was put on hold as of October 1, 2012, Booz Allen only conducted limited stakeholder interviews and document analysis.[3]

We assessed current CDRH training program evaluation processes against 18 identified industry and government best practices, which we aligned to the four levels of the Kirkpatrick Model, a standard for training evaluation.[4] We also documented the implementation of these best practices by CDER and USPTO, which were selected as the internal and external benchmark organizations for this study on the basis of common characteristics identified between the organizations.

As part of our evaluation, we assessed the MDUFA III training content provided to CDRH staff prior to the October 1, 2012 implementation date, which is currently included in the RCP. We determined that while the MDUFA training material contains essential process elements for each key MDUFA III review process (i.e., RTA, SI, IR, and Missed MDUFA Decision (MMD)), reviewers did not receive in-depth formal training on updated guidance documents and clinical standards. In addition, our survey data indicated that both reviewers and management have a better understanding of the MDUFA III-specific material now (90%) compared to the initial time of training (55%), indicating that CDRH staff continued to substantially increase their knowledge and understanding of relevant processes through on-the-job learning outside of formal training programs. For example, Master Reviewers (MR), are often leveraged by staff to support on-the-job learning. However, we found that ODE reviewers with less than two years of experience were significantly less aware (40% versus 70%) of MRs in their division and also less likely to seek assistance from this resource than new OIR reviewers or experienced ODE and OIR reviewers. A majority of review staff surveyed also believed that informal opportunities for on-the-job learning were valuable methods to identify review process best practices and lessons learned from seasoned staff.

Booz Allen determined that CDRH performs 5 of the 18 identified training evaluation best practices, which is significantly lower than both CDER (11 of 18) and USPTO (15 of 18). Specifically, CDRH currently does not have mechanisms in place to measure the quality and effectiveness of its training programs. Notable best practices not performed by CDRH, but by at least one benchmark organization, include:

- Annual competency-based needs assessment is conducted[5]
- Pre- and post-course test assessments are conducted and results analyzed
- Internal standard operating procedures (SOPs) in place for timing of evaluations, process, etc.
- Customized evaluations of successful/unsuccessful behavior changes are conducted

[3] Resources were preferentially allocated to RCP, LEAD, and ELP.
[4] The four levels of the Kirkpatrick Model include “Reaction”, “Learning”, “Behavior”, and “Results” and are a highly influential model for training course evaluation. Kirkpatrick, D.L., & Kirkpatrick, J.D. (1994). Evaluating Training Programs, Berrett-Koehler Publishers.
[5] FDA indicated that based on human and financial resource levels, OCE’s Division of Employee of Training and Development (DETD) intends to conduct a smaller scale training needs assessment annually and will conduct a larger, more granular needs assessment every 3-5 years.

- Feedback from trainers is recorded and analyzed
- Surveys are sent out for additional assessments of knowledge transfer and implementation
- Result metrics are identified for each course
- Program-specific re-certification process exists
- Informal workshops exist to supplement training materials and reinforce participant behavioral changes.

FDA staff survey data generally supported staff satisfaction with the RCP, LEAD, and ELP programs in fulfilling reviewers' needs. However, we observed that OIR management expressed lower levels of satisfaction with the training programs than ODE management and ODE/OIR reviewers. Reviewers (60%) and management (>70%) also indicated that an expansion of RCP to RCP-ineligible reviewers and to staff who previously completed RCP would improve review quality and consistency.

1.8. Assessment of Staff Turnover

Booz Allen also sought to determine the extent of attrition at CDRH and benchmark attrition rates to CDER and USPTO. Based on our analysis of adjusted attrition rates,[6] CDRH's attrition rates decreased from FY11 to FY13, while both CDER and USPTO attrition rates increased during the same time period. Furthermore, while CDRH's FY13 attrition rate was greater than that of CDER, it was comparable to USPTO attrition.

To understand the impact that current attrition has on review processes, we sought reviewer opinions through our CDRH staff survey. We found that while the majority of reviewers were confident in their division's ability to manage through attrition, OIR was significantly more confident than ODE. In addition, OIR reviewers indicated attrition had a lower degree of impact on their ability to complete timely review submissions than did ODE reviewers. While standard operating procedures for management of review staff changes during the review of a premarket submission exist, formal transition and succession plans are not employed at either the Center or Office levels. ODE and OIR both incorporate informal practices at the Division level. Development and implementation a succession plan will promote seamless transitions when turnover occurs and help mitigate disruption to timely and consistent reviews.

1.9. Recommendations

Booz Allen developed a set of recommendations based on the findings and analysis conducted during the evaluation and documented in this report. Together, these recommendations are intended to improve the medical device review process by reducing total review times, and improving predictability, consistency and transparency. The priority recommendations that were developed and published earlier in the study are also documented here, and are denoted as such. For each recommendation, we have also provided suggestions for specific actions that FDA might take to address the recommendation, as resources are available; however, FDA may determine at its discretion to take action on these recommendations in alternative ways.

[6] Attrition rates were adjusted for CDRH by excluding employees leaving the Center due to retirement, inter-Center transfer, and inter-Agency government transfer, to normalize the calculation and allow a direct comparison with USPTO. Unadjusted attrition is also reported in the study.

The second phase of the independent assessment will entail an evaluation of the progress made by FDA to implement recommendations resulting from this first phase of the assessment. Our recommendations are based on an identification of areas needed to improve the medical device review process, and do not fully consider FDA resources available for implementation. Some of our recommendations have resource implications, and therefore, may require additional resources to implement. We also expect that some recommendations could require a longer timeframe for implementation, and that FDA may not fully implement all of our recommendations during the second phase of the evaluation due to the timing of FDA's completion of its plans of action.

Quality Management

1. Adopt a holistic, multi-pronged approach to address five quality component areas to standardize process lifecycle management activities and improve consistency of reviews *(Priority Recommendation)*

We referenced standard quality components (i.e., Senior Management Responsibility, Resource Management, Document Control, Process Improvement, and System Evaluation) and adapted them to include only those elements most meaningful for assessing the design of various FDA-specific processes. From our evaluation of Quality Management (QM) processes, we derived the following specific recommendations:

a. Senior Management: Document and communicate a mechanism for issue accountability and follow-up

Senior management currently reviews new issues as they arise through existing mechanisms while each level of management is accountable for ensuring successful process implementation and resolution of issues. This feedback loop is not formally documented, which can result in missed opportunities and ambiguity among different levels of management. We recommend that CDRH formally document the issue resolution pathway, FDA points of contact, and a clear communication plan to staff.

b. Resource Management: Deploy formal, regularly-scheduled training on new review processes to standardize awareness. Use quantitative methods to assess understanding and activation of behavioral changes.

The training recommendation detailed in Recommendation 9 (i.e., FDA should identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes) addresses this QM issue.

c. Document Management: Deploy planned document control system enhancements (e.g., CTS, DocMan, Image2000+, SharePoint, eCopy) using a quality-oriented focus to optimize the utility of system changes to all review staff

We identified inconsistencies within document control elements that detract from review performance. This is not the intended practice and results in errors and inefficiencies when performing document searches. When document control system transitions and/or upgrades are made that impact review processes, we recommend that CDRH incorporate quality management components into its roll-out strategy to ensure that these upgrades are positioned for successful use.

d. Corrective and Preventive Action (CAPA) and Continuous Process Improvement (CPI): Develop a more formal method for logging, prioritizing, tracking, communicating and providing feedback on non-CAPA issues and improvement ideas

Our review determined that although ODE has implemented a CAPA database to resolve issues that impact multiple Divisions, no formal method to log, track, prioritize, or communicate issues exists for non-CAPA (i.e., Division-specific) issues. Since standard methods across divisions do not currently exist, we recommend that CDRH develop a formal method to be applied consistently across divisions for tracking non-CAPA issues.

e. System Evaluation: Identify and develop internal metrics to monitor the quality and effectiveness of review processes and facilitate continuous process improvement

Program operations staff has noticed that for several submissions that did not meet their MDUFA Goal Dates, the milestones were missed early in the review process. As a result, operations staff now focuses on these indicators and sends reminders to Lead Reviewers of upcoming due dates. We recommend that CDRH identify internal metrics to ensure the quality and effectiveness of sub-processes within the large submission review to support the monitoring process and facilitate continuous process improvement.

Evaluation of Review Process

2. Develop criteria and establish mechanisms to improve consistency in decision-making throughout the review process *(Priority Recommendation)*

A recurring issue that was identified during our analyses was inconsistent decision-making throughout various stages of the review process, in particular, a lack of transparency in thresholds or requirements used to trigger AI requests. Development of tools, criteria, and/or mechanisms for assessing and ensuring the consistency of review processes, such as an AI Request Checklist to clarify the categories of deficiencies that applications may be subject to receiving, would help ameliorate this issue.

3. Optimize RTA process by improving awareness of and clarity around Administrative requirements for 510(k) submissions

Our analysis revealed that more than 50% of closed Traditional 510(k) submissions received within CY13 received a rejected RTA decision during the first cycle, and that submissions with a greater number of RTA cycles were associated with longer TTD and TST. The Administrative category of the RTA checklist had the most frequently identified elements during RTA Acceptance Review, with more than 80% of submissions containing at least one missing/deficient element that resulted in an RTA decision. Therefore, we recommend promoting increased awareness of and clarity for Sponsors around Administrative requirements for 510(k) submissions.

4. Perform a retrospective root cause analysis of withdrawn submissions and develop a mechanism to minimize their occurrence

Rates of withdrawn submissions increased 50% between the M2 and M3 Study Cohorts. Further analysis of withdrawn submissions revealed that two-thirds of these were withdrawn during the MDUFA Interactive Review phase, of which nearly 30% were withdrawn with fewer

than 10 days remaining on the review clock. CDRH review staff cited an inability to resolve deficiencies within MDUFA timeframes as a reason for withdrawn submissions, as well as the Sponsor's inability to provide adequate data to support an SE decision. While MDUFA III limited FDA to one hold at Substantive Interaction to promote high quality submissions, this also inhibited reviewers and Sponsors from resolving minor deficiencies within the MDUFA III timeframe, possibly leading to an NSE decision. Analysis of our limited study sample signaled a potential issue that warrants further investigation through another study. We recommend that FDA conduct a larger-scale retrospective study using withdrawn submissions to identify submissions with characteristics that might benefit from additional review time (e.g., submissions with minor deficiencies that may be quickly resolved). FDA should communicate study findings with public stakeholders and depending on study outcomes, develop mitigation strategies, such as a limited additional hold or other mechanism.

5. Implement a consistent practice for communicating early and frequently with Sponsors during the Substantive Review phase to address and resolve potential issues prior to Substantive Interaction

Our evaluation of communication practices for both ODE and OIR submissions revealed that OIR reviewers held more frequent communications with Sponsors throughout the course of the entire review. More specifically, OIR had more communications during the Substantive Review phase than did ODE. This increase in overall communications among OIR submissions was also associated with fewer deficiencies/issues identified within SI, and an overall shorter TTD. We recommend that FDA implement a consistent practice for early and frequent communication with Sponsors to address issues prior to SI.

Evaluation of IT Infrastructure and Workload Management Tools

6. Provide mandatory training for the three primary IT systems that support MDUFA III reviews *(Priority Recommendation)*

New IT systems, as well as system upgrades, were developed in support of MDUFA III process changes for streamlining reviews and providing tools for new procedures. While reviewers were required to take training prior to October 1, 2012, awareness and retention of knowledge regarding changes to specific review processes varies. Our survey data indicated that many staff did not report participation in the system training, but that the majority of those who received training indicated that it eased medical device reviews. Therefore, we recommend that CDRH ensures all reviewers complete the appropriate system training courses.

7. Provide increased clarity to applicants beyond existing eCopy guidance to enhance organized submission structure

Reviewers and managers noted inconsistencies in the structure and quality of eCopy submissions from industry, which often render them unsearchable or difficult to read. We recommend that CDRH provide greater clarity (e.g., webinars) to applicants to emphasize the rationale for applying navigation support (e.g., scanning, bookmarking, hyperlinking) and provide greater specificity to existing application submission instructions to ease FDA staff navigation of submission reviews.

8. Evaluate tools for providing a comprehensive view of staff workload

Although there are two primary tools used for workload management decisions (i.e., CARS and CTS), managers indicated that they primarily rely on CTS because it contains real-time information on current submission assignments. However, neither system has all of the critical data for informing workload decisions (e.g., number of ICCs, submissions on hold). Therefore, managers create their own support tools by piecing together information from multiple sources. We recommend that CDRH perform an assessment to identify methods of providing a more comprehensive view of current and evolving reviewer workload to help managers more efficiently use staff resources.

Evaluation of Training Programs

9. FDA should identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes. *(Priority Recommendation)*

Our analysis of the four training programs uncovered gaps in CDRH's ability to fully take into account the needs of staff, evaluate improvements in knowledge, and objectively assess the impact of learning participants' behavioral changes. We derived sub-recommendations, described below, to enable CDRH to ensure the quality and effectiveness of its training programs. These recommendations are organized according to the training level in the Kirkpatrick Model:

a. Level 1: Perform annual training needs assessments to fully consider and identify changes in reviewers' and management's training needs in both Offices to improve review process efficacy and efficiency

Although ODE management as well as both ODE and OIR reviewers were generally satisfied that training programs fulfill their needs as reviewers, OIR management tended to be less satisfied with the benefits of reviewer training programs. These differences highlight a potential gap in adequately addressing training needs and perspectives of OIR management. CDRH should perform an annual needs assessment to garner feedback from review staff and management from both Offices and adjust programs accordingly. This will also serve the purpose of the Ad Hoc program by allowing reviewers and management to identify new needs annually for incorporation into applicable training programs.

b. Level 1: Periodically re-assess training program material and objectives to ensure they continue to support reviewer needs

Training administrators need to understand whether training courses are meeting set objectives, and if not, what aspects need to be adjusted to accomplish that goal. In addition, training course material should be modified periodically according to updated training objectives, training needs and/or feedback obtained from course evaluations and surveys assessing participants' behavioral changes. Periodic reviews of objectives for each training program, taking into account management and review staff feedback, would help ensure that training curriculum continue to remain relevant in supporting staff review functions.

c. Level 2: Perform pre- and post-course test assessments to gauge knowledge transfer and course metrics for learning *(Priority Recommendation)*

Pre- and post-course test assessments are a recognized training best practice used to assess the extent to which a training course supports staff learning. While the current post-test covers material across all courses, participant knowledge of specific material from individual required courses is not assessed, limiting CDRH's ability to understand course utility. We recommend that CDRH implement pre- and post-course assessments for individual reviewer training courses, to gauge participant knowledge and skills.

d. Level 2: Develop internal SOPs on the timing of evaluations and training processes

CDRH does not currently have SOPs in place for consistently implementing training evaluation techniques across its training curriculum. An SOP is critical for defining an organization's standard practices and maintaining consistency across training programs. CDRH should develop an internal SOP to establish standard guidelines highlighting its intended course evaluation methods.

e. Levels 3-4: Collect, record, and analyze feedback from trainers to improve reviewer training curriculum

CDRH does not currently employ methods to record and analyze trainer feedback, while other benchmark organizations implement this best practice. We recommend that CDRH develop a means to consistently obtain course feedback in a standardized format from trainers, analyze findings, and incorporate their insights into regular training program updates.

f. Levels 3-4: Establish a refresher program for RCP to improve core review skills of RCP-ineligible review staff and re-certify RCP graduates

Currently, only new CDRH reviewers and those that joined after October 1, 2012 are eligible for RCP. No RCP refresher or recertification program is currently available for RCP graduates to update or reinforce their knowledge and skills. CDRH staff believes RCP certification would be beneficial to RCP-ineligible staff when performing reviews. Therefore, we recommend that CDRH expand RCP into a refresher program available to more experienced reviewers to improve overall review quality and consistency, and enable RCP graduates to obtain RCP re-certification.

g. Levels 3-4: Deploy post-course completion surveys and/or interviews to assess staff behavioral changes based on knowledge gained during training courses

Post-training assessments that ascertain participants' integration of knowledge learned from training courses serve as important resources in validating training, identifying a need for training course updates and assessing the extent to which staff learning translated into implementation of desired behaviors. Currently, CDRH does not have the ability to assess the extent to which knowledge and skills have transferred to staff review functions. The development of post-course assessment surveys would enable CDRH to assess the extent to which training material is put into practice, as well as to identify areas for training program improvement.

h. Levels 3-4: Assess program results by developing course metrics

CDRH currently lacks program success metrics for both individual training courses and RCP as a whole. Course outcomes metrics are measurable through post-course completion surveys, participant interviews, or select submission audits. CDRH should identify and develop outcome metrics for training courses that will enable them to assess, tailor and refine its training programs to be more effective and to enable more consistent reviews.

10. Promote informal training and knowledge sharing by seasoned staff for review staff and management to share division or science-specific review processes, lessons learned, and best practices

Due to the complexity of scientific reviews of product submissions, formal training programs are limited in the extent to which they can impart knowledge and skills to participants. Only 55% of OIR staff and 57% of ODE staff were confident in their understanding of MDUFA III processes at the time of training compared to 90% and 92% of staff at the time of our survey, respectively. We identified staff rounds, Division meetings, and Master Reviewers as resources available to review staff for on-the-job training. Our findings indicated that currently, new ODE reviewers are the least aware of Master Reviewers in their Divisions and are least likely to seek them out for assistance compared to more experienced review staff and new OIR reviewers. Survey findings indicated staff interest in informal opportunities for on-the-job training, such as brown bag sessions on review process topics discussing review best practices and lessons learned provided at the Division level would be beneficial to reviewers.

Assessment of Staff Turnover

11. Develop CDRH-wide staff transition and succession plans to mitigate the impact of turnover on submission reviews

An analysis of attrition at CDRH indicated that overall attrition has improved and that the rate is not significantly different from that of USPTO, when utilizing a common calculation methodology. ODE staff perceive staff turnover as having a more significant impact on their ability to perform timely reviews than does OIR staff. Similarly, ODE reviewers believe their Divisions are not as well prepared to successfully manage through attrition as OIR when attrition does occur. While standard operating procedures for management of review staff changes during the review of a premarket submission exist, formal transition and succession plans are not employed at either the Center or Office levels. ODE and OIR both incorporate informal practices at the Division level. Development and implementation of a CDRH management succession plan and review staff transition plan can promote more seamless transitions when turnover occurs and help mitigate disruption to timely and consistent reviews.

2. PROJECT BACKGROUND AND OBJECTIVES

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting public health by ensuring that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. In support of this mission, the FDA was granted the authority under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) to collect user fees from medical device manufacturers to support activities aimed at expediting the availability of innovative new products. These activities included: enhancing premarket review processes; modernizing information technology systems; hiring new staff to expand capacity; and providing more guidance to prospective applicants. Congress subsequently reauthorized the medical device user fee program under the Medical Device User Fee Amendments of 2007 (MDUFA II), which established more rigorous performance goal timelines and set mandates to improve the timeliness and predictability of medical device reviews. Although FDA successfully met and exceeded most of its MDUFA II goals, total review times for regulatory submissions increased, raising concerns from industry stakeholders. In an effort to address these trends, the Agency has made a concerted push in recent years to focus efforts on improving the predictability, consistency, and transparency of its premarket review programs and identifying factors contributing to longer total review times.

On July 9, 2012, Congress enacted the Medical Device User Fee Amendments of 2012 (MDUFA III) as part of Public Law 112-144, also known as the Food and Drug Administration Safety and Innovation Act (FDASIA), reauthorizing FDA to assess user fees on medical device manufacturers. In exchange, the Agency committed to meet certain performance goals aimed to increase the speed and efficiency of its premarket review programs and expedite the approval of safe and effective medical devices to market. Following negotiations with multiple medical technology industry associations, consultations with patient and consumer advocates, and public input, the Agency published the MDUFA III Commitment Letter, which outlined planned measures designed to increase the predictability and efficiency of the device review process. The letter included provisions intended to improve the pre-submission process, revise submission acceptance criteria, enhance communications with industry, implement a Third-Party Review program, and develop additional guidance documents. It also created a more transparent and predictable decision-making framework while maintaining the existing rigor and evidence-based approval standards set by the FDA device review program.

Pursuant to the Performance Goals and Procedures adopted in the MDUFA III Commitment Letter, FDA agreed to participate with the medical device industry in a comprehensive independent assessment of its medical device submissions review processes. This independent assessment was specified to be performed in two phases and required an objective analysis of the Agency's premarket review processes implemented as a result of the MDUFA III negotiations, including Refuse to Accept (RTA), Substantive Interaction (SI), Interactive Review (IR), and Missed MDUFA Decision (MMD) communications. Moreover, the evaluation entailed an analysis of FDA's existing quality management systems, IT infrastructure, workload management tools, and training and retention policies and practices. The objective of the first phase, which took place over a one-year period, was to identify opportunities for improvements that would significantly impact the review of medical device premarket submissions. The second phase of the assessment will entail an evaluation of the progress made by FDA to implement recommendations resulting from the first phase of the assessment.

Booz Allen was selected to conduct the independent assessment of the processes associated with the review of premarket medical device submissions in accordance with the MDUFA III Commitment Letter. The first phase of the evaluation focused on the identification of best practices and prioritization of process improvements for conducting predictable, efficient, and consistent premarket reviews that meet FDA's regulatory standards. It also required an in-depth analysis of review process elements to identify opportunities for improvement. In particular, this assessment consisted of the following activities:

- Identify issues contributing to longer total time to decision and determine whether these issues were effectively addressed by implementation of new MDUFA III processes
- Determine the extent to which quality management components were implemented in the design of major new MDUFA III processes
- Evaluate implementation of major new MDUFA III processes and their impact on submission outcomes
- Assess the quality and effectiveness of CDRH's reviewer training programs, including current policies and procedures, to ensure staff has the necessary skills to perform efficient and timely reviews
- Identify best practices to enhance employee retention and minimize staff turnover
- Assess whether IT systems and workload management tools effectively support a timely and efficient review process.

To meet these objectives, Booz Allen conducted a series of analyses involving key aspects of the premarket review processes and engaged stakeholders from the medical device industry and FDA to communicate findings and solicit feedback. The MDUFA III Commitment Letter specified that the independent assessment provide findings on a set of priority recommendations (i.e., those likely to have a significant impact on review times) within six months of contract award, and final comprehensive recommendations for the full evaluation within one year. Booz Allen's preliminary assessment culminated in the development of four priority recommendations, published by FDA on December 11, 2013, aimed at improving the efficiency and review times of the medical device submission review process:

- Develop criteria and establish mechanisms to improve consistency in decision making throughout the review process
- Provide mandatory full staff training for the three primary IT systems that support MDUFA III reviews
- Identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes
- Adopt a holistic, multi-pronged approach to address five quality component areas to standardize process lifecycle management activities and improve consistency of reviews.

This final report summarizes the methodologies, findings, and recommendations supporting Booz Allen's approach to assess whether FDA has the processes, practices, and systems in place to successfully meet new requirements under MDUFA III. While Booz Allen considered

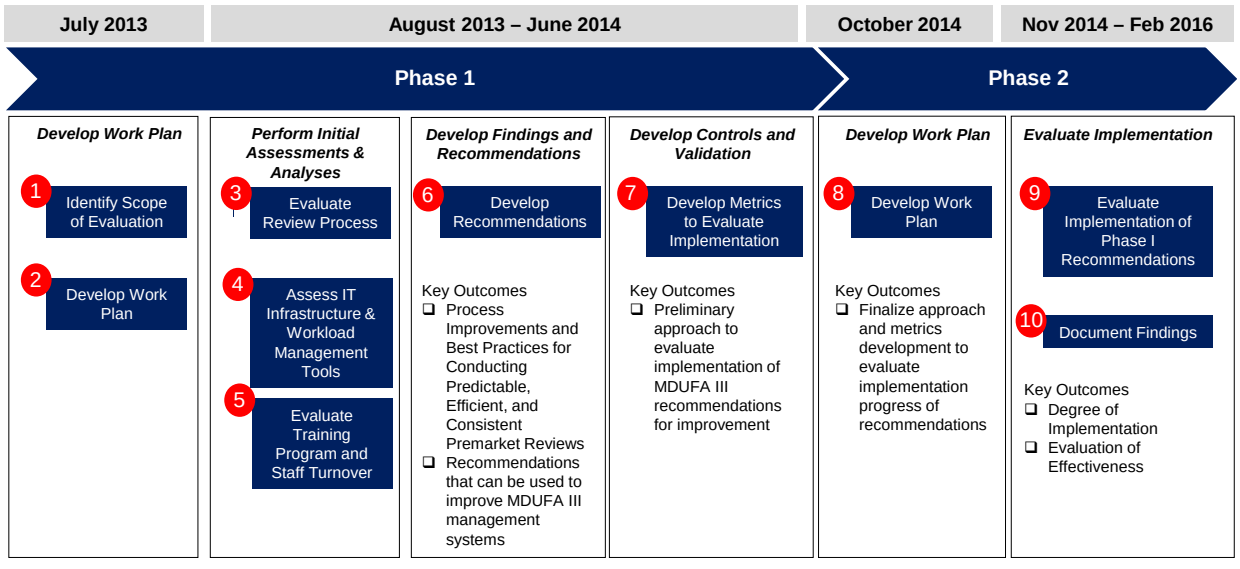
resource requirements to a limited degree in developing these recommendations, certain recommendations may have resource implications that could impact FDA's ability to fully implement them. In addition, although FDA's implementation of these recommendations will be independently evaluated in the next phase of the project, Booz Allen did not consider the evaluation timeframe when developing these recommendations. Therefore, it is possible that activities to address some recommendations will not be fully implemented before the end of the evaluation period.

It is important to note that this study did not, and was not intended to, evaluate the quality of the review, the scientific and medical evaluation, or the technical merit of submission review decisions. The array of submission review activities and milestones constitute important elements for improving the effectiveness and efficiency of the medical device review process. However, our assessment of submission review activities should not be interpreted as a failure of the review process or by FDA reviewers in conducting a thorough, quality review.

3. METHODOLOGY

The study consists of two major phases spanning ten steps, as illustrated by the study framework shown in Exhibit 1. This report summarizes our approach, findings, and recommendations for the four activity areas (Steps 1-7) that comprise Phase 1 of the evaluation. The final activity areas (Steps 8-10) will be initiated by an independent evaluator in Phase 2.

Exhibit 1. MDUFA II/III Assessment Approach



The first phase of the study consists of the following four activity areas:

1. **Develop Work Plan (Steps 1-2)**. Initial hypotheses were developed and data sources and data requirements were identified.

2. **Perform Initial Assessments and Analyses (Steps 3-5)**. The primary focus of this study is to conduct a management review to assess CDRH's status in establishing

reporting mechanisms, quality controls, and other systems that pertain to a quality management system; and, to identify key contributors that negatively impact expedient reviews, using a cohort of MDUFA II and MDUFA III submissions for analysis, and to determine the extent to which new MDUFA III enhancements have been developed to address identified factors.

3. **Develop Findings and Recommendations (Step 6)**. Initial findings and high priority recommendations were submitted in a preliminary report for FDA and industry feedback, and published to the FDA website. This final report incorporates additional insights, feedback, and recommendations from continued data collection and analysis during the remainder of this Phase 1 evaluation.

4. **Develop Metrics to Evaluate Recommendations (Step 7)**. At the end of Phase 1, the preliminary approach that will be used to evaluate implementation of the recommendations was briefed to FDA and industry stakeholders.

The focus of Phase 2 is to develop methods and metrics to evaluate FDA's implementation of recommendations from Phase 1 and assess FDA implementation of recommended actions.

The methodology for each Phase 1 activity area is described in Sections 3.1 and 3.2.

3.1. Develop Work Plan

During the initial planning phase, Booz Allen developed a work plan that outlined project activities and objectives, described the primary and secondary data collection approach, identified data sources, and summarized the preliminary study cohort selection process. The work plan also presented initial hypotheses on a number of areas, including submission characteristics, management practices, review processes, training program, and IT review tools.

Booz Allen also developed an industry engagement strategy to ensure that key medical device industry stakeholders participating in MDUFA III negotiations had an opportunity to provide feedback for improving the efficiency, consistency, and predictability of the Agency's regulation of medical device submissions.

3.2. Perform Initial Assessments and Analyses

Data sources for this study included published documents, FDA databases, interviews with FDA review staff and division leadership, focus groups with branch leaders, interviews with points of contact from benchmarking organizations, and an online CDRH staff survey (Appendix D). Booz Allen also convened a number of industry meetings to solicit feedback from industry and industry organization representatives (Exhibit 2). These industry meetings were conducted to take into account any concerns expressed by industry, consider areas for further investigation in the study, and provide updates and clarification on preliminary and final recommendations.

Exhibit 2. Description of Industry Stakeholders

Medical Technology Industry Associations	Description
AdvaMed Advanced Medical Technology Association	▪ The Advanced Medical Technology Association (AdvaMed), is a trade association that leads the effort to advance medical technology in order to achieve healthier lives and healthier economies around the world ▪ AdvaMed advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation ▪ AdvaMed represents 80 percent of medical technology firms in the United States
MITA MEDICAL IMAGING & TECHNOLOGY ALLIANCE A DIVISION OF NEMA	▪ The Medical Imaging & Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA), is the leading organization and collective voice of medical imaging equipment, radiation therapy, and radiopharmaceutical manufacturers, innovators and product developers ▪ MITA represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology ▪ MITA provides leadership for the medical imaging and radiation therapy industries on legislative and regulatory issues at the state, federal and international levels
MDMA MEDICAL DEVICE MANUFACTURERS ASSOCIATION	▪ The Medical Device Manufacturers Association (MDMA) is a national trade association providing educational and advocacy assistance to innovative and entrepreneurial medical technology companies ▪ MDMA promotes public health and improves patient care through the advocacy of innovative, research-driven medical device technology

3.2.1. Issues Analysis

Booz Allen identified and analyzed review process issues from the MDUFA II timeframe to assess whether they were addressed with the implementation of new MDUFA III processes or systems. Issues were identified from a variety of primary and secondary sources including: 1) a literature review comprised of industry reports, MDUFA III negotiation meeting minutes, and published FDA studies, among others; 2) focus groups with FDA and industry stakeholders; 3) an in-depth review of Premarket Notification (510(k)) and Premarket Approval (PMA) submissions selected in our MDUFA II Study Cohort that had a longer than average Total Time to Decision (TTD); and 4) a Lead Reviewer survey, which asked Lead Reviewers responsible for submissions selected in our MDUFA II Study Cohort to provide feedback on key issues identified during those submission reviews. The complete list of data sources for the issues analysis is provided in Appendix B.

Booz Allen assessed whether FDA had taken steps to address the issues identified by researching available MDUFA III review process information, published material on FDA's website, and insights gleaned through FDA focus groups. We validated our findings through discussions with FDA to obtain additional documentation or information FDA had available, including mechanisms it has put into place, to address these remaining issues.

3.2.2. Quality Management Assessment

Booz Allen conducted a senior management focus group as well as interviews with FDA program leadership and Regulatory Advisors in the Office of Device Evaluation (ODE) to evaluate the design of the review processes with respect to high-level quality management principles that were found in International Organization Standards for Quality Management

Systems (ISO 9001:2008), FDA Staff Manual Guide (SMG) 2020, and the newly-created CDRH Quality Management Framework. The quality assessment was not intended to be an audit, and thus for this assessment only the components we determined to be most meaningful to CDRH premarket submission review processes were adapted and qualitatively evaluated.

CDRH staff interviews were conducted to examine the degree to which the quality management practices were incorporated to build quality into the development and implementation of MDUFA III review processes.

3.2.3. **Evaluation of Review Process**

Booz Allen applied a hypothesis-driven approach to assess the impact of MDUFA III review processes on review performance. A cohort of MDUFA II submissions was also selected to establish a baseline for selected medical device submission types. Data collection methods and data sources were determined based on metrics corresponding to each hypothesis. This section describes our approach for developing hypotheses, collecting data, selecting cohort submissions for data collection, conducting analysis, and reporting findings.

3.2.3.1 Study Hypotheses

The following exhibit lists the key study hypotheses developed for each review process subject area identified for the assessment (Exhibit 3).

Exhibit 3. Hypotheses for Review Process

Subject	Hypotheses	Metrics	Data Source
Overall Review Process	• The new review processes implemented in MDUFA III have a positive impact on review outcome • Use of the RTA process and RTA checklist has a positive impact on TTD • Use of the RTA process and RTA checklist has a positive impact on Total Submission Time (TST)[7,8] • An early start on Substantive Review in the course of a review positively impacts TTD • Office/Division practices have no impact on review processes and review outcomes	• MDUFA III review processes for each review phase • MDUFA III review processes across Offices/ Divisions • MDUFA III TTD/TST across Offices/Divisions • MDUFA II TTD	• FDA data systems (i.e., CTS, CARS, DocMan, and Image2000+)
Submission Characteristics	• Submission completeness, as defined by submission acceptance (RTAA), has a positive impact on the review process (e.g., fewer RTA cycles, earlier start of Substantive Review (SR))	• RTA cycles • SR start date	• FDA data systems
Sponsor/ Applicant Characteristics	• Applicant experience has a positive impact on the review process (e.g., domestic origin of applicant)	• Domestic/Foreign origin of applicant	• FDA data systems
Review	• Lead Reviewer turnover during the course of	• Reviewer experience	• FDA data

[7] For this study, Booz Allen assessed whether RTA implementation was associated with any decrease in TTD and TST; however, based on MDUFA III negotiations, the RTA process was implemented to enable FDA to utilize its limited resources on reviewing only complete and high quality submissions.
[8] TST is not a measure used by FDA or industry to assess review time as part of its MDUFA III negotiated agreements; however, Booz Allen analyzed the impact of RTA on TST to assess FDA and sponsor days spent on submission reviews.

Subject	Hypotheses	Metrics	Data Source
Characteristics	the review negatively impacts TTD • Longer reviewer experience positively impacts TTD • High communication frequency between industry and FDA during the Substantive Review phase has a positive impact on TTD	• Communication frequency (e.g., number of industry meetings/ conference calls, etc.) • Timing of communications	systems • FDA staff survey

In addition to testing the listed hypotheses, a subset of MDUFA III submissions were studied to further investigate the following topic areas of particular concern to industry and FDA stakeholders:

- Conversion of Special 510(k) to Traditional 510(k) submissions
- Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application dual process
- Companion diagnostics submissions
- Combination product submissions
- Withdrawn submissions re-submitted within a short period of time
- Current review processes for Investigational Device Exemption (IDE) and Q-Submissions.

3.2.3.2 Cohort Selection

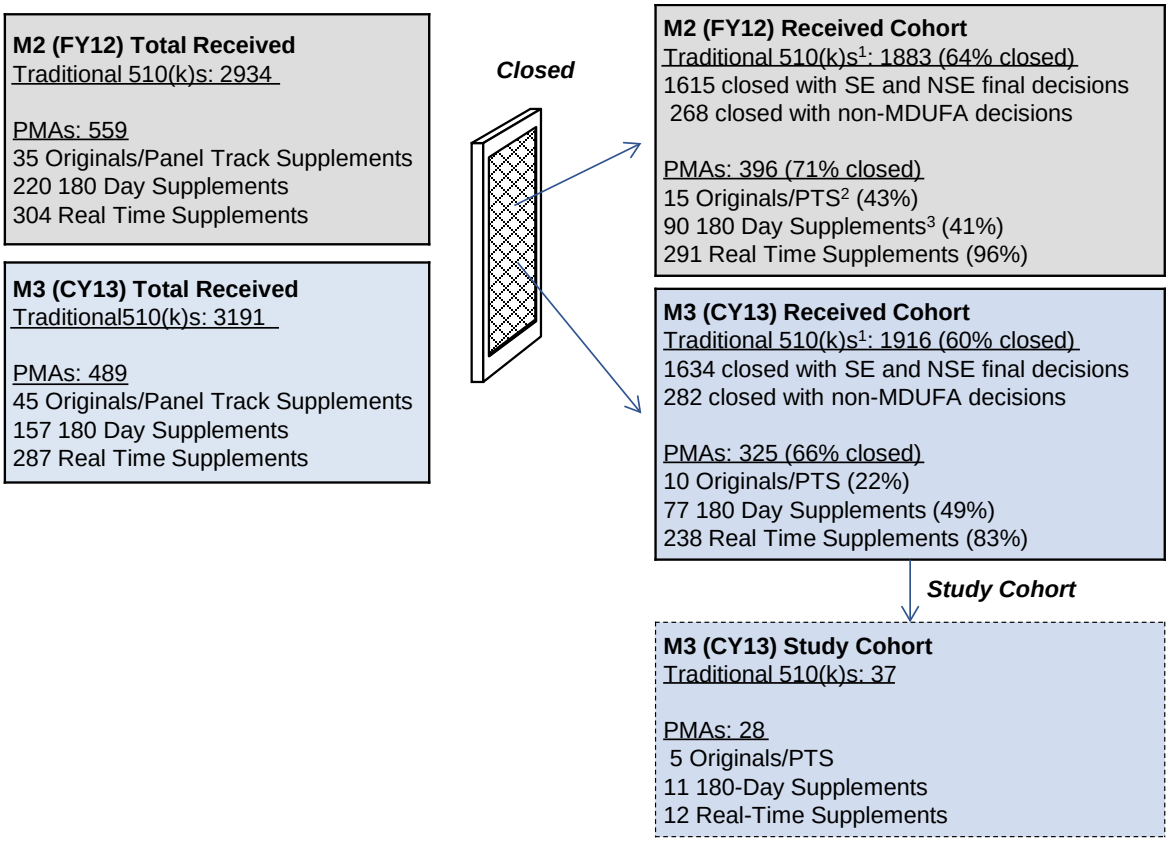
To fully evaluate the impact of MDUFA III processes, Booz Allen reviewed closed submissions from both M2 and M3 Received Cohorts. We also identified a subset of the M3 Received Cohort, termed the M3 Study Cohort, for which we have performed more in-depth analyses. The various cohorts analyzed in the evaluation are described below. Our comparative analyses of MDUFA II and MDUFA III processes are based on samples of applications received during FY12 (M2 Received Cohort) and CY13 (M3 Received and Study Cohorts). MDUFA II performance from FY08-FY11 is not included in the analyses.[9]

M2 Received Cohort

To perform comparative analyses, we identified 1,883 Traditional 510(k)s, which represented 64% of all received submissions during the MDUFA II timeframe. Of these submissions, 1,615 of 1,883 were closed with final decisions of Substantially Equivalent (SE) or Not Substantially Equivalent (NSE), and therefore included for analysis. For PMAs, a total of 15 PMA Original (PMAO) and Panel-Track Supplements (PTS), 90 180-Day Supplements (180 DS), and 292 Real Time Supplements (RTS), were included in the M2 Received Cohort (Exhibit 4) as closed submissions for analysis.

[9] MDUFA II review times are assessed only for the FY12 year in this study and should not be used to make conclusions about the overall performance of MDUFA II, which spans FY08-FY12. Information on review performance of the remaining years is publicly available.

Exhibit 4. Characterization of Received and Study Cohorts



Notes: [1] For 510(k), counts exclude De Novo submissions and submissions that did not meet user fee and eCopy requirements within the range of Date Received; [2] For PMAO+PTS, one submission was withdrawn prior to filing and was excluded from further analysis; [3] For 180 Day supplements, one submission was withdrawn prior to filing and subsequently excluded from analysis

M3 Received Cohort

Similarly, a total of 1,916 Traditional 510(k)s were included in the M3 Received Cohort, representing 60% of the total Traditional 510(k)s received in the MDUFA III timeframe. Of these, 1,634 submissions were closed with final decisions of SE or NSE and included for analyses. For PMAs, 10 PMA Original and Panel-Track Supplements, 77 180-Day Supplements, and 238 Real Time Supplements were included in the M3 Received Cohort (Exhibit 4).

M3 Study Cohort

The M3 Study Cohort was used to conduct deep dive analyses on various factors such as number and types of submission issues, communication practices, types of consult requests and other metrics not reported through the FDA CARS system. The M3 Study Cohort was identified based on Booz Allen's judgment to select submissions for study purposes, comprising at least one submission selected from each Division and taking into account a range of TTD and decision outcomes to ensure representation of the larger M3 Received Cohort. Specifically, the M3 Study Cohort included 37 Traditional 510(k) and 28 PMA submissions (12 PMA Real Time Supplements, 11 PMA 180-Day Supplements, and five PMA Original and Panel-Track Supplements) that were identified to fairly represent submissions from the larger M3 Received

Cohort in terms of TTD (Appendix C). Submissions with shorter than average TTD and longer than average TTD were selected from the M3 Received Cohort to enable Booz Allen to identify factors contributing to longer TTD as well as best practices that could potentially reduce TTD.

Case Studies
A number of case studies were performed on particular topic areas of interest to industry and FDA stakeholders, as shown in Exhibit 5.

Exhibit 5. Summary of Selection Method for Case Study Cohorts

Topic Area	Description of Evaluation
Conversion of Special 510(k) to Traditional 510(k)	• Performed keyword search in FDA system (DocMan), resulting in 111 submissions converted from Special 510(k) to Traditional in CY13
CLIA Waiver by Application	• Searched FDA data systems (CARS, Image2000+ and DocMan) and located 9 cases of CLIA Waiver by Application in CY13
Companion Diagnostics	• Executed a CARS report using the companion diagnostics flag and identified three 510(k)s and 16 PMAs
Combination Products	• Executed a CARS report on combination products and identified 50 510(k)s and 31 PMAs
Withdrawn Submissions with Subsequent Re-submissions	• Pulled ad hoc CARS reports to identify re-submissions from the same company that had previously withdrawn the same product code submission within a short timeframe; eight pairs of withdrawals/resubmissions were identified in CY13
IDE	• Extracted ad hoc CARS report to identify all IDE Original submissions in CY13 with analysis performed only on IDE Original submissions excluding supplements or annual reports (n=280)
Q-Submissions	• Executed ad hoc CARS reports to identify all Q-Sub submissions in CY13 with analysis performed only on original pre-submissions with meeting feedback (n=303)

3.2.3.3 Data Collection

An Excel-based data collection instrument (DCI) was developed to include a comprehensive set of process milestones and activities, and was used as a data repository for all secondary data gathered for each submission selected in the Study Cohorts. A portion of the data elements in the data collection instrument were populated through report output generated from queries of the FDA CARS data system, based on the CDRH Business Objects reporting tool.

For the M3 Study Cohort, the DCI also included a number of data elements that could not be populated using the customized FDA data system reports described above. Booz Allen conducted an in-depth examination of individual submissions using review content available through FDA data systems (e.g., CTS, DocMan, Image2000+), and performed manual data collection based on review of submission information to derive secondary data used to perform frequency analyses in deep-dive analysis areas.

For the case studies, all cases identified for conversions of Special 510(k) to Traditional 510(k) submissions, and all cases of withdrawn submissions that were subsequently re-submitted were

investigated to discern specific issues. All cases of CLIA Waivers by Application and a subset of companion diagnostic and combination product submissions were reviewed by Booz Allen and feedback was solicited from Lead Reviewers for these submission types during focus group meetings. Key data elements gathered for IDE and Pre-submissions were analyzed to determine the extent to which submissions complied with established review processes for these submission types.

3.2.3.4 Data Analysis

Review activities and data points of review milestones gathered for submissions in the received cohort enabled a broad assessment of cohort performance in terms of length of review time and other milestones. In particular for length of review, TTD, which is the time from FDA initial clock start to final decision, is a key indicator of submission cohort performance and represents one of the critical metrics used in our assessment.[10] Total Submission Time (TST), which is the duration from the submission receipt date to the final FDA decision date, is another key metric in our assessment to evaluate outcomes of MDUFA III implementation. TST includes the days prior to acceptance from submission receipt in addition to TTD.[11] Each individual submission selected in the study cohort was also assessed to evaluate the impact of different review activities on the medical device review process. By analyzing data qualitatively and quantitatively, Booz Allen sought to identify the root cause behind factors impacting review outcomes for each submission in the study cohort. Data collected was analyzed to ascertain themes, categories, and where possible, include basic statistics (e.g., frequencies, percentages). Due to the limited sample size, completeness of documentation, and the qualitative nature several focus areas identified for this study, statistical significance could not be determined for this study. Therefore, the results of our numeric calculations should not be interpreted as statistically significant values, but as trends indicative of identified behaviors.

3.2.4. **Assessment of IT Infrastructure and Workload**

To conduct our analyses of the IT infrastructure and workload management systems supporting MDUFA III review processes, Booz Allen leveraged a variety of primary and secondary sources, listed in .

Exhibit 6.

We also examined the use of IT systems in the context of supporting review staff in performing premarket medical device submission reviews; reviewed FDA literature and polices that facilitate the use of these systems and processes; conducted a CDRH-wide staff survey; conducted interviews with CDRH Division Directors and staff; and held focus groups with Branch Chiefs to identify technical and workload management challenges of staff.

[10] The review clock begins on the date of receipt of the submission that enables the submission to be accepted.
[11] Days prior to acceptance includes the time for RTA review, which would include any industry and FDA time for which a submission has been rejected.

Exhibit 6. Primary and Secondary Sources Used for the IT Infrastructure and Workload Management Assessment

Data Collection Source	Description
Center Tracking System (CTS)	• Document tracking tool for premarket submissions
DocMan	• Document Management System that provides a single location to manage MDUFA III submission review records, interactive review e-mails, memos, and also allows reviewers to manage workflow with peers
Image2000+	• Final repository of industry submissions and review artifacts
CDRH Ad Hoc Reporting System (CARS)	• Reporting system supports queries, internal reports, and MDUFA performance reports of medical device submissions (e.g., 510(k), PMAs)
FDA Literature and Documentation related to IT System Use	• Quick Guides, Cheat Sheets, tutorials, and Standard Operating Procedures that provide instructions for staff use of IT systems supporting MDUFA III reviews
FDA Branch Chief Focus Groups	• Interviews with Branch Chiefs from the Office of Device Evaluation and Office of Office of In Vitro Diagnostics and Radiological Devices for insight into workload management processes and challenges
FDA Division Director Interviews	• Interviews with Division Directors from the Office of Device Evaluation and Office of In Vitro Diagnostics and Radiological Devices for insight into workload management processes and challenges
FDA Staff Interviews	• Interviews with Directors, Reviewers, and other FDA stakeholders to gain insights on MDUFA III implementation challenges around IT Infrastructure and Workload Management • Interviews with FDA staff to understand mechanisms in place to assess staff resource use from a quality systems perspective
FDA Staff Survey	• Structured survey developed for the purpose of gathering information from FDA staff regarding the impact of specific IT Infrastructure updates

3.2.5. Evaluation of Training Programs and Staff Turnover

As part of this study, Booz Allen identified best practices and performed a benchmarking analysis against industry and government organizations for both training and employee retention. A list of data sources used for these analyses is provided in Exhibit 7.

Exhibit 7. Data Collection Sources for Training and Staff Turnover Evaluation

Data Collection Source	Description
FDA Focus Groups	• Interviews with six Branch Chiefs from the Office of Device Evaluation and Office of In Vitro Diagnostics and Radiological Devices for insight into training and retention processes and challenges
CDRH Staff Interviews	• Conducted interviews with 11 representatives from CDRH to identify current CDRH Training Programs and Retention policies

Data Collection Source	Description
Benchmark Organization Interviews	• Conducted interviews with four senior representatives from the United States Patent and Trademark Office's (USPTO) Human Resource Department and Patent Training Academy to identify USPTO's practices and procedures for training review staff • Conducted five interviews with USPTO senior representatives to gather attrition data and obtain insights on organizational retention best practices • Conducted five interviews with CDER training program leadership and task leads to collect training survey data and obtain insights on organizational retention best practices
FDA Staff Survey	• Developed a structured online survey to gather FDA staff insights regarding available training programs and attrition issues
Pathlore Learning Management System (LMS)	• Reviewed data from the automating record-keeping and employee registration system for CDRH training courses
Employee Viewpoint Survey (EVS)	• Reviewed and extrapolated selected data elements pertinent to FDA and USPTO from a federally mandated government-wide survey, which measures employees' perceptions on organizational success factors
FDA Literature and Documentation on Training Programs and Staff Turnover	• Reviewed training materials, tutorials, and standard operating procedures (SOP) related to CDRH training programs and retention policies/practices and CDER training programs
Benchmark Organization Literature and Documentation related to Training Program Evaluation and Staff Turnover	• Reviewed annual reports, strategic plans, training materials, and standard operating procedures (SOPs) related to training program evaluation and employee retention best practices

3.2.5.1 Analysis of Training Program

Booz Allen conducted interviews with Division of Employee Training and Development (DETD) leadership and reviewed pertinent documentation to characterize each program, including program objectives, intended audience, curriculum, participation rates, and other metrics captured by Office of Communication and Education (OCE) (Appendix E). We also applied the Kirkpatrick Model[12] (detailed in Exhibit 76), a widely-recognized training evaluation framework used in industry and Federal agencies, to assess the extent to which each training program meets best practices that enable evaluation of training programs across the full lifecycle of learning, from initial participation in training to subsequent improvements in work functions.

Booz Allen reviewed and analyzed published literature for best practices that were aligned to the Kirkpatrick levels and used as a basis for evaluating each CDRH training program. We also applied benchmarking practices to inform FDA of activities implemented by other organizations that were considered particularly important to the success of those training programs. While there are inherent limitations to making comparisons between organizations with differences in core missions, performance metrics, and organizational structure, we made an effort to identify organizations comparable on a number of key characteristics impacting staff training program operations:

[12] The four levels of the Kirkpatrick Model include "Reaction", "Learning", "Behavior", and "Results" and are a highly influential model for training course evaluation. Kirkpatrick, D.L., & Kirkpatrick, J.D. (1994). Evaluating Training Programs, Berrett-Koehler Publishers.

- **Type of work product.** Applications are continually submitted and follow a similar structure and format
- **Staff functions.** Review staff performs a variety of concurrent submission reviews
- **Training requirements.** Rigorous training and staff specialization needed to perform submission reviews using a set of agency-approved processes.

The United States Patent and Trademark Office (USPTO) served as the external benchmark organization selected for further analysis and to lend insights to CDRH, on the basis of similarities to CDRH in terms of work product, staff functions, training requirements, and interest among FDA and industry stakeholders. Additionally, USPTO is recognized among the Federal Government as an award-winning, high-performing organization, and its training program complies with industry-recognized quality system standards through ISO 9001:2008 Quality Assurance certification. USPTO has also demonstrated significant improvement in government rankings, rising from a rank of 56 in 2010 to first place of a total of 300 agency subcomponents in 2013 (Exhibit 8).

Exhibit 8. "Best Places to Work" in Federal Government Rankings[13]

Year	USPTO	FDA
2010	56	89
2011	19	73
2012	5	47
2013	1	32

Two organizations within the Center for Drug Evaluation and Research (CDER), the Office of Executive Programs (OEP) and the Office of New Drugs (OND), were selected as internal organizational benchmarks due to their similarities to CDRH with respect to organizational mission, work functions, review processes, work products and maturity of the training program. OEP oversees training on core skills, such as organizational commitment, time and resource management, policies and procedures, and OND complements OEP training with science-specific curriculum.

Booz Allen interviewed key stakeholders and leadership from CDRH, OEP, OND, and USPTO to obtain leadership feedback on existing training programs and identify internal training evaluation policies and practices. Interview findings were analyzed using the Kirkpatrick Model as a framework to identify operational gaps and prioritize potential recommendations for CDRH.

Secondary sources that supported stakeholder feedback included an external Federal Agency-wide Employee Viewpoint Survey (EVS). Booz Allen also collected data through a CDRH survey to further understand reviewer and management perspectives on training programs and validate hypotheses.

3.2.5.2 Analysis of Staff Turnover

We characterized attrition in CDRH by gathering staff attrition data at the Center and Office levels, and comparing similar data collected from benchmark organizations. Calculations were

[13] *The Best Places to Work in the Federal Government (2013)*, Partnership for Public Service, Deloitte, The Hay Group.

applied to adjust the data so that a true comparison could be made between attrition rates for the different organizations.

Although there is variation among published retention frameworks, five key elements consistently emerged as impacting staff retention, which could be leveraged for use by CDRH to improve retention practices. These elements are described below and elaborated upon further in Appendix G.

- **Employee Engagement.** Increased employee commitment and involvement to go above and beyond their normal duties to improve the organization and advance its mission
- **Employee Recognition.** Awards and/or recognition from colleagues and/or supervisors for staff performance and acknowledging staff contributions to the agency's mission
- **Career Development.** Increased capacity to perform through training, assignments that introduce new skills, or improved work processes
- **Benefit Programs (Work/Life Balance).** Programs in place to improve employee quality of life, including but not limited to work/life balance, teleworking, on-site daycare
- **Succession Planning.** Organizational preparedness to reduce adverse impacts of employee attrition, such as through transition plans or knowledge databases.

We conducted interviews with CDRH personnel and reviewed available process documentation to evaluate current CDRH policies and practices used to support employee retention against these five elements. Additionally, we interviewed key stakeholders from USPTO to capture their perspectives on their most successful retention policies, methodologies, or best practices that may be potential opportunities for CDRH to implement. EVS data was reviewed to understand CDRH and USPTO staff perceptions of job satisfaction and other factors impacting retention. Booz Allen's CDRH-wide survey also captured review staff and management feedback on these policies and practices.

3.3. Develop Findings and Recommendations

This final report provides analyses and findings from the first phase of this study, which includes findings developed in conjunction with the initial set of priority recommendations that were provided to FDA during the first six months of contract award. Results compiled and documented include review processes, behaviors, and tools that promote or inhibit consistent and efficient review processes. Recommendations highlight potential areas of improvement, and suggestions as to potential system or procedural changes that could provide the most value to the device review process.

4. FINDINGS

The study's findings are organized into the following subsections:

- Analysis of issues identified in documents prior to MDUFA III and determination of whether the new processes implemented by CDRH address these issues
- Assessment of quality management components in the design and continued implementation of MDUFA III review processes

- Analysis and findings related to quality controls and reliability of management systems in place for FDA to facilitate efficient and consistent medical device reviews, as well as factors and activities that appear to positively or negatively influence review times
- Analysis and findings from our assessment of FDA's IT infrastructure and data systems that facilitate medical device submission reviews, and workload management tools used to support reviewer workload allocation practices
- Analysis and findings from our evaluation of CDRH review staff training programs and assessment of staff turnover from CDRH and selected benchmark organizations.

4.1. Issues Analysis

The purpose of the issues analysis was to assess the extent to which known issues identified during the MDUFA II timeframe had been addressed through the implementation of MDUFA III processes or other initiatives. As described in Section 3.2.1, we used a variety of data sources to identify previously-documented review process issues to determine whether FDA had begun to take steps to address these issues during the MDUFA III timeframe. Given the relatively short timeframe since the implementation of MDUFA III, the assessment was not designed to consider whether the measures put forward had successfully resolved the issues, only whether efforts were already underway and therefore, did not require a priority recommendation for this review.

Issues identified from the MDUFA II timeframe were consolidated and yielded a list of 31 unique issues. These issues were organized into six categories: submission quality, communication between Sponsors and FDA, review tools, review decision-making, management oversight, and workload. Exhibit 9 summarizes Booz Allen's identification and categorization of issues, and also denotes the data source(s) from which each issue was identified. For each issue, we assessed whether FDA had taken steps to address the issue and categorized our assessment of actions as either a MDUFA III provision (e.g., implementation of RTA process), FDA provision (e.g., development of guidance documents), other step taken, or a potential gap. In Exhibit 9, we also reference any Booz Allen recommendations, which were developed and proposed based on our assessment of review processes and management systems, to address a gap or further support initial actions already taken by FDA to address an issue.

Booz Allen's preliminary assessment revealed that FDA appeared to have taken steps to address 21 of the 31 issues identified, either through the development and implementation of new MDUFA III provisions, updated systems, processes for review staff, and/or guidance for industry. We asked FDA to provide validation and documentation on actions taken for each of the remaining 10 issues that appeared potentially unaddressed through our preliminary research. Booz Allen analyzed the additional information provided by FDA during the validation step and determined that one outstanding issue remained unaddressed, to be resolved with a priority recommendation: FDA lacked sufficient tools and metrics to assess the consistency of decision making across the program. Actions taken to address this issue could positively impact TTD, TST, and help address industry needs for a more consistent review process.

Exhibit 9. Summary of Issues Identified from MDUFA II Issues Analysis

Issue Type	Issue Description	Lit Review	Industry	M2 Cohort	LR Survey	Provision/Step Taken during MDUFA III or Potential Gap
Submission Quality	Discrepancies or missing data in submissions	●		●	●	*Provision:* Implementation of RTA process and checklist requires the presence of administrative elements
	Inconsistent, unstructured application format	●	●			*Step Taken:* FDA has taken steps for initiating a pilot program for electronic submissions that will take users through the process of constructing and submitting 510(k) submissions electronically. The pilot program was announced in a May 1, 2014 FR notice.
	Multiple Clinical Deficiencies identified requiring lengthy review	●		●		*Provision;* FDA finalized guidance to industry on design considerations for pivotal clinical investigations *Booz Allen put forth recommendation (5, Early and Frequent Communication)*
	Sponsor submitted incorrect submission type	●		●		*Provision:* New pre-submission guidance released February 14, 2014
	Sponsor did not select appropriate 510(k) predicate device			●	●	*Provision:* Draft guidance on industry selection of predicates devices; "How to Find A Predicate Device" webpage; Identification of predicates via product code database, classified 510(k) database, and 510(k) summaries
	Lack of Sponsor experience	●	●		●	*Step Taken*: FDA holds workshops and meetings with industry (e.g., pre-submission meetings); hosts public medical device meetings and workshops; provides online training modules (CDRH Learn) on a variety of premarket topics (e.g., Premarket Notification Process – 510(k); offers Guidance Documents and Standard Operating Procedures (SOPs); hosts public medical device databases for reference by industry; triages Sponsor questions that are addressed by Division of Industry and Consumer Education (DICE); provides a Device Advice informational webpage
Sponsor and FDA Communication	Insufficient communication from FDA	●	●	●		*Provision:* Development of communications guidance and continued use of interactive review (IR) process *Booz Allen put forth recommendation (5, Early and Frequent Communication)*
	Insufficient communication of current or evolving regulatory thinking to all affected parties in a timely and meaningful manner		●			*Provision:* Improvement in interactive review (IR) and continued development and revision of guidance documents to clarify submission requirements
	Late/delayed communication and decisions from FDA	●	●	●		*Provision:* Implementation of substantive interaction (SI) and interactive review (IR) processes per MDUFA III *Booz Allen put forth recommendation (5, Early and Frequent Communication)*
	Incomplete responses to AI from Sponsor	●		●	●	*Provision:* Implementation of substantive interaction (SI) and interactive review (IR) processes per MDUFA III
	Late/prolonged response to AI from Sponsor	●		●	●	*Step Taken:* Booz Allen Traditional 510(k) TTD analysis demonstrated that Sponsors have provided AI/TH responses sooner in the MDUFA III timeframe [14]
Review Tools	Lack of tools to support review process	●			●	*Step Taken:* Implementation of IT systems including CTS, DocMan, Image2000+, and CARS and applied worksheets by submission type

[14] This issue was not identified as an FDA potential gap but was analyzed further in this study.

Issue Type	Issue Description	Lit Review	Industry	M2 Cohort	LR Survey	Provision/Step Taken during MDUFA III or Potential Gap
	Limitations in existing CDRH IT and knowledge management infrastructure and tools	●			●	*Step Taken:* Implementation of CTS, DocMan, Image2000+, and CARS systems. *Booz Allen put forth Priority Recommendation (3.2, Mandatory training on IT systems)*
Review Decision	Inconsistent adherence to pre-submission agreements		●	●	●	*Step Taken:* FDA is currently instituting a more structured process to manage pre-submissions; release of new pre-submission guidance
	Unclear submission requirements and guidance documents		●			*Step Taken:* FDA is updating and developing new guidance documents to clarify submission requirements; implementation of RTA process
	Inconsistent use of existing/ recognized policies or standards	●	●	●		*Step Taken:* FDA is updating and removing old guidance documents; FDA has planned webinars to educate staff on new guidance documents and standards
	Unclear processes for CLIA Waiver Application		●			*Provision:* FDA has published an administrative procedure guidance including processes for CLIA Waiver by Application
	Lack of clarity about decision process for conversion of submissions		●			*Provision:* FDA issued an RTA Policy for 510(k)s Guidance for Industry and FDA Staff, which states four criteria for conversion of Special to Traditional 510(k)s (December 31, 2013) *Booz Allen identified areas for improvement through the conversion analysis (4.3.1.7).*
Management – Oversight	High ratio of reviewers to managers	●	●			*Step Taken:* CDRH reorganization underway to lower staff ratio and additional staff hired per user fee collected to reduce reviewer/supervisor ratio
	Inadequate management oversight of decisions	●	●		●	*Step Taken:* Management training was implemented (e.g., LEAD) for Branch Chiefs and Division Directors *Booz Allen identified areas for improvement through Priority Recommendation (3.4, Senior Management)*
	High staff turnover/too many changes in reviewers	●	●	●		*Step Taken:* Booz Allen assessed CDRH attrition and summarized best practices to mitigate the impact of turnover for FDA consideration
	Insufficient tools and metrics in place to assess the consistency of decision making across the program		●			*Step Taken:* Reviewers were observed using the decision tree worksheet while conducting review *Potential Gap: Booz Allen identified areas for improvement through Priority Recommendation (3.1, Improve consistency in decision-making) to address this issue*
	For combination products, delays by CDER/CBER review process slow CDRH approval of PMAs		●		●	*Step Taken:* Booz Allen analyzed challenges for combination products and companion diagnostics submissions and noted lack of synchronicity between the MDUFA and PDUFA review timelines for Inter-Center Consults (ICC) *Booz Allen identified potential area of improvement through ICC analysis (4.3.2.7).*
Management – Workload	Reviewers required to spend significant time on non-application review related activities	●	●		●	*Step Taken:* Hiring of additional review staff to lessen workload
	High reviewer workload	●	●		●	*Step Taken:* Hiring of additional review staff to lessen workload
	Reviewers not experienced on new technologies	●	●		●	*Step Taken:* Providing timely specialized training to all staff via establishment of Experiential Learning Program (ELP)
	Difficult for reviewers to utilize external scientific expertise in a timely manner	●	●			*Step Taken:* Establishment of Experiential Learning Program (ELP)

Issue Type	Issue Description	Lit Review	Industry	M2 Cohort	LR Survey	Provision/Step Taken during MDUFA III or Potential Gap
	Inefficient use of Third Party Review program		●	●	●	*Step Taken:* Improving Third Party Review program and establishing new procedures to improve transparency
	Increasing number of consults and long consult review times	●		●		*Step Taken:* FDA formed a working group to develop a Consults SOP, which is being prepared for management review, and subsequently, Center roll-out
	Suboptimal process of screening/triaging 510(k) submissions for reviewer assignment	●	●			*Step Taken:* FDA data systems currently used by management to inform reviewer assignments *Booz Allen put forth a recommendation (8 Evaluate tools for providing comprehensive view of staff workload).*
	Inefficient use of De Novo Classification	●				*Step Taken:* Creation of new regulations and draft guidance for the *De Novo* process are underway; FDA internal SOP for *De Novo* roles and responsibilities recently developed; review templates and controls documents to streamline processes have also been created

4.2. Quality Management Assessment

Booz Allen performed a quality management (QM) assessment to evaluate the design of major new MDUFA III processes for their potential to address the identified issues and for consistency with QM principles. We employed a quality assessment framework drawn from established quality management principles, consisting of five components described below:

- **Senior management.** Leadership has overseen the development of quality components for new business processes, prioritized and approved new processes and quality activities, provided adequate resources for development, and reviewed and analyzed quality data. For the purposes of this assessment, we consider senior management the anchoring component for the other quality components

- **Resource Management.** Adequate resources are dedicated to develop and implement new business processes. Staff received training and has an adequate understanding to execute on new business processes and quality activities

- **Document Control.** Mechanisms are in place to make current business process documentation easily accessible to staff, and to encourage use

- **Corrective and Preventive Action (CAPA) and Continuous Process Improvement (CPI).** Documented methods are in place to collect and review new process issues and concerns, escalate issues, track and document CAPAs, provide feedback; there is a standard method to engage in CPI

- **System Evaluation.** Standard methods and tools are in place to evaluate performance of new business processes.

Our findings from each of these component areas are discussed below.

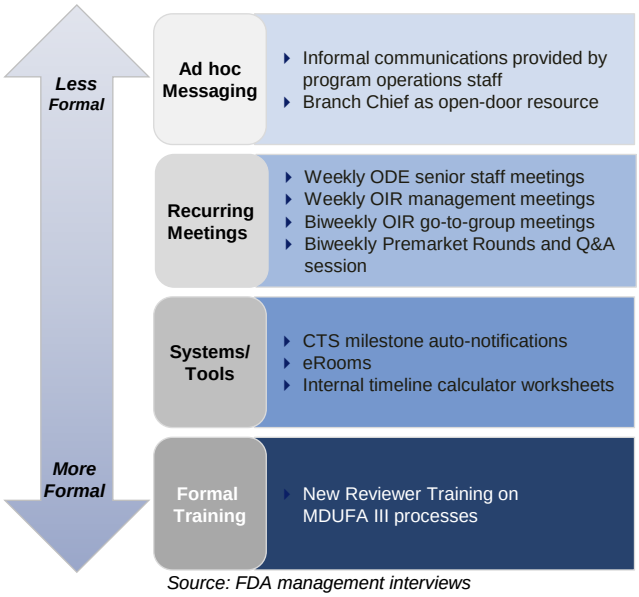
4.2.1.1 Senior Management

The evaluation of this component consisted of determining whether there was a mechanism for senior management to provide oversight of new process development, prioritization of quality activities, and analysis of quality data. The MDUFA III Implementation Steering Committee was formed to oversee and coordinate the implementation of new MDUFA III processes and systems. Through our review, we noted that representatives from all levels of management participated to determine how each new MDUFA III process would be operationalized and assessed. For example, an RTA working group was tasked with operationalizing and auditing the RTA process. Senior management monitors the implementation of the processes and reviews new issues as they arise through existing mechanisms. Each level of management from the branch to the Center is accountable to ensure successful process implementation and to raise and resolve issues. However, this feedback loop is not formally documented (e.g., the process to intervene on submission issues), which can result in missed opportunities and ambiguity among different management levels to assume all of the necessary steps to see through all issues to resolution.

4.2.1.2 Resource Management

For the resource management component, we assessed the extent to which review staff has resources available to ensure an adequate understanding of how to execute new business processes and quality activities; however, reviewer workload was not evaluated in this assessment. We obtained information from program and division leadership on the methods review staff has available to learn about MDUFA III processes, best practices, and how to apply these processes to submission reviews. A variety of informal and formal methods are available to help staff understand new and existing review practices (Exhibit 10). For example, programmatic issues are discussed at weekly senior staff meetings among division- and office-level managers. Premarket rounds include question and answer sessions to educate staff on the practical implications of program changes, audit findings, and document updates. In addition, new reviewer training formally held at the outset of MDUFA III implementation also provided baseline material to all review staff.

Exhibit 10. Methods Available to Review Staff to Understand MDUFA III Processes



Source: FDA management interviews

Through this review, we observed that most of the available methods rely on the initiative of review staff to participate and learn about review processes. Specifically, FDA does not deploy surveys or use metrics or other evaluative methods to assess whether staff has adequately understood programmatic changes.

Some Division or Branch management encourages internal timeframes for reviewers to complete review milestones to ensure that MDUFA goals are met. Branches or Divisions may build in soft deadlines to ensure that Lead Reviewers submit review summaries for management review and concurrence to ensure that goals are met on time. Internal milestone tracking worksheets are used by some Lead Reviewers to help them manage these internal timeframes and to facilitate efficient reviews. However, data from a Lead Reviewer Survey, which was gathered from Lead Reviewers who were responsible for reviewing Traditional 510(k) and PMAs selected in our initial study cohort, indicated that significant variability exists not only between Divisions but also within Division review staff on expectations for internal milestone timeframes.

4.2.1.3 Lifecycle Management: Document Management

We investigated the various document control IT systems (i.e., CTS, DocMan, Image2000+) for quality in process design. We found that CDRH employs various mechanisms for introducing quality into its document control and document management processes. For example, there are methods to store submission review templates, reference guides, and collaborative review materials. In addition, access controls are in place, and there are mechanisms to notify staff of document updates. However, interviews with senior management confirmed that inconsistencies within document control elements detract from review performance. For example, DocMan folders often contain many duplicative and/or outdated documents (e.g., three versions of the same summary but with different reviewer/Branch Chief/Division Director signatures). This is not the intended practice and results in errors and inefficiencies when performing document searches.

eRooms represent another document control system currently used by staff to reference program and division-specific templates, SOPs, checklists, process flows, and user guides in support of submission review processes. Due to the near-term migration of content from eRooms into a new SharePoint system, we did not perform a detailed assessment of eRooms.

4.2.1.4 Lifecycle Management: Corrective and Preventive Action (CAPA) and Continuous Process Improvement (CPI)

Our review found that the Office of Device Evaluation (ODE) has implemented a CAPA database to resolve issues that impact multiple Divisions. Examples of CAPA issues include updates to guidance to standardize labeling, resolution of an appeal, or development of an SOP to clarify submission review milestones. The CAPA database tracks issues until they are resolved, and senior management holds quarterly CAPA meetings to discuss progress and methods for issue resolution. In the Office of In Vitro Diagnostics and Radiological Health (OIR), management holds weekly meetings with Policy Analysts to resolve issues and coordinate with ODE as relevant; however, OIR does not have a CAPA database.

For non-CAPA (i.e., Division-specific) issues, there is currently no formal method to log, track, or prioritize issues, or communicate feedback, as shown in Exhibit 11. For example, non-CAPA issues could include a review inconsistency found in an NSE recommendation, or a Division issue with a labeling claim. Staff currently may raise and address non-CAPA issues but do not use a database or employ other systematic methods to manage and record issue resolution.

Exhibit 11. Mechanisms to Resolve Division and Office-Specific Issues

	CAPA Issue (ODE Only)	Non-CAPA Issue (ODE and OIR)
Description	• Issues with cross-cutting Division impact	• Singular Division-specific issues
Issue example	• Update guidance to standardize labeling • Develop SOP on consult requests • Resolve an appeal	• Review inconsistency found in NSE recommendation • Division issue with labeling claim
Applicability to MDUFA III	• Yes[15]	• Yes
Mechanism to Log/Track Issues	• CAPA Access database tracks issues until resolved	• No formal methods used
Mechanism to Review/Resolve Issues	• Quarterly CAPA meetings • No set timelines to resolve an issue	• Weekly Regulatory Advisor meetings (ODE) or Policy Analyst meetings (OIR) • Case-by-case use of phone calls, e-mails , meetings, or POS
Issue Prioritization	• No formal criteria	• No formal criteria
Feedback Mechanism	• Premarket Rounds • Program mailbox communications • No formal methods to communicate resolution to issue originator • Quarterly Industry Meetings	• No formal methods

Source: FDA management interviews, Regulatory Advisor interviews

[15] At the time that FDA management interviews were conducted, no issues in the CAPA database pertained to MDUFA III processes.

Areas for improvement may be originated by review staff, program operations staff, Regulatory Advisors, or senior management. Suggestions for improvement, which occur on an ad hoc basis and are raised informally, are typically coordinated by a designated group in ODE and OIR. However, across both offices, standard methods across divisions do not exist to log, review, and close out suggestions for process improvement.

4.2.1.5 System Evaluation

CDRH senior management diligently monitors and reports on submission status, and relies heavily on MDUFA goal milestones for evaluating progress and success. For example, senior management regularly tracks performance trends to identify changes in TTD over time, and also uses MDUFA goal milestone data to identify any submission issues that must be addressed with Branch Chiefs and Division Directors. CDRH also performs periodic ad hoc audits on certain processes (e.g., RTA audit), as well as annual audits to ensure administrative compliance (e.g., 510(k) program). Program operations staff has noticed that for several submissions that did not meet their MDUFA goal dates, milestones were missed earlier in the process. As a result, program operations staff now pays more attention to these indicators and send reminders to Lead Reviewers of upcoming due dates based on workload reports from the CARS and CTS. While this mechanism may work to identify some submissions at risk for longer review times, more granular internal metrics are needed to ensure the quality and effectiveness of sub-processes (e.g., RTA or IR) within the larger submission review process.

4.3. Evaluation of Review Process

Booz Allen evaluated the premarket review processes for the following submission types: Traditional 510(k)s, PMA Originals, PMA Panel-Track Supplements, PMA 180-Day Supplements, PMA Real Time Supplements, IDEs and Q-Submissions. Our analysis focuses on the impact of MDUFA III review processes occurring during the Acceptance Review phase, Substantive Review (SR)/Substantive Interaction (SI) phase, and MDUFA/Interactive Review (IR) phase on review outcome.

MDUFA III required the development and implementation of a number of new review practices, including review staff use of RTA checklists to determine completeness of submissions, communication of a substantive interaction decision by Day 60, and use of interactive review during the MDUFA review phase. While these new processes were applicable at the onset of MDUFA III (October 1, 2012), they were not fully implemented until the end of 2012. To fully evaluate the impact of MDUFA III review processes, the timeframe used to select the MDUFA III (M3) submission cohort was adjusted to consider only submissions received during calendar year 2013 (CY13), which reflects the full implementation of new processes. While the MDUFA II timeframe comprises submissions received during FY 2008-2012, Booz Allen only selected submissions received during FY12 for the assessment. Therefore, performance prior to FY12 is not part of this study, and the findings for this cohort should not be considered representative of the full MDUFA II timeframe.

Booz Allen took into consideration a brief maturity window[16] for the submissions in the sample cohorts we analyzed, so that submissions received by FDA during the relatively short timeframe

[16] Booz Allen defined the “maturity window” to mean a period of time . following the timeframe Booz Allen selected for submissions to be received by FDA (e.g. January 1, 2013 to December 31, 2013 for the M3 Received Cohort) to

from the implementation of MDUFA III would have additional time to close and enable study analysis. Exhibit 12 highlights the parameters used in our cohort selection process.

Exhibit 12. Cohort Selection Criteria

Cohort	MDUFA III	MDUFA II
	M3 Received & M3 Study (CY13)	M2 Received (FY12)
Submission Received Date	1/1/13 – 12/31/13	10/1/11 – 9/30/12
Final Decision Deadline	2/28/14	11/30/12
Maturity Window	2 months	2 months

MDUFA III new process requirements (i.e., RTA and SI) apply to 510(k) and PMA Original and Panel-Track Supplements, whereas only the SI process applies to PMA 180-Day Supplements, and no new MDUFA III processes are required of Real Time Supplements. Our analyses and findings of applicable review processes are organized by submission type in the sections below.

4.3.1. 510(k) Submissions Analysis

Our analysis of the Traditional 510(k) review processes includes characterization of TTD and TST across divisions for both the M2 and M3 Cohorts. We investigated underlying factors that contribute to the changes in TTD and TST observed from MDUFA II and MDUFA III, including the impact of RTA cycles, RTA checklist, RTA issues, Sponsor origin, timing of initiation and completion of substantive review, number of SI issues and issue categories identified, timing of MDUFA decision and withdrawals, timing and frequency of communications during review phases, and consult requests and reviews. Lastly, we summarize our findings from case study analyses of Special 510(k) to Traditional 510(k) conversions and the CLIA Waiver dual process.

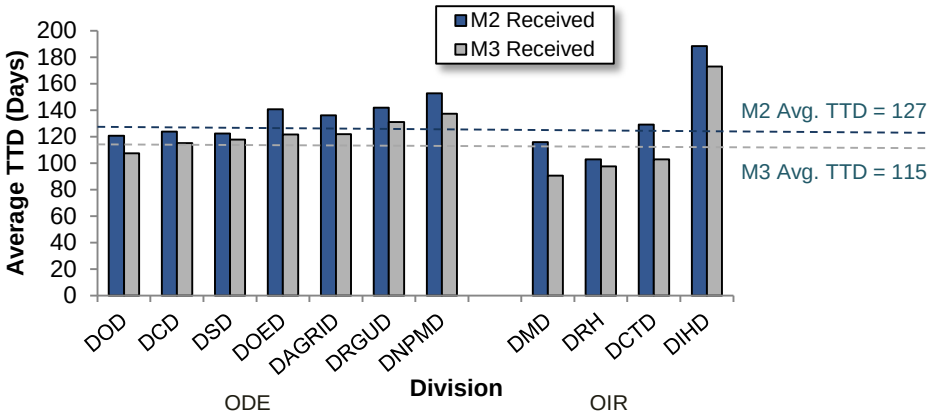
4.3.1.1 TTD and TST Characterization of M2 and M3 Cohorts

Booz Allen calculated TTD for the M2 and M3 Received Cohorts[17] to determine review times across Divisions. Our data, shown in Exhibit 13, showed a decrease in TTD from the M2 Received Cohort to the M3 Received Cohort (127 days versus 115 days, respectively). This difference between M2 and M3 was observed across both offices and all Divisions. In addition, submissions within ODE had higher average TTD than submissions within OIR and this was observed in both the M2 and M3 Received Cohort. There are several factors that may lead to the difference in TTD between ODE and OIR, and we provide additional analysis in Section 4.3.1.5.

increase the potential sample of submissions that reached final decision to facilitate study analysis. Due to the timing of this study, a maturity window of two months could be applied to capture closed submissions for analysis. Given the short maturity window, submissions with particularly long review times had not reached final decision, and are not represented in the M3 Received Cohort. To avoid any bias in review times when comparing M2 Cohort submissions to M3 Cohort submissions, a consistent two-month maturity window was applied to analyze both M2 Received and M3 Received Cohorts.

[17] The M2 and M3 Received Cohorts only include submissions that have reached final decisions of SE or NSE.

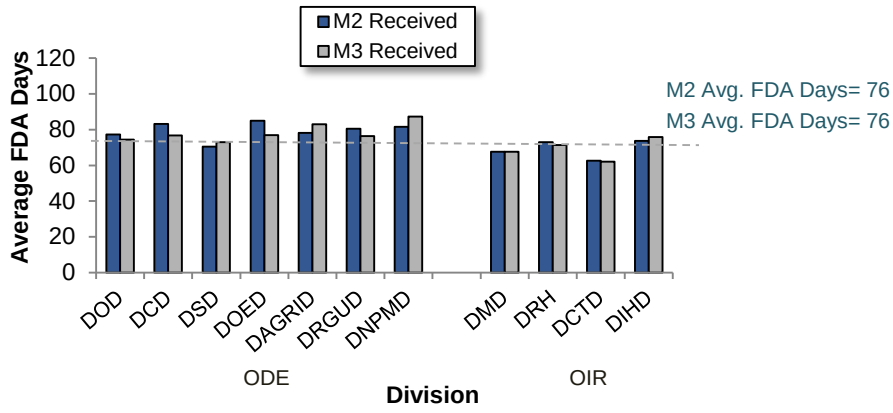
Exhibit 13. Average TTD for Traditional 510(k)s by Division



Number of Submissions	DOD	DCD	DSD	DOED	DAGRID	DRGUD	DNPMD		DMD	DRH	DCTD	DIHD
M2 (n)	286	179	210	50	330	106	85		49	206	98	16
M3 (n)	348	175	186	69	291	114	90		40	190	103	28

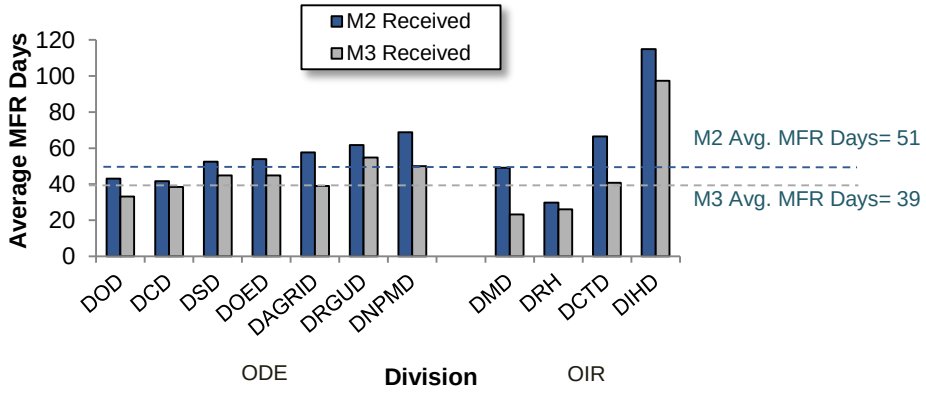
We further analyzed TTD data by FDA Days and Manufacturer (MFR) Days to identify the source of the decreased TTD between the M2 and M3 Received Cohorts. Our analysis, shown in Exhibit 14, demonstrated that FDA Days remained similar between the M2 and M3 Received Cohorts (76 days for both), regardless of Division or Office.

Exhibit 14. TTD/FDA Days for Traditional 510(k)s by Cohort and Division



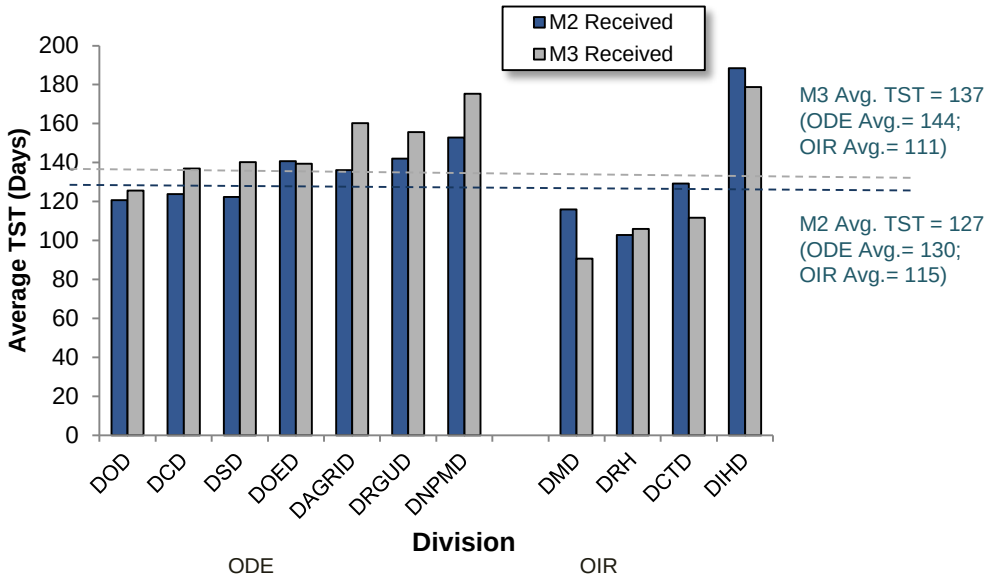
In contrast, we identified a decrease of 12 days in Manufacturer Days from the M2 to M3 Received Cohorts (Exhibit 15), which explains the decrease in overall TTD between the two cohorts.

Exhibit 15. TTD/Manufacturer Days for Traditional 510(k)s by Cohort and Division



In addition to TTD, we calculated average TST, which is the time from submission receipt to final decision, for the M2 and M3 Received Cohorts.[18,19] Our analysis, shown in Exhibit 16, revealed that the average M2 TST (127 days) was shorter than the average M3 TST (137 days). When analyzed by office, we observed an overall decrease in TST between the M2 and M3 Received Cohorts for OIR submissions (115 to 111 days), while overall TST increased between the M2 and M3 Received Cohorts for ODE submissions (130 to 144 days).

Exhibit 16. Average TST for Traditional 510(k)s by Division

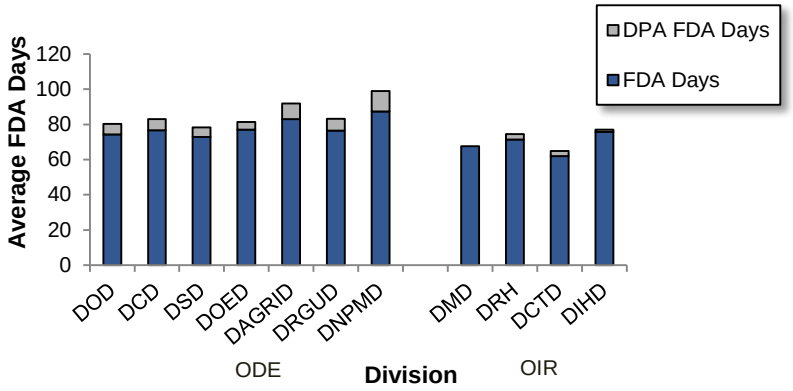


[18] Because RTA processes were not in place for MDUFA II submissions, TST is equivalent to TTD for MDUFA II submissions, while TST for MDUFA III submissions includes FDA Days and Manufacturer Days prior to submission acceptance in addition to TTD.

[19] Booz Allen analyzed TST to determine FDA and sponsor days spent prior to submission acceptance; however, TST is not currently used by FDA or industry to assess review time as part of its MDUFA III negotiated agreements

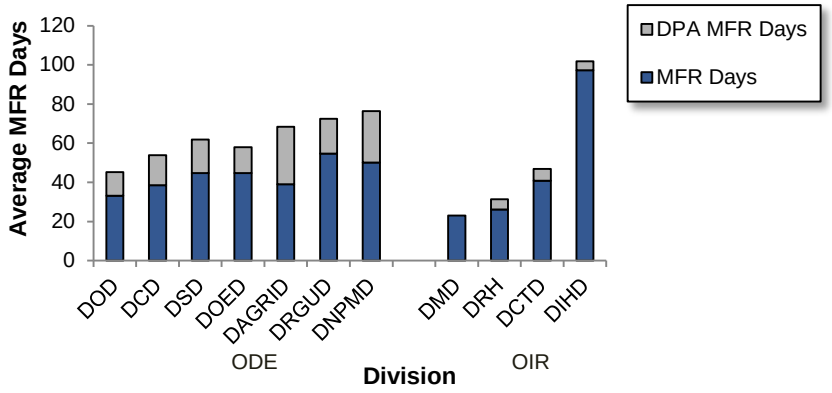
Similarly, we analyzed data by FDA Days and Manufacturer Days to identify the source of Office differences in TST for the M3 Received Cohort. Data on FDA Days, shown in Exhibit 17, indicates that ODE submissions had a higher average number of FDA Days than OIR (78 versus 69 days, respectively). ODE submissions were also associated with a higher average number of days prior to acceptance (DPA) (7 days) as compared to OIR submissions (2.5 days).

Exhibit 17. TST/FDA Days for Traditional 510(k)s by Division



With the exception of DIHD, average ODE Manufacturer Days were greater than in OIR (41 versus 35 days), as shown in Exhibit 18. In addition, ODE had a significantly greater average number of Manufacturer Days prior to acceptance than OIR (19 versus 5 days), which is indicative of more RTA cycles and more time needed by sponsors to provide an administratively complete submission. More effective use of the RTA checklist by applicants may be one method of contributing to a decrease in TST.

Exhibit 18. TST/Manufacturer Days for Traditional 510(k)s by Division

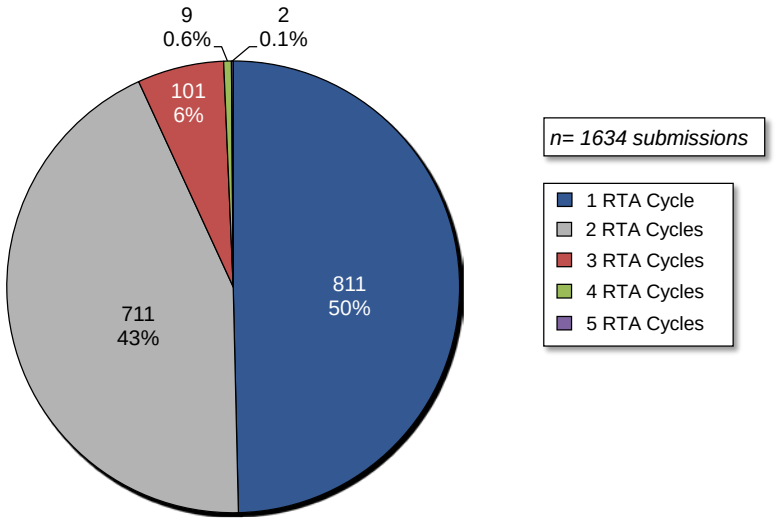


4.3.1.2 RTA Impact

Booz Allen sought to understand the significance of the RTA process and its potential impact on both TTD and TST. Of the 1,634 M3 submissions in the cohort, only 50% of submissions

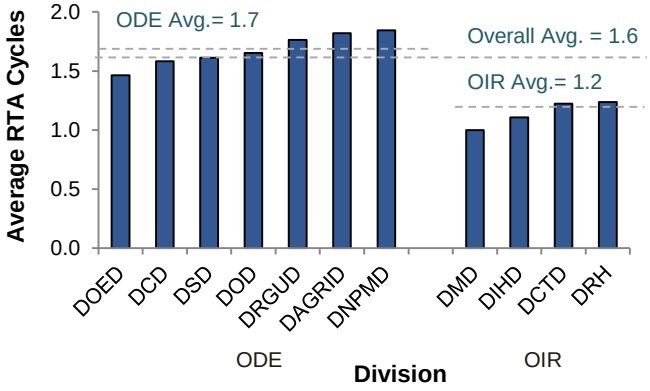
received RTA approval during the first RTA review cycle (Exhibit 19). Only 7% of M3 submissions required more than two RTA cycles.

Exhibit 19. Distribution of Number of RTA Cycles in M3 Cohort



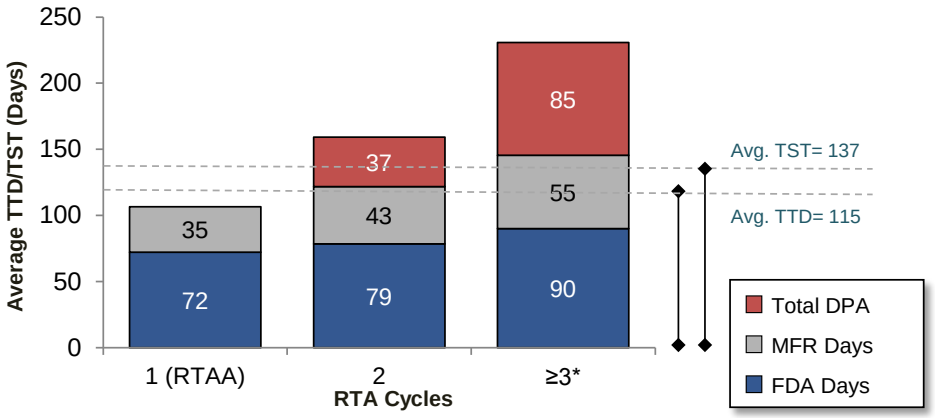
The average number of RTA cycles for Traditional 510(k) submissions across all Divisions was 1.6. We characterized the number of RTA cycles to identify potential variation by Division and Office, as shown in Exhibit 20. While variation exists between Divisions, the average number of RTA cycles for ODE submissions (1.7) was slightly higher than for OIR submissions (1.2).

Exhibit 20. Average RTA Cycles by Division



We further examined whether an increasing number of RTA cycles for submissions was associated with differences in average TTD and TST. As shown in Exhibit 21, we observed that an increase in RTA cycles is associated with an increase in TTD and TST. Interestingly, as the number of RTA cycles increases, the increase in TST is substantially greater than the increase observed for TTD. Further analysis is required to better understand the association between number of RTA cycles and length of review time.

Exhibit 21. Average TTD and TST by RTA Cycles in Traditional 510(k) M3 Received Cohort

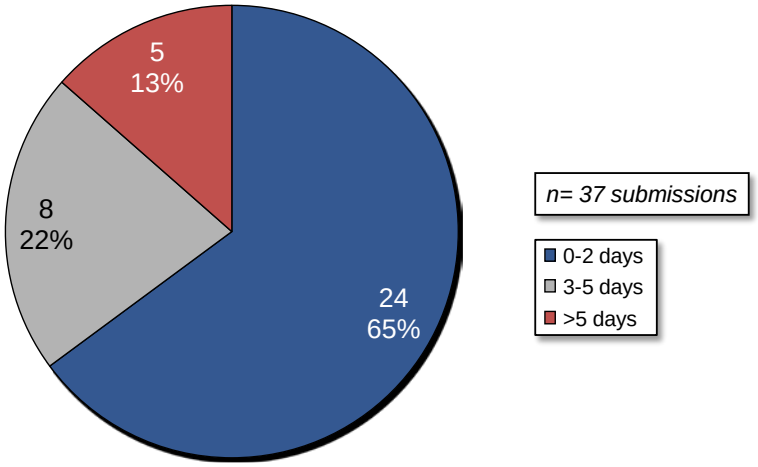


	1(RTAA)	2	≥3
n= 1634	811	711	112
% of 510(k)	49.6%	43.5%	6.9%

**. ≥3 RTA cycles includes 9 submissions with 4 RTA cycles and 2 submissions with 5 RTA cycles*

FDA survey and focus group interviews indicated that delays in receiving submissions by the Division negatively impacted timely submission assignments to review staff. The MDUFA clock begins for a submission review when the submission is stamped as received by the document management center (DMC). Since only 15 calendar days are allowed for completion of Acceptance Reviews, any delays reviewers experience in receiving submissions limits staff time for performing Acceptance Reviews. We reviewed the first RTA cycle for the 37 submissions in our Study Cohort and characterized submissions by the day each submission was received by a Division. We observed that while 65% of submissions were received by a Division within two days, 22% of submissions were received within 3-5 days, and 13% submissions required more than five days to reach a Division (Exhibit 22).

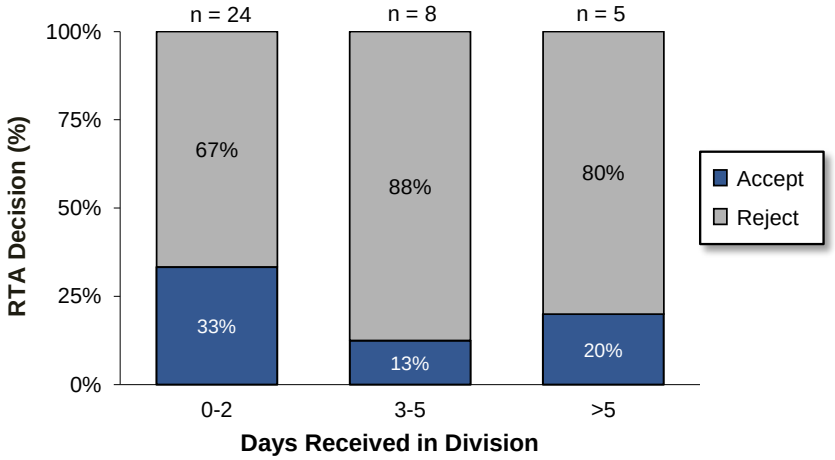
Exhibit 22. Percent Submissions Received by Review Division, by Day



Note: Only 1st RTA cycles are included in this analysis

We further reviewed these 37 submissions to determine whether there was any correlation with time to receipt by Division and the outcome of an RTA Acceptance review. As shown in Exhibit 23, there was a reduction in RTA approvals in our sample once days to receipt by Division exceeded two days among submissions in our Study Cohort. However, no conclusive findings could be drawn from this analysis due to the relatively small sample size.

Exhibit 23. RTA Decision by Days to Division Receipt

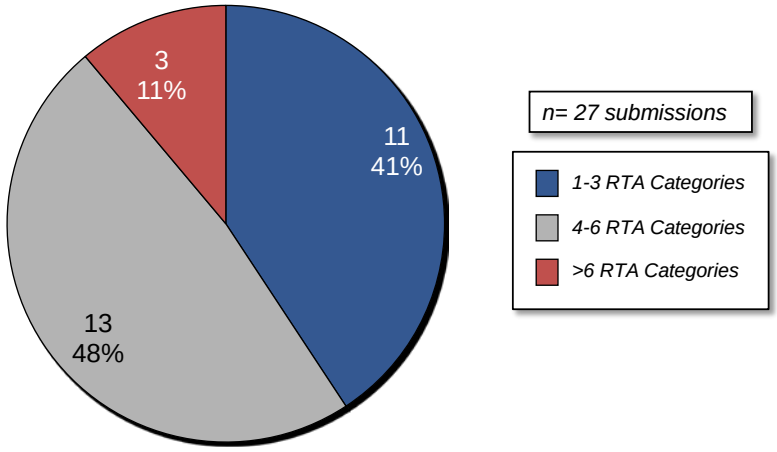


Note: Percentages may not add up to 100% due to rounding

Within the M3 Study Cohort, 27 of the 37 Traditional 510(k) submissions were rejected during the first RTA cycle. To better characterize submissions with first cycle RTA rejections, we evaluated these 27 submissions for deficiencies within the 10 RTA categories for which submissions are evaluated for completeness during Acceptance Review using an RTA checklist. These categories include Administrative, SE discussion, Performance Data or Characteristics, Labeling, and others that are specific to the type of device. As shown in Exhibit

24, we observed that 59% of submissions had missing or deficient elements in four or more categories.

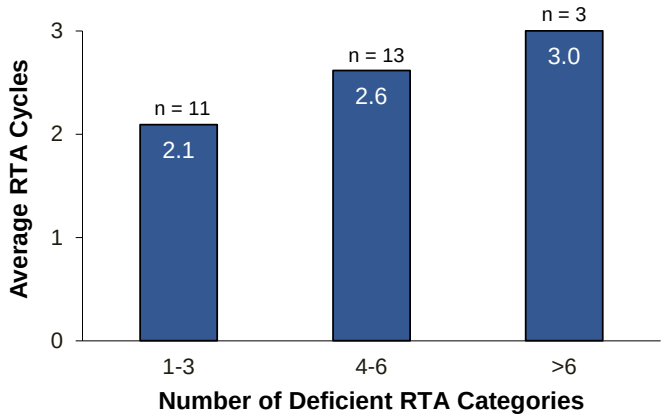
Exhibit 24. Percentage of Submissions with Missing/Deficient Element by RTA Categories



Note: Includes analysis of 1st cycle RTA rejections only

We further analyzed these 27 submissions to identify whether submissions with missing/deficient elements in multiple RTA categories were correlated with more RTA cycles. As shown in Exhibit 25, submissions with deficiencies in 4-6 categories and more than six categories were associated with an increase in the average number of RTA cycles (25% and 50%, respectively) compared to submissions with deficiencies in 1-3 categories. Our previous analysis demonstrated that increased RTA cycles are correlated with longer TTD and/or TST (refer to Exhibit 21).

Exhibit 25. Average RTA Cycles by Categories with Missing/Deficient Elements

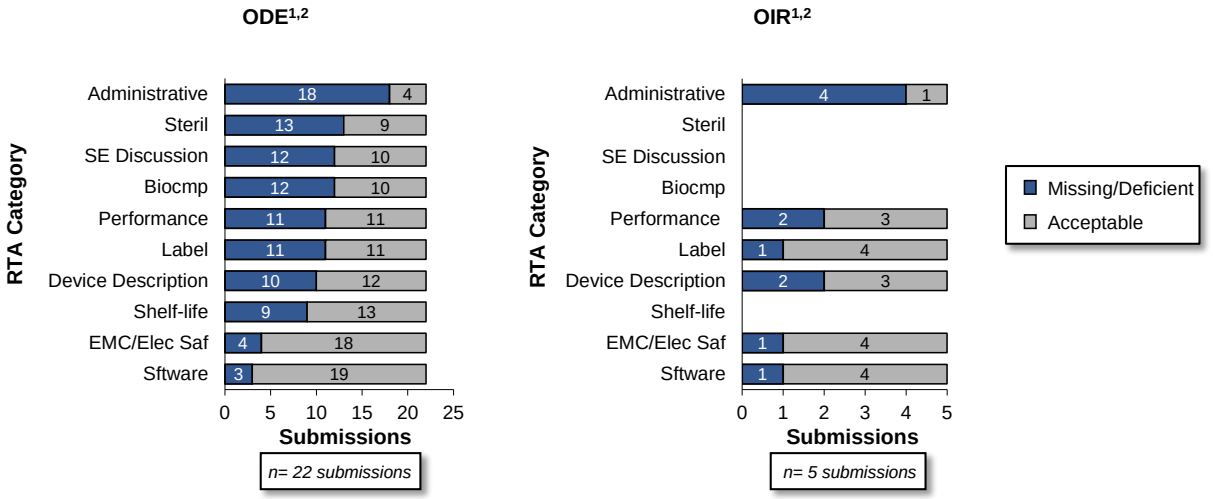


Note: Includes analysis of 1st cycle RTA rejections only

Booz Allen characterized the 27 submissions (22 ODE, 5 OIR) for specific RTA categories in which missing/deficient elements were present in the first RTA rejection (Exhibit 26). Noting that

some RTA categories are not applicable to all submissions, we observed that a majority (>80%) of submissions had deficiencies within the Administrative category (18 of 22 ODE submissions and four of five OIR submissions).

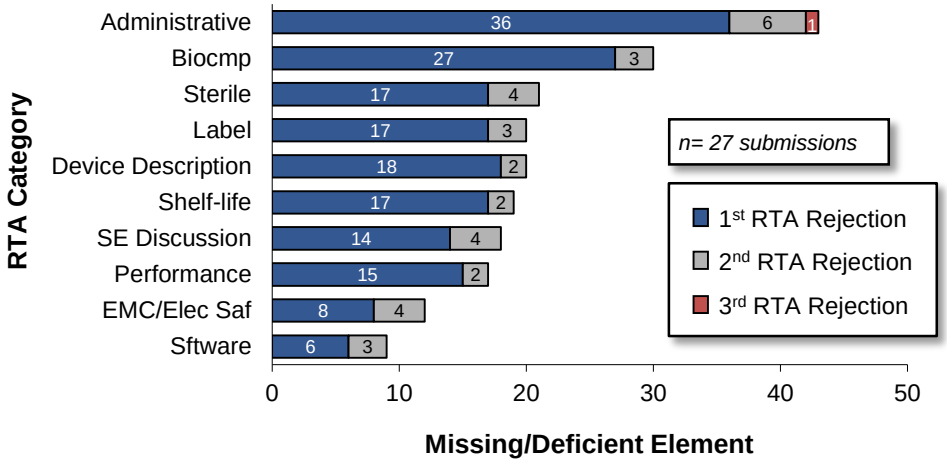
Exhibit 26. Number of Submissions with Missing/Deficient Elements by Specific RTA Categories



Notes: [1] Includes analysis of 1st cycle RTA rejections only; [2] Analysis represents whether a deficiency was identified within an RTA checklist category only. Some categories may not be applicable to all device types/submissions

In addition, Booz Allen performed deep-dive analyses of RTA checklist elements that were missing or deficient, including elements that were identified in all RTA cycles for each submission, to identify any trends. The 27 submissions reviewed had 209 specific missing or deficient RTA elements across the 10 RTA categories for all RTA cycles. As shown in Exhibit 27, Administrative elements were most frequently identified as missing or deficient during Acceptance Review across all RTA cycles.

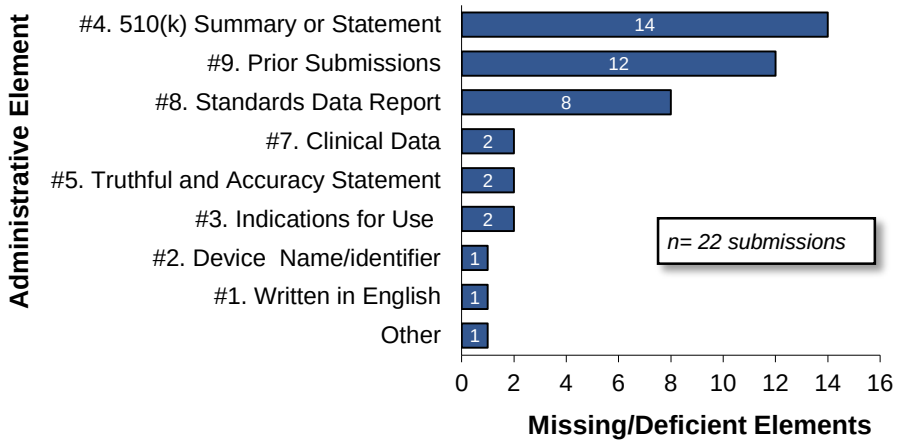
Exhibit 27. Frequency of Missing/Deficient RTA Elements Across All RTA Cycles



We performed further analysis of the Administrative RTA category to identify specific elements that may occur more frequently than others. As shown in Exhibit 28, the most common elements

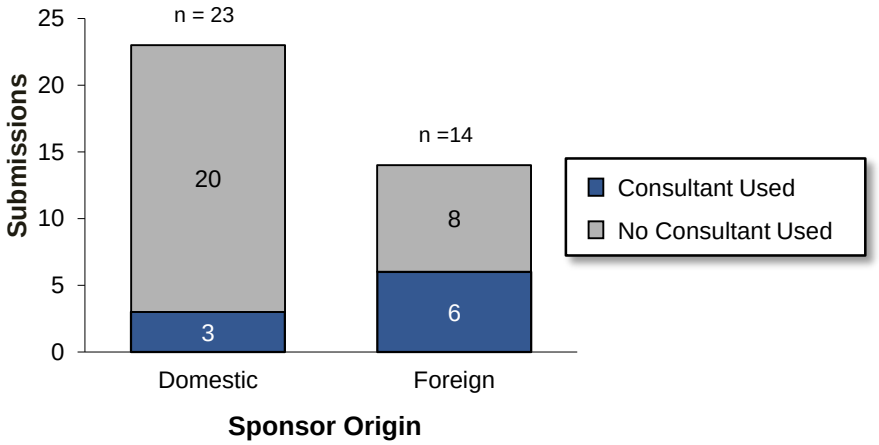
of the Administrative category that were identified as missing or deficient were the 510(k) summary/statement, identification of prior submissions, and Standards Data Reports.

Exhibit 28. Frequency of Specific Elements within the Administrative RTA Category



Another area of investigation among Traditional 510(k) submissions in our study cohort relates to Sponsor characteristics, specifically Sponsor origin. The 37 submissions from the M3 Study Cohort were characterized on whether the submitting Sponsor was from a domestic or foreign organization, and whether Sponsors had used consultants to support their submissions. As shown in Exhibit 29, the M3 Study Cohort had 23 domestic Sponsors, of which only three used a consultant. Of the 14 foreign Sponsors, six employed a consultant to support their submissions.

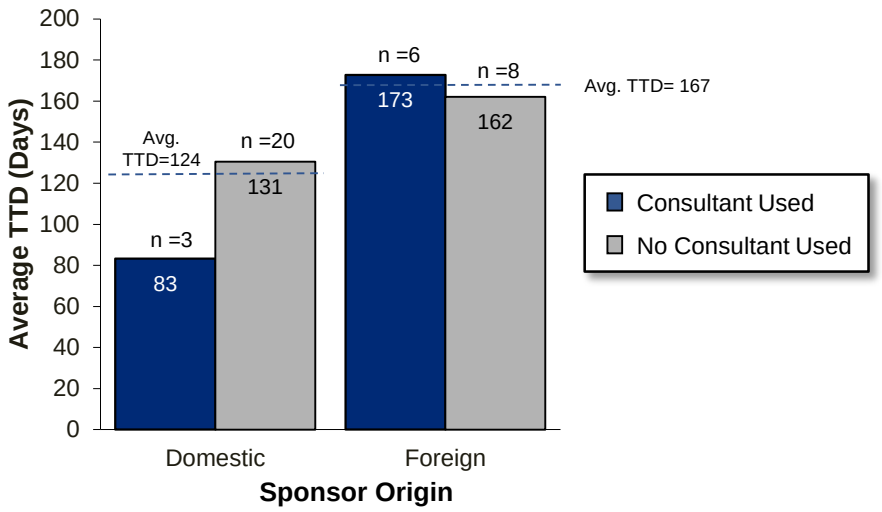
Exhibit 29. Sponsor Origin and Use of Consultant



We also analyzed whether Sponsor origin for a submission was associated with differences in TTD. Our data, shown in Exhibit 30, illustrates that TTD for foreign Sponsors was greater than for domestic Sponsors (167 versus 124 days) in our Study Cohort. The use of a consultant by foreign Sponsors was associated with a slight increase in TTD of 11 days, on average, but this difference is not significant, due to the small sample size. Similarly, while we observed a shorter TTD for domestic Sponsors who used a consultant, the number of submissions in our study

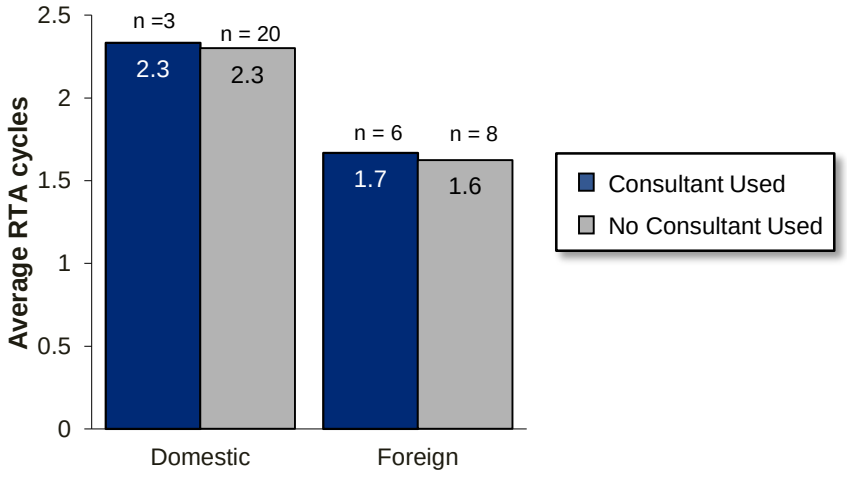
cohort for which a domestic Sponsor used a consultant was too small to draw significant conclusions.

Exhibit 30. Average TTD by Sponsor Origin



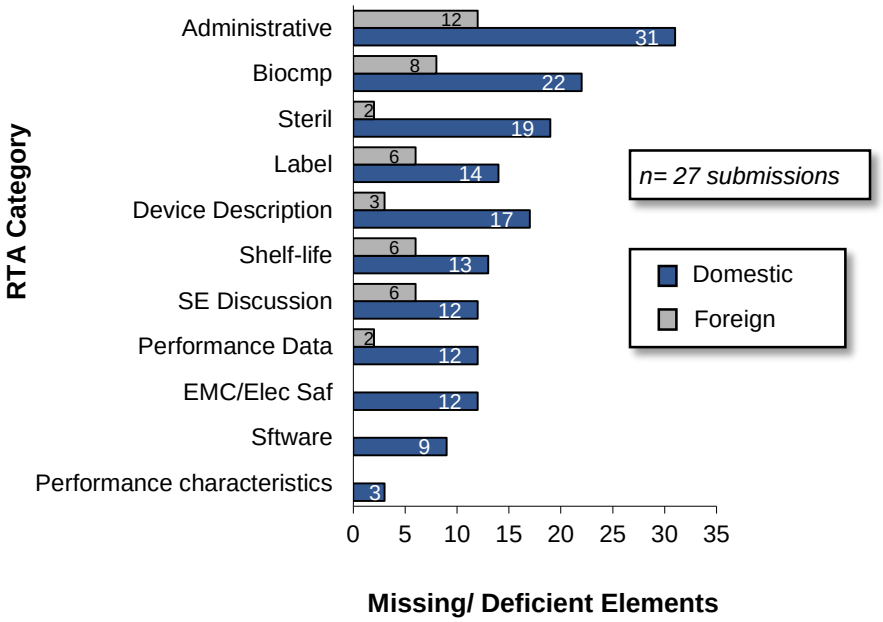
Interestingly, our data also indicated that domestic Sponsors had a greater average number of RTA cycles than foreign Sponsors (2.3 versus 1.6); our limited sample also suggests that use of a consultant did not appear to impact average RTA cycles for either foreign or domestic Sponsors (Exhibit 31).

Exhibit 31. Average RTA Cycles by Sponsor Origin



Similar to our previous analysis of most frequently missing or deficient RTA categories, we investigated submissions with missing or deficient elements by Sponsor origin. As shown in Exhibit 32, the Administrative category constituted the most frequently occurring missing/deficient elements for both domestic and foreign Sponsors.

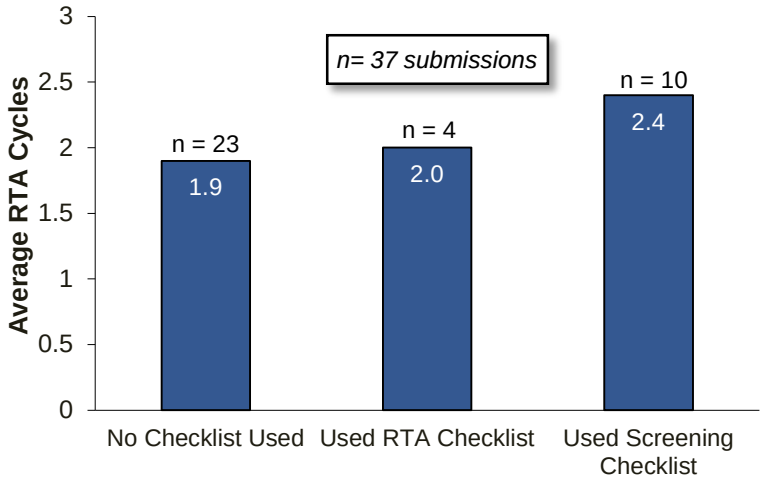
Exhibit 32. RTA Checklist Categories with Missing/Deficient Elements by Sponsor Origin



Notes: Includes analysis of all RTA cycles; Differences in Missing/Deficient items between Domestic and Foreign sponsors is in part due to the difference in sample size (Foreign sponsors=7 submissions and Domestic Sponsors=20 submissions)

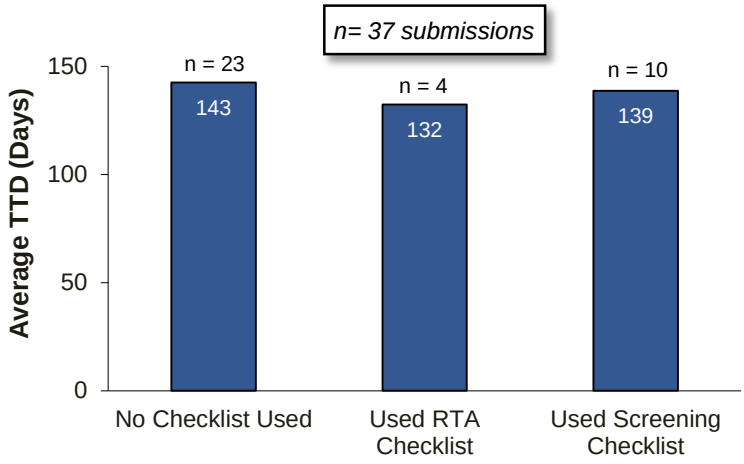
Understanding the impact of multiple RTA cycles on TTD and TST, we investigated the impact of Sponsor use of the formal RTA checklist. Within the M3 Study Cohort, we reviewed the 37 submissions and identified whether the Sponsor had used the formal RTA checklist when submitting their application. We observed that while most Sponsors did not use the formal RTA checklist (23), four Sponsors did use it, while ten sponsors utilized a screening checklist that is similar to the RTA checklist but only contained high-level questions regarding the presence or absence of key submission elements. Exhibit 33 indicates that no significant differences exist in the Study Cohort between the average number of RTA cycles between Sponsors that did and did not use the formal RTA checklist. However, further analysis with a larger sample is necessary to draw any definitive conclusion regarding the impact of the use of the RTA Checklist by Sponsors on the number of RTA cycles.

Exhibit 33. Impact of Sponsor Use of RTA Checklist on Average Number of RTA Cycles



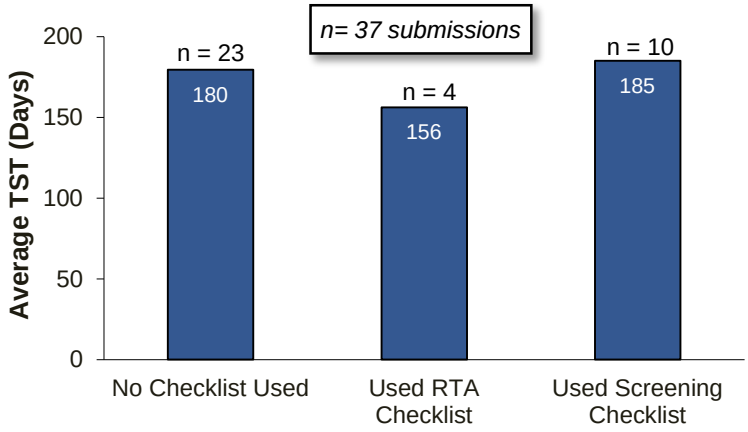
We also assessed the impact of Sponsor use of RTA checklist on TTD. Our data (Exhibit 34) shows that use of the formal RTA checklist was associated with a slight decrease in average TTD as compared to submissions for which Sponsors did not use the RTA checklist in our Study Cohort. Due to the small sample, this difference was not significant enough to draw conclusions, and further analysis of a larger sample is needed to assess the impact of Sponsor use of the RTA checklist on TTD.

Exhibit 34. Impact of Sponsor Use of RTA Checklist on Average TTD



We conducted a similar analysis of the impact of Sponsor use of an RTA checklist on TST. In our Study Cohort, the average TST of submissions for which Sponsors used the formal RTA checklist was 24 days shorter compared to no checklist (Exhibit 35). Together, our data suggests that Sponsor use of the formal RTA checklist may improve overall review times, for both TTD and TST. Interestingly, the use of the RTA screening checklist had little to no impact on overall review times.

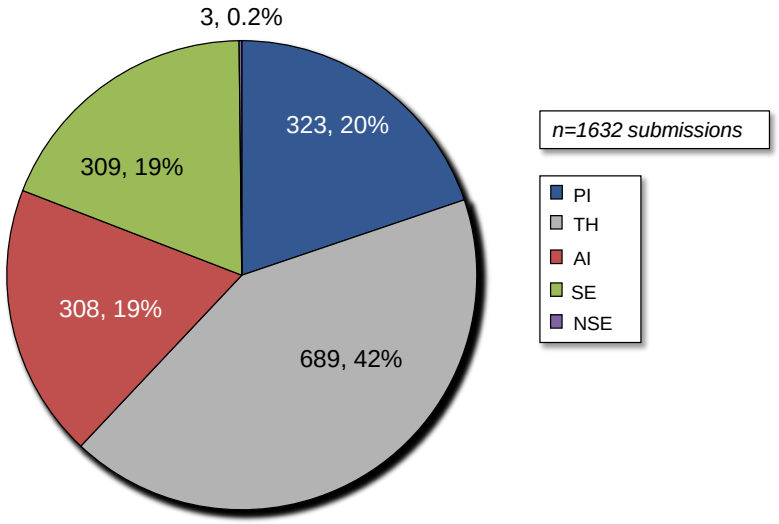
Exhibit 35. Impact of Sponsor Use of RTA Checklist on Average TST



4.3.1.3 SI Impact

Booz Allen characterized SI decisions for 1,632[20] submissions in the M3 Received Cohort (Exhibit 36). We found that 61% of submissions were put on hold (42% TH, 19% AI), while 19% reached a final decision (SE or NSE); 20% of submissions received a decision to proceed to Interactive Review.

Exhibit 36. SI Decision Characterization for M3 Received Cohort



Note: According to CTS, SI was "skipped" for two submissions

We calculated average TTD for the various SI decisions. Our data, shown in Exhibit 37, indicate that those submissions put on hold (AI and TH) had more than 75% longer TTD (153 and 145

[20] According to CTS, two submissions skipped SI among the 1,634 510(k) submissions that received either an SE or NSE decision within the M3 Received Cohort.

days, respectively) compared to those that proceeded interactively (82 days), and more than 200% longer TTD compared to those that reached final decision (48 days).

Exhibit 37. Average TTD by SI Decision for M3 Received Cohort

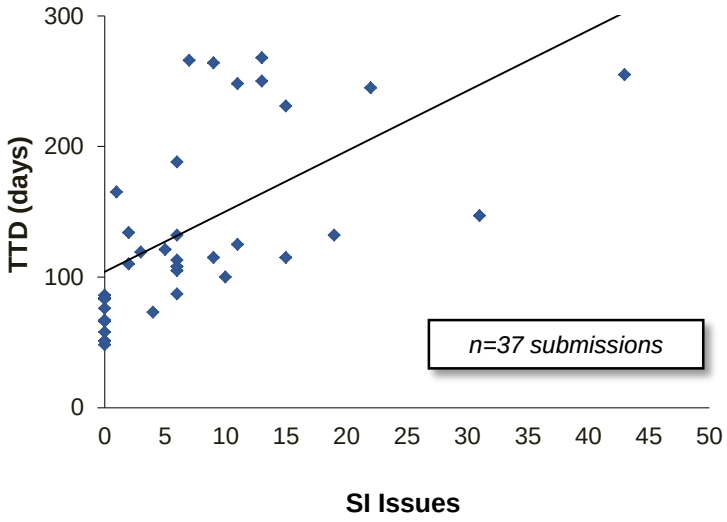
SI Decision	n	Average TTD
PI	322	82
TH	688	145
AI	306	153
Final (SE*/NSE)	312	48

**SE includes CS, SD, and SU as well*

We hypothesize that the earlier the Substantive Review (SR) starts and the earlier the SI decision is communicated to the Sponsor, the shorter the TTD. Booz Allen analyzed the FDA Days the SR started and the FDA Days the SI decision was issued across Divisions, and observed no correlation with TTD. We also evaluated whether timing of SI decision impacted TTD and observed no significant correlation between FDA Days to SI issuance and TTD.

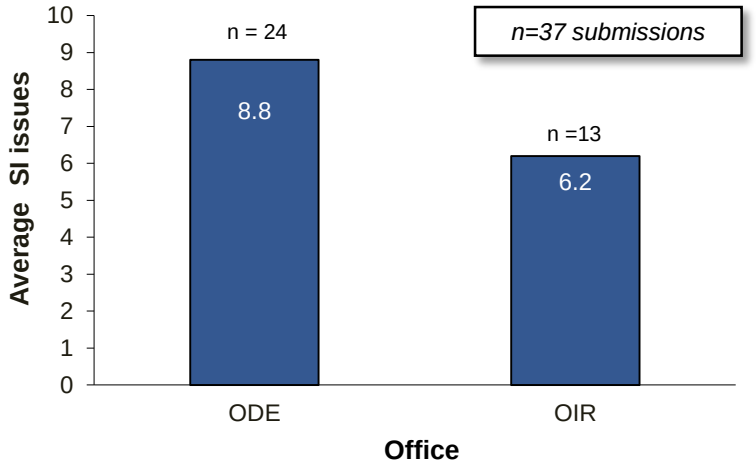
We also performed a deep-dive analysis on our M3 Study Cohort, comparing the number of SI issues with TTD. Our analysis revealed a positive correlation, as expected, and shown in Exhibit 38.

Exhibit 38. TTD vs. Number of SI Issues for M3 Study Cohort



We then analyzed these submissions by Office and found that ODE had a greater average number of SI issues than OIR (8.8 versus 6.2), as shown in Exhibit 39.

Exhibit 39. Average Number of SI Issues by Office for M3 Study Cohort



Note: Submissions that had no SI issues were included in the analysis

Booz Allen grouped the 27 submissions that received a hold (AI or TH decision) by the number of SI categories in which they had deficiencies. We found that the majority of submissions had deficiencies in 3-4 SI categories (14 of 27, 52%), while 18% (5 of 27) and 30% (8 of 27) of submissions had issues in 1-2 and >4 SI categories, respectively (Exhibit 40). We also observed a positive correlation between number of deficient SI categories and length of TTD (Exhibit 41).

Exhibit 40. Number of Submissions Receiving Hold Decisions with Deficiencies in Multiple SI Categories

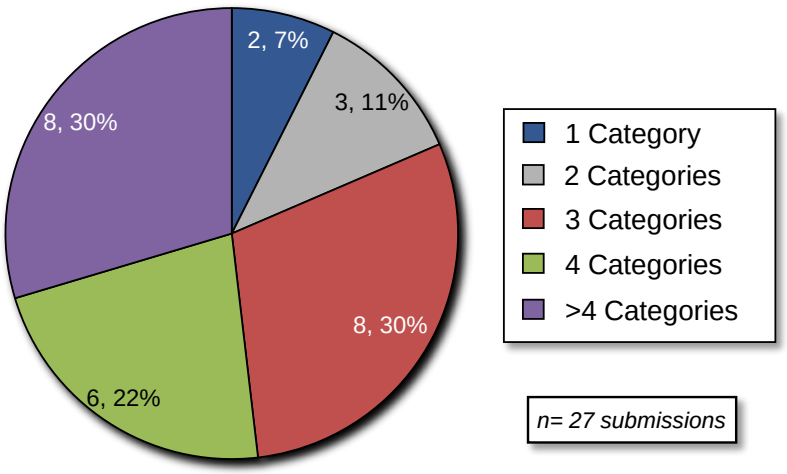
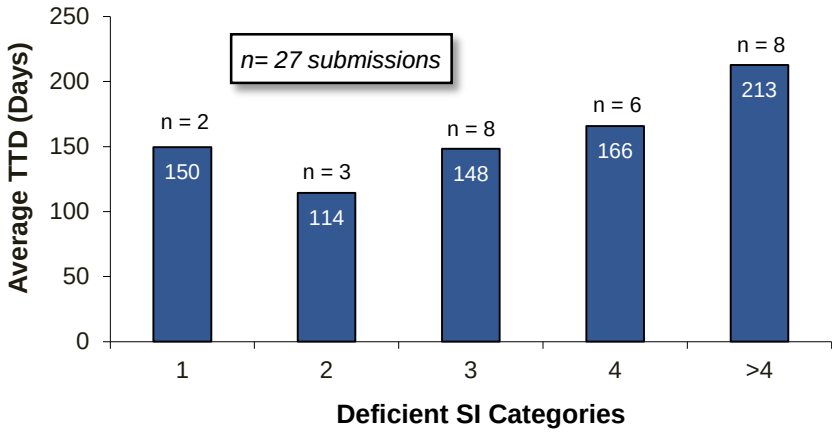
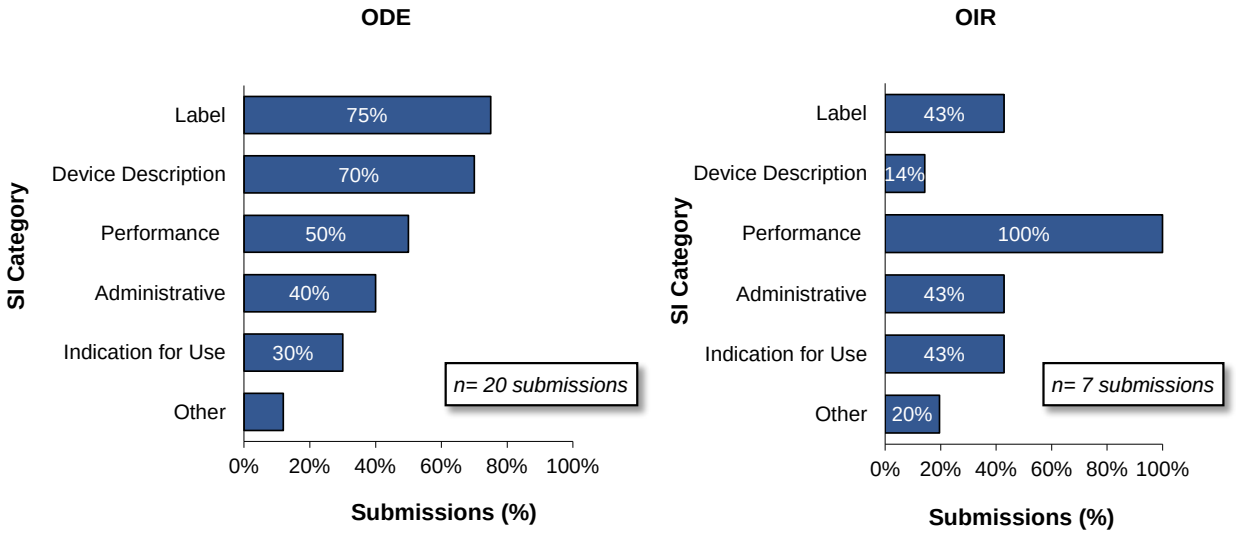


Exhibit 41. Average TTD for Submissions Receiving Hold Decisions with Deficiencies in Multiple SI Categories



We further characterized the SI categories containing deficiencies for the 27 submissions to identify the most frequently occurring categories by office. We found that "Labeling" and "Device Description" SI issues were identified in more than 70% of ODE submissions, while OIR's most common issue category was "Performance Characteristics", which was identified in all OIR submissions that were put on hold within our M3 Study Cohort (Exhibit 42).

Exhibit 42. Percent Submissions with SI Deficiencies by SI Category, by Office

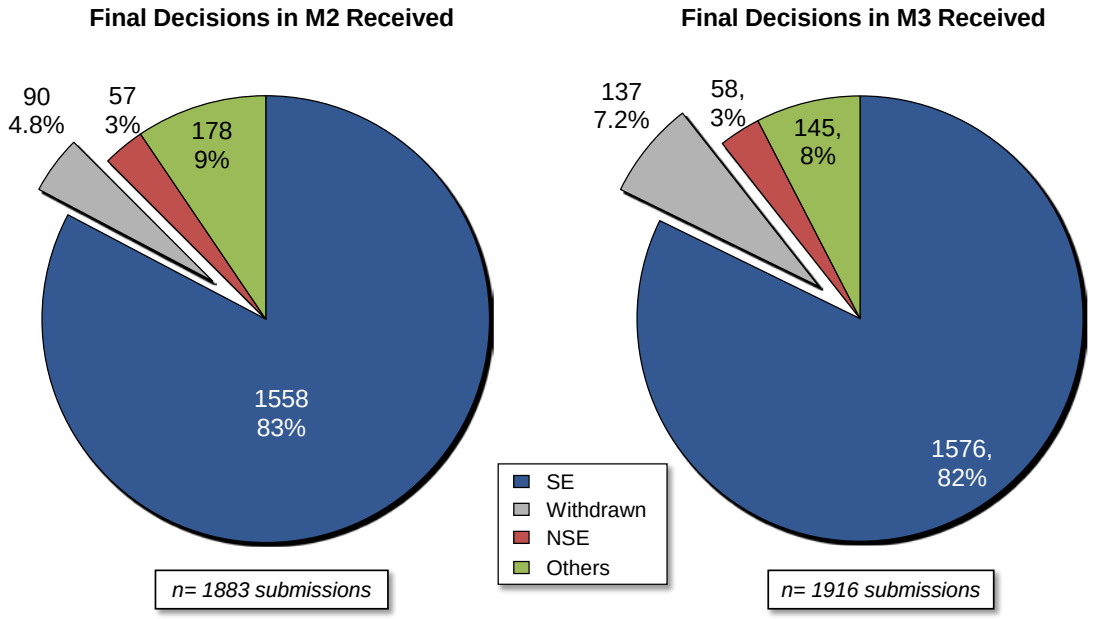


4.3.1.4 MDUFA Decision and Withdrawal Analysis

Once the Sponsor submits the full response to all SI issues, the MDUFA/Interactive Review phase begins. The MDUFA decision (i.e., final decision) is usually made at the end of this phase. In the rare occasion that a decision is not rendered by the MDUFA Goal Date, the submission follows procedures for Missed MDUFA Decision (MMD). Booz Allen examined the final decision outcomes across all closed submissions within the M2 and M3 Received Cohorts, including withdrawn submissions and other non-MDUFA decisions.

Exhibit 43 shows that for both Received Cohorts, the rates of SE decisions were consistent at approximately 83%, as were the rates for NSE at 3%. For the M3 NSE decisions, we analyzed the types of NSE decision in Exhibit 44. Approximately 67% of NSE decisions from the M3 Received Cohort were due to lack of or inadequate performance data (51% NP, 16% NL).

Exhibit 43. Final Decisions in M2 Received vs. M3 Received



Note: Percentage of final decisions was calculated using all closed submissions within the Received Cohorts. These include submissions with MDUFA Decisions (SE and NSE) and non-MDUFA decisions (e.g., withdrawals and others)

Exhibit 44. NSE Reasons Analysis

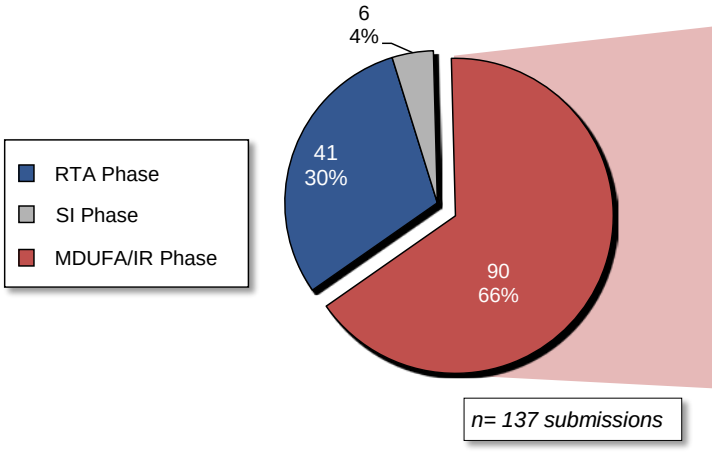
NSE Type	n	Percentage
Lack of Performance Data (NP)	31	51%
Inadequate Performance Data and/or Inadequate Response (NL)	10	16%
Other NSEs	20	33%
Total	61	100%

A significant observation was the 50% increase in withdrawal decisions from the M2 (90 of 1883, 4.8%) to M3 (137 of 1916, 7.2%) Received Cohorts (Exhibit 43). To further investigate this observation, we analyzed withdrawn submissions within the M3 Received Cohort to explore the timing of the withdrawal and potential reasons. Exhibit 45 shows that 66% of the M3 Received Cohort submissions were withdrawn during the MDUFA/Interactive Review (IR) phase, while 30% were withdrawn during the RTA phase and 4% during the SI phase. Booz Allen speculates that a potential reason for the significant number of submissions being

withdrawn during the RTA phase is that Applicants are able to request a refund of user fees before the submission is accepted. Further characterization of the submissions withdrawn during the MDUFA/IR phase revealed that while a majority of submissions were withdrawn with more than 20 days remaining prior to the MDUFA Goal Date, a substantial portion of submissions (29%) were withdrawn with fewer than 10 days until the MDUFA Goal Date.

Exhibit 45. Withdrawn Submissions by Review Phase

Withdrawn Submissions by Review Phase



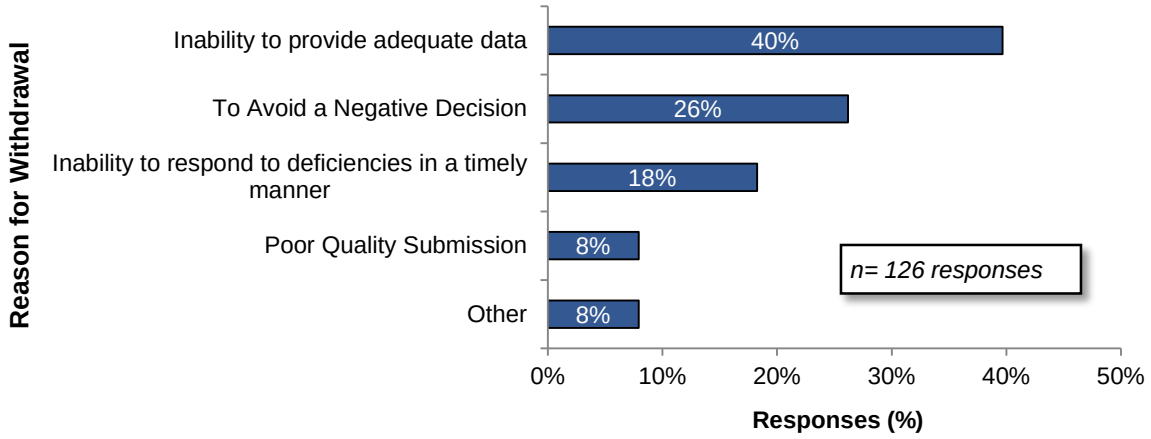
Submissions Withdrawn During Specific Phases of MDUFA/IR

Days Remaining Until MDUFA Goal Date	Number (%) of Submissions Withdrawn During MDUFA/ IR Phase
<10 days	26 (29%)
10-20 days	10 (11%)
>20 days	54 (60%)
TOTAL	**90 (100%)**

We surveyed FDA reviewers to better identify potential reasons for withdrawn submissions and why approximately two-thirds of withdrawals occurred during the MDUFA Phase in the M3 Received Cohort. As shown in Exhibit 46, a majority of respondents cited that the reasons for withdrawal of a submission was due to the Applicant's inability to provide adequate data in response to AI letters (40%), as well as Applicants wanting to avoid receiving an NSE decision (26%). Interestingly, an industry sponsored survey of Sponsors provided to Booz Allen indicated the same reasons for withdrawn submissions[21]. Another reason for withdrawals often identified by FDA reviewers was the inability to resolve deficiencies within MDUFA III timeframes, which may explain the substantial portion of submissions that were withdrawn with fewer than 10 days remaining on the review clock. Prior to MDUFA III implementation, it was common practice to put submissions on multiple holds to resolve deficiencies, which could contribute to longer review times. A new practice introduced within MDUFA III to shorten review times was to limit submissions to one hold at SI and only on rare circumstances could a reviewer receive permission from senior management for an additional hold. This new practice was implemented in part to encourage submission of high quality and complete applications up front, and to encourage complete and thorough reviews during the Substantive Review phase. It is our observation that an unintended consequence of limiting additional holds is the inability to resolve minor deficiencies during the MDUFA/IR phase within the MDUFA III timeframe, as suggested by focus group and interview participants. Consistent with this observation, a better implementation of additional holds was the most frequent suggestion by CDRH survey respondents to help staff meet MDUFA III timelines, which is shown in Exhibit 47.

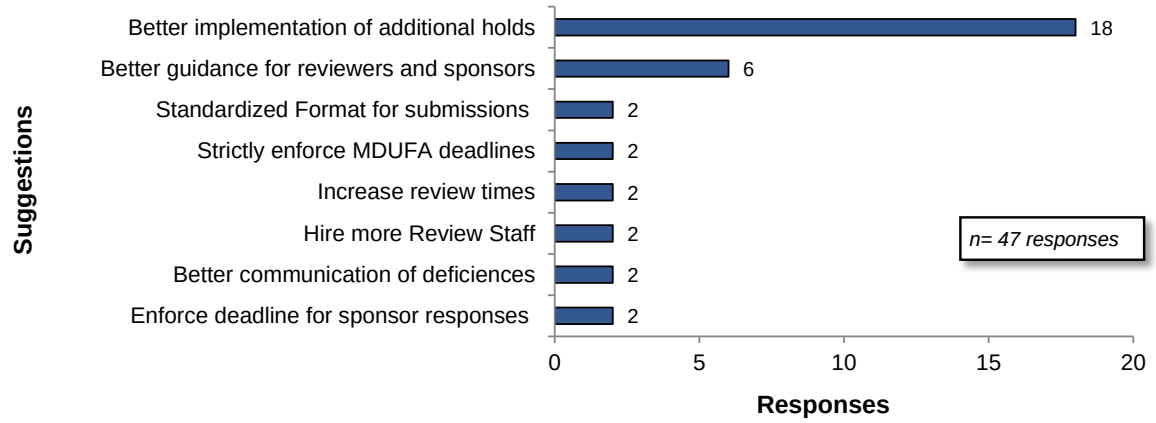
[21] AdvaMed, MITA and MDMA conducted a private survey across their members, and shared some of the results with Booz Allen for use in this evaluation.

Exhibit 46. Reasons Cited for Submission Withdrawal



Source: FDA Staff Survey

Exhibit 47. Suggestions by CDRH Review Staff to Help Meet MDUFA III Timelines

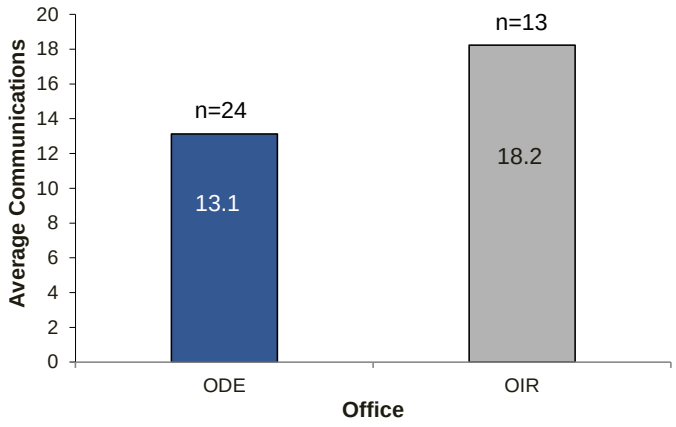


Note: Only suggestions made by at least 2 different reviewers are shown; an additional 11 suggestions were made by one reviewer each.

4.3.1.5 Communications Analysis

As indicated in the MDUFA III Commitment Letter, interactions between FDA and Sponsors are critical in performing an efficient and timely review of medical device submissions. To evaluate the impact of interactions between FDA and Sponsors, Booz Allen evaluated submissions within the M3 Study Cohort for the frequency and timing of communications throughout the course of the review. Among the Traditional 510(k) submissions in the M3 Study Cohort, the average number of communications was greater for applications reviewed in OIR (18.2) than for those reviewed in ODE (13.1), as shown in Exhibit 48.

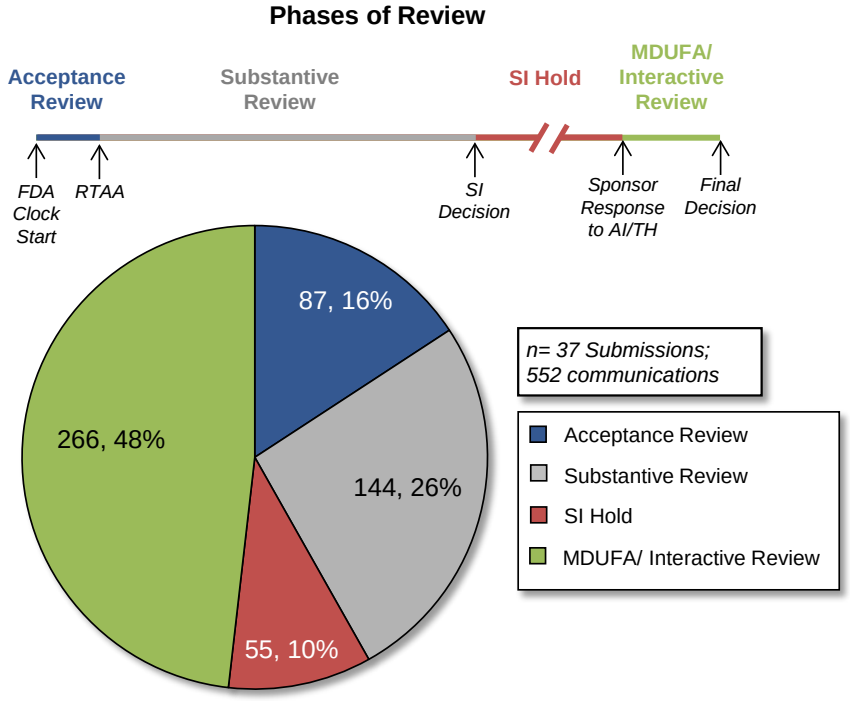
Exhibit 48. Average Number of Communications by Office



Note: Communications included official email and letter correspondences, phone and teleconferences

Communications between the Applicant and FDA may take place throughout the course of the review and across all review phases. Booz Allen analyzed the timing of communications in all submissions in the Study Cohort to characterize the distribution of communications by review phase. While communications take place in all four phases of the review process, nearly half (48%) of all communications occur in the MDUFA/IR phase, as shown in Exhibit 49.

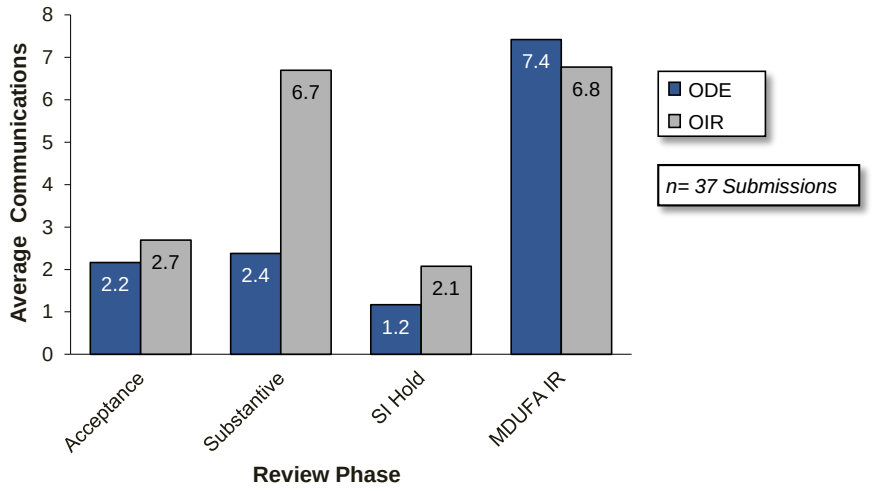
Exhibit 49. Number of Communications by Review Phase



Note: Communications included official email and letter correspondences, phone and teleconferences

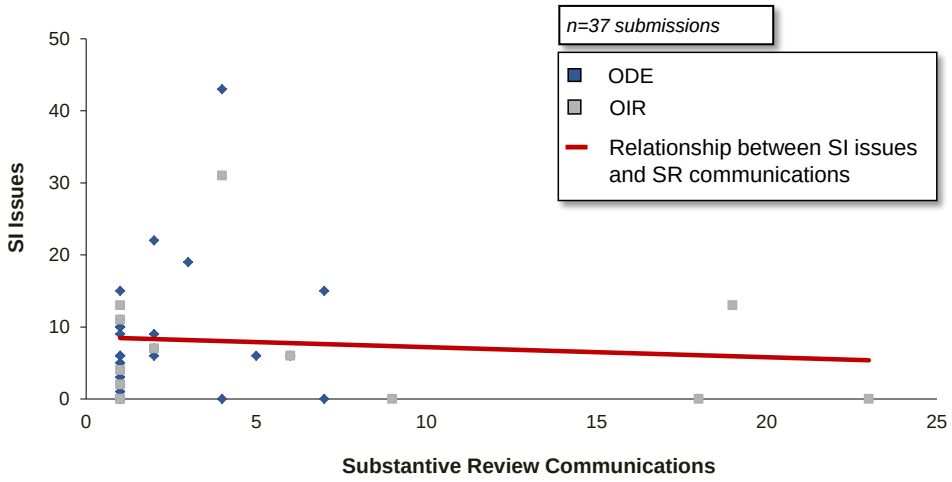
Booz Allen also analyzed the average number of communications in each review phase for applications reviewed in ODE and OIR, shown in Exhibit 50. Not surprisingly, the review phase with the greatest average number of communications was the MDUFA/IR phase for both ODE (7.4) and OIR (6.8), which is consistent with the data depicted in Exhibit 49. The average number of communications was similar for both Offices in the Acceptance, SI Hold, and MDUFA/IR phases. However, there was a significant difference in the average number of communications in the Substantive Review phase between ODE (2.4) and OIR (6.7). This difference alone accounts for 84% of the difference in total average communications across the review process between the two Offices. Interviews with CDRH staff indicate a reason for this difference in communication practices between Offices is that OIR management strongly promotes earlier and more frequent communications to engage with Sponsors to resolve issues as they arise.

Exhibit 50. Average Number of Communications by Office and Review Phase



The Substantive Review phase provides the opportunity for FDA and applicants to attempt to resolve potential SI issues through communications. Booz Allen hypothesized that a greater number of communications during the Substantive Review phase would be associated with a smaller number of SI issues. We analyzed the number of communications during the Substantive Review phase and the number of SI issues identified for every application in the study cohort. As depicted in Exhibit 51, there is a slight inverse correlation between the number of communications in the Substantive Review phase and the number of SI issues across all applications in the Study Cohort. This is consistent with our hypothesis and suggests that more communications during the Substantive Review phase may facilitate earlier resolution of a greater number of potential SI issues.

Exhibit 51. Number of Substantive Review Communications by Number of SI Issues

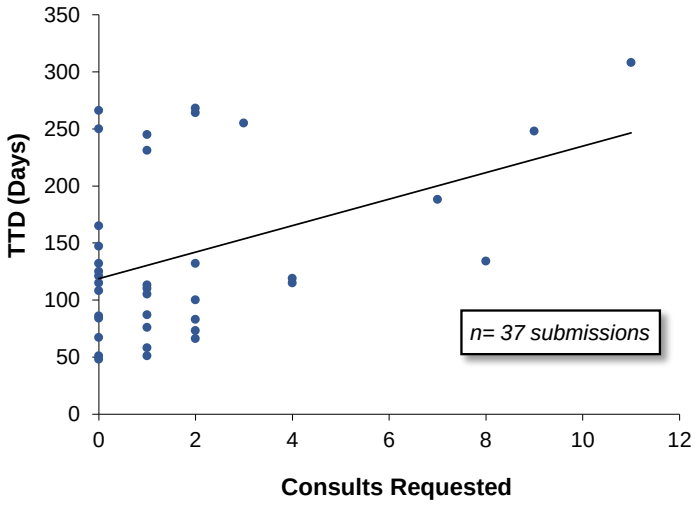


Analysis of the M3 Study Cohort described in Section 4.3.1.3 illustrated that a greater number of SI issues associated with a submission correlated with a longer TTD. Consistent with this finding and our analysis above, among submissions in our Study Cohort, OIR has a shorter TTD (125.5 days) than ODE (148.5 days). Booz Allen speculates that OIR is able to resolve a greater number of potential SI issues earlier in the review process through more communications with applicants during the Substantive Review phase, which leads to a shorter average TTD than for submissions in ODE.

4.3.1.6 Consult Analysis

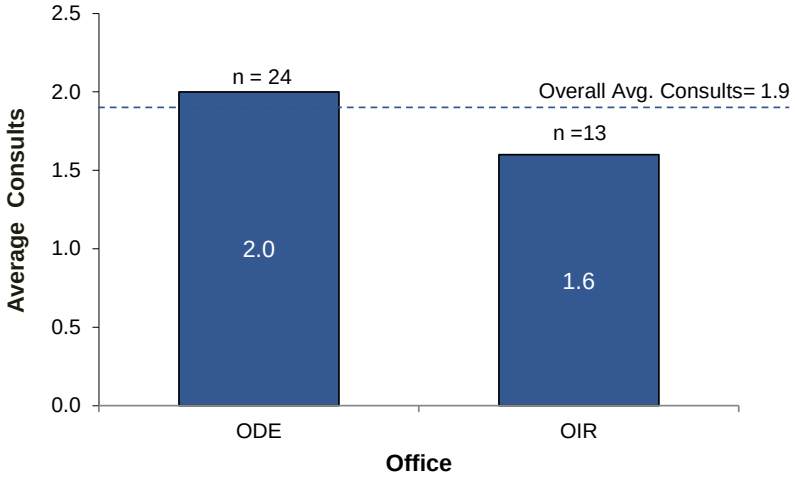
In cases where a Lead Reviewer may not have the in-depth knowledge necessary to complete a thorough review of the 510(k) submission, the Lead Reviewer may request consult reviews from review staff within the Division, Office or external to CDRH. To assess the impact of consult requests on review processes, we analyzed the frequency and types of consults requested for submissions within the M3 Study Cohort. Examination of Traditional 510(k) submissions in the M3 Study Cohort demonstrated a positive correlation between the number of consults requested and length of TTD (Exhibit 52).

Exhibit 52. Number of Consults vs. TTD



Overall, the average number of consults requested for 510(k) submissions within the M3 Study Cohort was 1.9. Of the 37 Traditional 510(k) submissions, 14 did not have any consult requests. Within Offices, the average number of consults requested per submission was higher in ODE (2.0) than submissions in OIR (1.6), as shown in Exhibit 53.

Exhibit 53. Average Number of Consults by Office



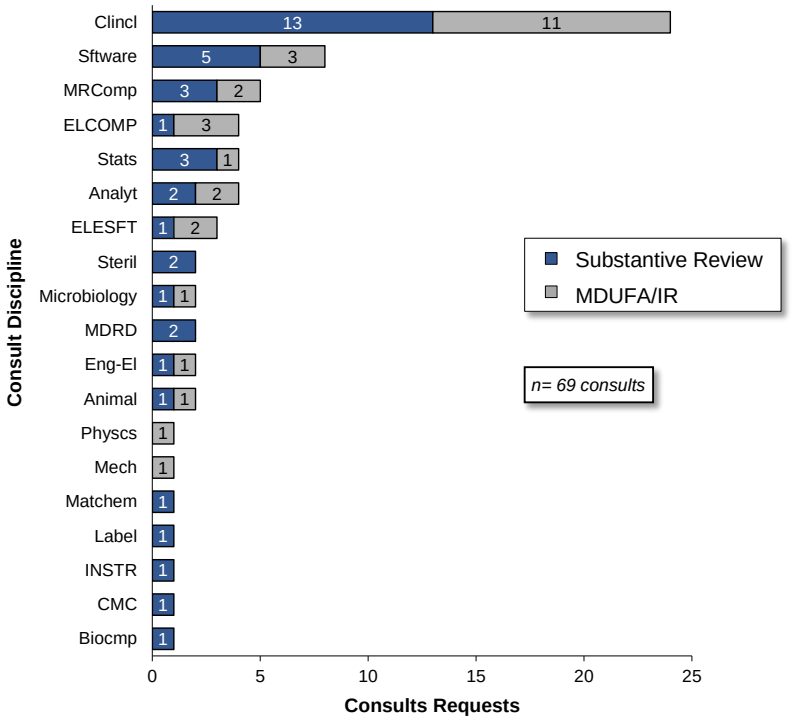
Note: 14 submissions did not have any consults; 10 in ODE and 4 in OIR

The number of consults requested by review phase was analyzed to identify which consult disciplines were requested most often and whether this varied depending on the phase in which they were completed. As Substantive Review entails a thorough and complete evaluation of the submission while MDUFA Interactive Review involves review of Sponsor responses to deficiencies, it may be that the nature of consult review requests differs between review phases.

Our analysis, shown in Exhibit 54, identified Clinical consults to be the most frequently requested consult discipline, and this finding was consistent among both Substantive Review and MDUFA/IR phase. Software and MRI Compatibility were the next most frequently requested

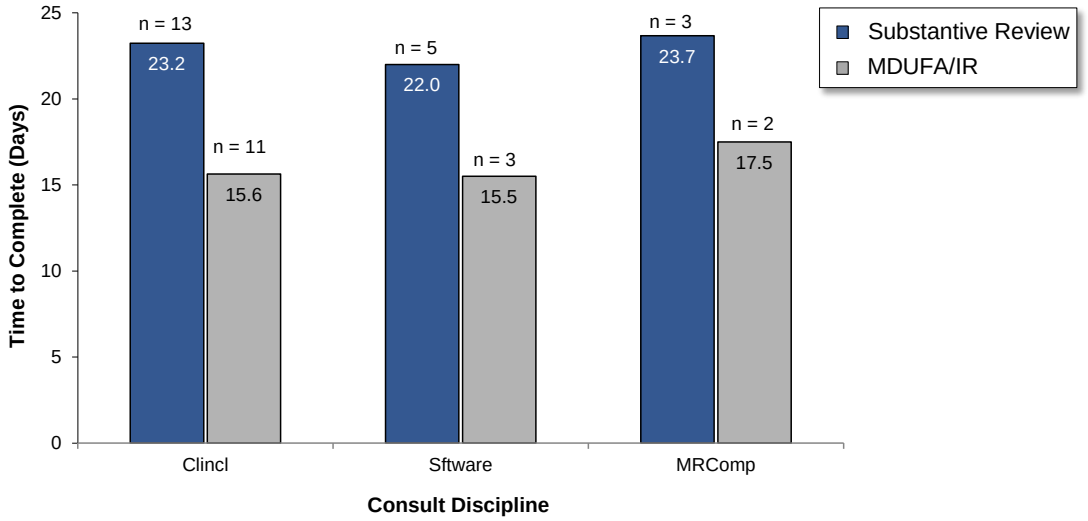
consults. However, these consults are highly dependent on the type of device submission, whereas Clinical consults are more common amongst a variety of device types.

Exhibit 54. Frequency of Consult Disciplines Requested by Phase of Review



For these three most frequently requested consult disciplines, we investigated whether any differences existed in days to complete the consult review, depending on the phase in which they were requested. Interestingly, we observed that the time to complete consult reviews were similar among the different disciplines, with the average days to complete these consults ranging between 22-23 days when requested during Substantive Review. In comparison, consults requested during MDUFA/IR ranged between 15-16 days (Exhibit 55). Consults requested during Substantive Review took significantly more time to complete than MDUFA IR consults, which was expected because the length of review time during the Substantive Review phase is normally longer than in the MDUFA/IR phase.

Exhibit 55. Duration of Consult Review by Consult Discipline and Phase of Review

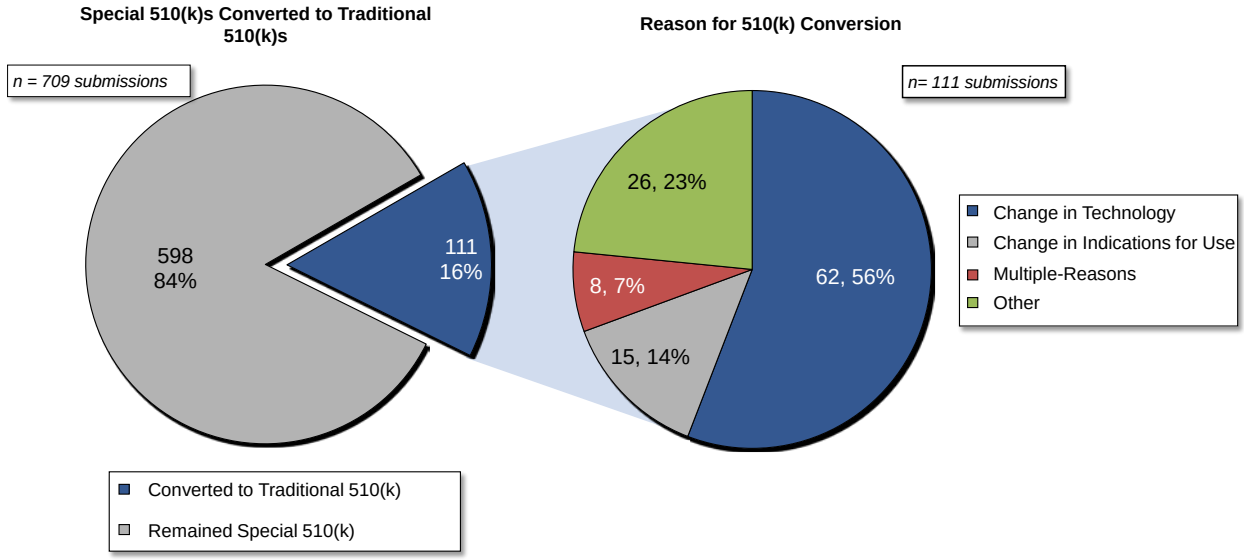


4.3.1.7 Conversions of Special 510(k) to Traditional 510(k) (Case Study)

Special 510(k) submissions are used when modifications have been made to a medical device that already has 510(k) clearance, and must meet all the criteria listed in the Acceptance Checklist for Special 510(k)s. During the review of the Special 510(k) submission, if it is determined that the submission does not meet the acceptance criteria, the Special 510(k) submission is automatically converted to a Traditional 510(k). The conversion process requires that the reviewer complete a Conversion Form stating the reason for the conversion and obtain concurrence from both the Branch Chief and Division Director. There is little opportunity for the Sponsors to resolve issues that could result in a conversion. In addition, the applicant is only notified once a determination to convert the Special 510(k) is final. After conversion, Sponsors do not have an opportunity to appeal the conversion decision.

Within the M3 Received Cohort, 709 Special 510(k)s were received, of which 111 (16%) were converted to Traditional 510(k)s, as shown in Exhibit 56. Analysis to determine the reason for conversion revealed that 30% (34 of 111) were due to “Other” or “Multiple-Reasons.” Further investigation of these 34 submissions revealed that 15 (44%) submissions had included unsolicited data. Since unsolicited data requires additional time for review that is not built into the review process for Special 510(k)s, these submissions are converted to Traditional 510(k) submissions to allow for a complete review of the submission, including the unsolicited data. Industry focus group participants indicated that there is a lack of clarity around what types of data are required for Special 510(k) submissions. Sponsors also indicated that they often include unsolicited data to ensure completeness of their submissions without realizing that this would trigger conversion of the submission type. A potential suggestion for improvement is for FDA to provide clarity around what data should and should not be included for Special 510(k) submissions, to prevent unnecessary conversion of Special 510(k) submissions.

Exhibit 56. Distribution of Reasons for Special 510(k) Conversions



4.3.1.8 CLIA Waivers by Application (Case Study)

Performance goals for CLIA Waiver by Application are required to be reported in accordance with the MDUFA III reauthorization. Due to the relatively small number of CLIA Waiver by Application submissions, Booz Allen conducted a case study analysis of the CLIA Waiver submissions received in CY13, and discussed issues around this process during reviewer focus groups. A summary of observations, challenges, and potential areas for improvement in the process are described in Exhibit 57.

Exhibit 57. CLIA Waiver Case Study Observations and Suggestions

	Observations/Challenges	Suggested Process Enhancements
Submissions	• In CY13, nine CLIA Waiver by Application submissions were received and all engaged in a SI by 90 days • 7 of 9 had reached final decisions all of which were reached before 180 FDA days • No dual submissions were submitted or under review • FDA reviewers cited inconsistent submission format for dual submissions as a factor impacting review times	For Industry: • When submitting a dual submission, the data required for 510(k) and CLIA Waiver applications should be organized separately as the reviews for 510(k) and then CLIA Waiver application is conducted in sequence • Pre-submission meeting(s) with the FDA to discuss study protocols should be conducted prior to initiating supportive studies
Process	• In March 2014, CDRH published final Industry and FDA guidance to detail the submission process for the CLIA Waiver by Application submissions; however, FDA focus groups perceive a lack of sponsor awareness around the CLIA application process • FDA also launched an automatic CTS tracking mechanism for CLIA Waiver by Application submissions in March 2014 • Pre-submission meeting(s) is mandatory for submitting Dual submission, however, sponsors do not seem to be aware of this requirement • Only one decision will be made at the end of a dual submission review. Even if a 510(k) is determined to be SE, the device will not be cleared without a CLIA waiver decision • Lack of available statisticians to conduct reviews and their lack of understanding of CLIA Waiver processes contributes to longer review times	For FDA: • Publish decision summaries after FIOA process to better educate industry of current FDA thinking • Establish standard format/template for dual submissions to facilitate efficient and timely review • Improve reviewer accessibility to OSB statisticians

Source: FDA Systems and FDA Focus Group

4.3.2. **PMA Submissions Analysis**

Our analysis of the PMA review processes includes characterization of TTD across review divisions for PMA Original, Panel-Track Supplements, 180-Day Supplements, and Real Time Supplements in both the M2 and M3 Received Cohorts. The M3 Study Cohort was used to assess the impact of MDUFA III processes including RTA, Substantive Interaction and MDUFA Interactive Review. In addition, we performed further analyses to characterize FDA and Sponsor communications, FDA consult review practices by submission type, and review processes for companion diagnostics, combination products, IDE and Q-submissions.

4.3.2.1 TTD Characterization of M2 and M3 Cohorts

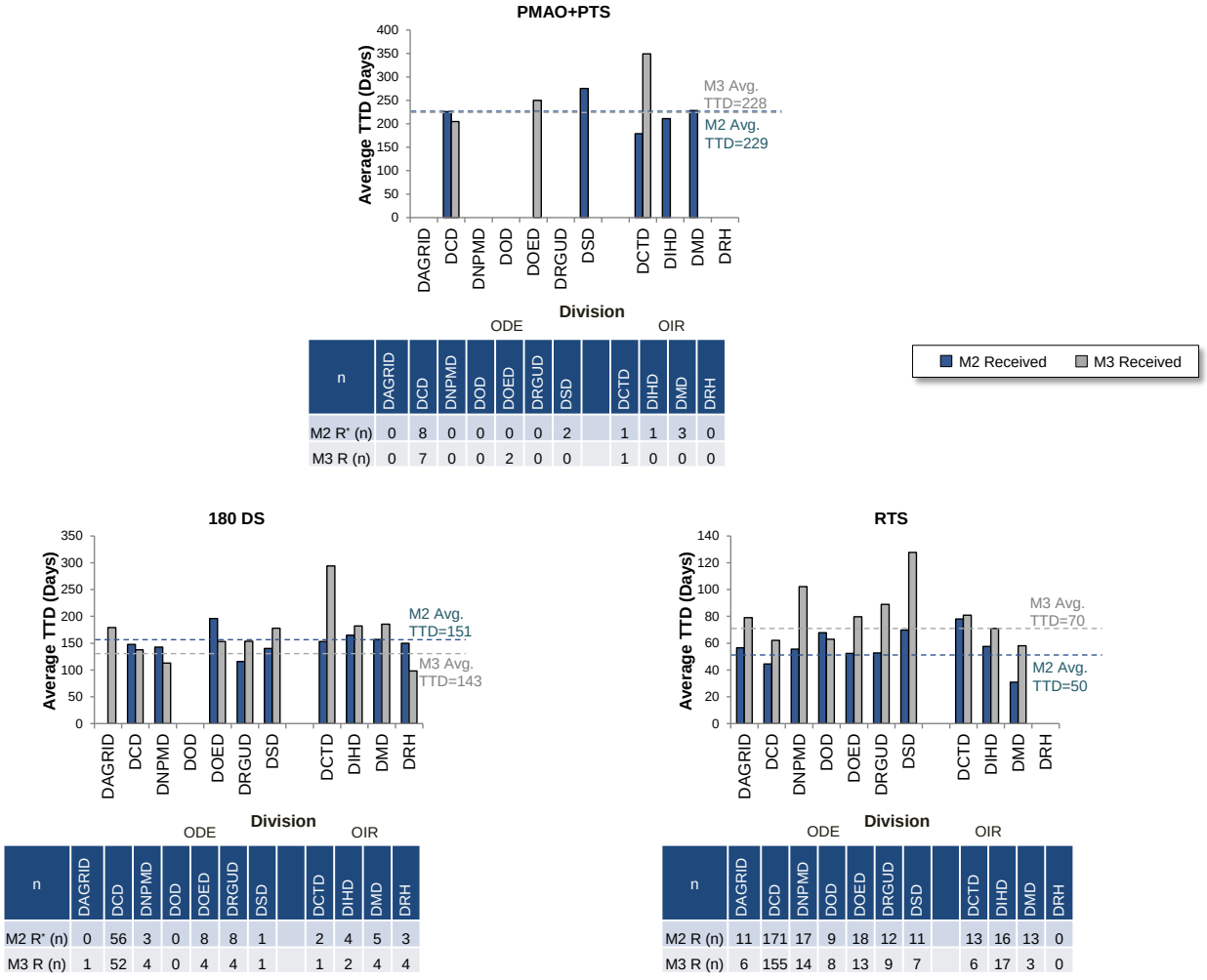
Booz Allen compared TTD of each PMA submission type in the M2 and M3 Received Cohorts. Due to the small number of closed submissions, we were only able to analyze a limited PMA sample in the M3 Received Cohort (10 PMA Original and Panel-Track Supplements) and M2 Received Cohort (15 PMA Original and Panel-Track Supplements).

For PMA Original and Panel-Track Supplements, average TTD was comparable between the M3 Received Cohort (228 days) and the M2 Received Cohort (229 days), as shown in Exhibit 58.[22] Among PMA 180-Day Supplements, average TTD was lower in the M3 Received Cohort (143 days) than in the M2 Received Cohort (151 days). In contrast, average TTD for PMA Real

[22] Publicly available FDA data using different sample sizes and closure rates will show the same trend, but has different cohort average values than the ones calculated in this study.

Time Supplements in the M3 Received Cohort was greater across most Divisions (except DOD) than that of the M2 Received Cohort. This increase in TTD from M2 and M3 for Real Time Supplements can be explained by the change in MDUFA goals from MDUFA II to MDUFA III. Specifically, the MDUFA II goal was 80% completed in 60 days and the MDUFA III goal was 90% completed within 90 days. While the limited sample prevented cross-Division comparisons, we noted that the highest number of closed submissions across all PMA submission types was reviewed by the Division of Cardiovascular Devices (DCD).

Exhibit 58. Average TTD for Each PMA Submission Type within M3 Received Cohort



n	DAGRID	DCD	DNPMD	DOD	DOED	DRGUD	DSD		DCTD	DIHD	DMD	DRH
M2 R* (n)	0	8	0	0	0	0	2		1	1	3	0
M3 R (n)	0	7	0	0	2	0	0		1	0	0	0

n	DAGRID	DCD	DNPMD	DOD	DOED	DRGUD	DSD		DCTD	DIHD	DMD	DRH
M2 R* (n)	0	56	3	0	8	8	1		2	4	5	3
M3 R (n)	1	52	4	0	4	4	1		1	2	4	4

n	DAGRID	DCD	DNPMD	DOD	DOED	DRGUD	DSD		DCTD	DIHD	DMD	DRH
M2 R (n)	11	171	17	9	18	12	11		13	16	13	0
M3 R (n)	6	155	14	8	13	9	7		6	17	3	0

*Note: *One PMAO+PTS submission and one 180 DS submission from the M2 Received Cohort were withdrawn prior to filing, therefore excluded in calculating TTD*

4.3.2.2 RTA Impact

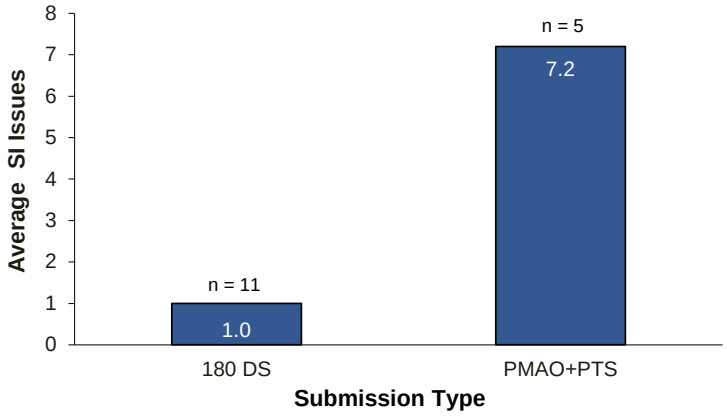
The only PMA submission types that implement RTA processes are PMA Original and Panel-Track Supplement submissions. Within the M3 Received Cohort, 9 of the 10 closed submissions were accepted within the first RTA cycle, while the one submission that was rejected during the first RTA cycle was subsequently accepted during the second RTA cycle. All submissions were filed within the first RTF cycle. The limited number of submissions and first cycle submission

acceptance for the vast majority of closed PMAs precluded a more detailed analysis of the impact of RTA on PMA reviews.

4.3.2.3 SI Impact

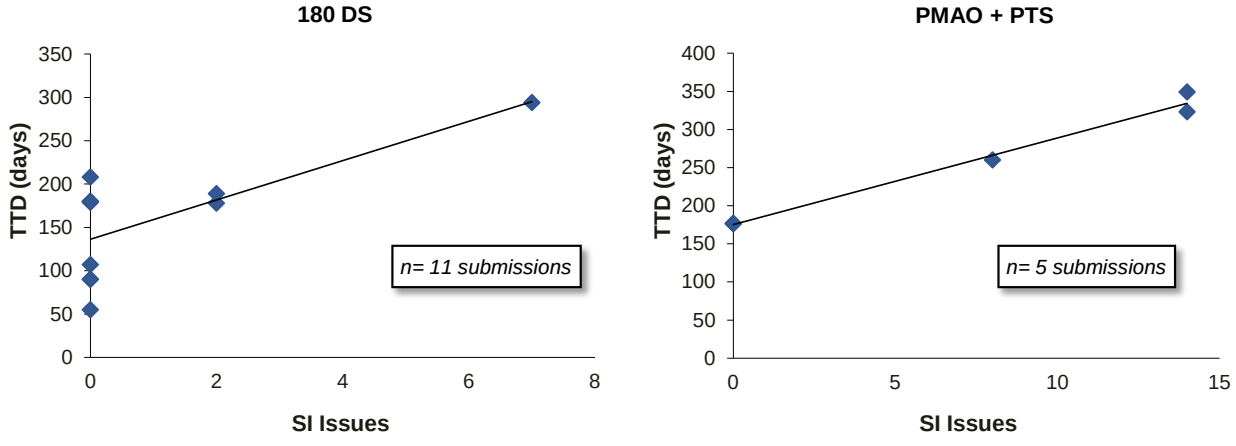
We evaluated the impact of issues identified during the Substantive Interaction process on TTD for PMA Original, Panel-Track Supplements and 180-Day Supplement submissions in the M3 Study Cohort, which are the three PMA submission types subject to the Substantive Interaction process. As expected, the average number of SI issues identified for PMA Original and Panel-Track Supplements was far greater than for 180-Day Supplements (7.2 versus 1.0, respectively) as shown in Exhibit 59. Although there were a limited number of PMA submissions, we plotted the number of SI issues per submission to determine whether any correlation was observed with TTD. For these three PMA submission types, an increasing number of SI issues were associated with longer TTD (Exhibit 61).

Exhibit 59. Average Number of SI Issues by Submission Type



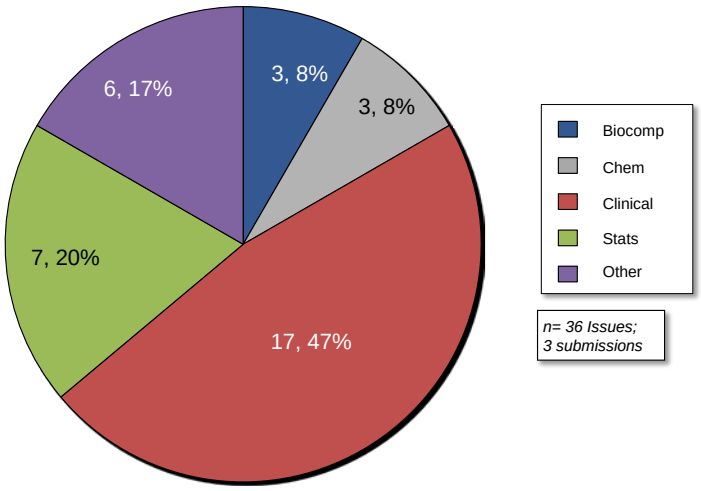
Note: Includes submissions with no SI issues; eight out of 11 180 DS had no SI Issues; two out of five PMAO+PTS had no SI Issues

Exhibit 60. TTD by Number of SI Issues



Booz Allen also examined PMA Originals and Panel-Track Supplements to identify the most frequent type of SI issue that was identified by FDA. Three of the five PMA Original and Panel-Track Supplements within the M3 Study Cohort received a Major Deficiency letter at SI. As expected, the most frequently identified SI issue categories were Clinical followed by Statistics (Exhibit 61).

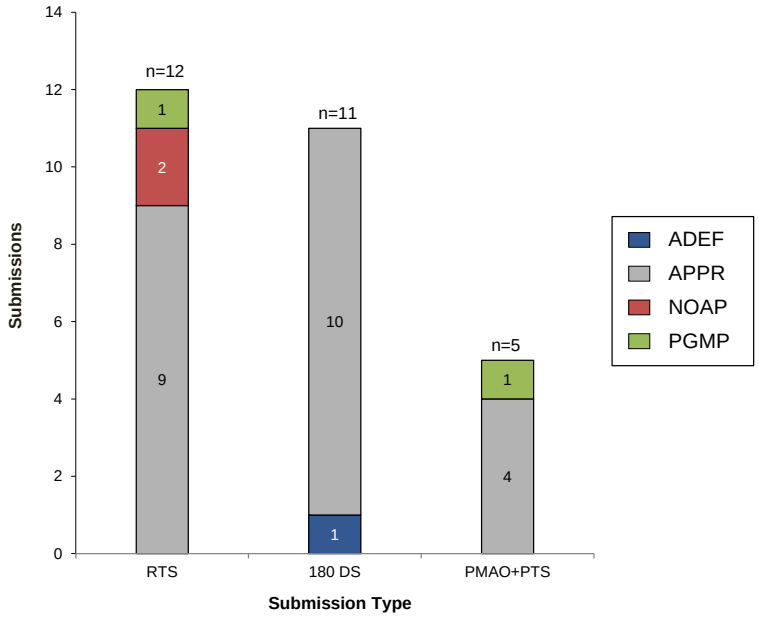
Exhibit 61. Number of SI Issues for PMA Original and Panel Track Supplements



4.3.2.4 MDUFA and Final Decision Analysis

The distribution of MDUFA decisions among PMA submission types from the M3 Study Cohort was examined and shown in Exhibit 62. A majority of all PMA submission types were approved by the MDUFA decision, and submissions not approved by the MDUFA Goal Date were subsequently approved at final decision.

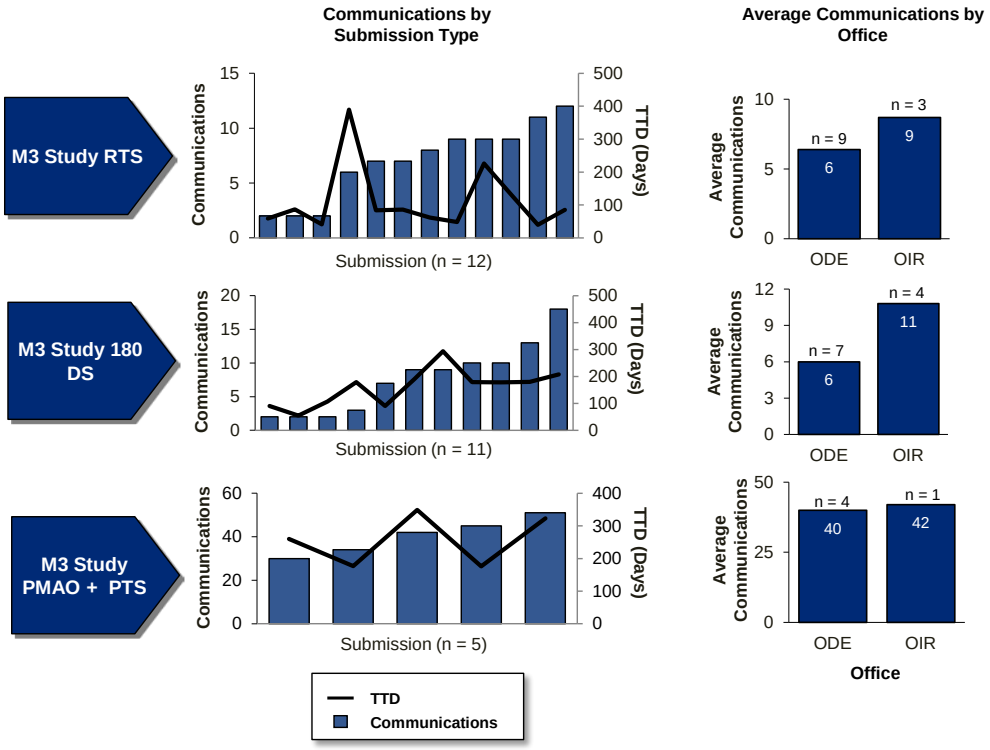
Exhibit 62. MDUFA Decisions by Submission Type



4.3.2.5 Communications

Booz Allen evaluated the number of communications that took place between FDA and Sponsors to determine whether a relationship existed between communications that took place during M3 Study Cohort PMA submission reviews and TTD (Exhibit 63). Among all PMA submission types, a positive correlation between the number of communications and TTD was observed only for PMA 180-Day Supplements. The limited number of submissions within the M3 Study Cohort for PMA Original and Panel-Track Supplements prevented any conclusive observations to be made on the impact of communications on TTD. However, similar to findings gleaned from our analysis of 510(k) submissions, the average number of communications held between FDA and Sponsors in OIR submissions was generally greater than in ODE for all PMA submission types (Exhibit 63).

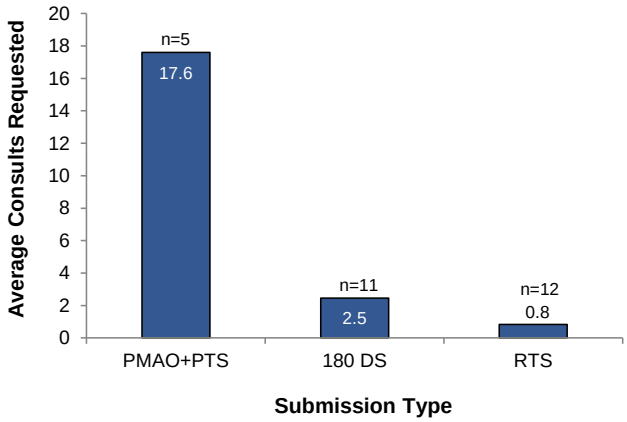
Exhibit 63. Communications by Submission Type Versus TTD and Average Number of Communications by Office



4.3.2.6 Consult Analysis

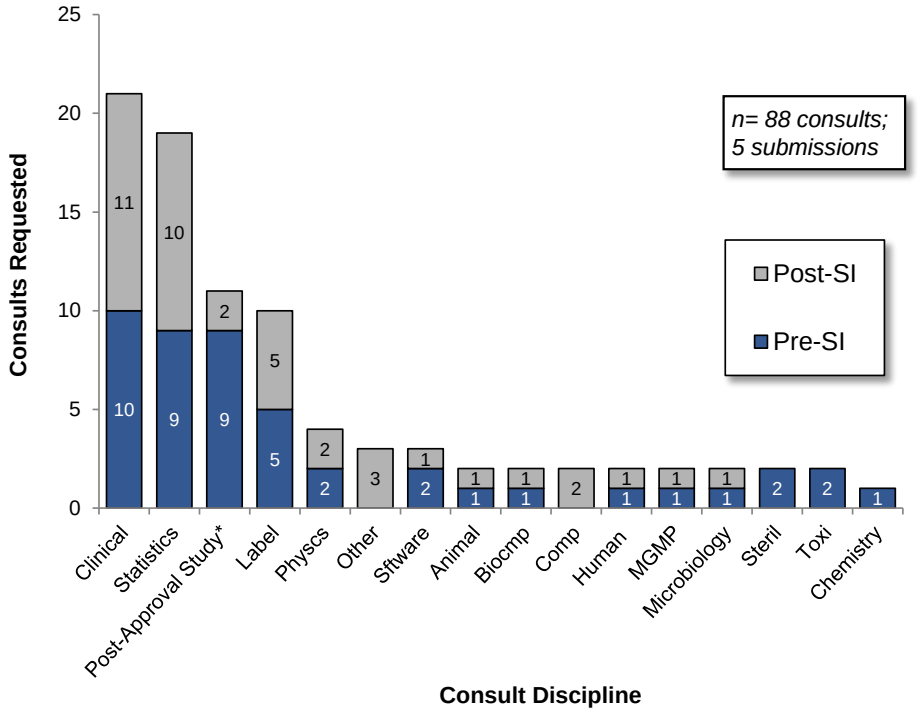
Analysis of PMA submissions within the M3 Study Cohort revealed that PMA Original and Panel-Track Supplements were associated with a significantly greater average number of consults requested than any other submission type. Exhibit 64 illustrates that PMA Originals and Panel-Track Supplements averaged 17.5 consults, as compared to 2.5 consults for 180-Day Supplements and 0.8 for Real Time Supplements.

Exhibit 64. Average Number Consults Requested by Submission Type



A closer analysis of PMA Originals and Panel-Track Supplements revealed that Clinical and Statistics consults were the most frequently requested discipline reviews, and this finding was consistent for consults requested prior to SI decisions and consults requested after SI decisions (Exhibit 65).

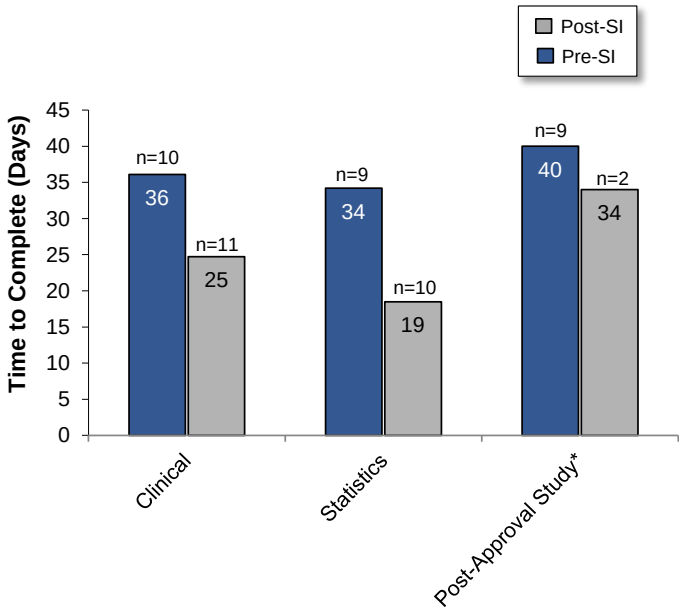
Exhibit 65. Number of Consults by Type for PMA Original/Panel-Track Supplements Submissions



*Note:*Post-Approval Study includes PrePMA and Epidemiology Consult Disciplines*

Consistent with findings from our analysis of consults performed in the Traditional 510(k) submission cohort, consults requested prior to SI decisions took longer to complete than consult reviews performed after SI decision. Of the two most frequently requested consults, Clinical consults required 36 days on average to complete when requested prior to SI decisions, and took an average of 25 days to complete after SI decisions were issued (Exhibit 66). Statistics consults averaged 34 days to complete when requested prior to SI decisions, and 19 days to complete after SI decisions were issued.

Exhibit 66. Average Days to Complete Consult Review by Review Phase



*Note:*Post-Approval Study includes PrePMA and Epidemiology Consult Disciplines*

4.3.2.7 Companion Diagnostics and Combination Products

Booz Allen conducted a case study analysis of companion diagnostics and combination product submissions to identify salient issues and potential areas of improvement for these two unique product submission types. Interviews and focus groups of FDA staff informed our summary of observations, challenges, and potential areas for improvement to existing review processes, which are provided in Exhibit 67.

Exhibit 67. Summary Observations and Suggestions for Companion Diagnostics and Combination Products

	Observations/Challenges	Suggestions for Process Enhancements
Companion Diagnostics	• Most companion diagnostics are PMAs and very few are 510(k)s • Most work conducted for companion diagnostics are at the IDE and Q-Sub submissions and these are not user fee funded • Review of companion diagnostics and/or consult requests are often initiated from the CDER/CBER. CDRH/OIR usually has very little control of the workload • Most companion diagnostic reviews are conducted in collaboration with CDER/Oncology and CDRH review staff indicate that collaborations are collegial • Lack of coordinated submission of therapeutic products and corresponding companion diagnostics was identified as a challenge to FDA performance of a timely and efficient review • External consult reviewers must manually enter request in the CDRH tracking system (i.e., CTS) • The overarching challenge for companion diagnostic review process is the lack synchronicity of milestone dates between MDUFA and PDUFA	• FDA prefers reviewing therapeutic products and the corresponding companion diagnostics simultaneously. To facilitate the review processes, Industry sponsors should coordinate the submission of both drug and companion diagnostic device applications • Develop an Integrated IT system across centers to support tracking the requests and monitoring workflow (e.g., upload CDER/CBER therapeutic products and related companion diagnostics submissions to CTS) • Evaluate the feasibility of consolidating PDUFA and MDUFA submission review milestones into a single timeline to facilitate coordination of reviews and minimize incompatible milestone dates across Centers
Combination Products	• Most combination product reviews were conducted by ODE • Focus group interviewees indicated that they are unaware of processes around Inter-Center Consult (ICCs) and heavily rely on supervisory support. FDA survey responses also indicated that a majority of the CDRH review staff felt that consult review processes with CDER and CBER were somewhat ineffective • For ICCs requested from CDER/CBER, the Lead Reviewer must manually create and enter the consult request within CDRH's tracking system	• Increase awareness of existing resources around ICCs • Develop an Integrated IT system across centers to support tracking the requests and monitoring workflow (e.g., upload CDER/CBER therapeutic products and related combination product submissions to CTS)

4.3.2.8 IDE Submissions

Booz Allen performed a study of IDE Original submissions excluding supplements or annual reports received in CY13 to determine whether these submissions met the goal of rendering a decision within the 30-day review timeframe. All IDE Original Submissions (excluding supplements and annual reports) met the goal of rendering a decision within 30 days. Comments from focus group interviews with review staff indicated that submissions in a standardized format would significantly aid the timely review of IDE submissions. A potential area for improvement would be to develop a standard submission format or template for IDE submissions.

4.3.2.9 Q-Submissions

Booz Allen performed a study of Q-submission reviews and analyzed a majority of Q-submissions with meeting feedback. These submission types (excluding supplements) were analyzed to determine whether they met the 75-90 Day deadline for holding meetings. More than 90% of submissions met the goal of holding the actual meeting within the 75-90 Day timeframe. Further analysis revealed that a few submissions were incorrectly categorized as Pre-Submission when they should have been categorized as Submission Issue Meetings. Submission Issue Meeting requests have a shorter timeline of 21 days. A potential area for improvements would be to identify methods to increase awareness and clarity of Q-submission application process for Sponsors and FDA to mitigate the potential for inaccurate categorization of Q-submission types.

4.4. Evaluation of IT Infrastructure and Workload Management Tools

Implementation of MDUFA III resulted in a variety of changes to FDA's IT infrastructure and workload management systems, each of which plays an important role in ensuring the efficiency and effectiveness of the medical device submission review process. Enhancements to IT infrastructure and workload management systems were implemented with the intent of helping review staff meet the MDUFA III review goals. Booz Allen analyzed four key existing IT infrastructure and data systems: eCopy, Image2000+, Center Tracking System (CTS), and DocMan.[23] Together, these systems serve as the sources of information and tools that review staff leverages for performing reviews.

As FDA reviewers use data systems to perform MDUFA III review processes, FDA also relies on a number of tools and methodologies to manage and monitor review staff workload. Booz Allen assessed current tools, such as CARS, CDRH Automated Time Reporting System (CTRS), and CTS, as well as management practices to allocate assignments, on their utility and perceived value. Additionally, we conducted a series of interviews and focus groups with CDRH management to evaluate workload management processes and identify best practices and recommendations for ensuring efficient processes.

4.4.1. Evaluation of IT Infrastructure

The role of each of the four primary IT systems differs, but each provides unique functions that enable reviewers to evaluate submissions when used together efficiently. A brief description of each system and associated MDUFA III enhancements are shown in Exhibit 68.

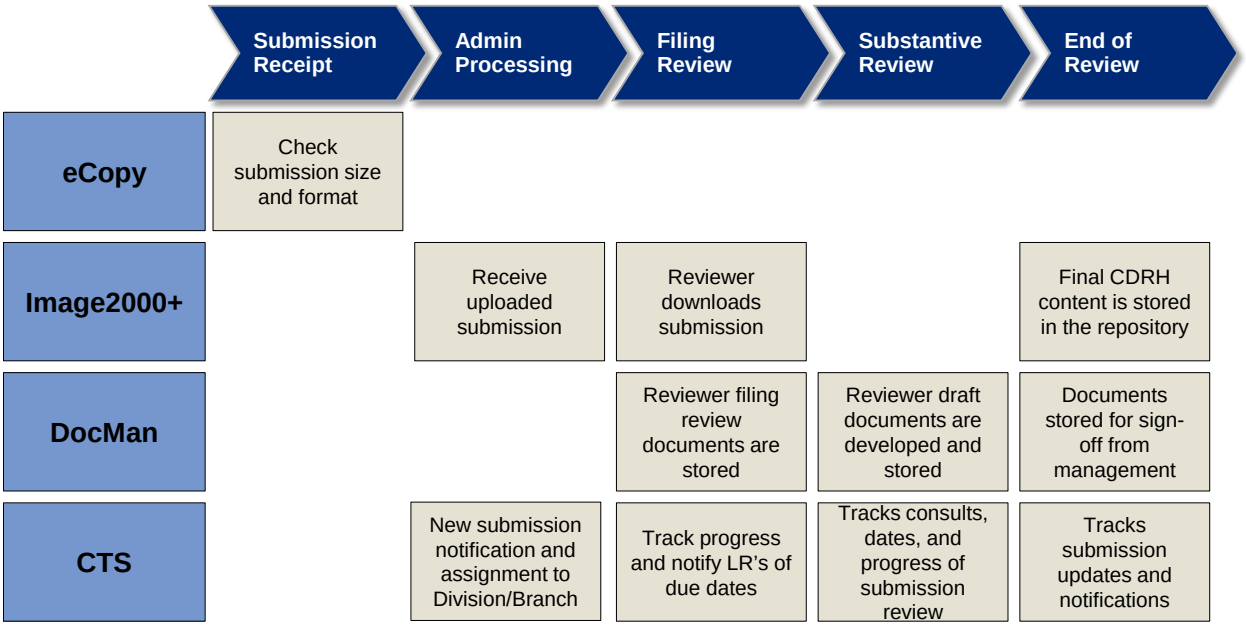
Exhibit 68. CDRH MDUFA III IT Infrastructure System Overview

System	System Description and Function	MDUFA III Enhancements
Electronic Copy (eCopy)	• Newly-implemented electronic submission system that validates submission requirements (e.g., size, document type) against eCopy program requirements.	• New system implementation
CTS	• Serves as a central document tracking tool for premarket submissions. • System has multiple modules depending on user's responsibilities • Links to Image2000+ and DocMan, enabling reviewers to reference the submission folder	• MDUFA III reviewer module • MDUFA III Division/Branch lead module • Data element modification • Link integration with DocMan
Image2000+	• Serves as a front-end to the official Documentum repository of industry submissions and review process artifacts • Folder structure allows reviewers to locate submissions by time and submission type	• Ability to download submission with folder structure to reviewer's computer
DocMan	• Newly-implemented document management system created to provide a central location for managing ongoing reviews	• New system implementation

[23] Booz Allen also considered eRoom, Traction, and SharePoint, but these systems were excluded from the evaluation as they are not primary MDUFA III review systems and play broader roles within FDA.

The four primary systems serve different functions during the course of the submission review. The complementary functions of each of the four IT systems throughout various stages of the review process are illustrated in Exhibit 69.

Exhibit 69. IT System Function Across the Review Process



Through our evaluation we identified system challenges that impact review process efficiency and highlighted opportunities for improvement. The primary areas examined during this evaluation include submission format, training and awareness, systems support of the review process, and document management.

4.4.1.1 Submission Format

During interviews and focus groups, reviewers indicated dissatisfaction with aspects of eCopy implementation due to challenges associated with the digital nature of reviews and supporting tools. In focus groups with Branch Chiefs, participants indicated that the transition from paper to digital copy has caused frustration among reviewers due to difficulty identifying information quickly. Focus group participants also reported encountering difficulties reading the text of scanned documents, searching documents that do not have optical character recognition (OCR), and locating specific administrative elements for RTA and SI reviews. Review staff identified similar themes when questioned about challenges associated with the data structure of submissions.

The eCopy guidance currently provides certain instructions, such as cover letter requirements, file size limits, titling instructions, as well as direction on how to attach non-PDFs to an eCopy.[24] However, the lack of a standardized format or ordered structure for information contained within the eCopy results in a lack of administrative consistency across submissions that increases

[24] eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff, October 10, 2013.

review times, according to focus group and survey responses. Applicants may create bookmarks in their electronic submissions, which help to organize and separate sections of the application and facilitates reviewer searches for specific content. However, bookmarking practices are inconsistently used by applicants, which impede review staff's ability to quickly locate information in the electronic submission. Guidance on electronic submissions created by FDA's CDER specifically highlights the efficiencies that may be gained from applicant submittal of searchable PDFs and bookmarked submissions.[25]

Another challenge related to eCopy submission review is the delay from the time of submission receipt to loading the eCopy into the system. According to focus groups, the lag time from when a submission is received and stamped by the Document Management Center (DMC) to the time it is loaded in Image2000+ may be three or more days late, as discussed in Section 4.3.1.2. Since Branch Chiefs only become aware of a submission once it is loaded into CTS and subsequently assign it to Lead Reviewers, several days of FDA time may be lost to perform acceptance review by the time a Lead Reviewer receives the submission. As a result, reviewers in these instances may need to meet even tighter deadlines than intended.

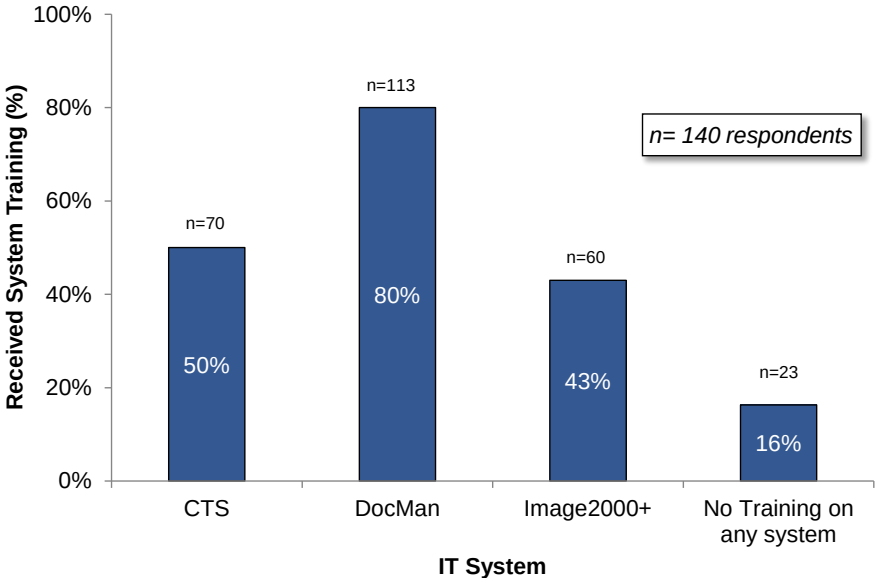
4.4.1.2 Training and Awareness

A variety of changes were made to accommodate the shift from paper to eCopy submissions and MDUFA II to MDUFA III goals. Accordingly, Booz Allen analyzed the IT infrastructure in the context of management systems that support the new changes to the review process. With the increasing reliance and impact of IT systems on review processes, reviewers' understanding of FDA's IT infrastructure that supports review staff activities and awareness of the intended role of the systems are increasingly critical for program success. To assess the extent to which review staff has an adequate understanding of MDUFA III enhancements in IT systems to support their submission reviews, we evaluated staff training for systems that underwent MDUFA III enhancements.

Booz Allen assessed the proportion of reviewers that received training on the three primary IT systems in the CDRH staff survey, shown in Exhibit 70. Among respondents who indicated that they did receive training, 50% received training on CTS, 80% received training on DocMan, and 43% received training on Image2000+. Survey results indicated that 16% of reviewers did not receive any training on any system.

[25] Draft Guidance for Industry, Providing Regulatory Submissions in Electronic Format – General Considerations, October 2003.

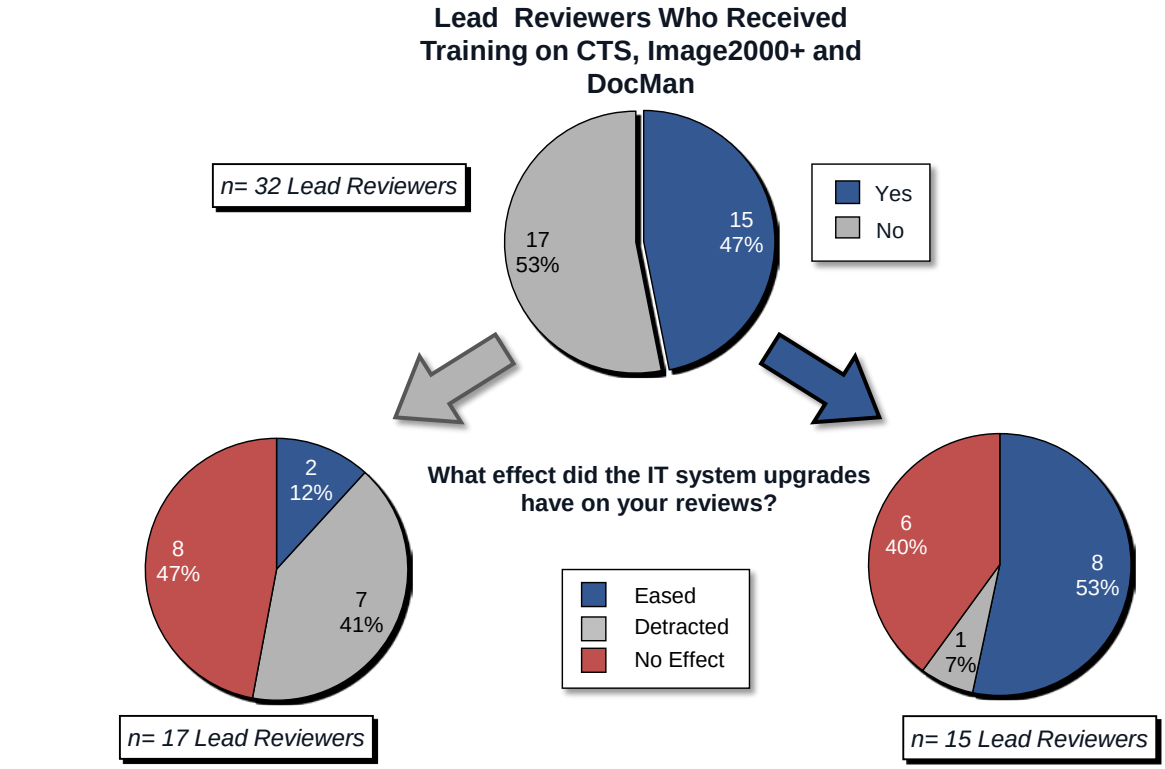
Exhibit 70. Reviewer IT System Training Received by System



Source: FDA Staff Survey

To further analyze the perspective of Lead Reviewers on training, Booz Allen distributed a questionnaire to Lead Reviewers responsible for reviewing submissions selected for deep dive analysis in our M3 Study Cohort. As shown in Exhibit 71, 47% (15 of 32) of the Lead Reviewers that responded reported receiving training on CTS, Image2000+ and DocMan. Among that group, 53% (8 of 15) indicated that it eased review, while 7% (1 of 15) said it detracted from review. By contrast, among those who reported that they did not receive the IT training, only 12% (2 of 17) said it eased reviews, while 41% (7 of 17) said it detracted from the review process. The sharp contrast in this limited sample suggests that training has a significant impact on the effectiveness of the new systems implemented.

Exhibit 71. Lead Reviewers Who Received Training on CTS, Image2000+ and DocMan



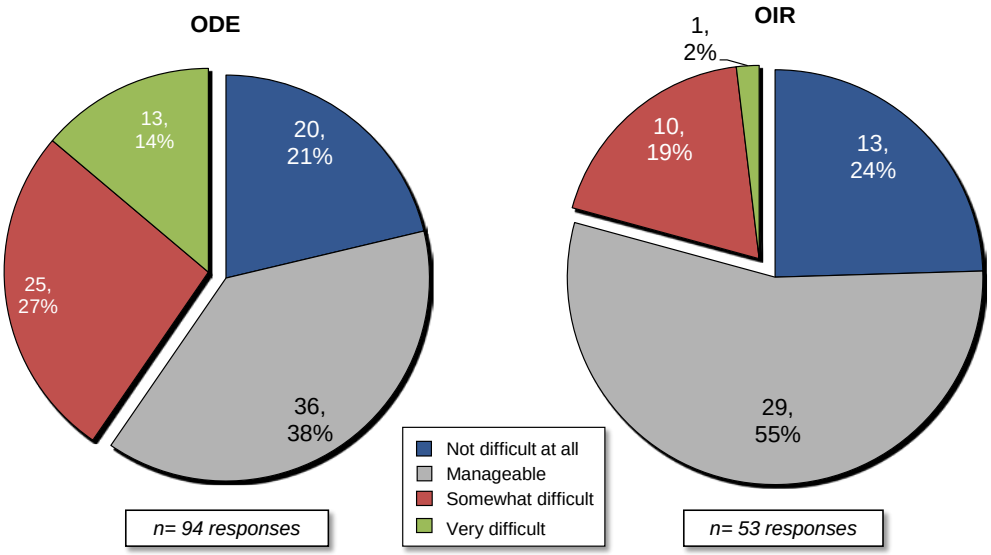
Note: Only reviewers who took all three IT system training courses were counted as "Yes".
Source: BAH survey of Lead Reviewers

Due to the short timeline for the rollout of these IT system enhancements, reviewers had a limited time to learn how these tools should be integrated into the MDUFA III review process. Reviewers report continued struggles to understand how these changes are to be integrated into their reviews. Documentation such as the Quick Guides and Cheat Sheets provide information on functionality, but focus group participants noted that these documents do not provide a sufficient explanation for how to incorporate the new functionality into their reviews.

4.4.1.3 IT Systems Support of the Review Process

There are three primary systems, discussed in Section 4.4.1, that play critical, supporting roles for medical device submission reviews, and reviewers must utilize all three systems for various functions throughout the review process. Recognizing this, Booz Allen surveyed reviewers and managers on the ease with which they could balance the three primary systems when conducting reviews. Exhibit 72 shows that the majority of staff in both ODE (59%) and OIR (79%) indicated that concurrent use of two or more data systems was manageable or not difficult, and did not hinder their work.

Exhibit 72. How Difficult is it to Manage Multiple Tools for Conducting Reviews?



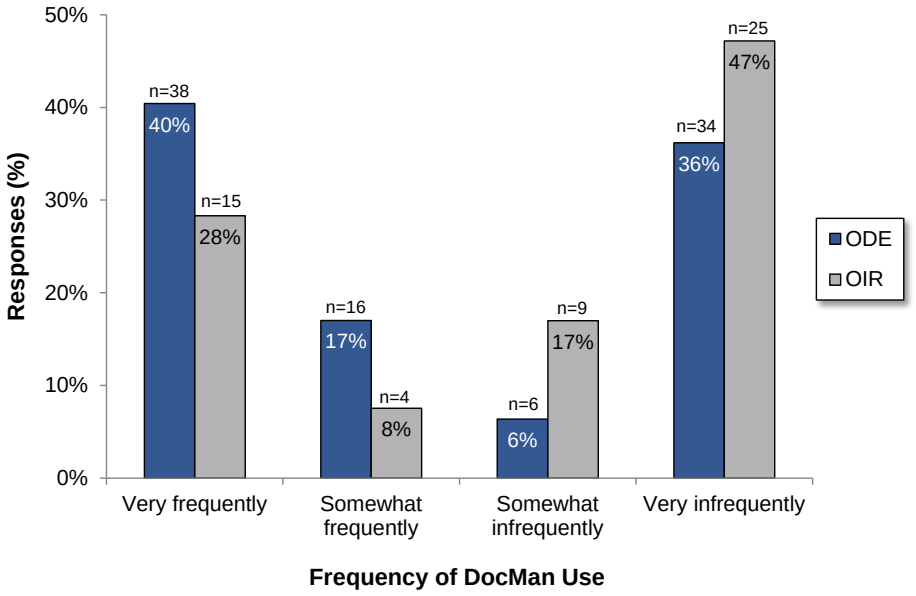
Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

4.4.1.4 Document Management

Reviewers currently use a variety of systems and tools, including DocMan, eRoom, e-mail, and shared drives, for sharing submission documents to perform collaborative reviews. These tools facilitate communication when insight from other staff (e.g., Branch Chiefs, consultants, peer reviews) is needed, as well as for transmission of files to management for review and sign-off. The variety of document sharing practices may be due to the fact that there is no specific policy that instructs reviewers on which tool or system to use. DocMan was introduced as a replacement for eRoom, a tool that reviewers have historically used for the storage of documentation and reference materials for submission reviews. DocMan is intended to be used as a collaborative workspace for MDUFA submission reviews.

According to the CDRH staff survey, review staff use of DocMan varies significantly between ODE and OIR. As shown in Exhibit 73, 57% of ODE review staff indicated that they use DocMan for storing documentation either very or somewhat frequently, while only 36% of OIR reviewers very or somewhat frequently use DocMan.

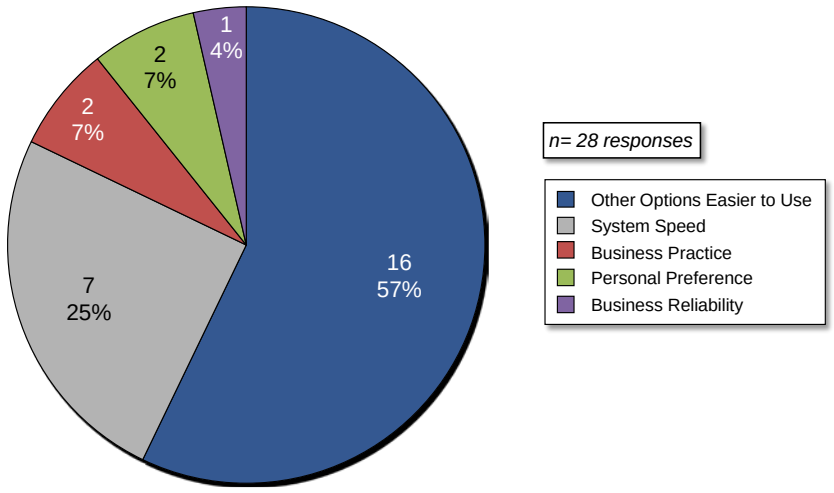
Exhibit 73. Frequency of DocMan Use for Storing Submission Documents



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

The most common reasons that reviewers indicated for using an alternative to DocMan for sharing information during reviews are shown in Exhibit 74. The single most common reason provided is that other options are easier to use (57%), followed by slow system speed compared to other options (25%). Reviewers' inconsistent practices in using DocMan support findings identified through our quality management assessment of CDRH document management practices (Section 4.2.1.3).

Exhibit 74. Reasons for Using DocMan Alternatives



Source: FDA Staff Survey

4.4.2. **Assessment of Workload Management**

The primary systems used by management for allocating and managing workload include CARS, CTS, and CTRS. CARS and CTS are the two primary IT systems that support reviewer workload management processes. CARS provides reports from a large database that is refreshed on a daily basis, while CTS utilizes information from a separate database that is updated in real-time and correlates with ongoing activities from user review accounts. Both systems enable the creation of reports on workload related to MDUFA Goal Dates for ongoing submissions and provide management detailed lists of documents coming due in the near term. CTRS is a time reporting system that gathers data about review staff activities over a two-week period during every quarter. Data captured and analyzed from CTRS is used by decision-makers to understand time spent by FDA staff on various program activities and support reporting of resource use.

4.4.2.1 Evaluation of CTS

In the context of workload, CTS modules indicate how many submissions a reviewer has currently under review, as well as when the review phase (e.g., RTA, SI) due dates are. Focus group participants identified opportunities for improvement related to information available in CTS. a more complete list of milestone dates; additional date-related data for submissions on hold; and an indicator of submission complexity.

Focus group participants indicated that current dashboards do not include all milestone dates (e.g., Branch due dates), which makes it difficult for managers to track a reviewer's individual performance and progress. For example, participants noted that they cannot track whether a reviewer consistently misses a branch due date, which would be helpful information when considering future assignment decisions.

The second opportunity for improvement relates to submissions that are on hold awaiting further action from applicants. The absence of this information in CTS modules makes it difficult for management to track how many submissions are truly aligned to each reviewer, and provides challenges for managers to anticipate and assess a reviewer's availability for taking on additional submissions.

The third opportunity relates to information to describe submission complexity. Inherently, medical device submissions vary in complexity depending on factors such as the submission type (e.g., 510(k), PMA, IDE) and therapeutic use. Presently, general submission type is the only indicator of complexity that is accounted for in any of the available reports. Interview and focus group participants indicated some measure of complexity in workload reporting be useful for transparency, both within review groups and for Center leadership. Currently, individual discussions between supervisors and reviewers are the only way to manage expectations and communicate the complexity of a submission.

4.4.2.2 Evaluation of CARS

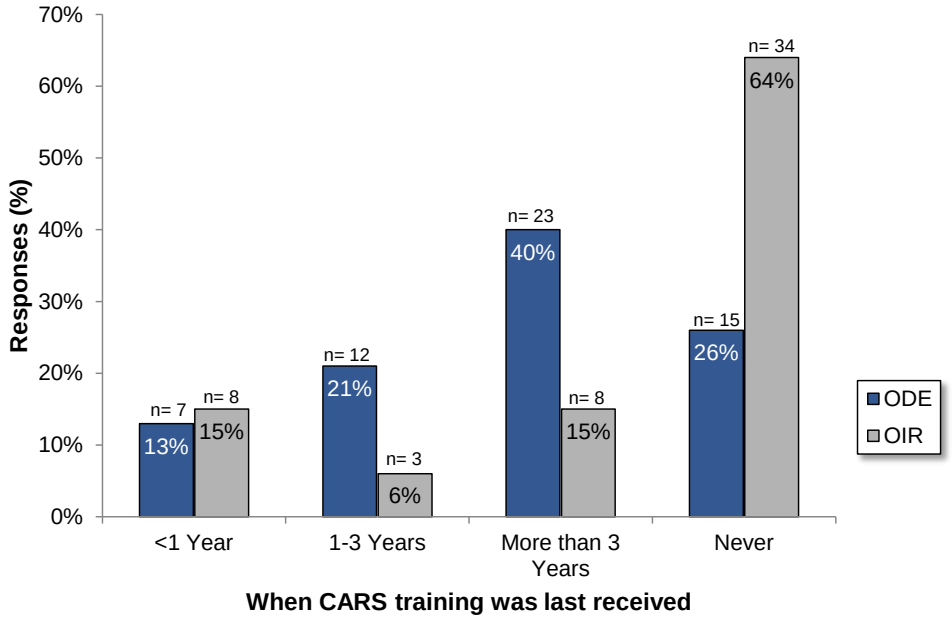
CARS is a more complex and data-rich system than CTS that is not well understood by CDRH users according to focus groups, interviews, and the staff survey. Staff feedback indicated that the complexity of CARS creates concerns regarding the validity of data in reports and often requires subsequent validation of any report that is pulled from the system. Additionally, during focus groups, Branch Chiefs noted that the user interface is difficult to learn and that it is very challenging to obtain specific information needed (i.e., content of data fields and the effect of data on the reports is not intuitive) for making decisions.

Each week, canned workload reports generated in CARS are delivered electronically to Division Directors and Branch Chiefs. Branch Chiefs indicated that the amount of information in these reports is overwhelming, making it difficult to analyze. Additionally, review staff names are not associated with the submissions, which then require managers to take an extra step to identify the reviewers responsible for particular assignments coming due. Due to the size and structure of the CARS report, managers often disregard CARS and rely on CTS as their primary source for assignment decisions and assignment tracking.

Another challenging aspect of CARS is that the system only refreshes the data once every 24 hours. This leads to outdated workload reports leading to staff confusion and frustration when examining reports, particularly early in the week, when changes have not been refreshed from the previous week. As a result, when a submission appears to be behind review schedule, Branch Chiefs will often spend time confirming that the lag is due to CARS refresh rates and not due to reviewer negligence. We speculate that this challenge in managers' ability to confirm the accuracy of reports may be another reason as to why CARS is often disregarded for assignment tracking.

Training and support for CARS were also evaluated through the staff survey. As shown in Exhibit 75, a majority of managers across offices responded that they had never received training or had not received training in more than three years (26% of ODE reviewers and 64% of OIR reviewers, and 40% of ODE and 15% of OIR managers, respectively). Furthermore, 15% or fewer responders in both ODE and OIR indicated that they had received training within the past year. The limited number of staff having received recent training may be a potential reason that contributes to the perceived complexity of the CARS system.

Exhibit 75. Time Elapsed Since CARS Training Received



Source: FDA Staff Survey

4.4.2.3 Inter-Center Consults

Current workload tools do not capture ICCs, which limits transparency around certain review-related activities. Currently, separate FDA systems are used for tracking these work products. For example, when an ICC is sent to CDRH, a General Document (GenDoc) number is manually created in CTS by the CDRH reviewer to enable tracking, but these documents are not included in CARS for workload reports. Some divisions have created a workaround by assigning an individual the responsibility of tracking ICCs for the division to ensure that work is properly accounted for and managed. Interviews and focus groups indicated that the absence of information on ICCs results in an inaccurate view of staffing availability.

4.4.2.4 Submission Assignment Practices

To understand workload management challenges related to medical device submission reviews, Booz Allen evaluated the submission assignment practices of Branch Chiefs. The current processes provided insight into best practices for workload allocation within CDRH.

Branch Chiefs consistently identified four criteria that are systematically used to inform the submission assignment process: 1) submission type; 2) upcoming reviewer deadlines; 3) reviewer expertise in a given field or type of medical device; and 4) a pre-existing relationship with the specific submission (e.g., the reviewer was involved with the pre-submission or IDE).

Through our evaluation of the management systems related to MDUFA III, workload allocation practices were found to be specific to the Division/Branch and personnel that comprise the group. There are several elements that managers identified as being useful for making submission assignment decisions beyond the four criteria described above. According to focus group participants, it is critical for Branch Chiefs to have a strong working knowledge of their

staff, which includes an awareness of staff experience with specific product types, educational background, and professional interests. Focus group participants indicated that the current number of submissions on a reviewer's docket, or the number of reviews staff have performed to date, is not sufficient information for supporting an informed decision on making submission assignments.

Focus group participants also emphasized that a balance must be established between best practices for the reviewer and supervisor in meeting MDUFA goals. An example of this kind of balance includes setting no more than two significant goals in one-week for a reviewer and expecting review staff to incorporate time for management review. Focus group participants indicated that the use of calendars to create a visualization of reviewer assignments is instrumental in making efficient assignment decisions, but these tools must also be custom created by managers. Additionally, managers stated that one-on-one meetings are helpful for ensuring a more detailed understanding of what reviewers are working on week to week (e.g., reviews, special projects, consults), and provides an opportunity for staff to flag difficult submissions if additional time is needed.

4.4.2.5 Quality Assessment of Methods to Determine Resource Use

As part of the workload assessment, Booz Allen sought to determine whether CDRH has a mechanism in place to assess resource use from a quality systems perspective. Consistent with the quality systems nature of this assessment, we did not audit the design or implementation of CDRH's time reporting tool. Through staff interviews with the Office of Management Operations (OMO) and Office of Information Management (OIM), we identified that CDRH uses a time reporting system (i.e., CTRS), a web-based application to collect staff time spent on program and special activities. CDRH uses CTRS as the mechanism to monitor how CDRH payroll resources are used within the Center, track staff resources performing MDUFA user fee activities, and provide supporting information for public reporting purposes.

The Center continually provides senior management oversight to this system via OMO, which leads deployment, data collection, and analysis of the time reporting survey, with technical support from OIM. The survey is administered in two-week collection windows on a quarterly basis, totaling eight weeks of captured time each year. Senior management at the Office level monitors survey participation against its 95% target, assigns coordinators to address staff questions, and conducts periodic reviews and revisions of CTRS program activities.

CDRH implemented a suite of training tools[26] and notifications to ensure that staff is aware of and completes the quarterly survey, and CDRH has consistently met its participation targets. A CTRS User Guide is updated annually and an online training course is offered through CDRH Staff College to help users understand accurate and proper survey reporting methods. Current versions of these materials and online training course link appear organized and accessible in a centralized location on the FDA intranet.

The Center has employed various methods to promote accuracy of the data collection process. For example, CDRH has developed a detailed list of more than 200 review-related activities to facilitate accurate staff time reporting, which has increased in specificity since MDUFA III

[26] FDA FY2014 CTRS User Guide, CTRS Activities, CTRS Special Activities Definitions, Introduction to CTRS Online Course, CTRS Program Activity Codes for Staff College Courses.

implementation (e.g., staff may report time on Q-submissions, Third Party 510(k)s, and each type of PMA). CDRH also selects staggered data collection timeframes each quarter to increase data representativeness. System-specific enhancements enable a user's workload to be automatically queried from CTS so users may select from their active submissions to report spent time. During an open survey, staff may contact CTRS coordinators for clarifications on time reporting, and management may voluntarily check and monitor data reported in their respective groups. Inconsistencies may be flagged through OMO reports and corrected during a one-week data reconciliation period.

CDRH has a mechanism in place to compute resource use. To mitigate sampling biases that might result from using short data collection windows, staff time reported for each program activity during the survey period is extrapolated to the quarter, and data from each quarterly survey is averaged to represent the relative proportion of staff time spent on each program activity in a given year. These percentages are applied to automated payroll reports of paid Full-Time Equivalents (FTEs) to estimate resources in each cost center performing a particular activity. Agency overhead is subsequently added to these estimates. Due to the aggregated nature of the CTRS data, Division or Branch management may not make individual workload allocation decisions. Reports are primarily used to calculate FTE and payroll dollars applied to all major CDRH activity areas for internal planning purposes. CTRS data is also used for public reports. For example, FTE and payroll data is used to support annual budget estimations for HHS, Office of Management and Budget (OMB), and Congress, and will likely also support a new FDA workload model to inform renegotiation discussions.

4.5. Evaluation of Training Programs

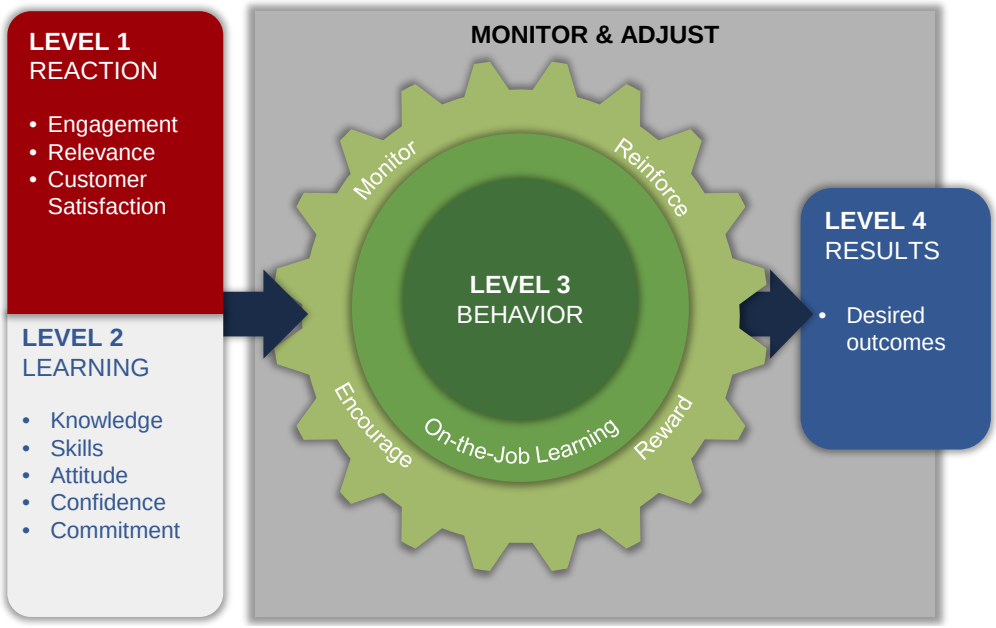
As part of the independent assessment, the quality and effectiveness of CDRH's reviewer training programs were assessed. Booz Allen assessed MDUFA III training program content released at the onset of MDUFA III to identify gaps in process information provided to trainees. We also identified and characterized four CDRH training programs, managed by DETD (formerly Staff College) within the OCE, which were most pertinent to supporting staff training on the medical device review process. This section also includes a summary of our benchmark analysis of CDRH's training program against comparable USPTO and CDER training programs. A description of each program is provided below:

- **Reviewer Certification Program (RCP).** Mandatory new reviewer training program, which covers core reviewer skills and competencies
- **Leadership Enhancement and Development Program (LEAD).** Mandatory training program for all supervisors, which offers core leadership skills
- **Experiential Learning Program (ELP).** Voluntary training program in which reviewers visit industry sites to gain first-hand experience of new processes, procedures, and technologies
- **Ad Hoc Training.**[27] Voluntary training to address just-in-time and new reviewer needs. Because this program was put on hold as of October 1, 2012, Booz Allen only conducted limited stakeholder interviews and document analysis.

[27] The Ad Hoc Training program is also referred to as "Call for Proposals" by DETD staff.

We applied the Kirkpatrick Model, a widely-recognized gold-standard training evaluation framework used in industry and government agencies, to assess the extent to which each training program meets best practices for successful evaluation of training programs across the full lifecycle of learning. The stages of this lifecycle, from initial participation in training to subsequent improvements in work functions, are depicted in Exhibit 76.

Exhibit 76. Kirkpatrick's Four Levels of Evaluating Training Programs



Source: Evaluating Training Programs: The Four Levels (3rd Edition), Donald Kirkpatrick and James Kirkpatrick, 2006.

Each of the four framework levels applies a unique and increasingly complex set of metrics to assess training program utility:

1. **Reaction.** Measures participant reaction to and satisfaction with received training
2. **Learning.** Evaluates changes in participants' attitudes, knowledge, and/or skills as a result of participating in the training program
3. **Behavior.** Assesses transfer of knowledge, skills, and/or attitude after completing training, based on performance in the participants' work environment
4. **Results.** Determines training results based on pre-identified program metrics, such as increased efficiency and/or predictability, or review consistency.

Booz Allen also performed a benchmarking analysis of the training programs of several other relevant organizations[28] to identify practices that may be particularly important to the success of those programs.

[28] This study does not intend to assess the design or implementation of training programs for our selected benchmark organizations; rather, best practices gleaned from these organizations are discussed to clarify areas where gaps may exist in CDRH training programs, and to shed light on activities that may be valuable for CDRH to emulate.

4.5.1. **MDUFA III Training Program**

The MDUFA III Training Program was initially administered as a separate mandatory training program to educate all CDRH staff on enhancements at the onset of MDUFA III (October 1, 2012), but the training material has since been absorbed into the RCP training curriculum. The MDUFA III Training consists of five training modules that cover various MDUFA III processes, such as RTA, SI, IR, and MMD, as well as other important submission review programs such as Third Party Review, *De Novo* classification, Pre-Submissions, and CLIA Waivers. As of September 30, 2012, training participation data provided by DETD indicates that 96% of ODE and 97% of OIR staff completed at least one MDUFA course, with 60% of ODE and OIR review staff having completed all required courses.

We developed a set of nine process elements with which to evaluate whether the training content for each MDUFA III new process and MDUFA-related submission program includes the end-to-end information needed to help a reviewer sufficiently understand and apply the process. For example, training content should include: a description and objectives of the new process; methods to communicate process information or milestone information to Sponsors; methods to pose questions and raise issues; steps to document and archive information, and; clearly delineated performance and reporting goals. Interviews with DETD management indicated that MDUFA material has been updated since the initial MDUFA III training from September 2012, but only as part of the RCP MDUFA courses. Therefore, only those reviewers that have participated in RCP since October 2012 will have been trained on any updated content. In addition, our analysis of the training material content, shown in Exhibit 77, shows that essential process elements were largely included for each key MDUFA III review process (i.e., RTA, SI, IR, and MMD). One process element that pertained to resources and support tools—checklists, SOPs and guidance documents—was partially included in MDUFA III module content. Specifically, checklists and some SOPs were included in the MDUFA III modules on RTA and SI, but reviewers did not appear to receive in-depth formal training on updated guidance documents and clinical standards. Discussions with DETD indicated that training courses and webinars are currently being developed for both industry and FDA staff which will highlight and summarize new guidance and other relevant documents.

Exhibit 77. Existence of Key Review Process Elements in MDUFA III Training Modules

Process Elements[1]	Refuse to Accept (RTA)	Substantive Interaction (SI)	Interactive Review (IR)	Missed MDUFA Decision (MMD)
Description of process and policies – Adapted to relevant submission types (e.g., 510(k)) as appropriate	✓	✓	✓	✓
Rationale and objectives – Stated for new process use	✓	✓	✓	✓
Methods for sponsor engagement – Description of communication methods, reviewer responsibilities	✓	✓	✓	✓
Issues and areas of improvement – Stated methods to communicate with management on issues	✓	✓	✓	✓
Scenarios – Suggested methods or mitigating actions to handle variations from typical processes	✓	✓	✓	NA
Document control steps – Stated process to log/file and upload documents, communications, signatures	✓	✓	✓	✓
Resources and support tools – Checklists, SOPs, etc., discussed in training to enable consistency	✓	✓	NA	NF
Timeframes to execute process step – Recommended or required days to completion	✓	✓	✓[4]	✓
Performance metrics and reporting goals – Accountability to meet metrics, as applicable	✓[2]	✓[3]	NA	✓[2]

Notes: 1.Training modules in this slide include materials in: Class 1 – 510(k)s, Class 1 – 510(k) RTA, Class 2 – PMAs, Class 4 – Electronic Workload Management Enhancements; 2. RTA and MMD do not have specific MDUFA goals but compliance is tracked for performance reporting purposes; 3. Description of processes includes use and timing of all SI types (AI/TH, IR, SE, MAJR); 4. Interactive Review describes timeframe for discretionary vs. expected IR; NA = Not Applicable; NF = Not Found

Using these same nine process elements, Booz Allen also assessed training content for programs integral to MDUFA III, such as Third Party Reviews, *De Novos*, Pre-submissions, and CLIA Waivers. Our evaluation revealed that while training materials exist to address each process area for pre-submissions and CLIA Waivers, many informational process elements were lacking for Third Party Reviews and *De Novos* (Exhibit 78). Discussions with DETD management indicated that training materials are currently being developed for inclusion in MDUFA training material under RCP.

Exhibit 78. Evidence of Training on MDUFA III Submission Program Elements

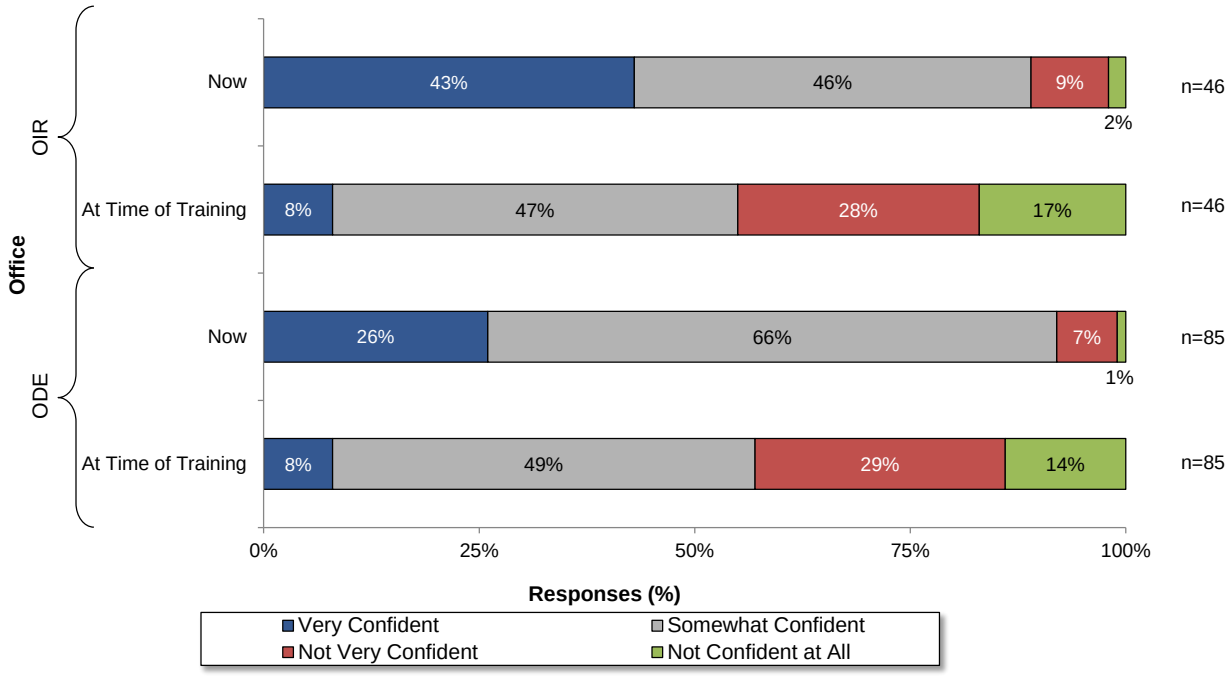
Process Elements[1]	Third Party Review	De Novo	Pre-submission	CLIA Waiver
Description of process and policies – Adapted to relevant submission types (e.g., 510(k)) as appropriate	✓	✓	✓	✓
Rationale and objectives – Stated for new process use	NF	NF	✓	✓
Methods for sponsor engagement – Description of communication methods, reviewer responsibilities	NF	NF	✓	✓
Issues and areas of improvement – Stated methods to communicate with management on issues	NF	NF	NF	✓
Scenarios – Suggested methods or mitigating actions to handle variations from typical processes	NF	NF	✓	NF
Document control steps – Stated process to log/file and upload documents, communications, signatures	NF	NF	✓	NF
Resources and support tools – Checklists, SOPs, etc., discussed in training to enable consistency	NF	✓[2]	✓	✓
Timeframes to execute process step – Recommended or required days to completion	NF	✓	✓	✓
Performance metrics and reporting goals – Accountability to meet metrics, as applicable	NF	NF	✓[3]	✓

Notes: 1.Training modules include materials in: Class 1 – 510(k)s, Class 1 – 510(k) RTA, Class 2 – PMAs, Class 3 – Pre-submissions, Class 4 – Electronic Workload Management Enhancements, and Class 5 – CLIA Waivers, which were used during M3 roll-out and in RCP training; 2. SOP and guidance is in development; 3. Pre-submissions have no specific MDUFA goal but there will be reporting on timeframes; NA = Not Applicable; NF = Not Found

While the content of the training modules on new MDUFA III processes for 510(k) and PMA submissions appears sufficient to support reviews, participant comprehension was not evaluated following training, similar to our findings from evaluation of CDRH's other training programs. Specifically, reviewer perceptions on the impact of training for enabling staff to perform reviews or to support a more efficient review process were not assessed.

To gain insight into program effectiveness, we surveyed FDA staff on their perceived level of understanding of MDUFA III new review processes at the time of training completion at the onset of MDUFA III compared to today. FDA survey data, shown in Exhibit 79, indicates that 57% of ODE review staff and 55% of OIR review staff expressed confidence in training material comprehension upon completing MDUFA training. However, 92% of ODE reviewers and 89% of OIR reviewers feel more confident now in their understanding of MDUFA III material than at the time of initial training. This finding is consistent with the perspective shared during management interviews and in managers' response to the Booz Allen Survey that following training course completion, reviewers and management continue to increase their knowledge and understanding through on-the-job learning and other informal mechanisms.

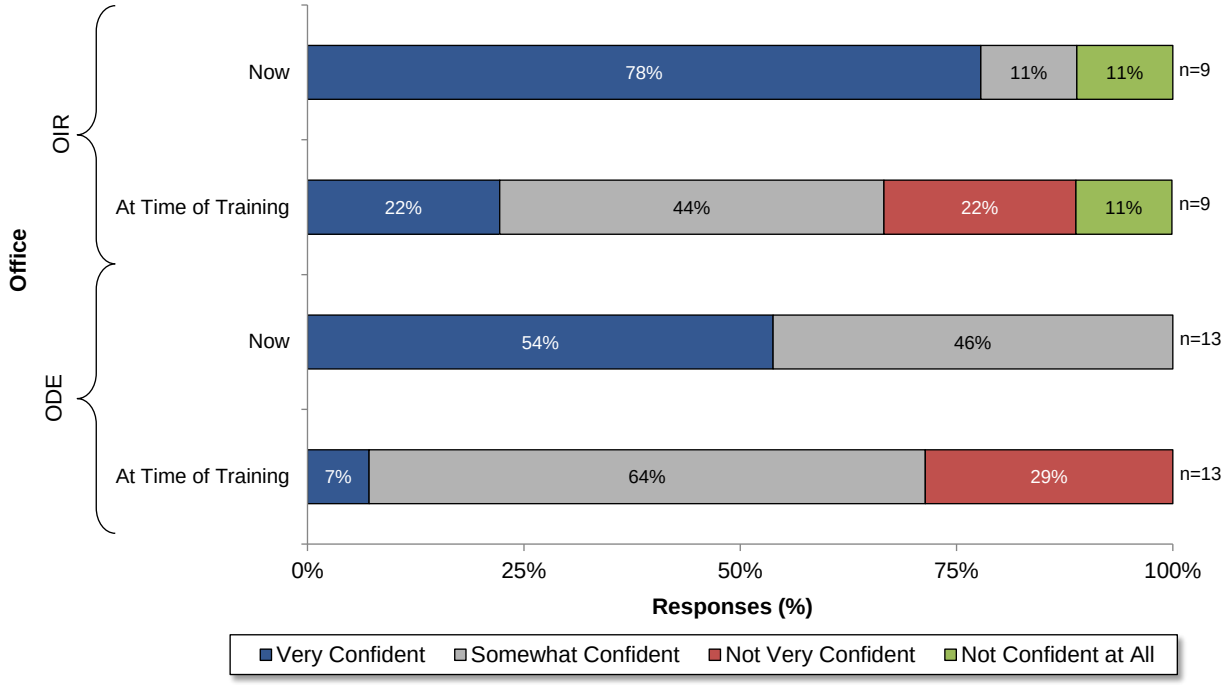
Exhibit 79. Reviewer Perception of Reviewers' Understanding of MDUFA III Material upon Completing MDUFA III Training at Time of Training vs. Now



Source: FDA Staff Survey

Survey data, depicted in Exhibit 80, also show that management perceived their comprehension of MDUFA III material to improve somewhat since training course completion. A larger proportion of ODE (71%) and OIR (66%) management expressed confidence in their initial knowledge at the time of training compared to review staff, and 100% of ODE and 89% of OIR were at least somewhat confident in their understanding at the time of the FDA staff survey.

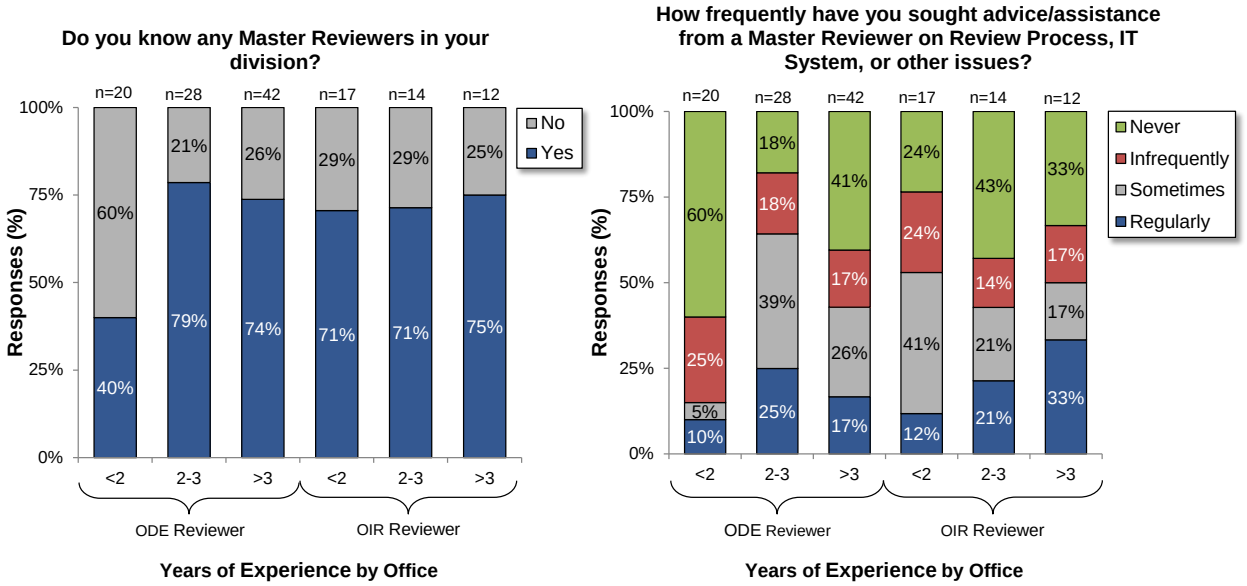
Exhibit 80. Management Perception of Management's Understanding of MDUFA III Material upon Completing MDUFA III Training at Time of Training vs. Now



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

One resource that we identified in both ODE and OIR for providing review staff with on-the-job training was Master Reviewers. Master Reviewers are highly experienced review staff who have been promoted on the basis of their superior review performance and knowledge, and serve as expert resources to other review staff. We explored the extent to which review staff is aware of Master Reviewers in their own divisions. Reviewer survey responses (Exhibit 81) show that only 40% of new ODE reviewers, defined as reviewers with less than two years of experience in their role, are aware of a Master Reviewer in their division, compared to more than 70% awareness among more seasoned ODE reviewers and among all OIR reviewers. Not surprisingly, this data appears to be associated with the frequency that reviewers of different tenure seek advice or assistance from a Master Reviewer on review processes or other issues. New ODE and OIR reviewers, who would likely benefit the most from leveraging support from Master Reviewers, differed substantially in their likelihood to seek help from Master Reviewers. While 85% of new ODE reviewers indicated that they infrequently or never consult Master Reviewers for assistance, only 48% of new OIR reviewers responded similarly. A larger proportion of seasoned reviewers (42-64%) responded that they occasionally or regularly seek help from Master Reviewers. These findings suggest that methods used to connect review staff to experienced resources, particularly for new ODE reviewers, could be enhanced.

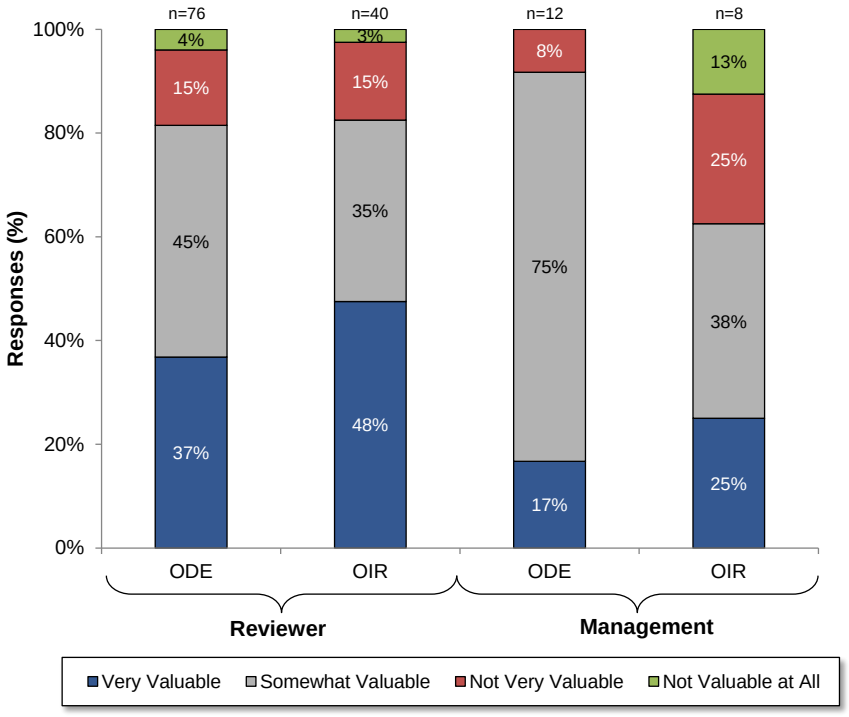
Exhibit 81. Awareness of and Frequency of Assistance Sought from Master Reviewers



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

Brown bag sessions are commonly used as an informal and voluntary mechanism for knowledge sharing in the workplace. Booz Allen surveyed FDA staff on the perceived utility of brown bags led by Master Reviewers as a potential method to increase opportunities for staff learning. Exhibit 82 indicates that both reviewers and management from ODE and OIR (92% and 93%, respectively) perceive that brown bag sessions offered by Master Reviewers to discuss lessons learned and best practices on performing submission reviews would be a valuable method for the reviewer community to learn about review processes outside of formal training. These findings are comparable to ODE management views (92%). Management interviews indicate that new OIR review staff is assigned product experts as well as mentors, who may be Master Reviewers, to lend their expertise, support and mentorship on submission reviews. We speculate that this robust support provided to new review staff may explain why a smaller percentage of OIR management finds additional brown bags valuable.

Exhibit 82. Value of Brown Bag Sessions Offered by Master Reviewers to Reviewers for Discussing Lessons Learned, Best Practices, etc.



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

4.5.2. **Summary of Organizational Best Practice Profiles**

Booz Allen identified training program evaluation best practices from a literature review of annual reports, strategic plans, booklets, guides, presentations, and other documents from numerous industry and governmental organizations (Appendix F) and grouped them according to the appropriate Kirkpatrick Model level based on the types of metrics put forth by each best practice. CDRH's training programs are summarized according to these identified best practices and compared to current CDER Office of Executive Programs (OEP), CDER Office of New Drugs (OND), and USPTO processes as shown in Exhibit 83, which in aggregate form each organization's best practice profile. CDRH results are aggregated as the four individual training programs all possess similar best practice profiles. Individual profiles for CDRH training program are summarized in Appendix E. USPTO results are similarly aggregated for its training programs which are performed by two different groups (Office of Patent Training, Office of Human Resources/Enterprise Training Division). Profiling these four organizations against the 18 best practices itemized above was conducted to help prioritize activities performed by other successful organizations and to focus CDRH's resources and efforts.

As shown in Exhibit 83, CDRH performs 5 of the 18 (28%) identified best practices, a significantly lower number as compared to OEP (50%; 9 of 18), OND (61%; 11 of 18) and USPTO (83%; 15 of 18). CDRH currently performs two of the four best practices aligned to Level 1, but does not perform any activities to assess learning and knowledge (Level 2). In addition, CDRH currently performs 3 of the 10 best practices aligned to Levels 3-4. In comparison, all benchmark organizations implement at least the same proportion of Level 1 best practices as CDRH (50%; 2 of 4), but the benchmark organizations also perform many activities that enable them to assess knowledge gained and behavioral change (Levels 2-4). For example, OND performs 5 of 9 Level 3-4 activities, while USPTO performs 8 of 9 Level 3-4 activities. There are three best practices that are not exhibited by CDRH or any of the benchmark organizations: a program-specific training plan (Level 1); time allocated for an end-of-training survey (Level 2); and linking training program completion to an individual development plan (Level 4). While these gaps represent opportunities for CDRH to improve their training program, the fact that all of the benchmarked organizations have these same gaps demonstrates that CDRH does not necessarily need to implement every best practice to become a best-in-class training organization.

Exhibit 83. Training Program Evaluation Best Practices Profiles Comparing CDRH to Benchmarked Organizations, Grouped by Kirkpatrick Level

	Best Practice	CDRH[1]	CDER/OEP	CDER/OND	USPTO
1: REACTION	A program-specific training plan exists.	No	No	No	No
	An annual competency-based needs assessment is conducted.	No[2]	No	No	Yes
	Curriculum is based off of most-current training needs assessment data.	Yes	Yes	Yes	Yes
	Participant satisfaction with training was captured and recorded.	Yes	Yes	Yes	Yes
2: LEARNING	A pre-course test is conducted and results recorded.	No	No	Yes	Yes
	A post-course test is conducted and results recorded.	No	No	Yes	Yes
	Internal SOPs in place for timing of evaluations, process, etc.	No	Yes	Yes	Yes
	Time is allocated and used for course survey at end of training course.	No	No[3]	No	No
	Customized evaluations of successful/un-successful behavior changes are conducted.	No	No	Yes	Yes
3. & 4. MONITOR & ADJUST BEHAVIOR AND RESULTS	Feedback from trainers is recorded/analyzed.	No	Yes	Yes	Yes
	Surveys are sent out for additional assessments of knowledge transfer and implementation.	No	Yes[4]	Yes[4]	Yes
	Training schedule/availability is easily accessible and disseminated to audience.	Yes	Yes	Yes	Yes
	Emerging learning tools (e.g. webinars, on-demand online course) are utilized.	Yes	Yes	Yes	Yes
	Result metrics are identified for each course.	No	No	No	Yes
	Participant training records are available for easy tracking of competency gaps by employee, occupational group, or competency.	Yes	Yes	Yes	Yes
	A program-specific re-certification process exists.	No	N/A	N/A	Yes
	Informal workshops exist to supplement training materials and reinforce participant behavioral changes.	No	Yes	No	Yes
	Training program completion is linked to Individual Development Plan (IDP).	No	No[5]	No[5]	No

Notes: 1. CDRH's ELP program is N/A (instead of No) for emerging learning tools, re-certification, and informal workshops. 2. Staff College performed an informal needs assessment through internal discussions. No formal assessment was conducted. DETD indicated future plans to conduct small-scale needs assessments annually and formal needs assessments every 3-5 years. 3. OEP provides electronic surveys within 24 hours of course, possibly in addition to paper surveys handed out in course. 4. CDER knowledge transfer surveys are currently for CE activities only. 5. IDPs are not required in CDER, although they can be used voluntarily by employees

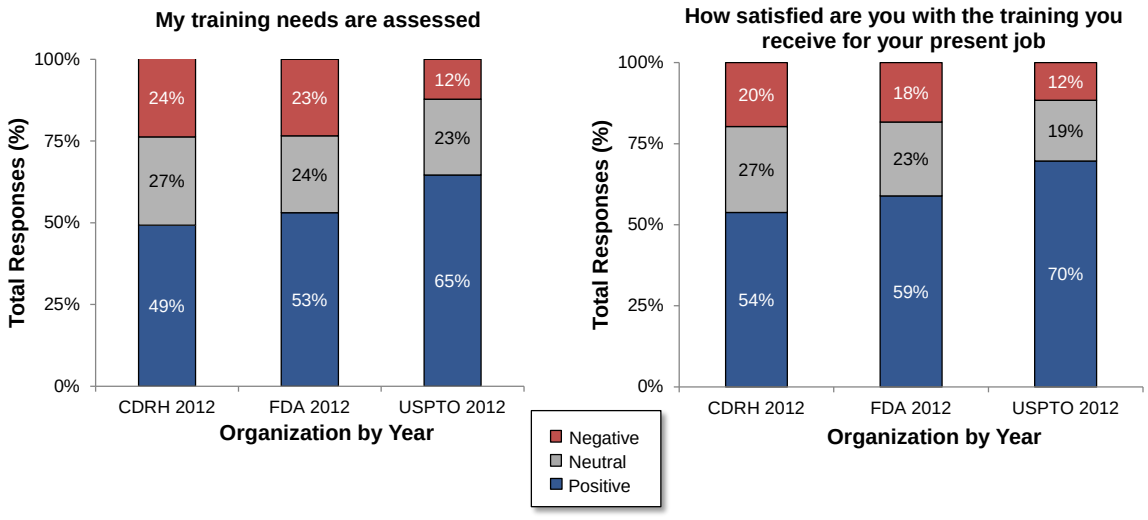
We identified a number of best practices within the Kirkpatrick Model that are not performed by CDRH, but are consistently performed by all three benchmark organizations:

- Internal SOPs documented for timing of evaluations, process, etc. (Level 2)
- Feedback from trainers is recorded/analyzed (Level 3)
- Surveys are sent out for additional assessments of knowledge transfer and implementation (Level 3-4)
- Program-specific re-certification process exists (Level 3-4).

An informal, internal needs assessment was conducted in 2012, relying on DETD employees' knowledge and experience, as well as past course evaluation data, to identify reviewer needs in the Center. Although soliciting direct feedback from the target audience for training is required to exhibit the best practice, these informal assessment results were reviewed and vetted by a working group represented by all offices. A list of potential course topics were developed and subsequently reviewed by the working group, resulting in the RCP curriculum. The curriculum is modified and adjusted annually based on participant satisfaction surveys and CDRH reviewer recommendations.

The potential benefit of conducting a needs assessment may be seen in the 2012 EVS data, shown in Exhibit 84. In CDRH, FDA, and USPTO, the proportion of staff who indicated that their training needs were assessed was similar to the proportion who was satisfied with the training they received. In 2012, only 49% of CDRH employees responded that their training needs were adequately assessed compared to 65% of USPTO staff. Correspondingly, only 54% of CDRH employees were satisfied with the training they received in 2012, compared to 70% of USPTO staff. While there are likely multiple factors that influence satisfaction with reviewer training, conducting a regular needs assessment to solicit input from reviewers can lead to more relevant training content that would be well-received by attendees.

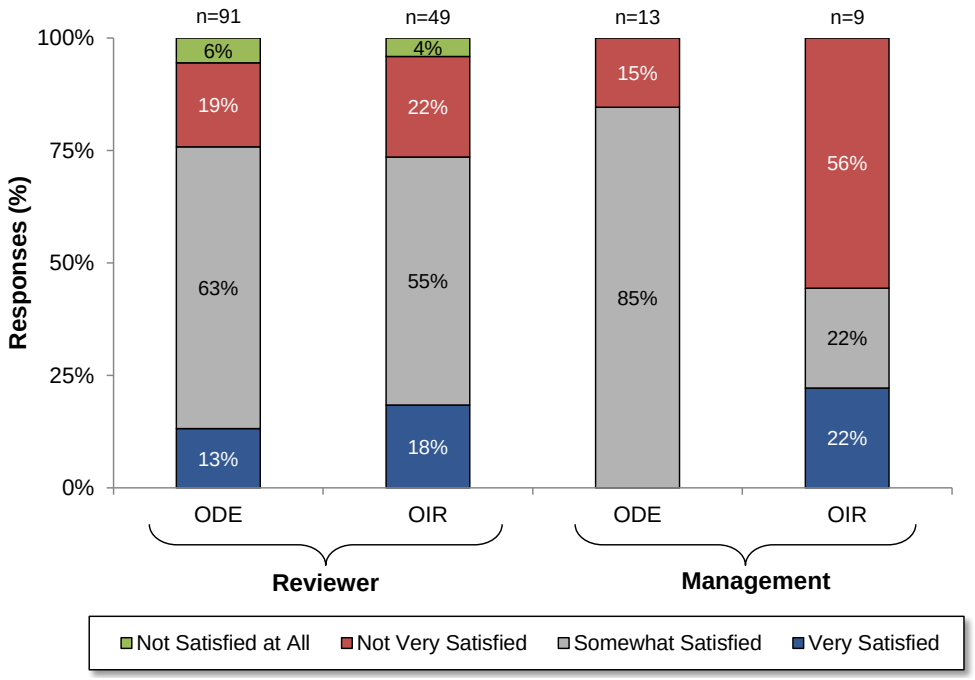
Exhibit 84. EVS Data for CDRH Assessing View on Training Needs Assessment and Satisfaction with Training Received



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

Booz Allen's 2014 survey findings, shown in Exhibit 84, suggest that satisfaction with CDRH reviewer training programs may have improved since 2012. The majority of review staff in ODE (76%) and OIR (74%) indicated that they were somewhat or very satisfied with reviewer-based training programs' ability to fulfill staff needs. Booz Allen speculates that this may be in part due to the development and implementation of course material in response to the informal needs assessment, as well as MDUFA III process-specific content.

Exhibit 85. How Satisfied are You With Training Programs Fulfilling Reviewers' Needs?



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

Analysis of management opinions reflects a more disparate view between Offices on reviewer training programs. Specifically, the majority of ODE supervisors (85%) believe that training programs fulfill their reviewers' needs while only 44% of OIR supervisors were similarly satisfied. This difference in management opinion regarding training was consistently observed across survey questions. Booz Allen conducted follow-up interviews with OIR management to identify the reason for this difference. We found that the training offered was not perceived by OIR management to be sufficiently specific to address reviewer needs to perform submission reviews. In addition, OIR management noted that current OIR practices, including mentoring, open-door policies, learning lunches, and close collaboration between colleagues for submission reviews, served as more valuable mechanisms beyond formal training to support review staff on submission reviews.

A description of our detailed assessment of each CDRH training program selected for this study is included in the sections below, followed by summaries of our evaluations of the benchmark organizations.

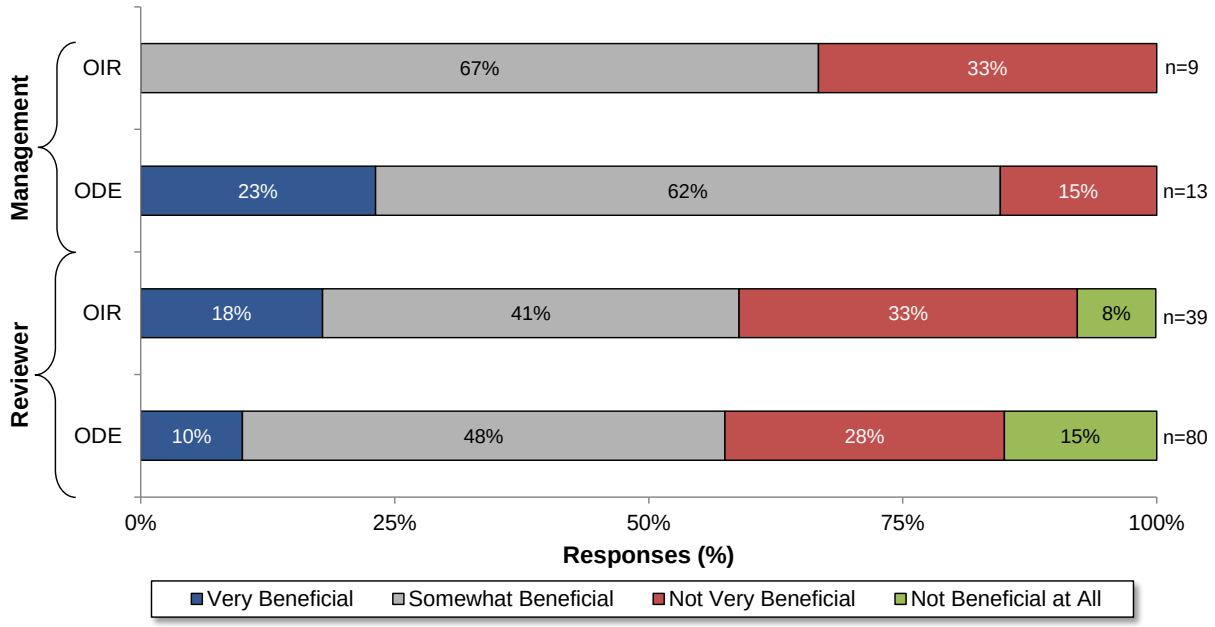
4.5.3. **CDRH Reviewer Certification Program**

CDRH's Reviewer Certification Program, implemented and maintained by DETD, is intended to serve as a new reviewer training program for new ODE and OIR pre-market reviewers. This structured program includes 23 courses that aim to address core competencies required of new reviewers by providing a baseline level of knowledge, skills, and abilities. The objective is to enhance workforce performance, consistency, and review quality.

CDRH assesses participant learning primarily through the use of a Pre-RCP and Post-RCP Certification process, which gauges reviewer comprehension of material taught from all 23 courses. New reviewers take a scored test prior to beginning RCP, and the same exam after completion of the required curriculum. A minimum score of 80% is required to complete Reviewer Certification. Data from the last six cohorts (Fall 2011 through Fall 2013) shows an average increase in post-RCP test scores of 21%, indicating an increased participant understanding of review processes as a result of completing RCP. However, while overall program knowledge testing occurs for RCP courses in the aggregate, each individually required course is not accompanied by pre- and post-course tests to assess specific knowledge acquired by participants during that course, an identified best practice utilized by many organizations and aligned to Level 2 of the Kirkpatrick Model.

Although only new reviewers are currently eligible to enroll in RCP, Booz Allen examined the perceived utility of expanding program participation to more experienced reviewers. Focus group findings indicated an interest among seasoned staff to have an opportunity to participate in RCP. This finding was further validated in the analysis of FDA survey data shown in Exhibit 86, which indicate that ~60% of all reviewer respondents and 67% and 85% of OIR and ODE management, respectively, believe that reviewers who were employed with the Agency prior to training rollout would benefit from the RCP training material.

Exhibit 86. How Beneficial Would Some/All of RCP Courses be to Those Ineligible for RCP Program?

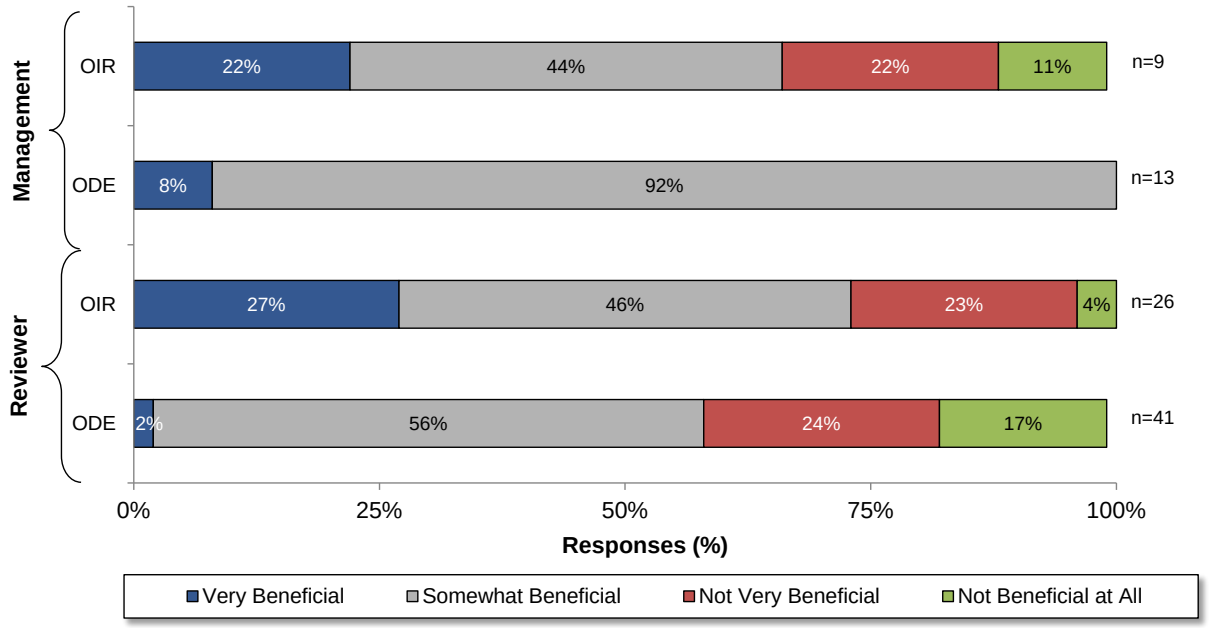


Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

In addition, CDRH currently does not have the ability to assess or gauge the extent to which knowledge and skills from training courses have transferred to participant responsibilities, representing evaluation metrics for Levels 3 and 4. There is no method to identify whether a participant made a decision or realized an opportunity to use a transferred knowledge or skill, or continued to use the skill on a regular basis. CDRH lacks success metrics for an individual training course and RCP as a whole, such as increased review consistency or utilization of knowledge gained across reviews and divisions. In addition, no refresher or re-certification program exists in RCP for reviewers who have completed RCP training or who are ineligible due to their tenure. This potential or second phase of RCP, could be utilized to update or reinforce reviewers' knowledge, allow them to gain additional review skills, and/or provide direct feedback to faculty on previously received training.

In the absence of Level 3-4 metrics described above, Booz Allen asked review staff to rate the perceived impact of RCP on review quality and consistency in the FDA survey. FDA survey data, as shown in Exhibit 87, indicates that 73% of OIR review staff and 66% of OIR management believe RCP has positively impacted overall review quality and consistency, and 58% of ODE review staff and 100% of ODE management shared this perception. The current lack of CDRH mechanisms to gather this type of outcomes-based feedback hampers the Center's ability to assess the utility of its training programs and to identify any areas for training program improvement.

Exhibit 87. How Beneficial has RCP Certification been in Improving Overall Review Quality and Consistency?



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

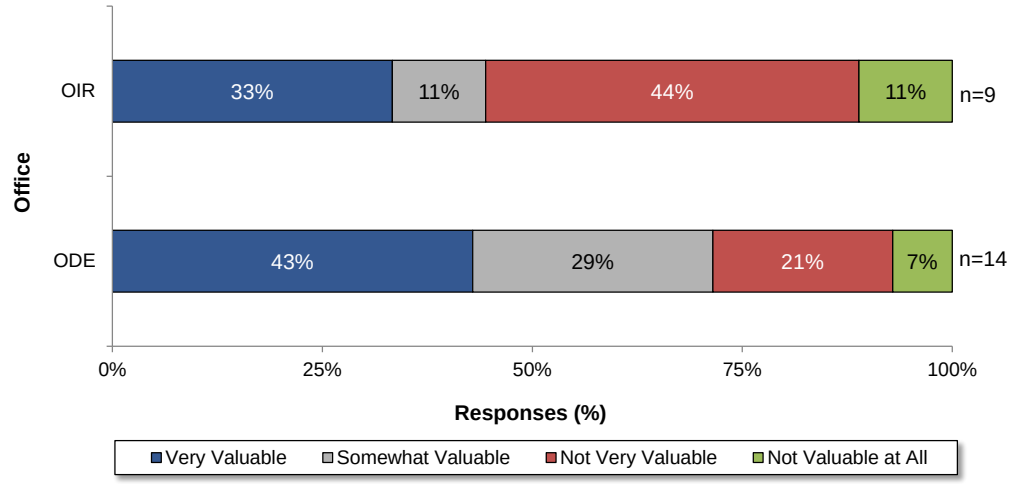
4.5.4. CDRH Leadership Enhancement and Development Program

CDRH's LEAD program serves as a mandatory supervisory training program for all CDRH supervisors, managers, and Team Leads. The curriculum supports the CDRH Management Competencies and addresses supervisory training requirements mandated by 5 CFR 412.

The CDRH LEAD program was developed by DETD, and shares a similar best practice profile with RCP. For example, the LEAD curriculum is also designed around the informal needs assessment from 2012, with a similar working group tasked with updating and reviewing program changes. However, the LEAD program differs from RCP in that its training requirements vary depending on one's title and time in that position within the Federal Government and CDRH (e.g., the number of required training hours varies based on a supervisor's tenure). After two years of initial training, supervisors must participate in mandatory annual refresher training.

While FDA survey data indicates that a majority of ODE management (72%) finds the LEAD program valuable in addressing their needs as a supervisor, OIR supervisors (44%) are less enthusiastic about the program (Exhibit 88). Follow-up interviews conducted with OIR management indicated that the training offered was too general and did not seem to address their reviewers' specific needs, such as how to perform reviews, and that greater OIR participation in the development of the training program curriculum may be beneficial.

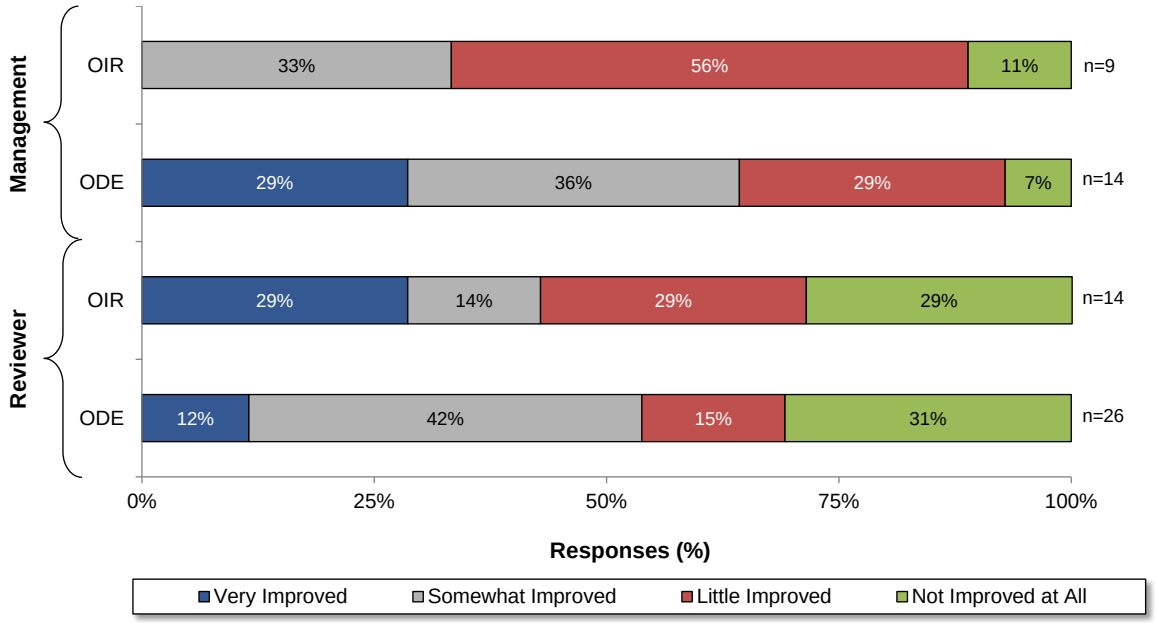
Exhibit 88. How Valuable is the LEAD Program in Addressing Your Needs as a Supervisor?



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

Similar to RCP, CDRH has not implemented any mechanisms to gauge knowledge or skill transfer to participants as a result of attending the LEAD training program (Level 2). CDRH also does not assess behavioral changes by evaluating application of knowledge gained (Level 3). As metrics are not identified for each individual LEAD course, CDRH cannot quantifiably measure the value of the LEAD program. In the absence of these metrics, we surveyed CDRH review staff and management staff to assess their perceptions on the extent to which the LEAD program improved management's competencies and behaviors.

Exhibit 89. How Has Participating in the LEAD Program Improved Management's Competencies and Behaviors?



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

More than half (54%) of ODE reviewers observed an improvement in their management's abilities, and 43% of OIR reviewers perceived an improvement. In addition, 65% of ODE management believed that LEAD contributed to an improvement in their own competencies, compared to only 33% in OIR. As noted earlier, informal discussions with OIR management indicated that OIR perceives greater value in on-the-job training and its mentoring program than current formal training programs.

In addition, CDRH currently runs the Leadership Readiness Program (LRP), an additional training program tasked with providing leadership skills to non-supervisory employees. LRP differs from LEAD in that it is a one-year opportunity for GS-12, -13, and non-supervisory -14 employees with more than two years FDA experience who are considering a supervisory career path and are interested in learning management competencies and skills. Admission into LRP requires an application response to a competitive announcement process, including short-answer responses in addition to supervisory approval and support. This voluntary program also permits inclusion of LRP completion in a participant's Annual Assessment (PMAP). Although participation is intended to provide employees with the skills to be successful in a supervisory position within CDRH, completion of LRP does not guarantee a supervisory position.

LRP began as a training program within ODE but was subsequently subsumed by DETD. Currently in its fourth iteration, LRP training sessions take place every 1.5 years, with a cohort of approximately15-20 participants. The program incorporates four phases. Personal Style, Building Capacity, Experience Speaks, and Integration. Training methodologies include self-assessments, classroom learning, mentoring, shadowing, long-term acting assignments, and strategy development on actual CDRH issues. A benchmarking assessment of USPTO's analogous leadership program is described in Section 4.5.8, and can serve as a model of a comprehensively structured all-staff leadership training program. CDRH may consider

unification of the LRP and LEAD into a tiered leadership training program to increase the visibility and/or utility of both programs as mechanisms to promote a strong leadership pipeline for succession planning.

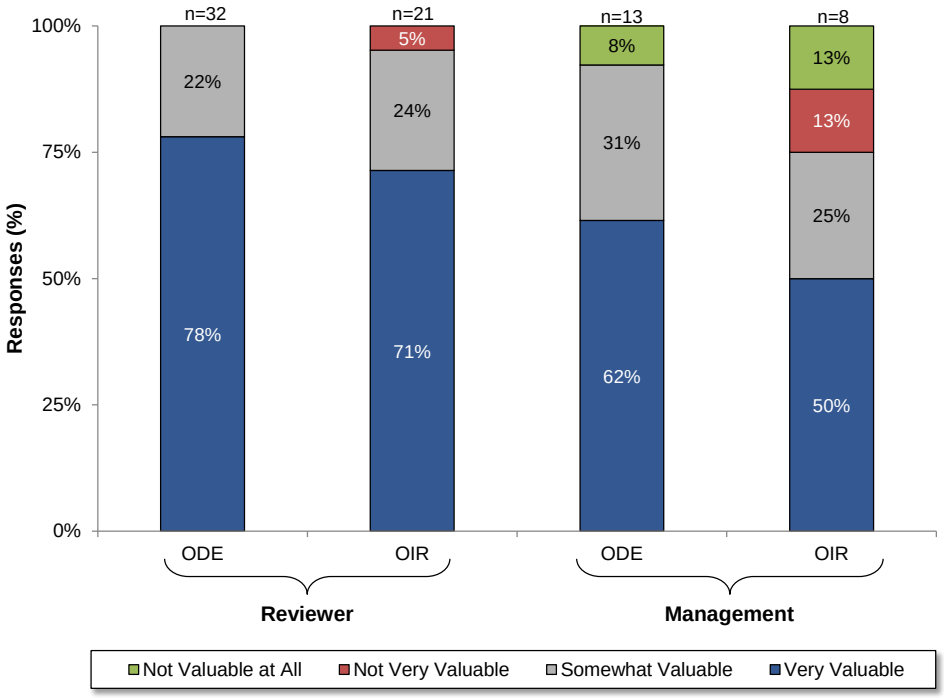
4.5.5. **CDRH Experiential Learning Program (ELP)**

The objective of CDRH's ELP is to improve the quality and reduce review times by providing hands-on experience with new technologies, facilities, and processes. This program is managed by DETD, is open to new and seasoned reviewers, and seeks to support review staff to improve critical thinking and problem-solving skills, transfer knowledge to application reviews, and gain awareness of new technologies.

CDRH senior management determines the ELP curriculum based on CDRH manager input and identification of staff needs through an annual training needs analysis performed in each CDRH office. Based on the prioritized needs, a variety of volunteer sites offer to serve as a location for an ELP training course, including manufacturing facilities, hospitals, and university research centers. While the ELP operated as a pilot program in 2012, it ran as a full training program in 2013 and DETD is currently performing a more complete evaluation.

Due to the hands-on nature of the ELP, certain best practices elements described in Exhibit 83 do not apply. Specifically, the program lacks a single training curriculum for all sites (or even site types), and metrics employed by standard training programs are not applicable, such as certification processes, pre- and post-course assessments, and workshops to supplement information. DETD attempts to gauge knowledge and participant satisfaction through electronic surveys and interviews. While aggregate evaluation data was not available, discussions with ELP managers indicated that participant feedback on the ELP was very positive. Our FDA survey data, seen in Exhibit 90, also shows that the vast majority of review staff considered ELP valuable in addressing their needs as reviewers. More than 95% of reviewers across ODE and OIR found the ELP valuable in addressing their needs as reviewers, while 83% of ODE management and 75% of OIR management found ELP valuable in addressing reviewer needs.

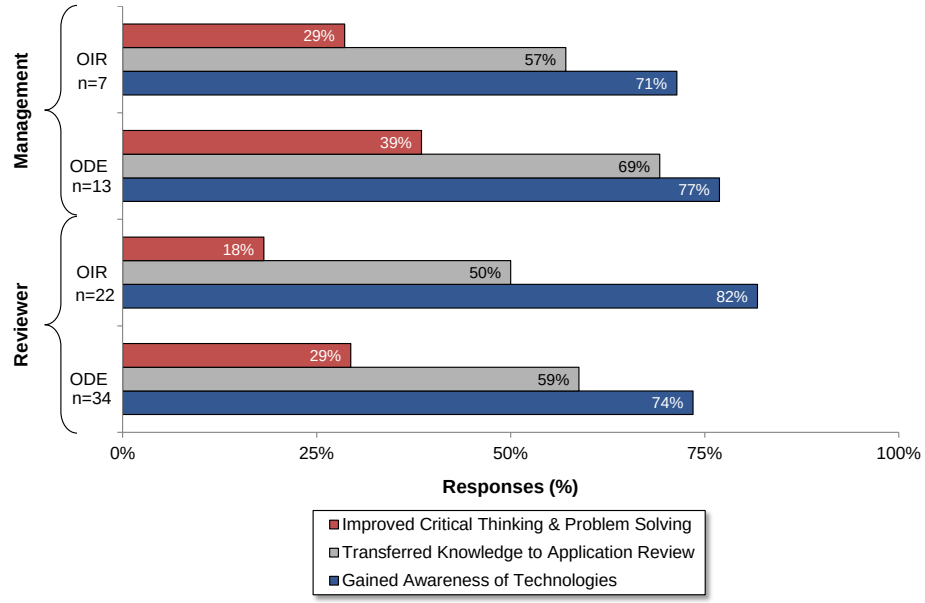
Exhibit 90. How Valuable is the ELP Program in Addressing Reviewers' Needs?



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

Within a week of returning from the ELP site, participants engage in formal and informal 360 degree feedback sessions to provide opinions on the event agenda, relevance to reviewer needs, and overall expectations, among other metrics. Although feedback from these sessions is reviewed by DETD, lessons learned and novel information are not stored in a manner that allows all reviewers, including those who did not attend the site visits, to share and reference. FDA survey data, as shown in Exhibit 91, indicates that reviewers and management from both ODE and OIR believe two of the three key ELP objectives are satisfied through the site visits. The majority of ODE and OIR staff responded that they "gained awareness of technologies" through ELP (71-82% among ODE/OIR reviewers and management), and more than half responded that they "transferred knowledge to application review" (50-69% among ODE/OIR reviewers and management). The third objective, "improved critical thinking and problem solving" did not seem to be adequately addressed by the ELP (18-39% among ODE/OIR reviewers and management), suggesting that program objectives should be re-evaluated and certain skills may be better enhanced through other training programs.

Exhibit 91. Check All Benefits Seen as a Result of Reviewers Participating in ELP



Source: FDA Staff Survey

4.5.6. **CDRH Ad Hoc Program**

The Ad Hoc training program is comprised of all training requested by reviewers, managers, or faculty not currently part of a CDRH training program to address new employee needs. This formalized process was halted due to an increased demand for resources from other MDUFA-mandated training programs. A form/template was provided to reviewers and managers as a method for soliciting recommendations for training by providing the rationale, material to be covered, and potential trainers. DETD staff would then review the proposals and work with the proposer to further develop the training course idea. A committee of office Deputy Directors would then review all proposals, and determine the courses that seemed to address the most significantly urgent needs. A vendor search firm would be engaged to identify potential course faculty.

Since the Ad Hoc program is currently not being implemented, Booz Allen was unable to fully evaluate this program against the Kirkpatrick Model. However, we noted that benchmark organizations in our study address these ad hoc requests through feedback received from training participants which are incorporated into future training needs assessment questions in order to maintain a single formalized process for collecting employee needs data.

4.5.7. **CDER Benchmark**

CDER training is managed by OEP (for core-competency skills) and each CDER Office (for scientific/technical skills). As part of our benchmarking analysis, we examined CDER training programs analogous to CDRH's RCP, LEAD, and ELP. We identified the following training programs in OEP and/or OND: New Reviewer Program (NRP), Leadership Training Program, and Regulatory Project Manager (RPM) Site Tour Program.

From our analysis, we identified differences in training evaluation between CDER and CDRH for all three program types. For example, CDER's Leadership Training Program is available to pre-

Team Leaders interested in pursuing a leadership role in the future, as opposed to current supervisors. Specifically, OEP offers two 10-month leadership programs: Preceptor for a Change (PAC) and Program for Authentic Leadership (PAL). PAC includes comprehensive training and individual coaching for Team Leaders and high-performing employees and is meant to foster mentorship relationships between more experienced and less experienced leaders. Conversely, PAL is targeted towards Directors, Deputy Directors, and Branch Chiefs in an effort to develop and refine leadership and supervisory skills, as well as create cross-work unit relationships. Training targeted at addressing specific competencies is managed by specific office units, such as OND.

While CDER does not have an analogous experiential learning program at the Center level, OND offers an RPM Site Tour program managed by a volunteer group of OND RPMs. The program provides RPMs with the opportunity to tour pharmaceutical facilities and to exchange regulatory experiences with industry counterparts, similar in nature to ELP. A main difference between the programs is that Site Tour participants are required to provide a short presentation to industry discussing relevant topics of interest to both parties, followed by a question and answer session, as a means of keeping open lines of communication between industry and FDA.

We also noted that implementation of best practices was performed in the same manner for training programs whether by OND or OEP. Exhibit 92 describes implementation methods by OEP and/or OND for those best practices that CDRH does not currently perform.

Exhibit 92. CDER's Implementation of Best Practices Not Currently Performed by CDRH

Best Practice	Kirkpatrick Level	CDER
Pre- and post-course tests are conducted and results recorded.	II	Performed for most courses; tests are tailored to specific course objectives
Internal SOPs in place for timing of evaluations, process, etc.	II	Electronic surveys are provided to participants within 24 hours of course completion; Data is compiled in comprehensive report and analyzed
Customized evaluations of successful/un-successful behavior changes are conducted.	II	Spot evaluations of behavioral changes are currently performed by training staff; plans in place to perform more regular assessments in near future
Feedback from trainers is recorded/analyzed.	III/IV	Standard process in place to solicit feedback from trainers following each course
Surveys are sent out for additional assessments of knowledge transfer and implementation.	III/IV	Electronic surveys are sent out to course participants currently for CE courses
Informal workshops exist to supplement training materials and reinforce participant behavioral changes.	III/IV	Live webinars and on-demand online courses exist to supplement training materials

4.5.8. **USPTO Benchmark**

Training at the USPTO is managed by both the Office of Patent Training (OPT) and the Enterprise Training Division (ETD). OPT manages the Patent Examiner Training Program (PETP), the analog to CDRH's RCP, and completion is also required of new employees. PETP is a two-phase, 12-month program with an initial four month residence in the Patent Training

Academy before examiners are relocated to their respective business units. Examiners then return to the Training Academy for one week at months 7 and 10 to receive additional training.

OPT also manages USPTO's Site Examiner Education (SEE) program, which serves as an analogous benchmark program to CDRH's ELP. The SEE program allows patent examiners to travel to companies to experience new technologies under development and to learn about technology updates. Unlike CDRH ELP, SEE sites are often recommended from an examiner's previous experience or history with a company or organization, as opposed to a respondent to a Federal Register notice.

ETD manages USPTO's Leadership Development Program as part of its general employee training, employee onboarding, and mandatory federal training programs for all USPTO employees. The leadership development program is comprised of a Leadership Training Pyramid, which organizes customized leadership training content into five tiers, ranging from individual leader to senior leader, to provide leadership skills and competencies to all employees to promote an organizational culture of leadership at the non-supervisory and supervisory levels.

We noted that implementation of best practices was performed in the same manner for training programs within a single organization (e.g., OPT). To that end, Exhibit 93 describes implementation methods by OPT and ETD of best practices which CDRH does not currently perform.

Exhibit 93. USPTO's Implementation of Best Practices Not Currently Performed by CDRH

Best Practice	Kirkpatrick Level	OPT	ETD
An annual competency-based needs assessment is conducted.	I	Issued electronically to all patent examiners each year; then compiled and reviewed by committee for potential changes to training program	Issued electronically to all patent examiners each year; then compiled and reviewed by committee for potential changes to training program
Pre- and post-course tests are conducted and results recorded.	II	Course assessments are administered and scored for the employee's and supervisor's knowledge after each training module	Pre- and post-self-assessments are used to gauge learning and desire to apply skills/knowledge
Internal SOPs in place for timing of evaluations, process, etc.	II	Web-based evaluation system for each training module; ongoing evaluations as well as electronic survey at course completion	Specified dates for completion of electronic course evaluation
Customized evaluations of successful/un-successful behavior changes are conducted.	II	Evaluations for behavioral changes are specific to course objectives and result metrics	Evaluations for behavioral changes are specific to course objectives and result metrics
Feedback from trainers is recorded/analyzed.	III/IV	Standard process in place to solicit feedback from trainers after each course; OPT also convenes trainer focus groups to obtain feedback	Standard process in place to solicit feedback from trainers after each course
Surveys are sent out for additional assessments of knowledge transfer and implementation.	III/IV	Dedicated FTE staff to perform course evaluations (in support of ISO-9001:2008 re-certification); annual surveys to certified examiners	Electronic evaluations are conducted 3 months after course completion

Best Practice	Kirkpatrick Level	OPT	ETD
Result metrics are identified for each course.	III/IV	Curriculum committee and faculty collaborate to identify tangible course metrics	Curriculum committee and faculty collaborate to identify tangible course metrics
A program-specific re-certification process exists.	III/IV	Refresher program to review staff with more than 1 year experience to reinforce skills	Refresher program available to review staff; multiple pyramid tiers for additional training
Informal workshops exist to supplement training materials and reinforce participant behavioral changes.	III/IV	Hands-on coaching with sample and real applications for real-time feedback; feedback includes evaluation on rating scale (not graded)	Leadership workshops, seminars, and off-site events are available for supervisors.

4.6. Assessment of CDRH Staff Turnover

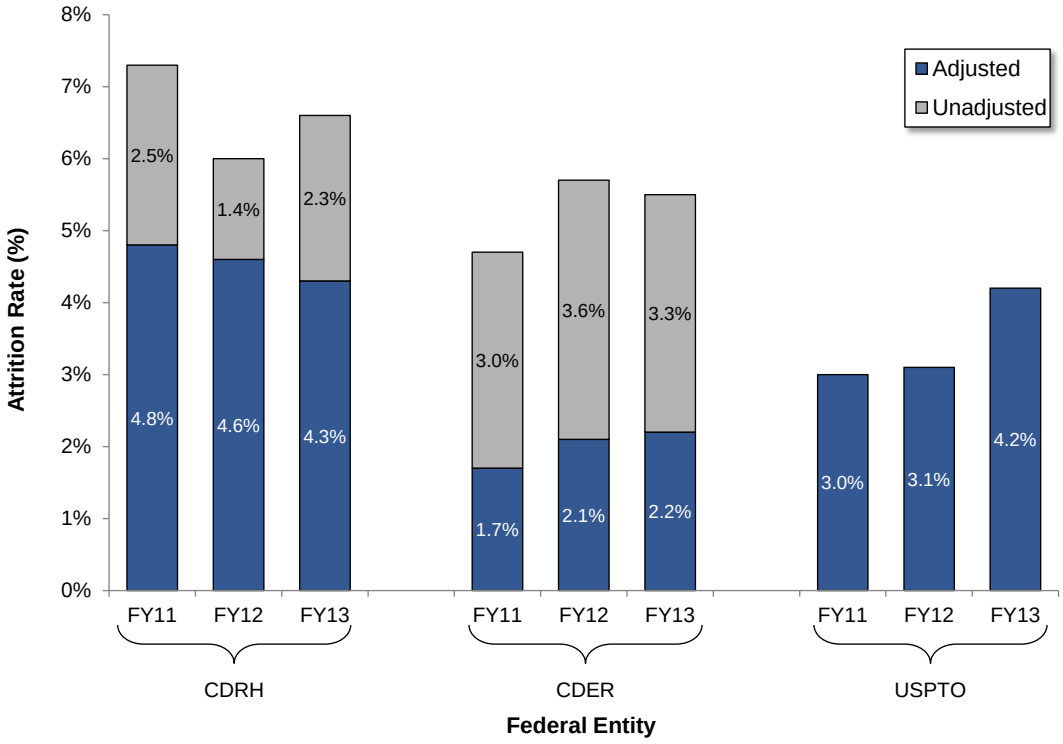
Booz Allen evaluated CDRH attrition rates based on FDA-provided data sources, identified retention best practices in transition and succession planning based on a literature review and FDA management interviews, and also identified retention practices used by benchmark organizations in our study. Findings from these areas are described below.

4.6.1. Analysis of CDRH Attrition

Booz Allen sought to first determine the extent of attrition at CDRH. We gathered CDRH attrition data from FY11-13 and compared the data to attrition rates and data provided by CDER, and USPTO.

Booz Allen assessed the extent of attrition at CDRH, using Center attrition data from FY11-13 and comparing it to attrition rates and data provided in CDER and USPTO provided by the respective organizations. To ensure an accurate comparison, adjustments were made to the attrition data to account for organizational differences in calculating attrition rates. Specifically, we adjusted CDRH and CDER data to exclude employees lost due to retirement, inter-Center transfer, and inter-Agency government transfer only for the purpose of facilitating more accurate and appropriate comparisons of attrition data with USPTO. Another limitation was that USPTO data only reflects attrition of patent examiners, and such granular data by role from CDRH or CDER was not available. However, we recognize that staff turnover resulting from retirements and transfers/reassignments could impact review times, the quality and consistency of review staff, and consistent oversight of management personnel. Both adjusted and unadjusted attrition rates for CDRH and benchmark organizations are depicted in Exhibit 94. While CDRH's adjusted attrition rate was higher than that of USPTO in both FY11 (4.8% versus 3.0%) and FY12 (4.6% versus 3.1%), the organizations' adjusted attrition rates were nearly identical in FY13 (4.3 versus 4.2%). CDER had a lower overall adjusted attrition rate than both USPTO and CDRH, only increasing from 1.7% to 2.2% across FY11-13. CDRH's attrition rate has decreased from FY11 to FY13, while both CDER and USPTO attrition rates have increased in the same time period. This data indicates that CDRH has a relatively low attrition rate, which is in line with that of comparable organizations.

Exhibit 94. Attrition Rates from FY11–13 for CDRH, CDER and USPTO

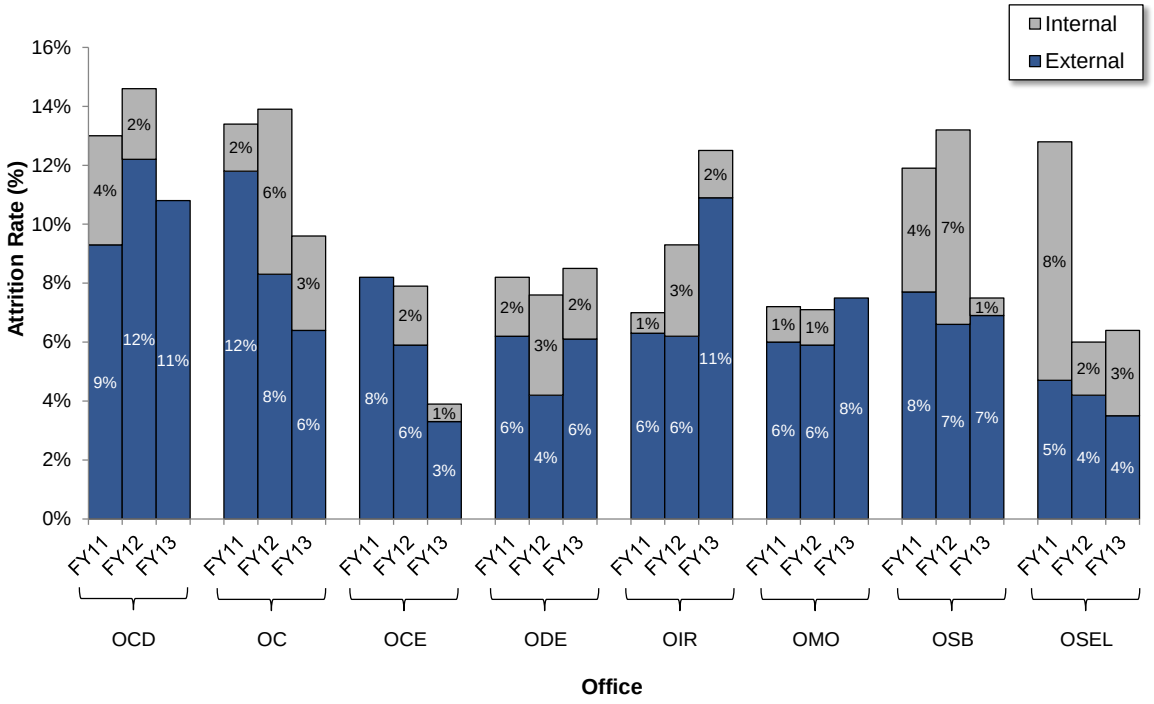


Source: FDA/CDRH/OMO and FDA/CDER/OMO Data; USPTO Performance and Accountability Report 2013

An analysis of attrition data by CDRH Office, as shown in Exhibit 95, indicates that most Offices experienced either stable or declining adjusted attrition rates. OIR adjusted attrition increased noticeably to approximately 11% in FY13, and unadjusted OIR attrition increased steadily from 7% in FY11 to 13% in FY13, as both a percentage and total number of losses. However, interviews with OIR management indicate that this may have been an anomaly due to reorganization.[29] Unadjusted ODE attrition remained stable at approximately 8% during the same timeframe.

[29] OIR management interviews indicate that a reorganization to incorporate the Division of Radiological Health from OCER (now OCE) with OIVD to form OIR may have contributed to the increased attrition rate. OCE attrition data indicate a decreased average attrition in FY13 by 4% since the reorganization and a corresponding increase in OIR attrition by 4% in FY13.

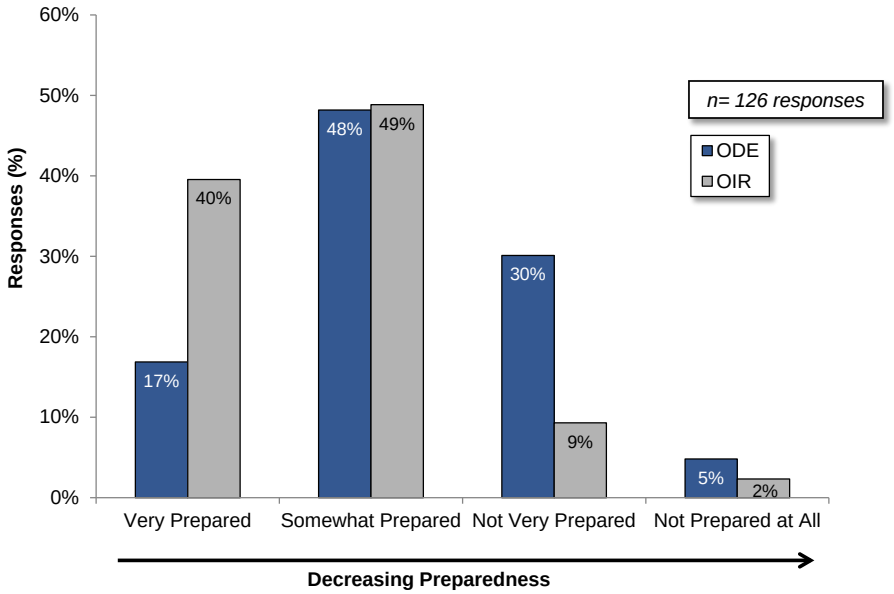
Exhibit 95. CDRH FY11-13 Attrition Rates (including internal and external transfers) by Office



Source: FDA/CDRH/OMO Data

While overall CDRH attrition appears comparable to benchmark organizations, employee turnover still occurs and may adversely impact review processes. For example, a change in Lead Reviewer or consultant during the review of an application can cause review delays and impact review consistency as a new reviewer is assigned. In addition, turnover of 7-8% a year could have a more substantial impact on management and review of some types of product submissions with longer review times (e.g., certain PMAs could require as many as five years to close). To assess the impact of turnover, Booz Allen surveyed FDA review staff to obtain reviewer perspectives on the extent to which their Divisions were prepared for staff attrition and its potential impact on submission reviews. As shown in Exhibit 96, a majority of reviewers indicated confidence that their Division is very or somewhat prepared to manage through staff attrition, and a greater proportion of OIR reviewers expressed confidence than those in ODE (89% versus 65%, respectively). Interviews with OIR management indicate that a number of factors may contribute to this finding. For example, due to the uniqueness of the products submitted for review in OIR, industry and FDA typically conduct a pre-submission meeting, so documentation of pre-submissions is available to enable substitute Lead Reviewers to quickly understand the context of a submission. In addition, while product technologies vary significantly by division, OIR submission reviews often include many similar analytical components, so staff may be easily leveraged from other branches or divisions within OIR to support review areas when turnover occurs.

Exhibit 96. Reviewer Opinion on their Division's Preparedness to Successfully Manage through Staff Attrition

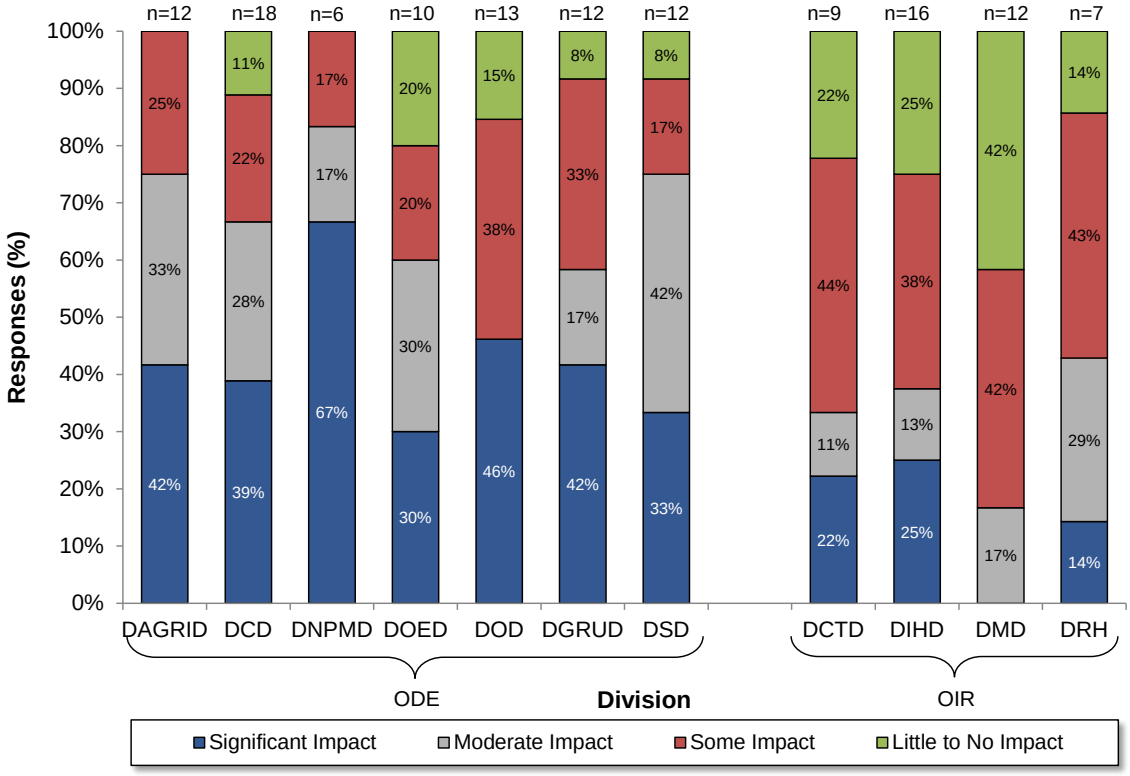


Source: FDA Staff Survey

We also gauged reviewer perspectives on the impact of attrition on their Division's ability to complete review submissions on time, shown in Exhibit 97. Not surprisingly, reviewers in OIR Divisions indicated a lower degree of impact of turnover on completing submissions on time compared to ODE reviewers, corresponding to the greater degree of confidence in their Office's ability to manage through employee turnover shown in Exhibit 96. In fact, all OIR Divisions believe the impact of turnover is smaller as compared to that in ODE Divisions.

In addition, no formal reviewer transition plans exist at the Center or Office levels. These findings suggest that existing informal staff transition and succession mechanisms currently in place may not be sufficient to efficiently reallocate reviewer or management responsibilities when turnover does occur.

Exhibit 97. Reviewer Opinion on Impact of Employee Turnover on their Division's Ability to Complete Submission Reviews on Time, by Division



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

4.6.2. Succession and Transition Planning

Although CDRH's attrition appears moderate and is comparable to benchmark organizations, it is still necessary to manage effectively through the invariable turnover that will occur. Booz Allen conducted a literature review to identify and outline a set of best practices around employee retention, and identified five key elements impacting staff retention. One of these elements, succession and transition planning, is discussed in this section, while the remaining elements, including employee engagement, employee recognition, career development, and benefits programs are detailed in Appendix G.

Succession planning is defined as the ongoing recruitment and development of potential successors to ensure a smooth transition and minimal loss of efficiency when vacancies occur in management or other key organizational roles. Published human capital research on succession planning indicates that a well-communicated organizational succession plan may be effective in mitigating the impacts of staff turnover when it occurs, particularly among management positions, and also contribute to improved staff engagement, retention, and career development expectations. Given the relatively modest level of attrition observed among CDRH staff, transition planning may be the most important for the Center to focus on, to minimize the impact of turnover when it does occur.

Development of a succession plan should take into account a number of core activities. First, management must identify key roles for which the organization intends to have successors in place. Next, competencies defined for each of these roles are needed to enable management to assess the fit of potential successors for a given role. Management's identification of employees with potential for increasing responsibilities enables organizations to ensure that a sufficient number of successors are in place for key roles. Finally, alignment of employees who are either formally or informally identified as successors to training and other career development opportunities allows successors to gain expertise and/or knowledge that will prepare them for future roles. Further, leadership engagement in supporting employee development may enable mentorship and advocacy opportunities and help ensure that employees are gaining the appropriate experience needed for future advancement.

Transition planning mitigates the negative impact of staff turnover by focusing on managing the day-to-day activities that are affected when organizations lose employees with valuable institutional knowledge. A formal transition plan that is well-documented and communicated to all divisions and employees may minimize disruption to daily activities and maintain business process continuity. Key elements of an organizational transition plan include the following:

- **Redundancy of responsibilities**. Cross-training of work or rotation of duties may help lessen the impact of attrition by providing employees with the ability to fill-in for anyone that leaves an organization
- **Knowledge sharing and documentation.** Intellectual capital, business relationships, business domain information, and formal position and roles and responsibilities documents may ease employee transition. Other examples include task-based documentation itemizing work steps needed to complete a task, storage of staff files or data in a centralized location or database, or standardized templates
- **Training**. The necessary skills and knowledge needed to effectively complete transitioned duties may require formal training
- **Shadowing.** Identified staff replacements may shadow departing employees to improve understanding of position intricacies, and validate that sufficient transition documentation is provided
- **Exit survey or checklist.** For both planned and unplanned staff exits, a survey or checklist may allow reassignment of duties for completion, or help ensure that duties and relationships are transferred appropriately. Exit surveys may serve as a final opportunity to gather information outside of shadowing and documentation methods
- **Flexible Policies for Retiring Employees.** Engagement of retired employees as consultants and mentors may allow for a longer transition period while also enabling an organization to leverage the retiring employee's knowledge, skills, and expertise.

While standard operating procedures for management of review staff changes during the review of a premarket submission exist, formal transition and succession plans are not employed at either the Center or Office levels. Interviews with OIR and ODE management indicated that both succession and transition planning elements are performed informally across divisions but are neither well-documented nor communicated[30]. For example, senior management in both Offices

[30] Although OIR and ODE do not formally implement succession and transition plans, FDA published an SOP on Change in Reviewer (last updated 2011) (http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm285034.htm).

currently identify and assess individuals who have expressed interest in and are potentially qualified for leadership positions, and may even recommend specific management training courses to them in order to promote internal leaders. As discussed in Section 4.6.1, most OIR submission reviews engage multiple reviewers, so multiple reviewers are at least somewhat knowledgeable of submission content and may transition more seamlessly into a Lead Reviewer role when turnover occurs. In ODE, management proactively begins transitioning work and knowledge through mentoring as employees begin to reach retirement age.

Discussions with USPTO officials indicated that succession and transition planning is currently not conducted according to a formal enterprise-wide process. Similar to ODE and OIR, business units execute both plans informally, leveraging training and mentorship as key elements. However, officials also noted that documenting and formalizing transition and succession plans across the Agency is a recognized best practice.

5. RECOMMENDATIONS

Booz Allen developed a broad range of recommendations based on the findings and analysis conducted during the evaluation and documented in this report. Together, these recommendations are intended to improve the medical device review process by reducing total review times, and improving predictability, consistency and transparency. Earlier in the evaluation, we developed a set of priority recommendations that were made public on December 11, 2013.[31] Those recommendations are also documented here, and are denoted as priority recommendations. For each recommendation, we have also provided suggestions for specific actions that FDA might take to address the recommendation, as resources are available; however, FDA may determine at their discretion to take action on these recommendations in alternative ways.

The second phase of the independent assessment will entail an evaluation of the progress made by FDA to implement recommendations resulting from this first phase of the assessment. Our recommendations are based on an identification of areas needed to improve the medical device review process, and do not fully consider FDA resources available for implementation. It is expected that some recommendations could require a longer timeframe for implementation and may not reach full implementation during the second phase of the evaluation due to the timing of FDA completion of its plans of action. Moreover, some of our recommendation have resource implications, and, therefore, may require additional resources to implement.

5.1. Quality Management Recommendations

1. **Adopt a holistic, multi-pronged approach to address five quality component areas to standardize process lifecycle management activities and improve consistency of reviews *(Priority Recommendation)***

The MDUFA III Commitment Letter emphasized an evaluation of FDA's premarket review processes using a quality framework drawing from accepted quality system standards. The current CDRH QM Framework is in a nascent stage, and was therefore not mature enough to

[31] The priority recommendations may be found on the FDA website: http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/overview/mdufaiii/ucm378202.pdf

use as an evaluation standard. We instead referenced standard quality components (i.e., Senior Management Responsibility, Resource Management, Document Control, Process Improvement, and System Evaluation) and adapted them to include only those elements most meaningful to assessing the design of various FDA-specific processes. From our evaluation of QM processes, we derived the following specific recommendations:

a. Senior Management: Document and communicate a mechanism for issue accountability and follow-up

The MDUFA III Implementation Steering Committee was formed as a result of MDUFA III and was tasked with coordinating efforts from various levels of management to determine how each new MDUFA process would be operationalized in CDRH. Senior management currently monitors the implementation of the processes and reviews new issues as they arise through existing mechanisms. Each level of management is accountable to ensure successful process implementation and to raise and resolve issues. However, this feedback loop is not formally documented (e.g., the process to intervene on submission issues), which can result in missed opportunities and ambiguity among different levels of management to assume all of the necessary steps for seeing through all issues to resolution. We recommend that CDRH formally document the issue resolution pathway and communicate this process to review staff to promote accountability and facilitate follow-up on raised issues. In addition, we recommend that FDA identify points of contact who are able to dedicate time for providing oversight of implementation of an integrated set of quality steps to ensure FDA progresses in each component area.

b. Resource Management: Deploy formal, regularly-scheduled training on new review processes to standardize awareness. Use quantitative methods to assess understanding and activation of behavioral changes

The training recommendation detailed in Recommendation 9 would address this particular QM issue. We deemed it to be sufficiently significant to elevate it to a priority recommendation.

c. Document Management: Deploy planned document control system enhancements (e.g., CTS, DocMan, Image2000+, SharePoint, eCopy) using a quality-oriented focus to optimize the utility of system changes to all review staff

We investigated the various document control IT systems (i.e., CTS, DocMan, Image2000+) for quality in process design. We found that CDRH employs various mechanisms for introducing quality into its document control and document management processes (e.g., methods to store submission review templates, reference guides, and collaborative review materials; access controls are in place; there are mechanisms to notify staff of document updates). However, interviews with senior management confirm that inconsistencies within document control elements detract from review performance. For example, DocMan folders often contain many duplicative and/or outdated documents (e.g. three versions of the same summary but with different reviewer/Branch Chief/Division Director signatures). This is not the intended practice and results in errors and inefficiencies when performing document searches. FDA staff survey results also support inconsistent practices among review staff to use and store documents in DocMan. To address this issue, we refer to the priority recommendation in Section 6 to

provide mandatory full staff training on the appropriate use of document control IT systems to facilitate consistent use and enable efficient reviews. Once complete, an audit of DocMan usage of selected submissions would identify any improvements in consistency of use among review staff. While eRooms represent another document control system currently used by staff to reference program- and Division-specific templates, SOPs, checklists, process flows, and user guides in support of submission review processes, the content in eRooms is anticipated to be migrated to SharePoint in the near-term. When eRoom and other important document control and/or data system transitions or upgrades are made that impact review processes, we recommend that CDRH focus on incorporating quality management components into its roll-out strategy to ensure that these upgrades are positioned for successful use (e.g., migration and roll-out should include required senior management oversight; staff training/workshops to ensure staff may adequately leverage new system functionality; clear mechanisms for staff to raise issues encountered from system use; methods for review staff to provide input on system needs, pilot the system, and provide continuous feedback; mechanisms in place to make improvements; and ways in which to assess utility of the system).

d. CAPA and CPI: Develop a more formal method for logging, prioritizing, tracking, communicating and providing feedback on non-CAPA issues and improvement ideas

Our review found that the ODE has implemented a CAPA database to resolve issues that impact multiple Divisions. However, for non-CAPA (i.e. Division-specific) issues, there is currently no formal method to log, track, or prioritize issues, or communicate feedback. For example, staff currently may raise and address non-CAPA issues but does not use a database or other systematic methods to manage and record issue resolution. Standard methods across divisions do not exist to log, review, and close out suggestions for process improvement. We recommend that CDRH develop a formal method to be applied consistently across divisions for tracking issues that do not rise to the level of a CAPA, in order to ensure that they are properly attended to and resolved.

e. System Evaluation: Identify and develop internal metrics to monitor the quality and effectiveness of review processes and facilitate continuous process improvement

CDRH senior management diligently monitors and reports on submission status, and relies heavily on MDUFA goal milestones for evaluating progress and success. For example, senior management regularly tracks performance trends to identify changes in TTD over time, while also leveraging MDUFA goal milestone data to identify any submission issues that must be addressed with Branch Chiefs and Division Directors. CDRH also performs periodic *ad hoc* audits on certain processes (e.g., RTA audit). Program operations staff has noticed that for several submissions which did not meet their MDUFA goal dates, milestones were missed earlier in the process. As a result, program operations staff now pays more attention to these indicators and send reminders to Lead Reviewers of upcoming due dates based on workload reports from the CARS and CTS. While this mechanism may work to identify some submissions at risk for longer review times, more granular internal metrics are needed to ensure the quality and effectiveness of sub-processes (e.g., RTA or IR) within the larger submission review process. To this end, we recommend that CDRH identify internal metrics to support the monitoring process and facilitate continuous process improvement.

5.2. Review Process Recommendations

2. Develop criteria and establish mechanisms to improve consistency in decision-making throughout the review process *(Priority Recommendation)*

A recurring issue that was identified during our analyses was inconsistent decision-making throughout various stages of the review process, in particular a lack of transparency in thresholds or requirements used to trigger AI requests. In addition, industry stakeholders reported inconsistencies between reviewers referencing outdated guidance during submission reviews, as well as reviewers referencing new standards that were not yet finalized at the time of original submission. Development of tools, criteria and/or mechanisms for assessing and ensuring the consistency of review processes would help ameliorate this issue. For example, Lead Reviewers could reference any applicable guidance or standards prior to or during the time of the AI request to help applicants better understand the scientific and regulatory basis for AI requests when they occur. More broadly, Lead Reviewers might explain which guidance documents and standards they intend to use for a given submission review, and clearly indicate whether applicants would be subject to any new standards or guidance updates which may be released during review of the submission. Development of a standard AI request checklist could clarify the categories of deficiencies that applicants may be subject to receiving. Regularly-occurring working groups of Lead Reviewers and Master Reviewers within review branches could be convened to develop a standard working list of criteria for decision making (e.g., within a review branch) that may evolve as technological advancements occur.

3. Optimize RTA process by improving awareness of and clarity around administrative requirements for 510(k) submissions

Of the closed Traditional 510(k) submissions received within CY13, more than 50% were rejected during the first RTA cycle. We also observed that submissions with a greater number of RTA cycles were associated with longer TTD and TST, suggesting that the RTA review process has a significant impact on review time. Deeper analysis of representative 510(k) submissions, specifically around the RTA review process, revealed that more than 80% of submissions contained at least one missing or deficient element within the Administrative category of the RTA checklist, resulting in a RTA rejection decision. Furthermore, elements within the Administrative category were the most frequently identified missing or deficient elements during RTA acceptance review. Together, these observations indicate a need for increased awareness of and clarity for Sponsors around administrative requirements for 510(k) submissions to mitigate RTA rejections due to Administrative deficiencies.

4. Perform a retrospective root cause analysis of withdrawn submissions and develop a mechanism to minimize their occurrence

Rates of withdrawn submissions increased 50% from the M2 to M3 Received Cohort. Analysis of withdrawn submissions from the MDUFA III Received Cohort revealed that two-thirds were withdrawn during the MDUFA/Interactive Review phase, of which nearly 30% were withdrawn with fewer than 10 days remaining on the review clock. The most frequently cited rationale for withdrawals according to both CDRH review staff and industry representatives is the inability to provide adequate data to demonstrate SE. Furthermore, CDRH review staff frequently cited the inability to resolve deficiencies within MDUFA timeframes as another reason for withdrawn submissions. MDUFA III introduced a new review practice limiting the use of additional holds after an SI decision. By allowing only one hold at Substantive Interaction, Sponsors have an increased motivation to submit high quality submissions upfront, while CDRH reviewers are

further motivated to perform a thorough and complete review of the submission during the Substantive Review phase. However, CDRH review staff revealed through surveys and focus group interviews that an unintended consequence of limiting the use of additional holds was the inability to resolve minor deficiencies within the MDUFA III timeframe, possibly leading to an NSE decision.

Analysis of our small study sample signaled a potential issue that warrants further investigation through another study. We recommend that FDA conduct a larger-scale retrospective study using withdrawn submissions to identify submissions with characteristics that might benefit from additional review time (e.g. submissions with minor deficiencies that may be quickly resolved). FDA should communicate study findings with public stakeholders and, depending on study outcomes, develop mitigation strategies, such as a limited additional hold or other mechanism.

5. **Implement a consistent practice for communicating early and frequently with Sponsors during the Substantive Review phase to address and resolve potential issues prior to Substantive Interaction**

As indicated in the MDUFA III Commitment Letter, interactions between FDA and Sponsors during the course of a submission review are critical in performing efficient and timely reviews of medical device submissions. Our evaluation of communication practices for both ODE and OIR submissions revealed that OIR reviewers held more frequent communications with Sponsors throughout the course of the entire review. This increase in overall communications among OIR submissions was also associated with overall shorter TTD. Further analysis within specific phases of the review process revealed that the average number of communications between FDA and Sponsors was significantly greater during the Substantive Review phase in OIR than in ODE, while the average number of communications for all other review phases was comparable between OIR and ODE, consistent with recognized communication practices between offices. As the primary goal of Substantive Review is to identify major and minor deficiencies/issues within the submission, we also observed that OIR submissions were associated with fewer deficiencies/issues identified within the Substantive Interaction (SI). Given that the number of SI deficiencies is positively associated with TTD, we believe that early and frequent communication during Substantive Review will ultimately contribute to shorter review times.

5.3. IT Infrastructure and Workload Recommendations

6. **Provide mandatory training for the three primary IT systems that support MDUFA III reviews *(Priority Recommendation)***

New IT infrastructure systems and system upgrades were developed to support MDUFA III process changes for streamlining reviews. While reviewers were offered training prior to October 1, 2012, focus groups and CDRH staff interviews indicate varies levels of awareness and retention of knowledge regarding specific review process changes. For example, users reported uncertainty about which documents to store in DocMan, where to store them, and which work processes would be integrated with DocMan capabilities. While CTS modules were also introduced to aid in managing goal dates and to identify where submissions were in the review process, some users reported that the new, multiple date fields were confusing. From the perspective of Lead Reviewers, IT training had a significant positive effect on facilitating more efficient reviews. Of those surveyed, 53% who reported having received training on CTS, Image2000+, and DocMan indicated that it eased review, while only 7% said it detracted from

review. In contrast, only 12% of staff who reported that they did not receive the IT training said it eased the review, while 41% said it detracted from the review process. Although we reviewed a limited sample of responses, this sharp contrast suggests that training has a significant impact on the effectiveness of the new systems implemented; thus, we recommend that CDRH ensures all reviewers complete the appropriate system training courses.

7. **Provide increased clarity to applicants beyond existing eCopy guidance to enhance organized submission structure**

Reviewers and managers noted inconsistencies in the structure and quality of eCopy submissions from industry, which often render them unsearchable or difficult to read. Focus group participants indicated that applicant submissions of searchable PDFs would enable more efficient reviews. Additionally, bookmarks were identified as helpful for quickly identifying important submission content as no formal structure is currently promoted. For comparison, final CDER Guidance on General Considerations when submitting paperless submissions contains robust language on the importance of non-scanned PDFs and a "how to" section for creation of PDF files and bookmarks. We recommend that CDRH provide increased clarity (e.g., webinars) to applicants to emphasize the rationale for applying navigation support (e.g., scanning, bookmarking, hyperlinking) and provide greater specificity to existing application submission instructions to ease FDA staff navigation of submission reviews.

8. **Evaluate tools for providing a comprehensive view of staff workload**

Currently, the two primary tools used by CDRH supervisors for workload management decisions are CARS and CTS. However, managers indicated that they do not use CARS and primarily rely on CTS. While CTS contains information on current submission assignments, the system does not have critical data for informing workload decisions, such as the number of Inter-Center Consults a reviewer may have or the number of submissions a reviewer has on hold. FDA staff interviews indicate that ICC requests are often initiated by CDER/CBER through a hard-copy paper request and/or through e-mail, and that Lead Reviewers must manually enter ICC requests in CTS to track those assignments. Accordingly, managers must create their own support tools, piecing together information from multiple sources. We recommend that an assessment be performed to identify methods of providing a more comprehensive view of each reviewer's current and evolving workload to help managers efficiently use staff resources and provide better insight on reviewer performance and areas of review difficulty.

5.4. Training Program Recommendations

9. **FDA should identify metrics and incorporate methods to better assess review process training satisfaction, learning, and staff behavior changes. *(Priority Recommendation)***

As a result of MDUFA III requirements, FDA launched a series of training programs to increase knowledge on new review processes for reviewers and management. Our analysis of the four training programs using the Kirkpatrick Model, an industry-recognized training evaluation framework, uncovered gaps in FDA's ability to fully take into account staff needs, evaluate improvements in knowledge, and objectively assess the impact of learning and the extent to which participants' review behaviors changed as a result of training. We derived a specific set of sub-recommendations based on recognized industry and governmental best practices to enable CDRH to ensure the quality and effectiveness of its training programs.

a. Level 1: Perform annual training needs assessments to fully consider and identify changes in reviewers' and management's training needs in both Offices to improve review process efficacy and efficiency

While CDRH conducted an informal needs assessment in 2012 to adjust curriculum based on received feedback, FDA staff survey data indicates that ODE and OIR management opinions differed widely as to whether reviewer-based and supervisor training programs fulfilled participant needs. For example, the majority of ODE management indicated that reviewer training programs met review staff needs, while less than half of OIR supervisors shared this opinion. CDRH should ensure that reviewer and management feedback from both Offices are captured during a formal annual needs assessment so that training curriculum continuously reflects staff needs.

b. Level 1: Periodically re-assess training program material and objectives to ensure they continue to support reviewer needs

A recognized best practice is for training administrators to periodically assess whether training courses are meeting set objectives, and update training course material according to changes in objectives, training needs, and/or feedback obtained from course evaluations and surveys assessing participants' behavioral changes. While FDA staff survey results indicate that training objectives are supported for MDUFA III processes (e.g., RTA and SI/IR processes), few staff agreed that the "improved critical thinking and problem solving" objective was adequately addressed for the ELP program. Periodic reviews of training program objectives, taking into account staff feedback, would help ensure that training curriculum remains relevant in supporting staff review functions.

c. Level 2: Perform pre- and post-course test assessments to gauge knowledge transfer and course metrics for learning *(Priority Recommendation)*

Pre- and post-course test assessments are a recognized training best practice, and used by benchmark organizations in this study, to assess the extent to which a training course supports staff learning. While CDRH currently assesses participant learning for the RCP program through a Pre-RCP and Post-RCP certification process, individual RCP courses are not accompanied by pre- and post-course tests to assess participant knowledge of individual course material, limiting CDRH's ability to assess the specific utility of each course. CDRH should implement pre- and post-course assessments for individual reviewer training courses, either through formal evaluations of material or using ungraded assessments, to gauge participant knowledge and skills.

d. Level 2: Develop internal SOPs on the timing of evaluations and training processes

FDA staff interviews indicate that CDRH does not currently have an SOP in place to establish standard guidelines to highlight its intended course evaluation methods. Benchmark organizations chosen for this study implement SOPs that specifically outline the timing of pre- and post-course assessments or evaluations, timeframes for additional surveys assessing knowledge transfer and implementation, timeframes for analyzing data and implementing training updates based on feedback, types of ratings used, and training modalities used, among other training practices. CDRH's development of an internal SOP would help promote consistency of its training evaluation methods.

e. Levels 3-4: Collect, record, and analyze feedback from trainers to improve reviewer training curriculum

A recognized training evaluation best practice is to solicit and consider course feedback from trainers to improve training curriculum. Interviews with selected benchmark organizations reveal that trainer insights into course participation, delivery modes, content, and evaluation methods are recorded and considered in curriculum updates. However, our assessment indicates that CDRH currently does not employ methods to record and analyze trainer feedback. We recommend that CDRH develop a means to consistently obtain course feedback in a standardized format from trainers, analyze findings, and incorporate insights, as relevant, into regular training program updates.

f. Levels 3-4: Establish a refresher program for RCP to improve core review skills of RCP-ineligible review staff, and to re-certify RCP graduates

Currently, RCP is available to new reviewers and CDRH does not provide RCP training content to ineligible review staff (those joining prior to October 1, 2012). In addition, no refresher program or RCP recertification is currently available for reviewers who have completed RCP training to update or reinforce knowledge, gain additional skills, and/or provide feedback to faculty on previously received training. FDA staff survey findings indicate that reviewers perceive utility in RCP-certification to improve review quality and consistency, and believe RCP would benefit ineligible/experienced reviewers. During focus groups, seasoned staff expressed interest in the opportunity to register for RCP. Expansion of RCP through a refresher program would serve two purposes: improve consistency and reinforce knowledge of core review skills among more experienced reviewers and provide all review staff updated training materials.

g. Levels 3-4: Deploy post-course completion surveys and/or interviews to assess staff behavioral changes based on knowledge gained during training courses

Post-training assessments on participants' use of knowledge learned from training courses are important to validate and identify gaps in curriculum and assess the extent to which staff learning translated into implementation of desired behaviors. All selected benchmark organizations perform post-course assessments through surveys and/or staff interviews to obtain feedback on training courses and staff behaviors. However, CDRH does not have the ability to assess or gauge the extent to which knowledge and skills from training courses have transferred to staff review functions. Development of post-course assessment surveys would enable CDRH to assess the extent to which training material is put into practice and identify areas for training program improvement.

h. Levels 3-4: Assess program results by developing tangible course metrics

Selected benchmark organizations conduct spot evaluations of behavior changes to assess program results and success, and/or develop course outcomes metrics that can be measured through post-course completion surveys, participant interviews, or select submission audits, for improving training programs. CDRH currently lacks success metrics, such as consistency of reviews, or consistency of review tools or data systems, to assess training outcomes. CDRH should identify and develop outcome metrics for training courses to enable CDRH to assess training impact.

10. Promote informal training and knowledge sharing by seasoned staff for review staff and management to share division or science-specific review processes, lessons learned, and best practices

CDRH review staff received mandatory formal MDUFA III training on premarket medical device submission reviews and milestones. However, FDA survey findings revealed that only 55% of OIR staff and 57% of ODE staff rated their understanding of MDUFA III processes with confidence at the time of training; staff confidence increased substantially during the course of their work (to 90% and 92%, respectively). Management interviews indicate that staff has opportunities through staff rounds, division meetings, and Master Reviewer support, to obtain on-the-job information on review process updates and relevant guidance and standards. However, FDA survey findings illustrate that newer ODE review staff was not only least likely to be aware of a Master Reviewer in their division, but also much less likely than newer review staff in OIR or staff with longer tenures in both Offices to solicit Master Reviewers for help and support on the job. FDA survey findings indicate a strong interest among CDRH review staff to participate in brown bags led by Master Reviewers or other experts to discuss review process best practices and lessons learned. Management interviews also noted that these sessions would be most helpful if topics are reviewer-driven and provided at the division level. OIR management indicated that some divisions already employ a similar, well-received “Lunch and Learn”, which may serve as a benchmark for other divisions across both Offices.

5.5. Staff Turnover Recommendations

11. Develop CDRH-wide staff transition and succession plans to mitigate the impact of turnover on submission reviews

An analysis of adjusted attrition rates at CDRH indicated that overall attrition has improved since FY11 and is not significantly different from that of USPTO, a benchmark organization selected for this study. While OIR has experienced a higher attrition rate than ODE, FDA survey findings reveal that ODE staff perceive staff turnover as having a more significant impact on their ability to perform timely reviews than in OIR. Similarly, ODE reviewers believe their Divisions are not as well prepared to successfully manage through attrition as OIR. Management interviews indicate that OIR fosters a strong culture of mentorship and collaborative learning, which may explain greater staff confidence to manage through attrition. A review of industry best practices pointed to the importance of transition and succession planning as a means of minimizing the adverse impact of staff turnover. However, CDRH management interviews indicate that formal transition and succession plans are not employed at either the Office or Center levels. Rather, ODE and OIR Divisions incorporate informal practices, such as leveraging Master Reviewers to assist review staff, reassigning submissions across branches when turnover occurs, and identifying and grooming potential successors for key management roles. Development and implementation of a CDRH-wide management succession plan and review staff transition plan would help promote more seamless transitions when review staff or management turnover occurs, and mitigate disruption to staff performance of timely and consistent reviews.

Appendix A: Acronym Glossary

Abbreviation	Definition
AC	Advisory Committee
ADEF	Approvable with Deficiencies
AdvaMed	Advanced Medical Technology Association
AGMP	Approved with Good Manufacturing Practices Deficiencies
AI	Additional Information Request
AP	Approved
APPR	Approved
BC	Branch Chief
Biocomp	Biocompatibility
BIS	Business Information System
BLA	Biologics License Application
CAPA	Corrective and Preventative Action
CARS	CDRH Ad Hoc Reporting System
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CDTL	Cross-Discipline Team Leader
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
Clincl	Clinical
CMC	Chemistry, Manufacturing, and Controls
COMP	Compliance Analysis
COR	Contract Officer Representative
CPI	Continuous Process Improvement
CRO	Clinical Research Organization
CTRS	CDRH Time Reporting System
CTS	Center Tracking System
CVM	Center for Veterinary Medicine
CY	Calendar Year
DAGRID	Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
DCD	Division of Cardiovascular Devices
DCI	Data Collection Instrument
DCTD	Division of Chemistry and Toxicology Devices
DD	Division Director
DDD	Deputy Division Director
DIHD	Division of Immunology and Hematology Devices
DLOD	Department of Learning and Development
DMC	Document Management Center
DMD	Division of Microbiology Devices
DNPMD	Division of Neurological and Physical Medicine Devices
DPA	Days Prior to Acceptance
DOD	Division of Orthopedic Devices
DOED	Division of Ophthalmic and Ear, Nose, and Throat Devices
DRGUD	Division of Reproductive, Gastrorenal and Urology Devices
DRH	Division of Radiological Health
DS	Day Supplement

Abbreviation	Definition
DSD	Division of Surgical Devices
EPA	United States Environmental Protection Agency
EL COMP	Electromagnetic Compatibility
ELESFT	Electrical Safety (Elec Saf)
ELP	Experiential Learning Program
EMC	Electromagnetic Compatibility
Epidem	Epidemiology
Eng-El	Electrical Engineering
ETD	Enterprise Training Division
EVS	Employee Viewpoint Survey
FDA	United States Food and Drug Administration
FDA TRACK	FDA Transparency-Results-Accountability-Credibility-Knowledge Sharing
FDASIA	Food and Drug Administration Safety and Innovation Act
FTE	Full-Time Equivalent
FURLS	FDA Unified Registration and Listing System
FY	Fiscal Year
GRMP	Good Review Management Practices
GS	General Schedule
HDE	Humanitarian Device Exemption
HR	Human Resources
Human	Human Factors
IDE	Investigational Device Exemption
IDP	Individual Development Plan
IFU	Instructions for Use
INSTR	Instrumentation
IP	Internet Protocol
IR	Interactive Review
ISO	International Organization for Standardization
ISO:9001	International Organization Standards for Quality Management Systems
IT	Information Technology
JIRA	Issue tracking system for IT Systems
Label	Labeling
LEAD	Leadership Enhancement and Development
LMS	Learning Management System
MAJR	Major Deficiency
MAPP	Manual of Policies and Procedures
Matchem	Materials Chemistry
MDMA	Medical Device Manufacturers Association
MDUFA	Medical Device User Fee Act
Mech	Mechanical Engineering
MFR	Manufacturer
MITA	Medical Imaging and Technology Alliance
MMD	Missed MDUFA Decision
MR	Master Reviewers
MR Comp	Magnetic Resonance Compatibility
n	Number
NA	Not Applicable
NEMA	National Electrical Manufacturers Association
NF	Not Found

Abbreviation	Definition
NIH	National Institutes of Health
NL	Lack of Performance Data and No Response
NOAP	Not Approved
NOFI	Not Filed
NP	Lack of Performance Data
NRC	United States Nuclear Regulatory Commission
NSE	Not Substantially Equivalent
OC	Office of Compliance
OCE	Office of Communication and Education
OCP	Office of Combination Products
ODE	Office of Device Evaluation
OEP	Office of Executive Programs
OIM	Office of Information Management
OIR	Office of In Vitro Diagnostics and Radiological Health
OMB	Office of Management and Budget
OMO	Office of Management Operations
OND	Office of New Drugs
OPT	Office of Patent Training (USPTO)
OSB	Office of Surveillance and Biometrics
OSEL	Office of Science and Engineering Laboratories
PAC	Preceptor for a Change
PAL	Program for Authentic Leadership
PD	Position Description
PDF	Portable Document Format
PDUFA	Prescription Drug User Fee Act
PETP	Patent Examiner Training Program
PGMP	Postponed Approval - No GMP Compliance
Physcs	Physics
PI	Proceed Interactively
PMA	Pre-Market Approval
PMAO	Pre-Market Approval Original
PMN / 510(k)	Pre-Market Notification
PMR	Post-Marketing Requirement
POS	Program Operations Staff
PPS	Partnership for Public Service
PrePMA	Post Approval Study – Pre-PMA Approval
PTO	United States Patent and Trademark Office
PTS	Panel Track Supplement
Q&A	Question & Answer
QA	Quality Assurance
QM	Quality Management
RA	Regulatory Advisor
RCP	Reviewer Certification Program
RFI	Request for Information
RPM	Regulatory Project Manager
RTA	Refuse to Accept
RTA1	Refuse to Accept – Decline Decision
RTAA	Refuse to Accept - Approve Decision
RTAN	Review Not Completed

Abbreviation	Definition
RTAX	Transitional Reject
RTF	Refuse to File
RTS	Real-Time Supplements
SC	Steering Committee
SE	Substantially Equivalent
SEE	Site Examiner Education
SI	Substantive Interaction
SMG	Staff Manual Guide
SOP	Standard Operating Procedure
SR	Substantive Review
SSA	Social Security Administration
Stats	Statistics
Steril	Sterility
TAG	Technical Advisory Group
TEAP	Telework Enhancement Act Pilot Program
TH	Telephone Hold
Toxi	Toxicology
TST	Total Submission Time
TTD	Total Time to Decision
USPTO	United States Patent and Trademark Office
VOIP	Voice over IP
VPN	Virtual Private Network

Appendix B: Data Sources for Issues Analysis

Exhibit 98. Data Sources Used to Document Pre-MDUFA III Issues

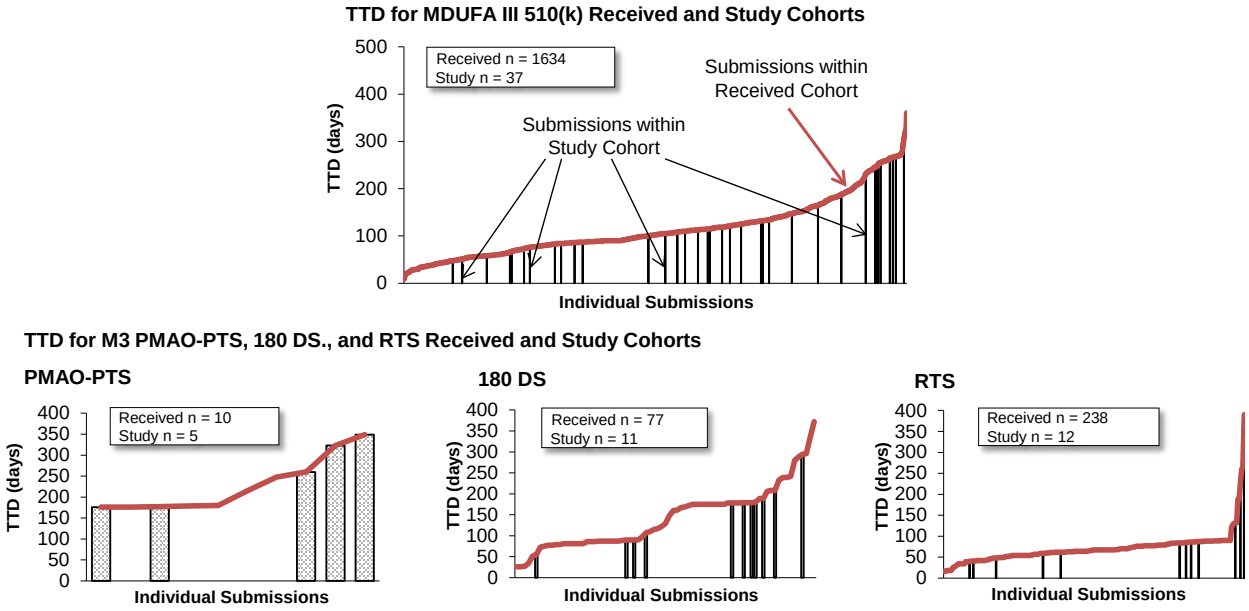
Data Collection Source	Description
FDA-Specific Documents *	• CDRH Input on IT Priorities, Pain Point and Tools • FDA CDRH Preliminary Internal Evaluations-Vol 1: 510(k) Working Group • FDA CDRH Preliminary Internal Evaluations-Vol 2: Task Force on the Utilization of Science in Regulatory Decision Making • FDA Presentation: MDUFA III Implementation • FDA Presentation: Examples of FDA Review Delays • FDA Study: 510(k) Program Assessment • FDA Study: Analysis of Premarket Review Times Under the 510(k) • FDA Study: FDA Perspectives on IR • FDA Study: Improvements in Device Review • FDA Study: Major Reasons Why PMA Reviews Exceed 180 Days—Root Causes
Other Secondary Sources	• GAO Report: FDA Has Met Most Performance Goals but Device Reviews are Taking Longer (2012) • Minutes From Negotiation Meetings on MDUFA III Reauthorization (2011-2012) • Industry Reports*
Focus Groups with FDA and Industry Stakeholders **	• Industry focus group meetings • FDA Technical Advisory Group (TAG) meetings
CDRH Staff Interviews **	• FDA staff provided reference material and documentation to support that identified issues were addressed during the MDUFA III timeframe
Study Cohort Submission Reviews **	• Booz Allen analyzed issues raised in submission reviews that were selected in the study cohort
Lead Reviewer Survey **	• FDA Lead Reviewers responsible for completing submissions in the study cohort explained their perceptions of submission issues through a survey

Notes: *: Source was an Agency-internal document that is not available for dissemination. **: Source is not published but is instead an artifact of this study.

Appendix C: Cohort TTD Distribution Characteristics

The distribution of TTD for applications in the M3 Received and Study Cohorts are depicted in Exhibit 99. The red line within each graph is a collation of TTDs for each submission within the M3 Received Cohort for the submission type while each vertical bar represents the TTD for specific submissions within the M3 Study Cohort.

Exhibit 99. TTD Distribution of M3 Received and Study Cohort Submissions



Appendix D: Respondent Characteristics for the FDA Online Staff Survey

An FDA staff survey was developed to refine initial themes from focus groups with CDRH senior management and interviews with Division Directors on issues relating to review processes, IT infrastructure and workload, and training and retention. A single survey was administered online using the SurveyMonkey tool in February 2014. The survey was administered to review staff and supervisors in CDRH (ODE and OIR) using existing CDRH electronic distribution lists totaling 729 invitees, 468 from ODE and 261 from OIR, which represent the sampling ceiling. Only reviewers and supervisors, which comprise a subset of staff in these distribution lists, were asked to complete the survey. The survey yielded a total of 164 responses. However, not all respondents answered every question in the survey, so total respondents vary for each survey question, as illustrated in the exhibits below.

Survey participant characteristics for the FDA/CDRH Staff Survey are described below.

Exhibit 100. Survey Participation by Office and Division

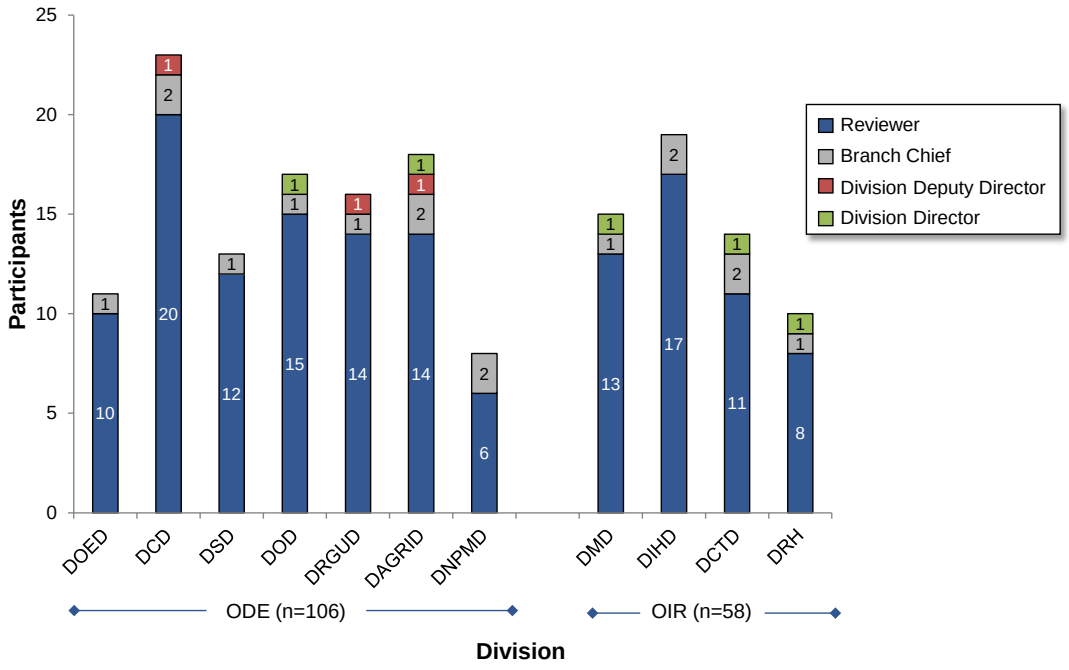


Exhibit 101. Survey Participation by Years of Experience in Any CDRH Role

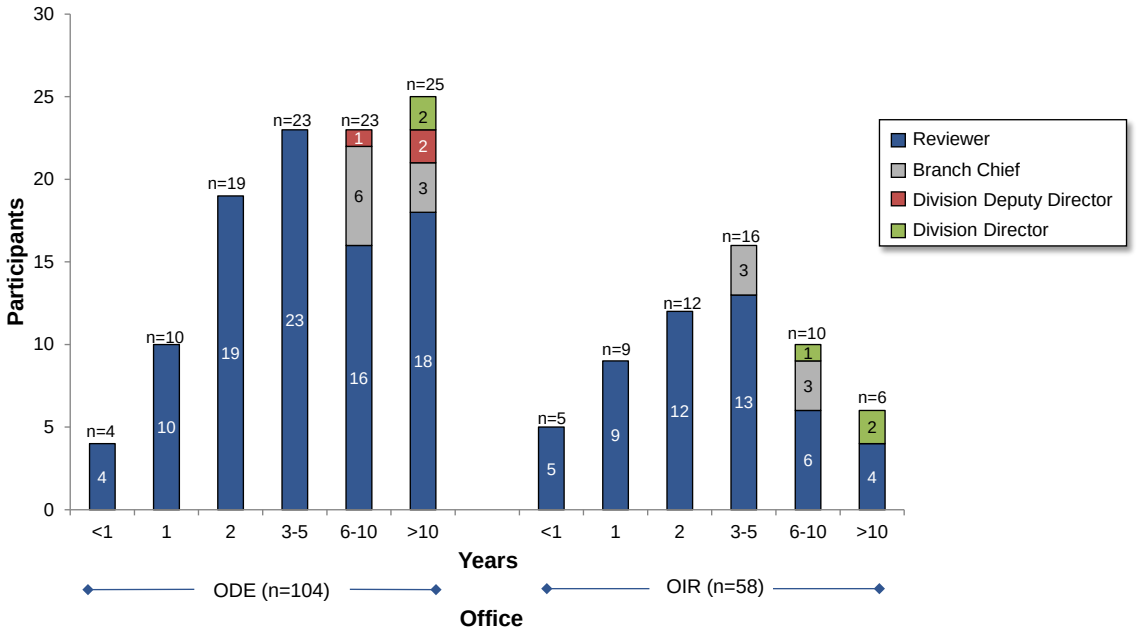
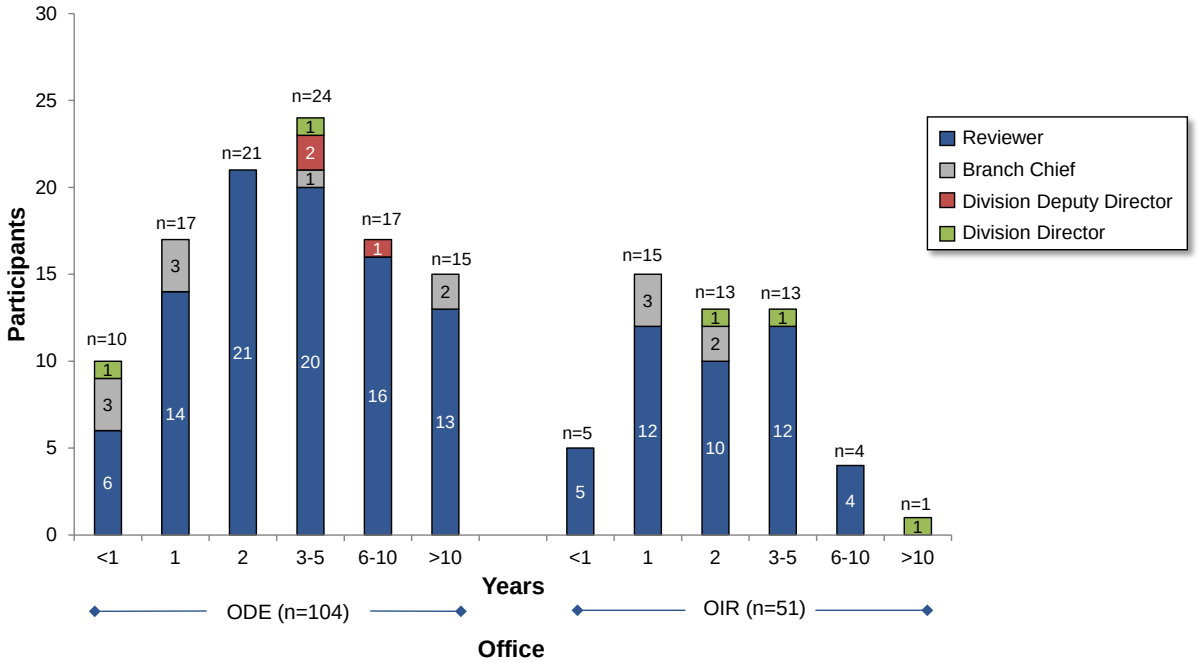


Exhibit 102. Survey Participation by Years of Experience in Current Role



Appendix E: Characterization of CDRH Training Programs

Exhibit 103. CDRH Reviewer Training Programs by Established Training Evaluation Best Practices

	Best Practice [1]	RCP	LEAD	ELP	Ad Hoc
1: REACTION	A program-specific training plan exists.	No	No	No	No
	An annual competency-based needs assessment is conducted.	No [1]	No [1]	No [1]	No [1]
	Curriculum is based off of most-current training needs assessment data.	Yes	Yes	Yes	No [2]
	Participant satisfaction with training was captured and recorded	Yes	Yes	Yes	Yes
2: LEARNING	A pre-course test is conducted and results recorded.	No	No	No	No
	A post-course test is conducted and results recorded.	No	No	No	No
	Internal SOPs in place for timing of evaluations, process, etc.	No	No	No	No
	Time is allocated and used for course survey at end of training course.	No	No	No	No
3 & 4: MONITOR & ADJUST BEHAVIOR & RESULTS	Customized evaluations of successful/un-successful behavior changes are conducted.	No	No	No	No
	Feedback from trainers is recorded/analyzed	No	No	No	No
	Surveys are sent out for additional assessments of knowledge transfer and implementation.	No	No	No	No
	Training schedule/availability is easily accessible and disseminated to audience.	Yes	Yes	Yes	Yes
	Emerging learning tools (e.g. webinars, on-demand online course) are utilized.	Yes	Yes	N/A	Yes
	Result metrics are identified for each course.	No	No	No	No
	Participant training records are available for easy tracking of competency gaps by employee, occupational group, or competency.	Yes	Yes	Yes	Yes
	A program-specific re-certification process exists.	No	No	N/A	No
	Informal workshops exist to supplement training materials and reinforce participant behavioral changes.	No	No	N/A	No
	Training program completion is linked to Individual Development Plan (IDP)	No	No	No	No

Notes: 1. CDRH/Staff College performed an informal needs assessment through internal discussions. No formal assessment was conducted. 2. Although the Ad Hoc program is not currently active, it inherently is based off emerging needs, not a previous needs assessment.

Sources: 1. Benchmarking organizations; Kirkpatrick 4 Levels of Evaluating Training Programs; 2. Interviews with various FDA/CDRH officials; course evaluation templates; focus-group discussions; online course catalog; Pathlore LMS transcript data

Appendix F: Training and Staff Turnover

Exhibit 104. FDA and External Benchmark Documents Used for Training and Staff Turnover Assessments

Agency-Published Sources
Center for Devices and Radiological Health Employee Satisfaction Work Group Findings and Analyses *
Center for Devices and Radiological Health Employee Survey (2012) *
Center for Devices and Radiological Health Honor Awards Program (2014)**
Center for Devices and Radiological Health Rewards and Recognition Program Details (2014)*
Center for Devices and Radiological Health Strategic Priorities (2012)
Center for Devices and Radiological Health Strategic Priorities (2013)
Center for Devices and Radiological Health Strategic Priorities (2014)
Center for Drug Evaluation and Research Division of Learning and Organizational Development Evaluation Framework Presentation (2014) *
Department of Treasury Human Capital Strategic Plan (2008-2013)
Environmental Protection Agency Annual Progress Report FY2012
National Institutes of Health Office of Human Resources Mentoring Program Information, Schedule & Competencies (2014)
National Institutes of Health Workforce Support and Development Division Training Center Highlights FY2012 (Q4)
Nuclear Regulatory Commission Strategic Plan for FY2008-2013
Nuclear Regulatory Commission Training and Development Strategic Plan (2007)
National Science Foundation Human Capital Strategic Plan 2011-2014
Office of Personnel Management Human Capital Assessment and Accountability Framework (HCAAF) (2014)
Office of Personnel Management Training and Evaluation Field Guide (2011)
Social Security Administration Vision of the Future: The First Steps on the Road to 2020 (2011)
"The State of CDER: An Update", Janet Woodcock (2012)
U.S. Patent and Trademark Office Examiner Refresher Training Booklet (2014) **
U.S. Patent and Trademark Office Presentation on Employee Engagement (March 2014) *
U.S. Patent and Trademark Office Press Release 13-40 (December 18, 2013)
U.S. Patent and Trademark Office Performance and Accountability Report FY2013
U.S. Patent and Trademark Office Strategic Human Capital Plan 2011-2015
U.S. Patent and Trademark Office Telework Annual Report (2011)
U.S. Patent and Trademark Office Training Curriculum Material (2014) *
Agency-External Sources
"Elements of Effective Succession Plans: A Working Paper for the UCEDDs". Caldwell, A.C. (2007, May). Silver Spring, MD: Association of University Centers on Disabilities.
Employee Viewport Survey Data for U.S. Food and Drug Administration (2012) *
Employee Viewport Survey Data for U.S. Patent and Trademark Office (2012) *
Employee Viewport Survey Data for National Institutes of Health (2012) *
Evaluating Training Programs: The Four Levels (3rd Ed.) (2006), Donald Kirkpatrick and James Kirkpatrick
Government Accountability Office Report GAO-08-582, Centers for Disease Control and Prevention Human Capital Efforts (2008)
Government Accountability Office Report GAO-10-226, Continued Opportunities Exist for FDA and OPM to Improve Oversight of Recruitment, Relocation, and Retention Incentives (2010)
Government Accountability Office Report GAO-13-459, Social Security Administration Long-Term Strategy Needed to Address Key Management Challenges (2013)
"How Six Federal Agencies Improved Employee Satisfaction and Commitment", Partnership for Public Service (2013)

"The State of the FDA Workforce", Partnership for Public Service (2012)
"Talent Retention: Six Technology-Enabled Best Practices", Oracle White Paper (2012)
Training Scientists to Make the Right Moves: A Practical Guide to Developing Programs in Scientific Management, Howard Hughes Medical Institute (2006)
"Twelve best practices for team training evaluation in health care", Weaver SJ, Salas E, and King HB. Jt Comm J Qual Patient Saf. 2011 Aug;37(8):341-9.
5 CFR 250.203 Establishes requirements for an agency to maintain a certain human capital plan and submit to OPM an annual human capital accountability report

Notes: *: Source was Agency-internal document that is not available to be shared. **: Some source information was public, and linked, but other information was reviewed from CDRH-internal documents that are not available to be shared. Many source documents contain information relevant to both training and retention/staff turnover topics.

Appendix G: Employee Retention Best Practices

Booz Allen conducted a literature review to identify and outline a set of best practices around employee retention, and identified five key elements impacting staff retention:

- **Employee Engagement.** Increased employee commitment and involvement to go above and beyond their normal duties to improve the organization and advance its mission
- **Employee Recognition.** Awards and/or recognition from colleagues and/or supervisors for staff performance and acknowledging staff contributions to the Agency's mission
- **Career Development.** Increased capacity to perform through training, assignments that introduce new skills, or improved work processes
- **Benefit Programs (Work/Life Balance).** Programs in place to improve employee quality of life, including but not limited to work/life balance, teleworking, on-site daycare
- **Succession Planning.** Organizational preparedness to reduce adverse impacts of employee attrition, such as through transition plans or knowledge databases.

Each of these elements is described below along with examples of how benchmark organizations have put each element into practice.

Employee Engagement

Employee engagement, defined as the extent to which employees commit to the organization, how hard they work, and how long they stay as a result of that commitment, is an important driver of retention. The 2012 EVS data, which directly reflects employee opinions and reveals areas for organizational improvement, indicates that the majority of CDRH staff both relate to the Agency's mission and understand how their work helps achieve that mission. However, EVS data also indicates that less than half (45%) of CDRH employees believe that the Center will use feedback from this Federal Government-wide survey to make CDRH a better place to work, despite the fact that a working group of CDRH review staff was tasked with identifying improvement opportunities based on EVS survey results. In comparison, the majority of USPTO staff (67%) responded that USPTO would use EVS results to incorporate improvements. Interviews with USPTO representatives revealed that USPTO actively engages employees by deploying staff working groups and a dedicated set of FTEs to analyze staff feedback, identifying potential areas for improvement, and supporting the implementation of organizational changes. Other organizations engage external specialists, such as the Partnership for Public Service (PPS), to help analyze results and identify methods to improve Agency rankings.

A number of other methods may be employed to improve employee engagement. For example, organizational efforts to improve the connection between work and organizational strategy, such as via the development of a Strategic Human Capital Plan[32], provide a people-oriented focus to help organizations meet mission objectives and/or reduce attrition. Efforts to strengthen staff performance and accountability, such as through the use of 360-degree employee performance evaluations that require supervisor ("upward"), subordinate ("downward"), and peer ("horizontal") feedback, empower employees and engage them more fully in the evaluation process, while minimizing concerns of favoritism and bias. Leadership communication with

[32] FDA published a human capital plan in 2010, which includes guidance for individual Centers to develop tailored plans. CVM developed a Strategic Human Capital Plan in 2011.

employees, using channels such as senior management blogs, e-mails, all-hands meetings, or intra-organization newsletters or magazines, help inform employees of organizational decisions and updates and promote a sense of transparency and workplace inclusion. Interactive forums can also encourage employees to be more involved with colleagues and the organization. For example, USPTO hosts a creativity competition where employees submit creative ideas on ways to improve USPTO. The winner not only receives rewards, but also earns recognition at the Agency all-hands meeting.

Employee Recognition

Employee recognition is an important retention mechanism, as it enables an organization to acknowledge an employee for behavior, effort, and accomplishments that support the organization's goals and values. Employee recognition mechanisms should allow an organization the ability to customize the type of recognition an employee would like to receive, whether financial or non-financial, as available.

Spot bonuses, promotions, and student loan repayment programs represent a number of financial incentives beyond salary that contribute to employee retention. EVS survey data indicates that 61% of CDRH employees responded positively regarding satisfaction with their pay, compared to the government-wide average of 59% satisfaction. In addition, the Master Reviewer program is a CDRH-specific method of recognizing review staff. This voluntary program promotes experienced reviewers to a GS-14 level without being in a supervisory position. The application process includes a rigorous review of the candidate's previous application reviews, interviews, and an overall assessment by a CDRH senior management committee. Reviewers who have demonstrated superior review performance and knowledge are recognized with a Master Reviewer designation; however, there are resource constraints that limit the number of Master Reviewers that may be designated within each Office. At the time this study was conducted, there were 29 Master Reviewers in ODE and 5 in OIR, 9 of whom participated in our FDA survey. Data from the FDA staff survey validates that reviewers pursue the Master Reviewer designation primarily for the increased salary, followed by additional recognition.

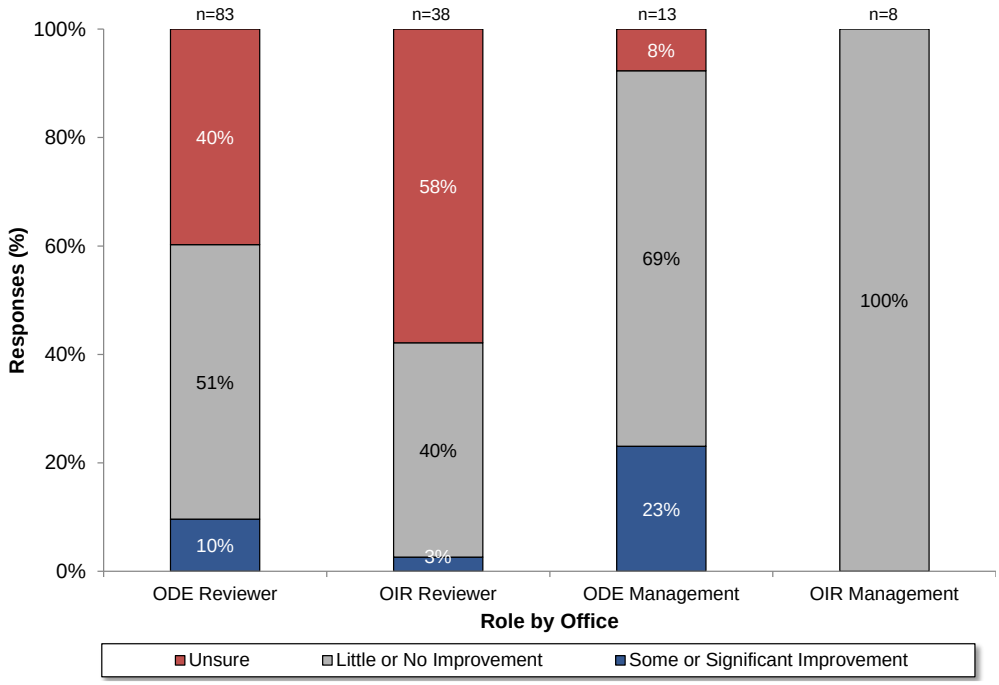
The CDRH Employee Satisfaction Work Group also determined that 75% of its survey participants perceived non-financial recognition methods as effective in recognizing good performance. CDRH currently provides several non-financial awards, which allow employees to nominate their peers and even themselves for various awards to recognize initiative and/or creativity in problem-solving, noteworthy one-time achievements, contributions outside the scope of their responsibilities, or overall outstanding performance. CDRH offers a number of staff awards, including FDA Honor Awards, CDRH Honor Awards, Time-off Awards, Length of Service Awards, and a new CDRH Process Improvement Award.

Despite the variety of awards available, there is likely room for CDRH improvement in offering non-financial recognition, as only 50% of CDRH employees were satisfied with the recognition received for doing a good job, compared to 70% satisfaction at USPTO[33]. A CDRH working group was tasked with improving employee recognition mechanisms by increasing the rigor of the Honor Awards process. However, FDA staff survey data reveals that this enhancement has not improved reviewer perceptions of the awards process (see Exhibit 105). In fact, a substantial percentage of reviewers in both ODE and OIR (40% and 58%, respectively) were

[33] EVS Survey Data 2012.

unsure of the impact of the modified award process. We speculate that this reaction is likely a result of poor communication to review staff of organizational improvements to the awards process.

Exhibit 105. To what Extent has Modified FDA/CDRH Annual Awards Process Improved Employee Recognition?



Note: Percentages may not add up to 100% due to rounding
Source: FDA Staff Survey

In addition, EVS data indicates that only 48% of employees perceived that awards correlated with employee performance, significantly lower than USPTO (78%). Only 38% CDRH employees believe performance is recognized in a meaningful way and less than half of employees surveyed (48%) believe that awards are based on how well employees perform in their jobs. During focus groups moderated by Booz Allen, supervisors explained that staff perceives "quotas" in CDRH funding pools, which limit the number of "high" PMAP ratings managers can provide to employees during performance assessments. This impression may explain why employees observe discrepancies between the quality of their work and level of recognition.

Career Development

Employee development and growth opportunities are another recognized method to improve employee retention. When organizations actively invest in their employees' job preparedness and assist in developing their careers within the organization, employees may have more confidence in their professional future and feel more inclined to stay.

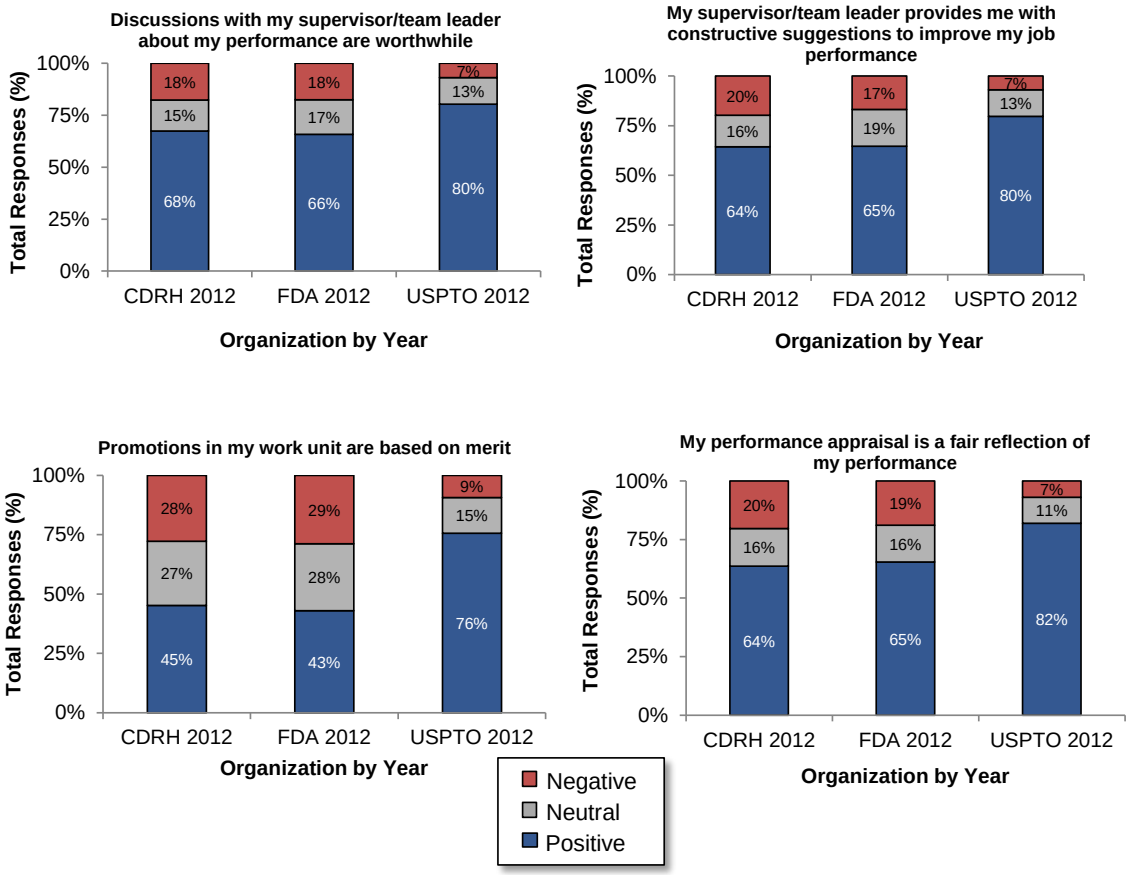
Organizations may foster employee development using internal and/or external development methods, and by offering opportunities suited to different stages of employees' careers. For example, including realistic job previews during the recruiting and hiring process enables

organizations and candidates to determine a better fit with open positions. In addition, customizing position descriptions (PD) based on characteristics of top performers in a similar or current position may yield a set of candidates that are more likely to qualify and succeed in the role. A common FDA practice is to employ a limited number of general position descriptions (PD) to accommodate various positions of responsibility to allow HR to select from a wider range of candidates. However, EVS data indicates that fewer CDRH employees (58%) believed that their work unit was able to recruit people with the right skills as compared with USPTO (68%). Use of more differentiated PDs might improve FDA's ability to identify and hire the right talent for positions that are more technical in nature.

Once hired, employees should have access to both high-quality training programs and experienced employees who can share their wealth of expertise and lessons learned. Best practices for sharing on-the-job information includes mentoring, brown bag sessions and office hours. Benchmark organizations have also put these methods into practice. For example, CDER provides its reviewers a voluntary mentoring program where mentees and mentors are paired for the 10-month program. The program is intended to build leadership capacity, increase job satisfaction, and improve retention. The USPTO patent examiner training also relies on mentoring from both reviewer managers and a supervisory patent examiner, matched to new examiners by technology center. This not only provides new hires with direct mentorship and live feedback from experienced staff, but also provides seasoned staff with management and mentorship experience that may help fulfill promotion requirements. In addition to direct line supervisors, CDRH currently has Master Reviewers to help coach and support review staff. As discussed in Section 4.6.2, the majority of CDRH review staff responded that brown bags led by Master Reviewers or other experts would be valuable to share information on submission review processes and other lessons learned.

Performance assessments comprise another internal method to promote employee career development. While the majority of CDRH employees have a favorable view of discussions with supervisors on their performance and on constructive feedback (68% and 64%, respectively), this data is somewhat lower than USPTO responses to the same survey questions (80% and 80%, respectively). In addition, 64% of CDRH staff agreed that performance appraisals were fair reflections of performance, and only 45% of CDRH staff agreed that promotions were based on merit, compared to 82% and 76% responses from USPTO staff, respectively. Establishment of tangible performance milestones or metrics allows employee advancement towards career goals to be objectively assessed and may decrease perceived subjectivity in the process. 360-degree performance assessments may offer a more comprehensive view of an employee's performance and abilities.

Exhibit 106. EVS Data Comparing CDRH with FDA and USPTO on Annual Performance and Supervisor Feedback (2012)



Note: Percentages may not add up to 100% due to rounding

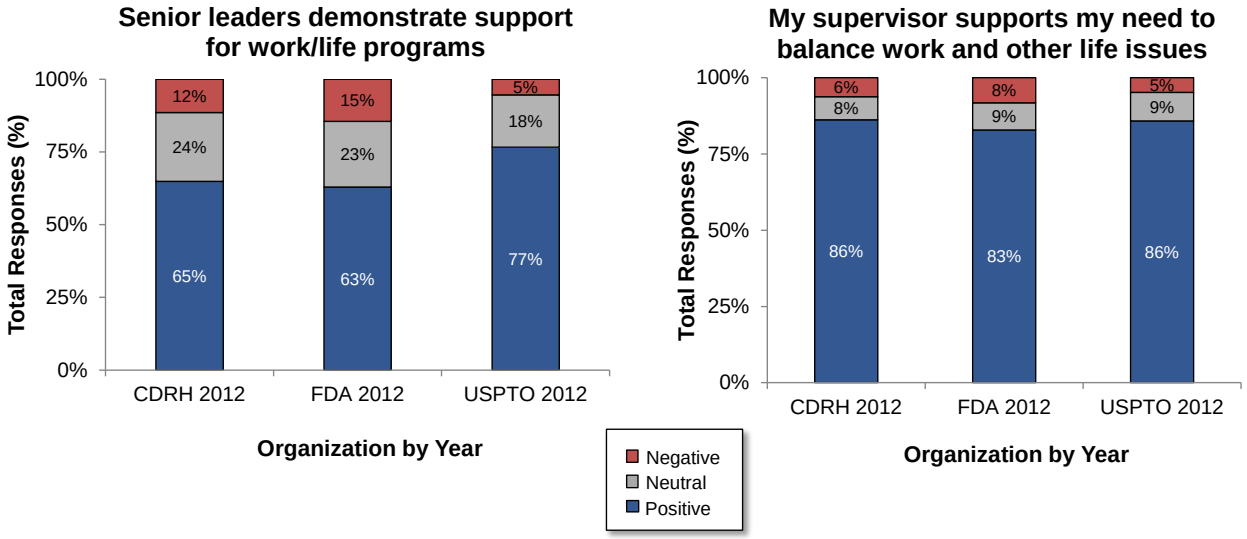
Source: EVS Survey Data

Employee details are another method to promote employee career development opportunities external to the employee's typical work units. Details may enable staff to gain experience in new and varied environments, develop new skills, enjoy a sense of accomplishment, and further contribute to the agency's mission. Currently, all FDA Centers, including CDRH, allow employees to go on detail to another Division, Office, or Center. To improve the impact of details, staff should bring knowledge back to their business units to help improve their business unit. At USPTO, employees may engage in a 2-year detail within OPT to serve as a mentor/instructor for new examiners, allowing participants to develop both leadership and examiner skills by demonstrating their domain expertise.

Benefits Programs

FDA and CDRH currently provide a variety of benefits programs to improve employee job satisfaction, including flexible work schedule, on-site gym, on-site clinics, wellness programs, and casual dress code. EVS survey data indicates that the majority of CDRH staff (86%) agrees that supervisors support employees' need to balance work with other life issues (Exhibit 107).

Exhibit 107. EVS Data Showing Management Support for Work/Life Programs

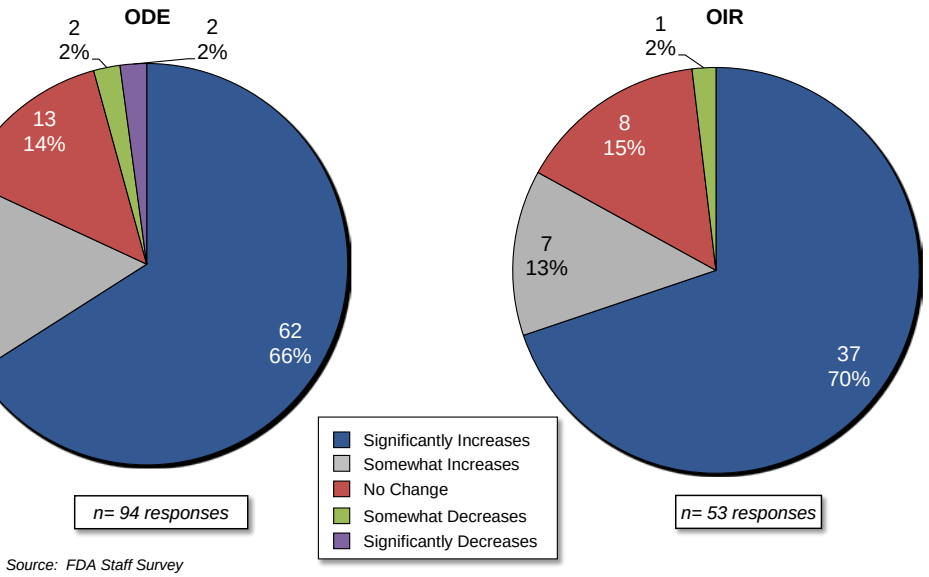


Note: Percentages may not add up to 100% due to rounding
Source: EVS Survey Data

Employee teleworking is also an increasingly common mechanism organizations employ to improve employee work/life balance. USPTO's telework program includes a number of technological enhancements to maximize the benefits of teleworking. The USPTO program adheres to the Telework Enhancement Act Pilot Program (TEAPP), which allows for increased hours to work from home while still maintaining an office onsite. Although 90% of USPTO participates in telework, restrictions exist (similar to CDRH) on eligibility to participate in the telework program. Specifically, employees must have been employed for at least 2 years, be at least a GS-12, and obtain supervisory approval. Employees are highly recommended to participate in various technology trainings (VPN, Microsoft Lync, VOIP, Hoteling, etc.) to fully capitalize on remote work. In addition, home work stations for all telework-eligible USPTO employees include a setup similar to their offices, including phone (VOIP), dual-monitors, and keyboard/mouse. Interviews with USPTO management indicate that technology, such as video conferencing, has significantly improved staff ability to communicate and operate effectively, thereby satisfying both examiners' and management's needs.

CDRH has implemented functionality for digital signatures as a technological advancement intended to streamline the review process and promote staff flexibility to finalize review documentation when working remotely. Prior to MDUFA III, reviewers and supervisors were required to apply signatures to review decisions by hand, which required staff to finalize documents at an FDA work location. When asked to estimate the time needed to apply a digital signature in an FDA staff survey, staff estimated that a single digital signature typically took between 1-8 minutes to apply, and in some instances could take 9-12 minutes or longer. FDA Branch Chiefs provided feedback during focus groups that staff appear to use inconsistent practices to convert, download, sign and upload signed documents in DocMan, which may be one factor contributing to the variability in time needed to perform this function. However, the vast majority of review staff (81%) and management (83%) still agree that implementation of digital signatures for MDUFA III reviews has significantly increased staff flexibility to advance the process of signing and finalizing submission documentation (Exhibit 108).

Exhibit 108. Impact of Digital Signature on Flexibility for Staff



Source: FDA Staff Survey

Succession and Transition Planning

Succession planning is defined as the ongoing recruitment and development of potential successors to ensure a smooth transition and minimal loss of efficiency when vacancies occur in management or other key organizational roles. Published human capital research on succession planning indicates that a well-communicated organizational succession plan may be effective in mitigating the impacts of staff turnover when it occurs, particularly among management positions, and also contribute to improved staff engagement, retention, and career development expectations. Given the relatively modest level of attrition observed among CDRH staff, transition planning may be the most important for the Center to focus on, to minimize the impact of turnover when it does occur.

Development of a succession plan should take into account a number of core activities. First, management must identify key roles for which the organization intends to have successors in place. Next, competencies defined for each of these roles are needed to enable management to assess the fit of potential successors for a given role. Management's identification of employees with potential for increasing responsibilities enables organizations to ensure that a sufficient number of successors are in place for key roles. Finally, alignment of employees who are either formally or informally identified as successors to training and other career development opportunities allows successors to gain expertise and/or knowledge that will prepare them for future roles. Further, leadership engagement in supporting employee development may enable mentorship and advocacy opportunities and help ensure that employees are gaining the appropriate experience needed for future advancement.

Transition planning mitigates the negative impact of staff turnover by focusing on managing the day-to-day activities that are affected when organizations lose employees with valuable institutional knowledge. A formal transition plan that is well-documented and communicated to all divisions and employees may minimize disruption to daily activities and maintain business process continuity. Key elements of an organizational transition plan include the following:

- **Redundancy of responsibilities**. Cross-training of work or rotation of duties may help lessen the impact of attrition by providing employees with the ability to fill-in for anyone that leaves an organization
- **Knowledge sharing and documentation.** Intellectual capital, business relationships, business domain information, and formal position and roles and responsibilities documents may ease employee transition. Other examples include task-based documentation itemizing work steps needed to complete a task, storage of staff files or data in a centralized location or database, or standardized templates
- **Training.** The necessary skills and knowledge needed to effectively complete transitioned duties may require formal training
- **Shadowing.** Identified staff replacements may shadow departing employees to improve understanding of position intricacies, and validate that sufficient transition documentation is provided
- **Exit survey or checklist.** For both planned and unplanned staff exits, a survey or checklist may allow reassignment of duties for completion, or help ensure that duties and relationships are transferred appropriately. Exit surveys may serve as a final opportunity to gather information outside of shadowing and documentation methods
- **Flexible Policies for Retiring Employees.** Engagement of retired employees as consultants and mentors may allow for a longer transition period while also enabling an organization to leverage the retiring employee's knowledge, skills, and expertise.

Interviews with OIR and ODE management indicated that both succession and transition planning elements are performed informally across divisions but are neither well-documented nor communicated. For example, senior management in both Offices currently identify and discuss individuals who have expressed interest in and are potentially qualified for leadership positions, and may even recommend specific management training courses to them in order to promote internal leaders. As discussed in Section 4.6.1, most OIR submission reviews engage multiple reviewers, so multiple reviewers are at least somewhat knowledgeable of submission content and may transition more seamlessly into a Lead Reviewer role when turnover occurs. In ODE, management proactively begins transitioning work and knowledge through mentoring as employees begin to reach retirement age.

Discussions with USPTO officials indicated that succession and transition planning is currently not conducted according to a formal enterprise-wide process. Similar to ODE and OIR, business units execute both plans informally, leveraging training and mentorship as key elements. However, officials also noted that documenting and formalizing transition and succession plans across the Agency is a recognized best practice.