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MDUFA Quarterly Performance
November 6, 2012

Guidance Development

- FDA issued 7 medical device guidance documents during the 4th quarter. *Barbara Zimmerman, CDRH-ODE*; *Sheryl Kochman, CBER; Don St. Pierre, CDRH-OIVD*

FDA MDUFMA / MDUFA Performance — Actions through Sept 30, 2012

- Reports on all decision goals for the FY 2008 - FY 2012 cohorts.
  - CBER: *Sheryl Kochman, CBER.*
  - CDRH: *Barbara Zimmerman, CDRH.*

CLIA Waiver Review Times

- Report on qualitative goals and number of pending waiver requests. *Don St. Pierre,* CDRH-OIVD.

CDRH Information Technology (IT) Update

- Report on CDRH IT. *Scott McCall*, CDRH-OCD

CDRH Staff Training Update

- Report on CDRH staff training. *Laura Stewart*, CDRH-OCER

CDRH Registration and Listing

- Report on registration and listing. *Dave Gartner*, CDRH-OC

Qualitative Update -Use of Resources – 4th Quarter of FY 2012

- Update on budget requests and appropriations. *Noni Buchanan*, CDRH-OMO.

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Medical Device Guidance Documents
Issued through 4th Quarter FY 2012
Through Sept. 30, 2012

A comprehensive list of guidances can be found at the following:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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Fourth Quarter (July 2012- Sept 2012)

1. Draft Guidance for Industry and Food and Drug Administration Staff - Refuse to Accept Policy for 510(k)s (PDF - 1.4MB), CDRH, CBER (8/13/2012).
2. Guidance for Industry and Food and Drug Administration Staff and Foreign Governments - FY 2013 Medical Device User Fee Small Business Qualification and Certification (PDF - 365KB), CDRH, CBER (8/1/2012).
3. Draft Guidance for Industry and Food and Drug Administration Staff- Acceptance and Filing Review for Premarket Approval Applications (PMAs), CDRH, CBER (7/31/2012).
4. Draft Guidance for Industry and Food and Drug Administration Staff - Safety Considerations for 510(k) Submissions to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications, CDRH. ODE/DRGURD (7/27/2012).
5. Draft Guidance for Industry and FDA Staff Medical Devices: The Pre-Submission Program and Meetings with FDA Staff, CDRH, CBER (7/13/2012).
6. Guidance for Industry and FDA Staff - Clinical Performance Assessment: Considerations for Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Approval (PMA) and Premarket Notification [510(k)] Submissions, CDRH. OSEL/DIAM OIVD/DRD (7/3/2012)
7. Guidance for Industry and Food and Drug Administration Staff - Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions, CDRH. OSEL/DIAM OIVD/DRD (7/3/2012).

Third Quarter (April 2012 – June 2012)

8. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Implanted Blood Access Devices for Hemodialysis, CDRH. ODE-DRGRUD (6/20/2012).
9. Considerations When Transferring Clinical Investigation Oversight to Another IRB5 (6/12/2012; FDA guidance, including CDRH)
10. Draft Guidance for Industry and Food and Drug Administration Staff - Pediatric Information for X-ray Imaging Device Premarket Notifications, CDRH. OIVD-DRD, OCER-DMQRP, OSEL-DIAM (5/10/2012).
11. Guidance for Industry and Food and Drug Administration Staff - FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act, CDRH, CBER (4/6/2012).
12. Guidance for Industry and Food and Drug Administration Staff - User Fees for 513(g) Requests for Information, CDRH, CBER (4/6/2012).

Second Quarter (January 2012- March 2012)

13. Guidance for Industry and FDA Staff - Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications, CDRH. ODE, OIVD (3/28/12).
14. Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Full Field Digital Mammography System, CDRH. OSEL-DIAM, OIVD-DRD (3/27/12).
15. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens, CDRH-OIVD (3/19/12).
16. Guidance for Industry, Third Parties and Food and Drug Administration Staff - Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program, CDRH, (3/19/12)
17. Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Norovirus Serological Reagents, CDRH-OIVD (3/9/12).
18. Guidance for Industry - Providing Regulatory Submissions in Electronic Format — Standardized Study Data, FDA (2/1/12)
19. Draft Guidance for Industry and Food and Drug Administration Staff - Medical Device Classification Product Codes, CDRH, CBER (1/3/12).

First Quarter (September 2011- December 2011)

20. Draft Guidance for Industry and Food and Drug Administration Staff - CDRH Appeals Processes, OCD (12/27/11).
21. Draft Guidance for Industry and Food and Drug Administration Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], ODE (12/27/11).
22. Guidance for Industry and Food and Drug Administration Staff - Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices, OIVD (12/20/11).
23. Draft Guidance for Industry and Food and Drug Administration Staff - Evaluation of Sex Differences in Medical Device Clinical Studies, OCD (12/19/11).
24. Draft Guidance for Industry and Food and Drug Administration Staff - The Content of Investigational Device Exemption (IDE) and Premarket Applications for Artificial Pancreas Device Systems, ODE (12/6/11).
25. Draft Guidance for Industry and Food and Drug Administration Staff - Humanitarian Use Device (HUD) Designations, FDA (12/1/11)
26. Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage, CBER (12/11).
27. Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses, OIVD (11/28/11).
28. Draft Guidance for Industry and Food and Drug Administration Staff - Investigational Device Exemptions (IDE) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies, CDRH (11/10/11).
29. Draft Guidance for Industry, Clinical Investigators, Institutional Review Boards, and Food and Drug Administration Staff - FDA Decisions for Investigational Device Exemption (IDE) Clinical Investigations, CDRH (11/10/11)

30. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Yersinia spp. Detection, OIVD (11/7/11).
31. Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: External Pacemaker Pulse Generator, ODE (10/17/11).
32. Draft Guidance for Industry and Food and Drug Administration Staff - De Novo Classification Process (Evaluation of Automatic Class III Designation), ODE (10/3/11).

Quarterly Update on
Medical Device Performance Goals
— CBER Performance Data —

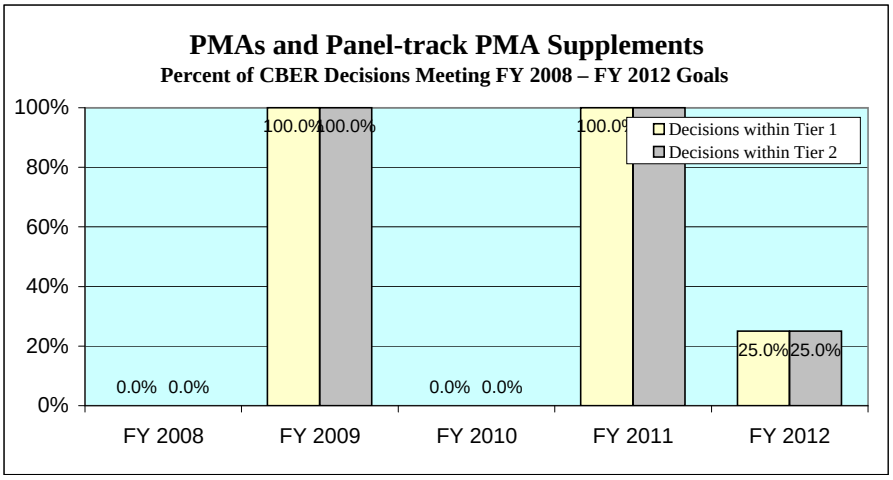
Actions through 30 September 2012

Data on FY 2008 – FY 2012 Cohorts

Actions through 30 September 2012

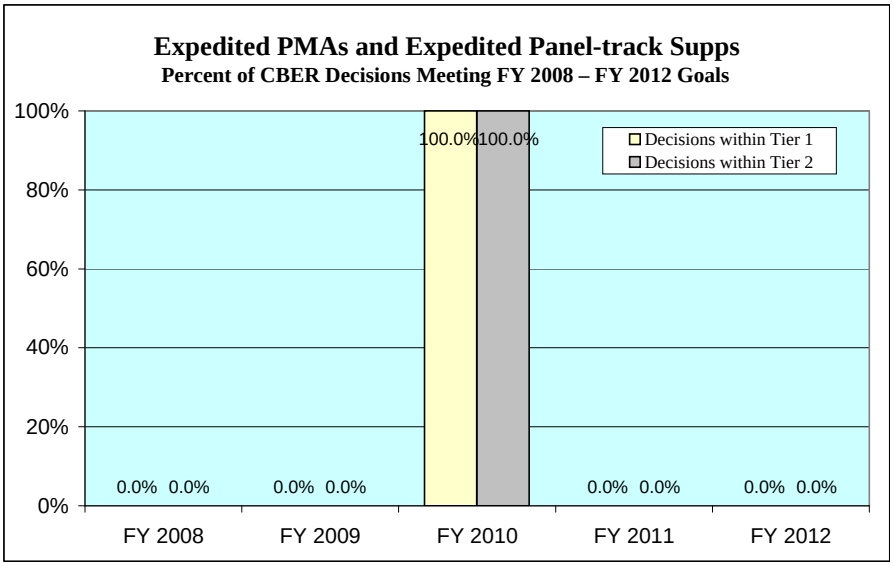
PMAs and Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	2	0	1	4
Total FDA Decisions	0	2	0	1	1
Percent within Tier 1 goal (180 days)	--	100.0%	--	100.0%	25.0%
Tier 1 goal — *Percent within 180 days*	*60%*	*60%*	*60%*	*60%*	*60%*
Percent within Tier 2 goal (295 days)	--	100.0%	--	100.0%	25.0%
Tier 2 goal — *Percent within 295 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



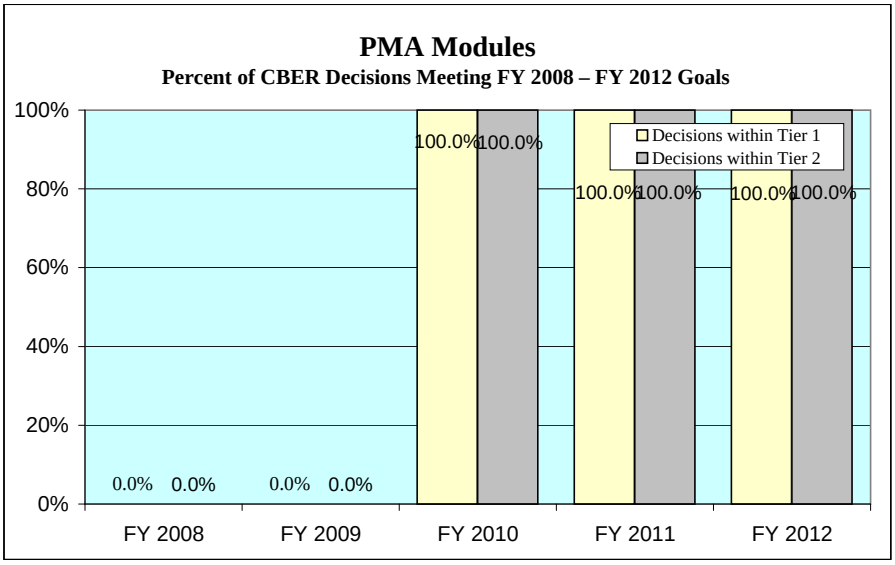
Expedited PMAs and Expedited Panel-track Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	0	0
Total FDA Decisions	0	0	1	0	0
Percent within Tier 1 goal (180 days)	--	--	100.0%	--	--
Tier 1 goal — *Percent within 180 days*	*50%*	*50%*	*50%*	*50%*	*50%*
Percent within Tier 2 goal (280 days)	--	--	100.0%	--	--
Tier 2 goal — *Percent within 280 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	*Complete*



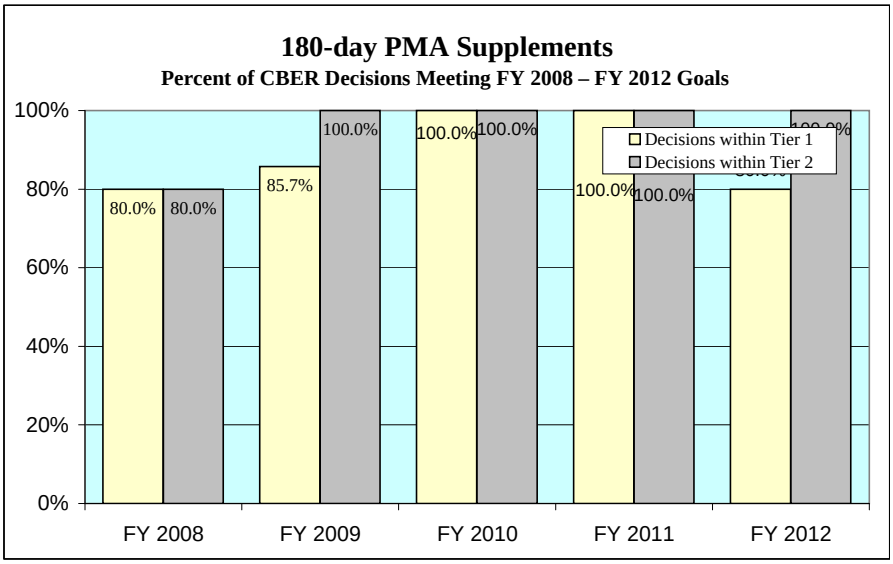
PMA Modules

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	0	0	1	5	4
MDUFMA Cohort	0	0	1	5	4
Total FDA Decisions	0	0	1	5	3
Percent within Tier 1 goal (90 days)	--	--	100.0%	100.0%	100.0%
Tier 1 goal — *Percent within 90 days*	*75%*	*75%*	*75%*	*75%*	*75%*
Percent within Tier 2 goal (120 days)	--	--	100.0%	100.0%	100.0%
Tier 2 goal — *Percent within 120 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



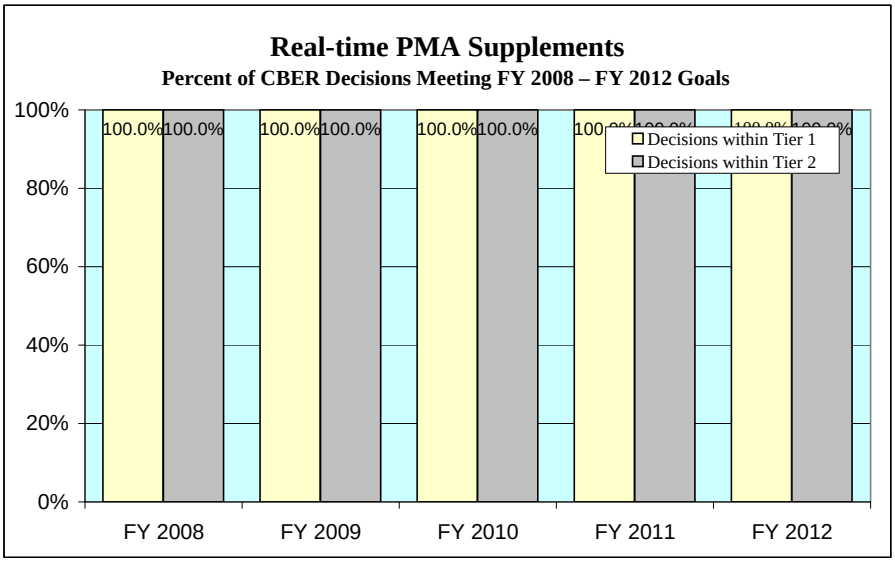
180-day PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	5	7	7	9	7
Total FDA Decisions	5	7	7	9	5
Percent within Tier 1 goal (180 days)	80.0%	85.7%	100.0%	100.0%	80.0%
Tier 1 goal — *Percent within 180 days*	*85%*	*85%*	*85%*	*85%*	*85%*
Percent within Tier 2 goal (210 days)	80.0%	100.0%	100.0%	100.0%	100.0%
Tier 2 goal — *Percent within 210 days*	*95%*	*95%*	*95%*	*95%*	*95%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



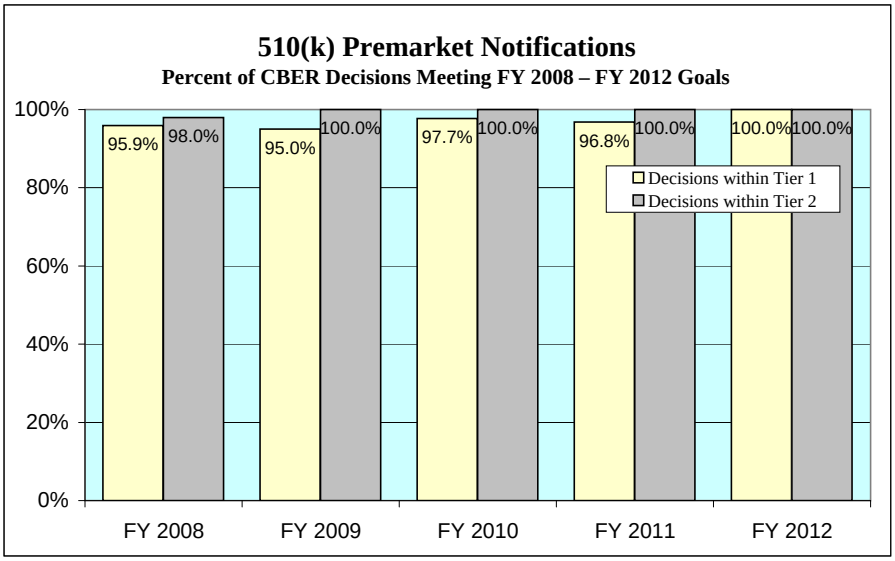
Real-time PMA Supplements

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	2	4	2	1	4
Total FDA Decisions	2	4	2	1	3
Percent within Tier 1 goal (60 days)	100.0%	100.0%	100.0%	100.0%	100.0%
Tier 1 goal — *Percent within 60 days*	*80%*	*80%*	*80%*	*80%*	*80%*
Percent within Tier 2 goal (90 days)	100.0%	100.0%	100.0%	100.0%	100.0%
Tier 2 goal — *Percent within 90 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Cohort status	*Complete*	*Complete*	*Complete*	*Complete*	Open



510(k)s

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	53	50	55	44	54
MDUFMA Cohort	49	40	43	35	51
Total FDA Decisions	49	40	43	31	27
Percent within Tier 1 goal (90 days)	95.9%	95.0%	97.7%	96.8%	100.0%
Tier 1 goal — *Percent within 90 days*	*90%*	*90%*	*90%*	*90%*	*90%*
Percent within Tier 2 goal (150 days)	98.0%	100.0%	100.0%	100.0%	100.0%
Tier 2 goal — *Percent within 150 days*	*98%*	*98%*	*98%*	*98%*	*98%*
Cohort status	*Complete*	*Complete*	*Complete*	Open	Open



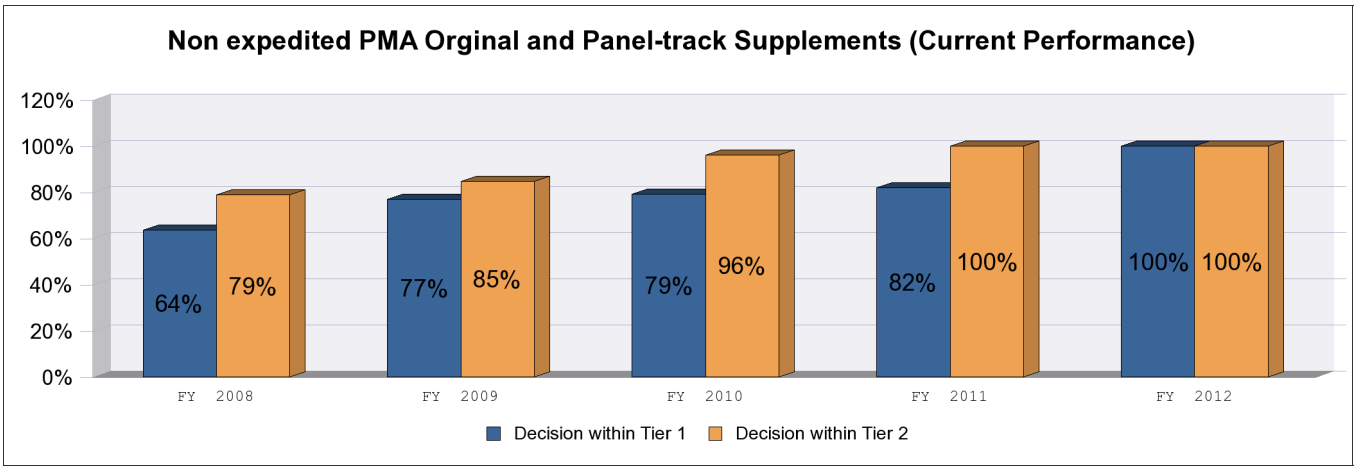
Quarterly Update on
Medical Device Performance Goals
---- CDRH Performance Data ----

Action through 30 September 2012

MDUFA II Quarterly (Non expedited PMA Orginal and Panel-track Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 9/30/2012 11:59:00 PM

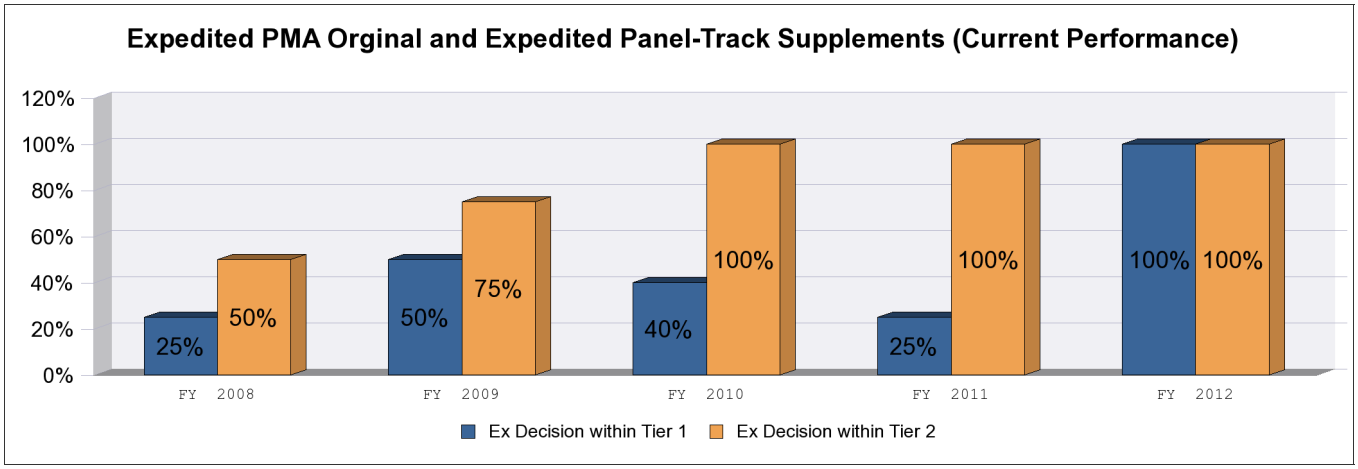
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	33	39	53	44	29
Total FDA Decision	33	39	53	39	7
Tier 1 goal -- Percent within 180 Days	*60%*	*60%*	*60%*	*60%*	*60%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	64%	77%	79%	82%	100%
Pending Performance-Worst Case	64%	77%	79%	73%	24%
Tier 2 goal -- Percent within 295 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	yes	unknown	unknown
Pending Performance-Best Case	79%	85%	96%	98%	100%
Pending Performance-Worst Case	79%	85%	96%	89%	24%
Cohort status	Complete	Complete	Complete	Open	Open



MDUFA II Quarterly (Expedited PMA Orginal and Expedited Panel-Track Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 9/30/2012 11:59:00 PM

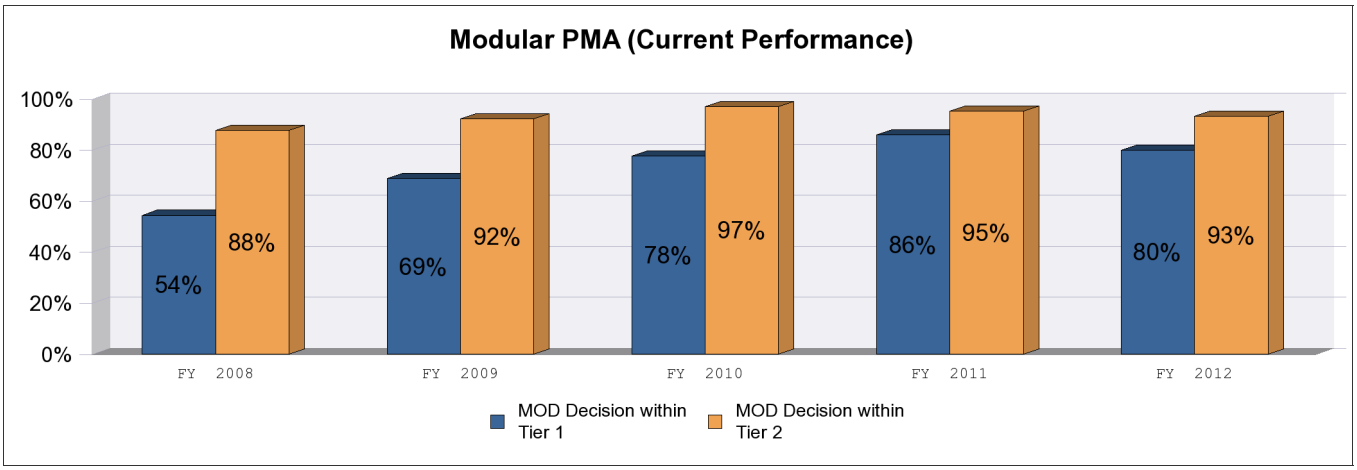
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	4	4	6	7	3
Total FDA Decision	4	4	5	4	2
Tier 1 goal -- Percent within 180 Days	*50%*	*50%*	*50%*	*50%*	*50%*
Goal met(yes/no/unknown)	no	yes	no	no	yes
Pending Performance-Best Case	25%	50%	33%	14%	100%
Pending Performance-Worst Case	25%	50%	33%	14%	67%
Tier 2 goal -- Percent within 280 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	no	no	no	unknown
Pending Performance-Best Case	50%	75%	83%	57%	100%
Pending Performance-Worst Case	50%	75%	83%	57%	67%
Cohort status	Complete	Complete	Open	Open	Open



MDUFA II Quarterly (Modular PMA)

For Submissions Filed Between Year 2008 to 2012 as of 9/30/2012 11:59:00 PM

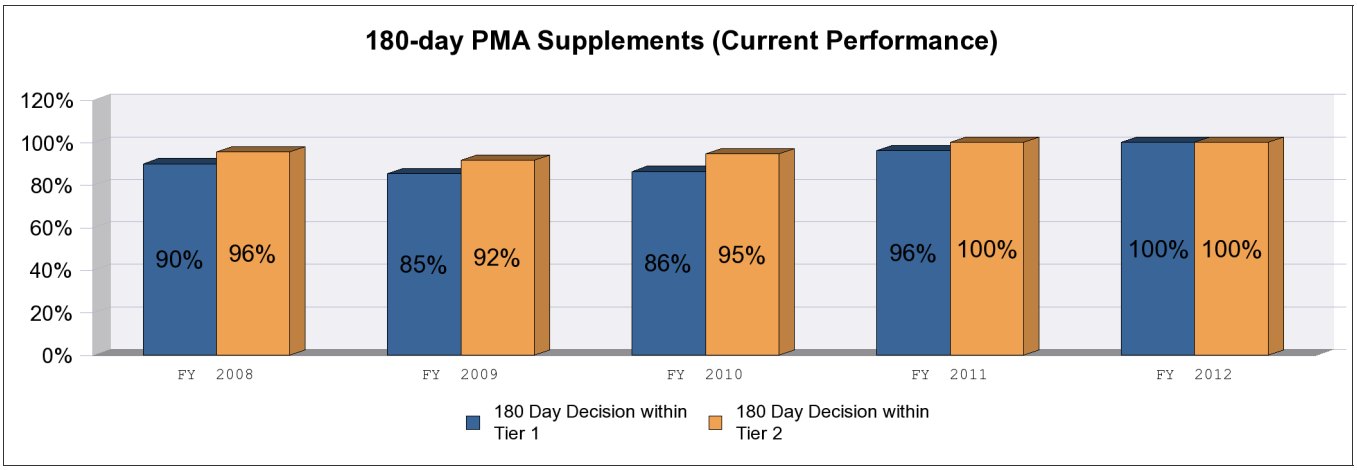
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Cycle Started)	57	90	104	85	64
Total FDA Decision	57	90	103	85	45
Tier 1 goal -- Percent within 90 Days	*75%*	*75%*	*75%*	*75%*	*75%*
Goal met(yes/no/unknown)	no	no	yes	yes	unknown
Pending Performance-Best Case	54%	69%	78%	86%	84%
Pending Performance-Worst Case	54%	69%	78%	86%	56%
Tier 2 goal -- Percent within 120 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	no	yes	yes	yes	unknown
Pending Performance-Best Case	88%	92%	97%	95%	95%
Pending Performance-Worst Case	88%	92%	97%	95%	66%
Cohort status	Complete	Complete	Complete	Complete	Open



MDUFA II Quarterly (180-day PMA Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 9/30/2012 11:59:00 PM

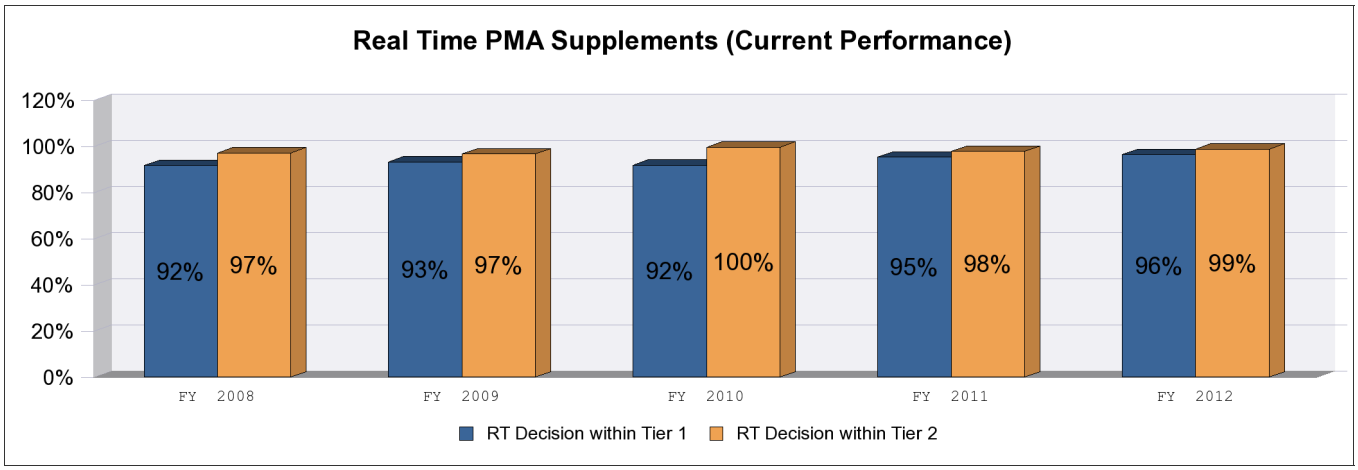
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	170	165	157	145	210
Total FDA Decision	160	158	132	128	61
Tier 1 goal -- Percent within 180 Days	*85%*	*85%*	*85%*	*85%*	*85%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	90%	85%	86%	95%	100%
Pending Performance-Worst Case	90%	85%	86%	95%	30%
Tier 2 goal -- Percent within 210 days	*95%*	*95%*	*95%*	*95%*	*95%*
Goal met(yes/no/unknown)	yes	no	yes	yes	unknown
Pending Performance-Best Case	96%	92%	95%	100%	100%
Pending Performance-Worst Case	96%	92%	95%	98%	30%
Cohort status	Complete	Complete	Complete	Open	Open



MDUFA II Quarterly (Real Time PMA Supplements)

For Submissions Filed Between Year 2008 to 2012 as of 9/30/2012 11:59:00 PM

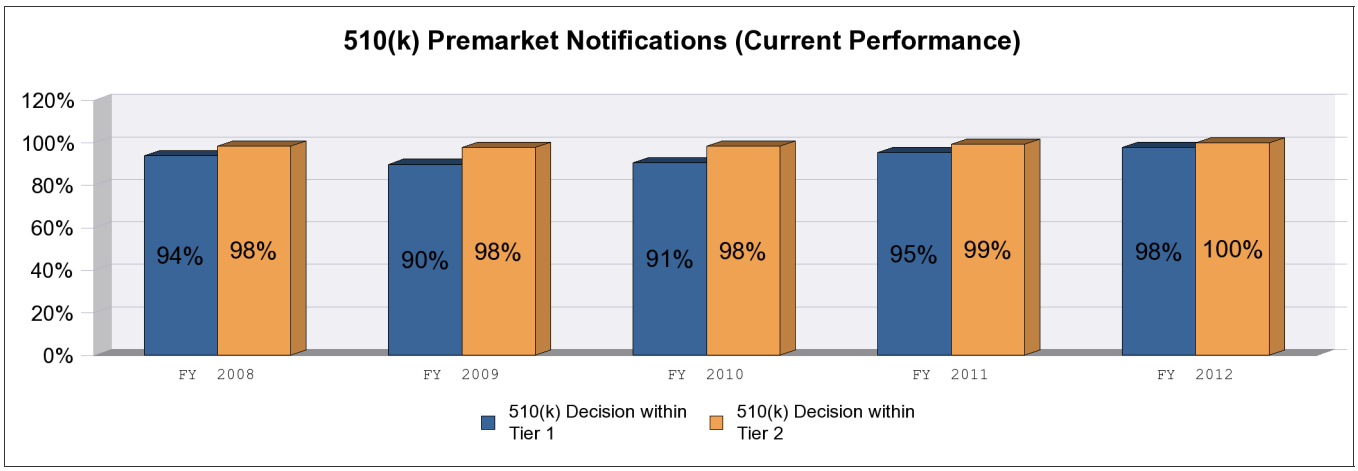
	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Filed to Date)	249	296	269	245	307
Total FDA Decision	241	280	257	235	246
Tier 1 goal -- Percent within 60 Days	*80%*	*80%*	*80%*	*80%*	*80%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	yes
Pending Performance-Best Case	92%	93%	92%	95%	97%
Pending Performance-Worst Case	92%	93%	92%	95%	80%
Tier 2 goal -- Percent within 90 days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	97%	97%	100%	98%	99%
Pending Performance-Worst Case	97%	97%	100%	98%	82%
Cohort status	Complete	Complete	Complete	Complete	Open



MDUFA II Quarterly (510(k) Premarket Notifications)

For Submissions Received Between Year 2008 to 2012 as of 9/30/2012 11:59:00 PM

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012
Workload (Received to Date)	3,848	4,103	3,880	3,833	3,990
MDUFA Cohort	3,260	3,403	3,146	3,223	3,780
Total FDA Decision	3,259	3,398	3,140	3,157	2,024
Tier 1 goal -- Percent within 90 Days	*90%*	*90%*	*90%*	*90%*	*90%*
Goal met(yes/no/unknown)	yes	yes	yes	yes	unknown
Pending Performance-Best Case	94%	90%	91%	95%	99%
Pending Performance-Worst Case	94%	90%	90%	93%	52%
Tier 2 goal -- Percent within 150 Days	*98%*	*98%*	*98%*	*98%*	*98%*
Goal met(yes/no/unknown)	yes	yes	yes	unknown	unknown
Pending Performance-Best Case	98%	98%	98%	99%	100%
Pending Performance-Worst Case	98%	98%	98%	97%	53%
Cohort status	Open	Open	Open	Open	Open



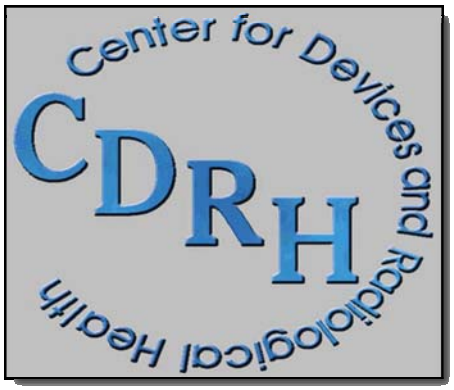
CLIA Waiver by Application Workload October 2012

Fiscal Year	Recommendation	Total FDA Days	Total Mfr Days	Total days
2008	Approved	398		398
		61		61
		248	38	286
		248	38	286
		398		398
	Denied	287		287
		199		199
		189		189
		320	424	744
		129		129
		102		102
	Telephone Hold	136	1590	1726
2008 Count	12			
2009	Approved	233		233
		204	64	268
	Denied	304	908	1212
		740		740
		285		285
		644	7	651
	Telephone Hold	33	1315	1348
2009 Count	7			
2010	Approved	77		77
		105	106	211
	Denied	172		172
		266		266
		248		248
2010 Count	5			
2011	Approved	27		27
		229	97	326
		165	87	252
	me	95	291	386
		95	291	386
2011 Count				
2012	Approved	79		79
		24		24
	Denied	153		153
		235		235
	Request For Additional Information	16	19	35
	Under Review	162		162
2012 Count	**6**			
Grand Total	**35**			

Waiver Report for October 09, 2012

Staff College Internal Training Summary Report

From 07/01/2012 to 9/30/2012



As of: **10/31/2012**

4th Qtr FY12 *(July 1, 2012 – September 30, 2012)* MDUFA-Related Training

FDA continues to invest in internal and external training opportunities supporting the medical devices review process. CDRH's Staff College is a workforce development organization that designs and delivers internal training opportunities to meet the professional needs of FDA staff. As medical device reviews grow increasingly complex, training must keep pace with these advancements. Staff College is committed to leveraging internal and external resources to enhance the training provided to Center staff.

Table X provides a summary of internal training conducted between July 1, 2012 and September 30, 2012. Two hundred Staff College learning events were offered addressing reviewer training, new scientific technologies, law, regulation and guidance updates or leadership and professional development. This training was designed to improve the device review process and support MDUFA goals and activities. Overall, 94% (1310) of the approximately 1400 Center staff participated in training and on average attended 6 (8203÷1310) learning events.

Table X: MDUFA 4th Qtr FY13 CDRH Staff College Internal Training

Category	# of Learning Events	Total # of Participants	Total Contact Hours	Examples of Training Conducted/Attended Between 7/1/12 – 9/30/12
Regulatory and Law (LAW)	118	6388	17376	• MDUFA III Training – Introduction to MDUFA III – 510(k)s – PMAs – Pre-Submissions – CLIA Waivers – Electronic Workload Management • Reviewer Certification Program – Medical Device Law – Basic Food and Drug Law – How to Write Effective Premarket Consulting Reviews – How to Write Deficiencies in Four-Part Harmony • Master Technical Writing: A Plain Writing Workshop
Leadership Education and Development (LED)	18	420	1426	• Crucial Conversations • Negotiation Workshop • Managing Projects and Priorities • Effective Communication as a Leader • Dynamic Mentoring Connections • CDRH Employee/Labor Relations • Delegating and Motivating
Professional Development (PRO)	22	723	3785	• New Employee Orientation • Effective Communication skills for Scientific and Technical Professionals • Managing Projects and Priorities • Organizational Awareness • The 7 Habits of Highly Effective People
Science (SCI)	42	672	2386	• CDRH Science Sharing Seminars – Topics include: – Foundations for Pre-clinical Review – Principles of Carcinogenisis – Electromagnetic Analysis of Deep Brain – Imaging Neural Damage in Real Time – Breast Imaging Research in DIAM – Chemical Analysis of Materials – Software Parallelization Techni2qques • Introduction to Public Health • Adaptive Trail Initiative – Bayesian Statistics • Understanding Pre-market Requirements for MRI Safety • CDRH Industry Forum
*Experiential Learning Program (ELP)	8	112	208	• Topic areas addressed during the ELP site visits include: – Orthopedic and Dental Device Coatings – Implantable Pacemakers/Defibrillators – Patient-matched Technologies – Clinical Trials – Microbiology Manufacturing – Molecular Devices – Diabetes Care Devices
**New Employee Orientation (NEO)	1	38	7	• New Employee Orientation: Discover the Mission, Embrace the Vision
Total:	**200**	**8203**	**24973**	

*** The ELP data has been incorporated under the Law category within the subsequent data charts.**

****The NEO data has been incorporated under the Professional Development category within the subsequent data charts.**

Leadership Readiness Program (LRP) Graduates ROI Update 2012
(Includes iterations for Program Years 2006-2007, 2008-2009, 2010-2011 and 2012-2013)

LRP Program Year	# of Enrolled Participants	# of Participant Completions
2006-2007	OIVD=3 ODE =13 Total = 16*	OIVD = 3 ODE = 12 Total = 15
2008-2009*	OIVD=3 ODE = 10 Total = 30**	OIVD = 3 ODE = 10 Total = 29**
2010-2011	OIVD = 3 ODE = 9 Total = 20**	OIVD = 3 ODE = 8 Total = 19**
2012-2013	OIVD = 3 ODE = 5 Total = 20**	***See Note Below***
Sub total	**OIVD=12** **ODE =37** **Total = 86****	**OIVD = 9** **ODE = 30** **Total = 63****

*This total represents LRP participants from ODE and OIVD. The 2006-2007 LRP consisted of participants from ODE and OIVD only.

**This total represents LRP participants from all CDRH Offices

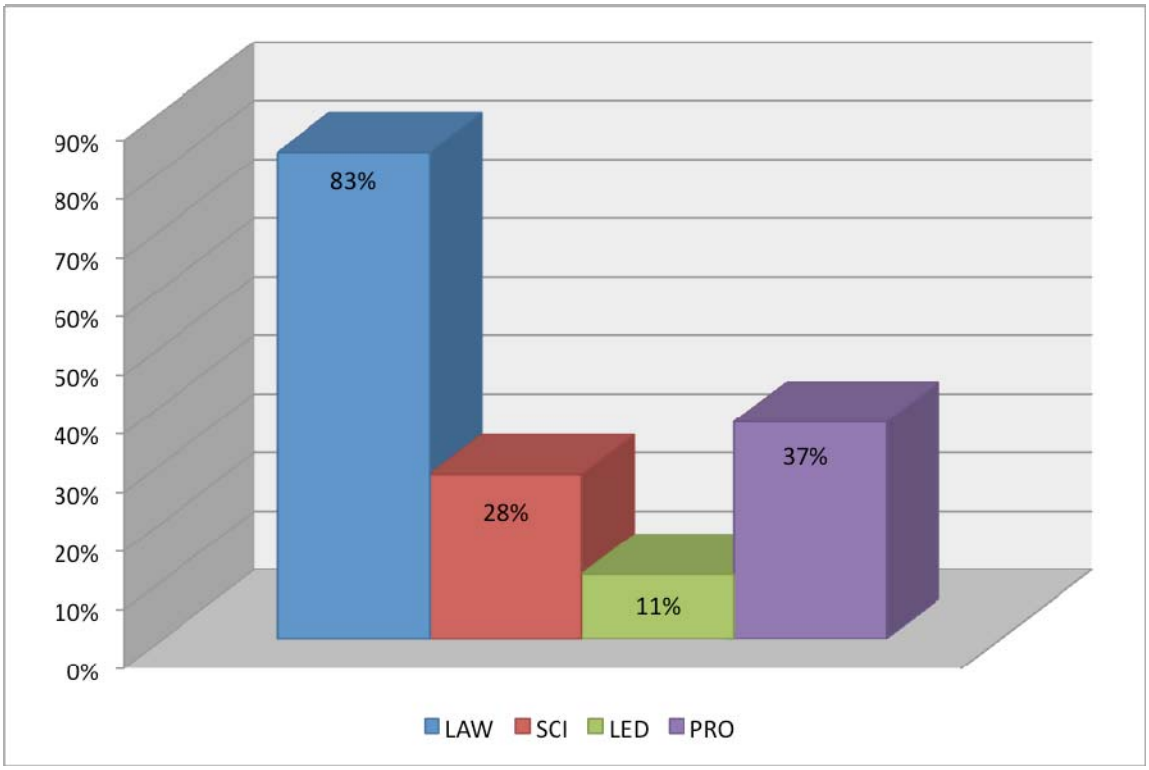
Note: The 2012-2013 LRP Program will be completed in June 2013.

Total Percentage of Unique Center Participation by Category

July 1, 2012 – September 30, 2012

Category	Center Participation (Unique)	% of Center Participation (Unique) *
LAW	1156	83%
SCI	392	28%
LED	150	11%
PRO	518	37%

* 94% (1310) of the approximately 1400 Center staff participated in at least one learning event.

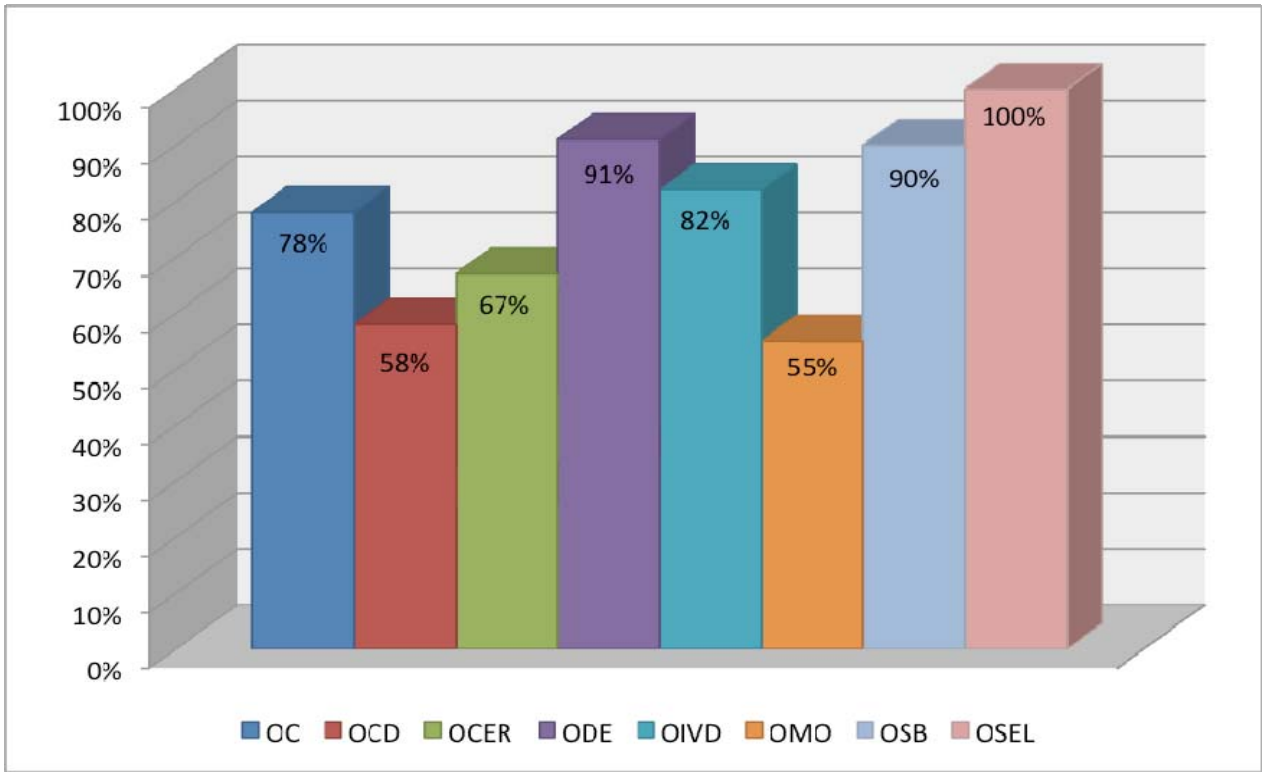


*These numbers indicate the percentage of staff within CDRH (~1400) that participated in at least one learning event for each category.

CDRH FY'12 Percentage of Participant Attendance by Office

July 1, 2012 – September 30, 2012

Office	% of Unique Student Attendance
OC	78%
OCD	58%
OCER	67%
ODE	91%
OIVD	82%
OMO	55%
OSB	90%
OSEL	100%



U.S. Department of Health & Human Services

U.S. Food and Drug Administration

MDUFA Quarterly Performance: Information Technology (IT) Update

Scott McCall

IT Program Manager

Office of the Center Director (CDRH)

November 6, 2012

MDUFA-Related IT Accomplishments (1 of 2)

- **MDUFA III** – Development, testing, and implementation for IT system changes in support of the MDUFA reauthorization
- Legacy Premarket Database Applications (**APPS**)
  - Modified data entry applications for each submission type to reflect the new and updated MDUFA Performance Goals and Procedures
- eCopy for Medical Device Submissions (**eCopies**)
  - Planning, analysis, design, and development of the MDUFA III eSubmitter eCopies tool in anticipation of guidance finalization
- Device Registration and Listing (**FURLS**)
  - Updated the system for MDUFA III's Requirements for Registration and Listing by Establishment Type

MDUFA-Related IT Accomplishments (2 of 2)

- Center Tracking System (**CTS**)
  - Support for Pre-submission document types
  - Support for eCopy changes
  - Additional workflow stages for submissions that include Refuse to Accept (RTA) review, Refuse to File (RTF) review, Substantive Interaction (SI), MDUFA decision, Missed MDUFA Decision (MMD), and Post-MDUFA
  - Tracking and recommendations for Proceed Interactively (PI), Meeting Minutes Amendments, and Minutes Disagreements, etc.
  - An email manager to support MDUFA III documents
- CDRH Document Manager (**DocMan**)
  - Used to support an interactive review process to provide for, and encourage, informal communication between FDA and industry
  - Stores internal, working review documents

Other CDRH IT Accomplishments

- CDRH Entry (**CEntry**)
  - The primary objective of the **CEntry** project is the modernization, in terms of reliability; functionality; quality; and technology, of CDRH's premarket data entry applications and databases.
  - Version 1.0 was released with Pre-Submissions being captured in this new system
  - Future releases will migrate all Legacy Premarket Database Applications into this new technology platform

Establishments by Establishment Type (October 2012)

		Domestic	Foreign	Total
1	Manufacturer	5291	7785	13076
2	Contract Manufacturer	305	726	1031
3	Contract Sterilizer	21	43	64
4	Specification Developer	1599	342	1941
5	Reprocessor of Single Use Devices	16	1	17
6	U.S. Manufacturer of Export Only Devices	133		133
7	Repackager/Relabeler	2030	483	2513
8	Remanufacturer	71	105	176
9	Foreign Exporter	6	1388	1394
10	Initial Distributor/Importer	5639		5639
	Unknown	2		2
	Total:	**15113**	**10873**	**25986**

FY 2012 Appropriations Update

Public Law 112-55, the Fiscal Year 2012 Agriculture, Commerce/Justice/Science (CJS), and Transportation/Housing and Urban Development (THUD) Appropriations bill, also known as the "Mini-bus," included the following funding for the Devices Program:

- Provided $322.672 million in budget authority for the Devices Program. CDRH received $241.475 million.
- Included $20.038 million for the Medical Countermeasures Initiative. CDRH received approximately $3 million of this funding.

FY 2013 Appropriations Update

On September 28, 2012 President Obama signed the Continuing Appropriations Resolution, 2013 (H.J. Res. 117). The continuing resolution:

- Provides funding to the federal government until March 27, 2013.
- The temporary funding measure continues funding at the FY 2012 rate of operations for federal agencies, programs and services.