Priority 1. Fully Implement a Total Product Life Cycle Approach

Strategy 1.1. Enhance and Integrate Premarket, Postmarket, and Compliance Information and Functions

1.1.1. Strengthen Premarket Review

Goal 1.1.1.1. In 2011, CDRH will continue to implement selected recommendations of the 510(k) Working Group.	
• By January 31, 2011, select recommendations to be implemented in 2011, develop implementation plans, and inform constituencies.	
• By June 30, 2011, begin implementation of the selected 2011 recommendations.	
• Within 2 months of IOM 510(k) Report release, complete an evaluation of the IOM recommendations.	
Goal 1.1.1.2. In 2011, CDRH will continue to take steps to address Class III device types currently allowed to enter the market through the 510(k) process.	
• By January 31, 2011, develop and launch a website to inform constituencies about actions that CDRH is taking to address Class III device types currently allowed to enter the market through the 510(k) process.	
• By December 31, 2012, complete classification of the remaining 25 Class III pre-amendment medical devices.	**Ongoing**
Goal 1.1.1.3. By September 30, 2011, CDRH will reassess the standard roles, responsibilities, practices, and procedures for the interactive review process and implement changes as necessary.	
• By April 30, 2011, obtain feedback from constituencies about the strengths and weaknesses of the interactive review process.	
• By June 30, 2011, clarify CDRH roles, responsibilities, and workflow for the interactive review process and improve the business process, if necessary, as well as develop performance goals and accompanying tracking tools.	**Awaiting Outcome of User Fee Reauthorization**
• By November 30, 2011, assess CDRH interactive review process performance and modify as necessary to meet interactive review performance goals.	**Awaiting Outcome of User Fee Reauthorization**

1.1.2. Align Scientific Resources throughout CDRH

Goal 1.1.2.1. By September 30, 2011, CDRH will establish additional policies and procedures to optimally use CDRH's scientific resources to support the Center's programmatic functions.	
• By February 28, 2011, identify FY 2011 CDRH Scientific Priorities using the Center's Science Prioritization Program.	
• By April 30, 2011, develop and begin to implement SOPs for use of Shared Scientific Facilities.	
• By September 30, 2011, conduct an assessment of CDRH's Science Prioritization Program to determine its effectiveness.	
Goal 1.1.2.2. In 2011, CDRH will continue to implement selected recommendations of the Task Force on the Utilization of Science in Regulatory Decision Making.	
• By January 31, 2011, select recommendations to be implemented in 2011, develop implementations plans, and inform constituencies.	
• By June 30, 2011, begin implementation of the selected 2011 recommendations.	

1.1.3. Optimize Data Collection and Analysis

Goal 1.1.3.1. By October 31, 2011, CDRH will implement strategies to increase near real-time adverse event reporting from healthcare providers.	
• By May 31, 2011, complete the MedSun Regional Representative Program expansion by adding 10 more hospitals and 2 additional Regional Representatives.	
• By October 31, 2011, increase by 20 percent the reporting of adverse events in 8 of the 10 new Regional Representative Program hospitals.	
• By October 31, 2011, establish direct submission of reports from MedSun sites to FDA.	
Goal 1.1.3.2. By January 31, 2012, CDRH will increase the use of structured product information to improve the quality of data in regulatory submissions.	
• By June 30, 2011, propose a system for Unique Device Identification of devices.	
• By June 30, 2011, finalize requirements for electronic submission of medical device reports.	

1.1.4. Address Challenges Associated with Globalization

Goal 1.1.4.1. By September 30, 2011, CDRH will have in place mechanisms to further harmonization efforts and exchange medical device information with foreign regulatory authorities.	
• By July 31, 2011, begin to utilize mechanisms for the routine exchange of medical device information with foreign regulatory authorities.	
• By September 30, 2011, establish a forum for global medical device regulators to address the implementation of harmonization efforts, facilitate the exchange of information, and foster collaboration.	
Goal 1.1.4.2. By January 31, 2012, CDRH will make use of Quality Systems Inspections conducted by other countries.	
• By June 30, 2011, begin to implement the Single Audit Initiative to accept third party audit reports.	
• By December 31, 2011, review third party audits conducted for Health Canada (HC) and FDA using the single audit process.	

1.1.5. Enhance Compliance Capability

Goal 1.1.5.1. By September 30, 2011, CDRH will complete and make public its "Case for Quality."	
• By March 31, 2011, finalize a report addressing obstacles to manufacturers' cross-organization integration of quality production practices, including strategies to enhance organization-wide integration of those practices.	
• By September 30, 2011, publicize the findings of the report and begin to conduct outreach to promote cross-organization adoption of best practices.	
Goal 1.1.5.2. By November 30, 2011, CDRH will enhance the efficiency and clarity of the medical device and radiation-emitting product recall processes.	
• By March 31, 2011, develop strategies to improve notification and classification of recalls.	

• By October 31, 2011, begin implementation of the identified strategies.	
• By August 31, 2011, clear within CDRH a draft guidance document describing the difference between modifying non-violative products to enhance performance versus modifying a product to correct safety or efficacy failure.	
Goal 1.1.5.3. By November 30, 2011, CDRH will streamline the warning letter development, clearance, and closure process.	
• By May 31, 2011, develop strategies to improve the development and clearance of warning letters to reduce the time between the identification of a violation that warrants a warning letter and the issuance of the letter.	
• By October 31, 2011, begin implementation of the identified strategies.	

PRIORITY 2. ENHANCE COMMUNICATION AND TRANSPARENCY

Strategy 2.1. Implement a Strategic Approach to Stakeholder Communication and Improve Communication with CDRH Staff

Goal 2.1.1. By September 30, 2011, CDRH will implement the CDRH Strategic Communication Program.	
• By February 28, 2011, establish clear roles and responsibilities among Center offices for managing external communications, including communications liaisons in each office at the Center to support the flow of important decisions, initiatives and actions.	
• By April 30, 2011, establish a means for tracking communications with our constituencies, identify feedback mechanisms and expand our external stakeholder contacts.	
• By June 30, 2011, begin to implement selected recommendations from CDRH's Environmental Assessment and staff feedback to improve internal communication	

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Strategy 2.2. Increase Transparency and Facilitate External Communications

Goal 2.2.1. By September 30, 2011, CDRH will take steps to strengthen information exchange and improve gathering feedback from our external constituencies.	
• By June 30, 2011, convene at least two Stakeholder Forums for patients and consumers and health care professionals to engage in dialogue about issues of interest to them.	
• By September 30, 2011, explore the feasibility of establishing a CDRH Policy Advisory Council to gain feedback on Center strategy, policy, and priority setting.	

Priority 3. Strengthen Our Workforce and Workplace

Strategy 3.1. Develop a Life Cycle Approach to CDRH Employee Education

Goal 3.1.1. By December 31, 2011, CDRH will develop a pilot for a Hands-on/Experiential Learning Program for employees, which provides practical experience through personal involvement in real-world development and use of medical devices.	
• By April 30, 2011, review options and begin to develop a pilot for a Hands-on/Experiential Learning Program.	
• By December 31, 2011, begin to implement a pilot for a Hands-on/Experiential Learning Program.	
Goal 3.1.2. By December 31, 2011, CDRH will develop and begin to implement strategies to support a life cycle approach to employee education.	
• By September 30, 2011, develop resource tools and job aids in support of CDRH's New Employee Orientation and Supervisory Training Programs.	
• By December 31, 2011, begin to implement a CDRH New Employee Orientation Program as recommended by the CDRH's Environmental Assessment and staff feedback .	
• By December 31, 2011, begin to implement a formal CDRH Supervisory Training program as recommended by the CDRH's Environmental Assessment and staff feedback.	
Goal 3.1.3. By December 31, 2011, CDRH will begin to develop core competencies, recommended coursework, and other formal programs for job-functions in support of "Employee Life Cycle" education.	
• By February 28, 2011, finalize core competencies and recommended coursework for premarket reviewers and medical officers and post on the Staff College website.	
• By March 31, 2011, begin to develop core competencies and recommended coursework for engineers, consumer safety officers and general health scientists.	
• By December 31, 2011, finalize core competencies and recommended coursework for engineers, consumer safety officers and general health scientists and post on the Staff College website.	

Strategy 3.2. Promote Transparent Employee Performance Review and Meaningful Recognition

Goal 3.2.1. By December 31, 2011, CDRH will develop and implement SOPs for managers and staff that promote more transparent and meaningful performance reviews.	
• By April 30, 2011, provide CDRH staff with a comprehensive overview of the DHHS Performance Management Appraisal Program (PMAP).	
• By April 30, 2011, collect input from CDRH employees about CDRH's implementation of DHHS's PMAP and solicit recommendations for improvement.	
• By July 31, 2011, develop SOPs for CDRH's implementation of DHHS's PMAP.	
• By July 31, 2011, develop standard criteria by which CDRH will evaluate managers on leadership performance and identify a feedback mechanism for employees to provide input on management performance.	 **Pilot Program Underway**
• By December 31, 2011, complete manager and staff training and implement the SOPs in preparation for 2012 performance period.	**Awaiting Pilot Program Results**

Strategy 3.3. Improve Workload Management

Goal 3.3.1.	By December 31, 2011, CDRH will develop and implement SOPs and training on workload management for managers and staff.
• By June 30, 2011, develop SOPs for how to effectively manage staff and managers' workload. The SOPs would include (1) ways in which to improve employee time management, such as ways to optimally organize the work week, appropriate use of emails; and (2) methods for accepting, prioritizing, and redistributing workload between staff and across organizational units.	 TRAINING FOR MANAGERS AND STAFF WILL BE MANAGED BY CDRH STAFF COLLEGE.
• By September 30, 2011, develop training modules for the workload management SOPs.	 TRAINING FOR MANAGERS AND STAFF WILL BE MANAGED BY CDRH STAFF COLLEGE.
• By December 31, 2011, complete manager and staff training and implement the SOPs.	 TRAINING FOR MANAGERS AND STAFF WILL BE MANAGED BY CDRH STAFF COLLEGE.

Strategy 3.4. Develop Meaningful Metrics

Goal 3.4.1	By December 31, 2011, CDRH will develop and begin to implement metrics to assess the impact of key Center activities.
• By February 28, 2011, select key Center activities for which developing metrics will help us improve our public health goals.	
• By June 30, 2011, complete development of metrics and accompanying monitoring tools for all efforts under the pilot, and begin to collect data.	

Priority 4. Proactively Facilitate Innovation and Address Unmet Public Health Needs

Strategy 4.1. Foster the Development of Innovative Medical Devices

Goal 4.1.1. By September 30, 2011, CDRH will take additional steps to facilitate the development of innovative medical devices and medical devices to address unmet public health needs.	
• By June 30, 2011, provide a progress report on at least 2 pilot programs developed to address unmet public health needs identified by the Council on Medical Device Innovation and provide an updated list of the top 5 unmet public health needs that could be cured, significantly improved, or prevented by the development or redesign of a medical device.	 CONSOLIDATED WITH INNOVATION EFFORTS
• By September 30, 2011, identify the barriers to utilization and optimal performance of CDRH's expedited review process and propose solutions.	
• By September 30, 2011, identify external partners and hold a public workshop to promote advances in medical device computational modeling and simulation.	
• By September 30, 2011, identify the initial steps necessary to establish at least one medical device regulatory science public-private partnership.	
Goal 4.1.2. By December 31, 2011, CDRH will establish a framework for the use of published literature as sufficient evidence to support pediatric device claims.	
• By June 30, 2011, hold a public workshop to solicit input from constituencies on the use of published literature and registries as sufficient evidence to support pediatric device claims.	
• By December 31, 2011, clear within CDRH a white paper on the use of published literature and registries as sufficient evidence to support pediatric device claims.	STARTED
Goal 4.1.3. By July 31, 2011, CDRH will develop and implement a Medical Device Innovation Initiative to facilitate the development and regulatory evaluation of innovative medical products.	
• By February 28, 2011, develop an Innovation Initiative white paper outlining additional steps CDRH can take to facilitate innovative product development such as expediting first-in-human trials and streamlining CDRH's review of innovative products.	
• By May 31, 2011, solicit feedback from constituencies on the proposed steps outlined in the Innovation Initiative.	
• By July 31, 2011, begin implementation of identified steps.	

Strategy 4.2. Develop a Personalized Medicine Program

Goal 4.2.1. By March 31, 2011, CDRH will establish a framework for the review of submissions addressing genomic tests.	
• By January 31, 2011, finalize a framework for validation and review of array CGH applications.	
• By March 31, 2011, hold a public meeting to provide advice and recommendations to the Agency on scientific, clinical practices, and other issues that will inform FDA's regulatory actions on Direct to Consumer (DTC) genetic testing indications.