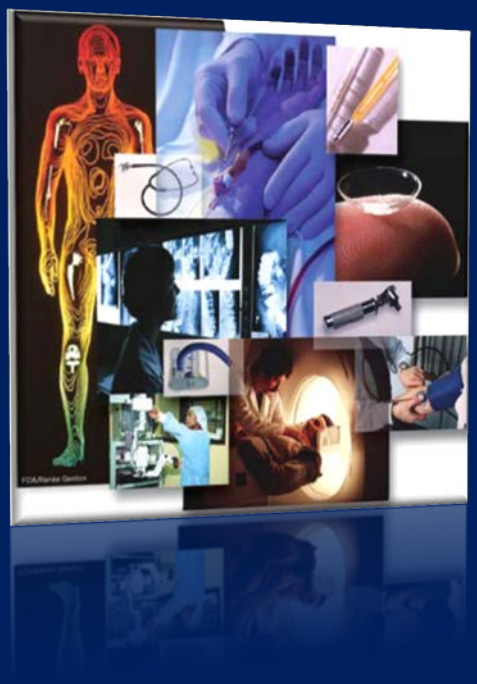

2014-2015 STRATEGIC PRIORITIES

2014 UPDATE

"Patients are at the heart of what we do."

The Center for Devices and Radiological Health's (CDRH) 2014-2015 Strategic Priorities describe the most important areas we are focusing on because they are critical to achieving our vision – that patients in U.S. have access to high-quality, safe and effective medical devices of public health importance first in the world. Our strategic priorities are: strengthen the clinical trial enterprise; strike the right balance between premarket and postmarket data collection; and provide excellent customer service. We hold ourselves accountable for implementing our priorities by achieving measurable outcomes and reporting our performance to the public.

STRENGTHEN THE CLINICAL TRIAL ENTERPRISE

CDRH is committed to improving U.S. patient access to high quality, safe and effective new devices by strengthening and streamlining the clinical trial enterprise so that medical device clinical trials are conducted in the U.S. in an efficient and cost-effective manner, while maintaining appropriate patient protections.

SUPPORTING ACTIONS

In 2014 CDRH took several actions to expedite the safe initiation of clinical trials in the U.S. and achieve the goals set for this priority

Clinical Trials Program Establish in the Office of Device Evaluation a premarket clinical trials program responsible for the oversight and performance of the IDE Program and the development and implementation of policies that contribute to the timely initiation and successful execution of medical device clinical trials.

✓ CDRH established the Clinical Trials Program, and appointed an acting director on February 9, 2014.

Education and Training Develop a clinical trials education and training program for CDRH review staff, managers, and industry.

✓ CDRH offered extensive education and training for CDRH review staff, managers and industry. The center issued guidance documents explaining FDA IDE decisions and introducing CDRH's new Early Feasibility Study (EFS) program. Both guidance documents were accompanied by public webinars. CDRH also held several internal training sessions on IDE decisions, EFS, and the IDE SOP referenced below.

In-Progress CDRH is currently developing a comprehensive training program for review staff. CDRH is also developing a web-based training module for internal and external stakeholders focused on the EFS program.

Improve the efficiency, consistency, and predictability of the IDE process to reduce the time and number of cycles needed to reach appropriate IDE full approval for medical devices, in general, and for devices of public health importance, in particular.

2014 Targets	Results
25% By September 30, 2014, reduce the number of IDEs requiring more than two cycles to an appropriate full approval decision by 25 percent compared to FY 2013 performance.	**34%** Compared to FY 2013, the number of IDE studies requiring more than two cycles to reach full approval in FY14 decreased by 34 percent. (as of October 31, 2014)
25% By September 30, 2014, reduce the overall median time to appropriate full IDE approval by 25 percent compared to FY 2013 performance.	**53%** Compared to FY 2013, the FY 2014 overall median time to full IDE approval decreased by 53 percent. (as of October 31, 2014)
Meeting to Occur within 10 Days By September 30, 2014, for disapproved IDEs, offer all sponsors a teleconference or in person meeting to occur within 10 business days of the IDE decision.	**100% in the last 5 months of FY 2014** A teleconference was offered to occur within 10 business days for 100 percent of disapproved IDEs for the last 5 months of FY 2014. Overall, since this program started, CDRH had missed this goal only once.

Benefit-Risk Framework Formalize the incorporation of our benefit-risk framework, including patient-specific factors such as tolerance for risk and perspective on benefit, into the IDE process.

✓ CDRH has developed a benefit-risk framework for IDEs.

In-Progress CDRH will issue draft guidance documents on benefit-risk determinations for IDEs and on Adaptive Clinical Studies in FY 2015.

Multi-Cycle IDEs Establish a process to efficiently and objectively resolve application-specific IDE issues to reduce the number of multi-cycle IDEs.

✓ CDRH developed a standard operating procedure entitled "Review of Investigational Device Exemption Application-Specific Issues", which took effect on March 1, 2014.

Metrics Develop real-time metrics to track CDRH and industry IDE and clinical trial performance.

✓ CDRH has established metrics so that Center management and staff can monitor IDE program performance and so that IDE performance can be publicly reported.

Strike the Right Balance between Premarket and Postmarket Data Collection

It is critical that we strike the right balance between premarket and postmarket data collection. If we can shift—when appropriate—some premarket data needs to the postmarket setting, we can directly impact patient access to high-quality, safe, and effective medical devices of public health importance.

Supporting Actions

In 2014 CDRH took several actions to achieve a total life cycle approach to understanding the benefit-risk profile of medical devices and strike the right balance between premarket and postmarket data collection.

Assure the appropriate balance between premarket and postmarket data requirements to facilitate and expedite the development and review of medical devices, in particular high-risk devices of public health importance.

2014 Targets	Results
50% By December 31, 2014, review 50 percent of device types subject to a PMA that have been on the market to determine whether or not to shift some premarket data requirements to the postmarket setting or to pursue down classification, and communicate those decisions to the public.	**69%** In 2014, CDRH reviewed 69 percent of device types subject to a PMA that have been on the market.

Balancing Premarket and Postmarket Data Collection

Develop and seek public comment on a framework for when it is appropriate to shift premarket data collection to the postmarket setting.

✓ On April 24, 2014 CDRH issued a draft guidance document outlining how FDA considers the role of postmarket information in determining the extent of data that should be collected in the premarket setting to support premarket approval, while still meeting the statutory standard of reasonable assurance of safety and effectiveness.

In-Progress CDRH will issue final guidance on balancing premarket and postmarket data collection in FY 2015.

Retrospective Review of all PMAs

Conduct a retrospective review of all PMA device types to determine whether or not to shift some premarket data requirements to the postmarket setting or to down classify device types in light of our current understanding of the technology.

✓ CDRH exceeded its 2014 goal of reviewing 50 percent of all PMA device types to determine whether or not to shift some premarket data requirements to the postmarket setting or to down classify device types in light of our current understanding of the technology. CDRH reviewed 69 percent of all PMA devices types in 2014.

In-progress By April 15, 2015 we will communicate to the public our current thinking on the already reviewed device types.

Expedited Access PMAs (EAP)

Using existing authorities, develop and seek public comment on a new pathway to market for devices subject to a PMA that address an unmet public health need by shifting appropriate premarket data needs to the postmarket setting and incorporating features of the Innovation Pathway pilots.

✓ On April 24, 2014 CDRH issued a draft guidance document proposing a new, voluntary program (EAP Program) for certain higher risk medical devices that demonstrate the potential to address unmet medical needs for life-threatening or irreversibly debilitating diseases or conditions and are subject to a PMA.

In-Progress CDRH will issue final EAP guidance in FY 2015.

PROVIDE EXCELLENT CUSTOMER SERVICE

Excellent customer service means understanding and addressing, as appropriate, stakeholders' and colleagues' needs through active listening, problem solving, seeking out the ideas of others, explaining the rationale for our decisions and requests for information, being respectful and knowledgeable, learning from our mistakes, and doing our best. Providing excellent customer service improves our interactions with stakeholders and colleagues and supports better regulatory outcomes, thereby improving patient health.

SUPPORTING ACTIONS

In 2014 CDRH took several actions aimed at providing excellent customer service.

Customer Service Standards of Excellence

Implement Customer Service Standards to promote excellent customer service.

✓ On February 5, 2014 CDRH implemented the CDRH Customer Service Standards of Excellence.

In-Progress On March 2014, CDRH began training all staff in customer service techniques and quality management basics. In 2014, over 90 percent of staff completed the mandatory training. CDRH expects to train all staff by January 2015.

Customer Service Survey

Assess customer satisfaction using a standardized survey tool embedded in emails and available on our website.

✓ On June 16, 2014 CDRH launched its Customer Service Survey to gather feedback about interactions with CDRH.

✓ On August 4, 2014, CDRH began sharing real-time results of our Customer Service survey with the public.

Provide excellent customer service.

2014 Targets	Results
70% By December 31, 2014, achieve at least 70 percent customer satisfaction.	**83%** In 2014 CDRH's rating was 83 percent.

FEEDBACK✓CDRH

Establish a CDRH program to monitor and address feedback on CDRH processes and services and improve quality and performance that includes corrective action and preventative action (CAPA) processes.

✓ On August 25, 2014, CDRH began to pilot FEEDBACK✓CDRH, a program to collect, monitor, and address feedback received from staff and external stakeholders. This program complements the CDRH Customer Service Survey, which has been collecting feedback from internal and external customers since its launching on June 16, 2014.

In-Progress FEEDBACK✓CDRH will transition from pilot to established program beginning February 2, 2015.

CDRH Quality Management Framework

Implement the principles and practices outlined in the CDRH Quality Management Framework to improve the quality and performance of CDRH processes and services.

✓ On January 24, 2014 CDRH issued the CDRH Quality Management Framework to facilitate establishment of the CDRH Quality Management Program. In July 2014, CDRH hired a Director of Quality Management to oversee the adoption of quality management in CDRH.

In-Progress As part of the 2012 Medical Device User Fee Amendments (MDUFA III), the Food and Drug Administration (FDA) agreed to participate with the medical device industry in a comprehensive assessment of the process for device submission review. Recognizing adoption of quality management is critical to standardizing process lifecycle management activities and improving consistency of premarket reviews, the Plan of Action CDRH is implementing in response to the independent contractor's findings and recommendations incorporates principles and practices outlined in the with the CDRH Quality Management Framework.