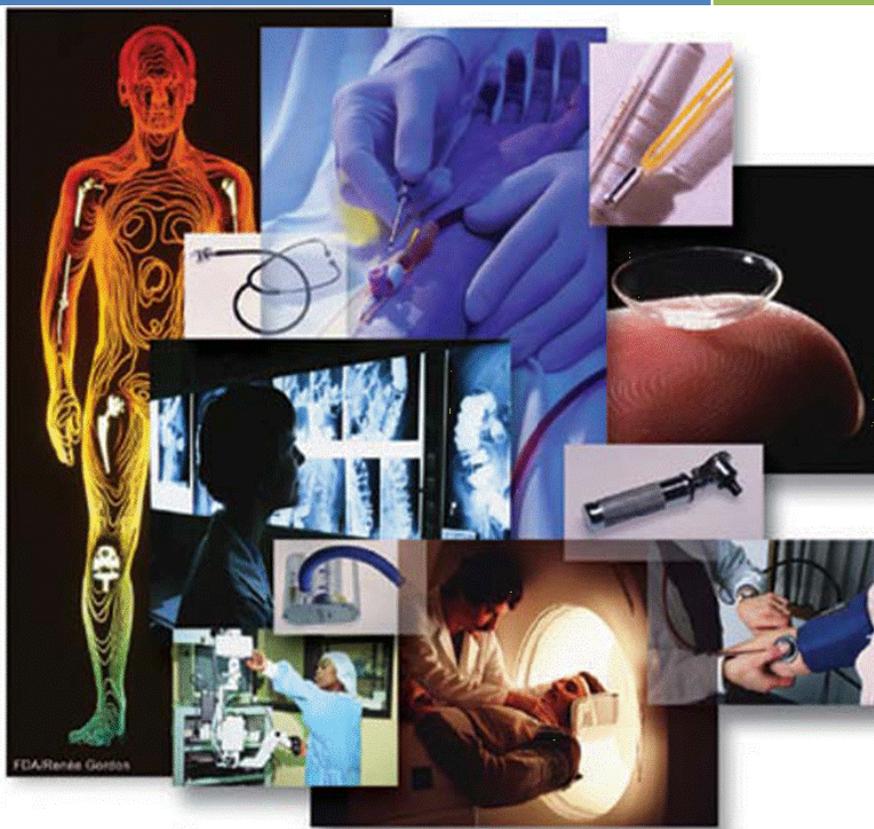


Center for Devices and Radiological Health

2013 Strategic Priorities



U.S. Food and Drug Administration
U.S. Department of Health and Human
Services

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Introduction

The Center for Devices and Radiological Health's (CDRH, the Center) 2013 Strategic Priorities continue and expand upon the work we first started three years ago to reset the direction of the Center towards smart regulation – protecting public health by assuring that devices that enter and remain on the U.S. market are safe and effective, and promoting public health by facilitating device innovation. However, the structure of this year's Strategic Priorities has been re-organized to align with CDRH's Vision, which, along with our Mission and Shared Values, immediately follow this Introduction. You will note that our Vision begins with the word *Patients*. We intentionally began our Vision with this word because what is at the heart of what we do and what we truly are about is saving the lives, improving the health and enhancing the quality of life of patients and those who one day will or would have been patients.

Although we have re-aligned our Strategic Priorities to support the achievement of our Vision, you will see that the objectives of our [2010-2012 Strategic Priorities](#) (such as fully implementing a total product life cycle approach) are encompassed within our 2013 plan. In addition, we have kept our earlier Strategic Priority of *Strengthening Our Workforce and Workplace* in the 2013 plan, consistent with the Center's Shared Value of *Our People*. A vibrant workforce and workplace are essential to achieving our Mission and Vision.

The primary purpose of CDRH's 2013 Strategic Priorities is to inform the public of some of the most important actions we are committing to implement this year to better understand the direction the Center is heading in and what to expect from us this year. It is not intended as a comprehensive blueprint of every action the Center may take in the coming months.

Lastly, in July 2012, Congress enacted the [Food and Drug Administration Safety and Improvement Act \(FDASIA\)](#), which includes reauthorization of the [medical device user fee program](#) and other device-related provisions. We consider implementation of FDASIA to be a top priority for CDRH. Therefore, as a well understood priority, we will implement or begin to implement all of the device-related provisions of FDASIA this year. However, because the FDA has provided a separate mechanism to inform the public of its efforts to implement FDASIA, we have generally not included actions specifically directed at implementing FDASIA in our 2013 Strategic Priorities.

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Mission *The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote the public health. We assure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices.*

Vision *Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world. The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety. U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance. Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality. Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.*

Shared Values

Public Health Focus• We focus on activities and outcomes that protect and promote public health.

Our People• Our staff is our most critical resource. We value individual excellence, teamwork, and personal and professional diversity.

Science-Based Decisions• We make decisions based on sound science using the best available data, methods, information, and tools. We value and take into account differing internal and external perspectives.

Innovation• We challenge the status quo and ourselves to foster positive change. We harness the creativity of our staff and stakeholders. We rapidly test and adopt new approaches to more effectively and efficiently accomplish our mission.

Honesty and Integrity• We maintain the public trust by acting with integrity and honesty. Our actions adhere to the highest ethical standards and the law.

Accountability• We hold ourselves accountable for the actions we do and do not take. We acknowledge our errors and learn from them.

Transparency• We foster public trust and predictability by providing meaningful and timely information about the products we regulate and the decisions we make.

Priority 1.
Patients in the U.S.
have access to
high-quality, safe,
and effective
medical devices of
public health
importance first in
the world.

Strategy 1.1. Strengthen our pre-market review programs

CDRH will improve the quality and consistency of our science-based decision making and provide the regulated industry with predictable pathways for the approval of new products.

Goal 1.1.1. In 2013, CDRH will continue implementation of the plan of action to strengthen pre-market review.

- By September 30, 2013, finalize all already issued draft guidance documents identified in the plan of action to strengthen pre-market review, with the exception of the guidance on deciding when to submit a 510(k) for a change to an existing medical device.
- By August 31, 2013, collect public input on deciding when to submit a 510(k) for a change to an existing device, i.e., 510(k) modifications.

Goal 1.1.2. By December 31, 2013, CDRH will take steps to modernize the infrastructure and processes for the review of pre-market applications.

- By March 31, 2013, improve management of pre-market review content and processes by incorporating commercial technologies and standardized information management practices.
- By December 31, 2013, launch a pilot with industry for the electronic submission of 510(k)s.

Priority 1.
Patients in the U.S.
have access to
high-quality, safe,
and effective
medical devices of
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importance first in
the world.

Strategy 1.2. Strengthen and streamline the clinical trial enterprise

Medical device clinical trials will be conducted in the U.S. in a safe, efficient, least burdensome, and cost-effective manner.

Goal 1.2.1. By September 30, 2013, CDRH will take steps to reduce the time and cost associated with the conduct of clinical trials in the U.S. while maintaining patient protection.

- By June 30, 2013, using the Entrepreneurs in Residence (EIR) program, begin a pilot project focused on reducing the time and cost of medical device clinical trials.
- By September 30, 2013, develop policies to facilitate better and more efficient use of existing registries for pre-market studies.

Strategy 1.3. Advance adoption of connected health care

CDRH will work collaboratively with our federal government partners and external constituencies to foster the development and adoption of connected health care, an innovative, patient-focused health care environment where medical devices and information technology provide increased opportunities for the delivery of care outside of traditional settings.

Goal 1.3.1. By September 30, 2013, CDRH will advance the adoption of connected health care by fostering innovative solutions and technology.

- By September 30, 2013, publish a report identifying opportunities to foster innovative solutions and technology in a connected health care environment.

Priority 1.
*Patients in the U.S.
have access to
high-quality, safe,
and effective
medical devices of
public health
importance first in
the world.*

Strategy 1.4. Strengthen the regulatory pathway from product concept to patient access

CDRH will work collaboratively with our federal government partners and external constituencies to reduce the time between pre-market approval and patient access to innovative medical devices.

Goal 1.4.1. By September 30, 2013, CDRH will take steps to streamline the pathway from FDA approval to reimbursement.

- By June 30, 2013, using the Entrepreneurs in Residence (EIR) program, begin a pilot project focused on ways to streamline the regulatory pathway from FDA approval to reimbursement.

Strategy 1.5. Further develop CDRH's Personalized Medicine Program

CDRH will work collaboratively with our federal government partners and external constituencies to assure the appropriate regulatory oversight of therapeutics and diagnostics when their safety and effectiveness are intimately tied to one another.

Goal 1.5.1. By September 30, 2013, CDRH will take steps to enhance the field of personalized medicine by defining the appropriate regulatory paths for diagnostic devices that are intrinsically tied to a therapeutic and for novel diagnostic devices.

- By March 31, 2013, issue the companion diagnostics final guidance.
- By September 30, 2013, issue a co-development draft guidance.
- By September 30, 2013, as part of the genomics standards development with the National Institute of Standards and Technology, select and sequence the human DNA and microbial DNA reference materials to support analytical validation of genetic sequencing technologies.

Priority 2.
The U.S. is the world's leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety.

Strategy 2.1. Strengthen our national regulatory science infrastructure

CDRH will work collaboratively to facilitate the development of innovative, safe and effective medical devices and advance regulatory science.

Goal 2.1.1. By September 30, 2013 CDRH will enhance our efforts to anticipate emerging technological trends and public health challenges and partner with federal and external constituents to advance medical device regulatory science.

- By September 30, 2013, facilitate the development of three Medical Device Innovation Consortium Subcommittees focused on the medical device subsector.
- By September 30, 2013, develop a framework for qualifying medical device development tools (MDDTs).
- By September 30, 2013, modify our horizon scanning system for new and emerging technologies from a periodic to a continuous system and expand public input to better inform regulatory science research prioritization and to better prepare CDRH to address new technologies.

Strategy 2.2. Strengthen CDRH's Radiological Health Program

As part of a balanced public health approach, CDRH will support the benefits of medical imaging exams while minimizing the risks to help assure that patients will get the right imaging exam, at the right time, with the right radiation dose.

Goal 2.2.1. By September 30, 2013, CDRH will develop recommendations for manufactures on how to reduce patient exposure to unnecessary ionizing radiation, including pediatric populations.

- By March 31, 2013 issue the final guidance on pediatric X-ray imaging.
- By September 30, 2013 issue draft guidance on computed tomography (CT).

Priority 3.
U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance.

Strategy 3.1. Strengthen our national system for medical device post-market surveillance

CDRH will enhance post-market tools and implement new initiatives that will help realize CDRH's vision for post-market surveillance.

Goal 3.1.1. By September 30, 2013, CDRH will begin to implement a comprehensive strategy to assess real world device performance.

- By February 28, 2013, establish a governance board for the Medical Device Epidemiology Network (MDEpiNet) public-private partnership.
- By January 31, 2013, publish next steps to establish a national system for medical device post-market surveillance, taking into consideration public feedback on the September 2012 proposed strategy and four-day public meeting.
- By September 30, 2013, establish a Center-wide signal management program for the timely evaluation and management of significant post-market signals.

Goal 3.1.2. By September 30, 2013, CDRH will take steps to strike the right balance between pre-market and post-market evidentiary requirements.

- By June 30, 2013, using the Entrepreneurs in Residence (EIR) program, begin a pilot project focused on ways to strike the right balance between pre-market and post-market evidentiary requirements.

Priority 4.
Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.

Strategy 4.1. Advance the Case for Quality Initiative

CDRH policies will go beyond compliance with regulations to an enhanced focus on quality device manufacturing.

Goal 4.1.1. By December 31, 2013, as part of the continued implementation of the Case for Quality initiative, CDRH will identify and prioritize systemic practices that advance device quality. CDRH will also increase the transparency and utility of device quality data and enhance FDA-external constituent engagement regarding device quality.

- By September 30, 2013, in collaboration with external constituents, identify and publicize systemic practices that are linked to device quality outcomes, including steps that CDRH and external constituents can take to support and adopt these practices.
- By September 30, 2013, publicize two quality-related medical device data analyses, such as trends in the types and root causes of device recalls.
- By December 31, 2013, inform quality-related regulatory decisions through focused discussions with external constituents at two national forums and one local forum.

Strategy 4.2. Establish a Voluntary Compliance Improvement Pilot Program

Working with FDA, certain manufacturers at risk of compliance action due to regulatory violations will be allowed to enter remediation agreements with the agency to achieve improved performance.

Goal 4.2.1. By September 30, 2013, CDRH will take steps to move certain manufacturers at risk of compliance action due to regulatory violations to a state of improved performance by allowing these manufacturers to enter into a remediation agreement with the agency, including action plans developed by the manufacturers and approved by FDA.

- By September 30, 2013, launch the Voluntary Compliance Improvement Pilot Program.

Priority 4.
Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality.

Strategy 4.3. Address challenges associated with globalization

CDRH will further medical device harmonization and regulatory convergence to enhance public health protection.

Goal 4.3.1. In 2013, CDRH will continue the development of a multi-lateral medical device single audit program, which will allow a single audit of a medical device manufacturer to be used by multiple regulators to assess the manufacturer's quality operation.

- By September 30, 2013, in collaboration with foreign regulatory authorities, develop the Medical Device Single Audit Program (MDSAP) Acceleration Plan.
- By September 30, 2013, present the plan for approval by the MDSAP Regulatory Authority Council to allow a MDSAP-recognized auditing organization to perform audits that will meet the needs of multiple regulatory jurisdictions in a pilot program in 2014.

Goal 4.3.2. In 2013, CDRH will continue working with the International Medical Device Regulators Forum (IMDRF) to accelerate international medical device regulatory harmonization and convergence.

- By November 30, 2013, as a member of the Regulatory Product Submission Workgroup, present to IMDRF Management Committee draft Tables of Contents for medical device and vitro medical device for common regulatory submissions.
- By November 30, 2013, as a member of the Unique Device Identification (UDI) Workgroup, present to IMDRF Management Committee a draft IMDRF guidance document on UDI to update the September 2011 Global Harmonization Task Force (GHTF) document entitled "Unique Device Identification (UDI) System for Medical Devices."
- By November 30, 2013, as the chair of the Medical Device Single Audit Program Workgroup, present to IMDRF Management Committee a draft final IMDRF guidance document on the "Recognition Criteria for Medical Device Auditing Organizations."

Priority 5.
Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.

Strategy 5.1. Improve the accessibility and usefulness of device labeling

Device labeling will be readily accessible and provide the information professional and lay users need to assure safe and effective use of medical devices.

Goal 5.1.1 By September 30, 2013, CDRH will propose initiatives to improve consistency, usefulness, and accessibility of labeling for home use devices.

- By December 31, 2012, publish draft guidance on home use medical devices.
- By September 30, 2013, publish a proposed rule to establish an online repository of labeling for home use devices.

Goal 5.1.2. By June 30, 2013, CDRH will assess device user needs to determine adequacy of current labeling practices and initiate discussion about content and format of device labeling.

- By June 30, 2013, complete study of users of device labeling.
- By June 30, 2013, hold public workshop with multiple stakeholder groups to discuss study findings, an on-line repository, and a standard content and format of device labeling.

Strategy 5.2. Explore the use of social media for gathering and sharing information with external constituents

CDRH will explore methods to monitor and contribute to social media conversations about medical devices and radiation-emitting products in order to provide meaningful and timely information about the products we regulate and the decisions we make.

Goal 5.2.1. By September 30, 2013, CDRH will take steps to incorporate the use of social media into CDRH communication processes.

- By April 30, 2013, conduct and evaluate a social media utilization pilot.
- By September 30, 2013, develop and begin to implement a plan for incorporating social media into the CDRH communication process.

Priority 6. Strengthen Our Workforce and Workplace

Strategy 6.1. Enhance employee engagement

CDRH recognizes the value of our employees and provides a workplace environment that supports productivity.

Goal 6.1.1. By September 30, 2013, CDRH will develop and begin to implement a plan of action to address the recommendations from the Employee Satisfaction Workgroup.

- By September 30, 2013, develop and begin to implement a plan to optimize the use of CDRH resources available for learning opportunities and travel.
- By September 30, 2013, develop and begin to implement a plan to improve internal communication, increase transparency and assure that staff are connected to the Center.
- By September 30, 2013, develop and begin to implement a plan to improve the selection and nomination process for CDRH Honors Awards.
- By September 30, 2013, develop and begin to implement a plan to improve staff recognition for good performance and to appropriately address poor performance.