2024
CDRH Safety Report

CDRH is committed to advancing the core pillars of medical device safety and innovation to protect, promote, and encourage public health for all.

U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health

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Introduction

Although medical devices provide great benefits to patients, they also present risks. CDRH's public health responsibilities span the life cycle of medical devices and, at every stage, we must make well-supported regulatory decisions, taking into account the totality of available evidence, to determine whether the benefits outweigh the risks.

CDRH strives to permit marketing of only devices with a favorable benefit-risk profile, but not all information regarding the benefits and risks of a device is available, nor can it be generally known, before a device reaches the market.

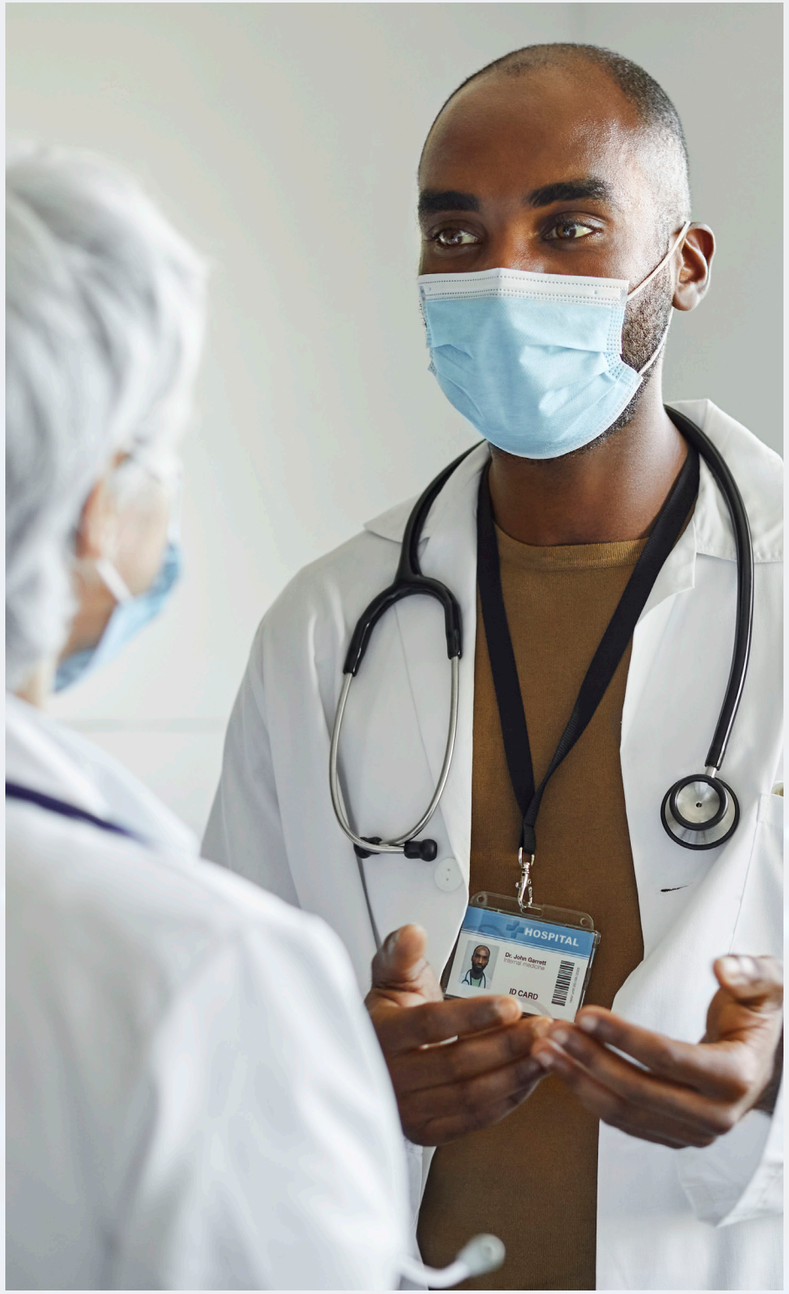
New information about the device's safety, such as reports of unexpected adverse events, may become available once the device is more widely distributed and used under real-world conditions, including routine clinical practice and in the home setting, as well as in broader patient populations, and by a broader range of clinicians. New information may also become available if risks associated with a device change, such as when modifications to a device introduce new or increased known risks, or changes in manufacturing adversely affect the quality of a device.

As noted in our **companion report on medical device innovation**, over a decade ago, CDRH established a new vision for the Center based on our two pillars of safety and innovation. We took an approach that both advances and interweaves our innovation and safety priorities. As device technology continues to evolve and the types of medical devices expand exponentially, we are mindful that the ways in which we assure reasonable device safety must also keep pace. Therefore, in parallel to our efforts to advance device innovation, we took and continue to take actions to improve the safety and our ability to identify and address new safety concerns of devices.

CDRH Vision

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

Our vision does not signal a competition with other countries, but rather, provides a metric for timely patient access to devices that meet the FDA's standards.



Enhancing Manufacturing Quality

One of CDRH's top priorities is a focus on the design and manufacture of high-quality devices, which can better protect and promote the public health. CDRH has continued to take appropriate steps, including enforcement actions, to assure product quality and compliance by manufacturers for the more than 257,000 different types of medical devices on the U.S. market and nearly 22,000 device manufacturing firms worldwide. As part of this commitment, we have worked proactively to help manufacturers identify and prevent problems before they occur, adapt to changes in science and technology, and rapidly address events that impact safety. This requires a shared responsibility among the FDA, industry, practitioners, and patients to evaluate and adjust continuously across the life cycle of a device. CDRH continues to explore ways to spur a competitive marketplace for device quality and innovation toward higher quality medical devices.

Launched the **Case for Quality Program** to elevate the focus of all medical device stakeholders from baseline regulatory compliance to sustained, predictive practices that advance medical device quality and safety to achieve better patient outcomes.	Developed the **Medical Device Single Audit Program (MDSAP)** in collaboration with other members of the International Medical Device Regulators Forum (IMDRF) to enable a single regulatory audit of a medical device manufacturer and expand the FDA's visibility of global manufacturing quality.	Launched the Advanced Manufacturing Initiative with the **Medical Device Innovation Consortium (MDIC)** to evaluate promising advanced design and manufacturing technologies across the Total Product Life Cycle.	Issued a **Quality Management System Regulation (QMSR) Final Rule** to modernize regulatory expectations for device manufacturers and importers by harmonizing domestic and international requirements.
Over 100 facilities enrolled in the Voluntary Improvement Program (VIP). Companies participating in VIP are showing a year-over-year downward trend in recalls.	Over 6,946 medical device manufacturers participating. Over 23,432 audit reports submitted between 2018 to 2023. 15 third party auditing organizations performing MDSAP audits.	Launched the **Advanced Manufacturing Clearing House (AMCH)** and the AMCH project submission portal. Accepted 5 projects in the AMCH. Initial results of a complaint management project show 65% improvement in complaint data accuracy and 53% improvement in resolution of complaints.	Final rule published on February 2, 2024. Full compliance expected by February 2, 2026.

Strengthening Postmarket Surveillance

CDRH has taken steps to significantly strengthen the postmarket surveillance infrastructure to assure medical device safety. Part of the Center's vision is that U.S. postmarket surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance. Over the past decade, CDRH has implemented improvements to its postmarket safety and postmarket surveillance activities, including **Medical Device Reporting** review, establishment and monitoring of FDA-mandated studies, including **"522" and post-approval studies**, and medical device tracking. We established the Signal Management Program to ensure consistency, efficiency, accountability, and transparency in how CDRH evaluates and addresses signals related to marketed medical devices. We review and take seriously all reports of adverse events associated with medical devices and conduct additional evaluation and analysis when necessary. As part of our broader commitment to device safety, we have taken the following actions to enhance postmarket surveillance:

As part of CDRH's **2016-2017 Strategic Priorities**, we envisioned the National Evaluation System for health Technology (NEST), now operated by the non-profit Medical Device Innovation Consortium (MDIC) with CDRH's support.

Utilizes real-world data to inform medical device development and evaluation throughout the Total Product Life Cycle (TPLC) of a device.

Established network of collaborators representing 266 hospitals and medical centers and 22,273 practice and specialty clinics.

Access to more than 161 million individual records.

Developed the **Unique Device Identifier System** and issued a final regulation requiring the inclusion of a unique device identifier on device labeling or the device itself.

Created the **Global Unique Device Identification Database (GUDID)**, a searchable database containing a list of all UDIs.

More than 4.34 million UDIs and associated device identification data in the database.

80% of Medical Device Reports (MDRs) display unique device identification (UDI), allowing for better tracking of devices throughout TPLC.

Established the Medical Data Enterprise Initiative through funds secured from Congress.

Initiated 36 postmarket studies on high priority device areas, including assessments of material safety, breast implants, pulse oximeters, radiology devices, and endovascular repair devices.

Increasing Data Transparency, Communication, and Collaboration

Over the years, we worked to expand existing capabilities and create new ones. Many of these expanded or new programs and systems took sustained effort and time to build, as CDRH worked with members of the public, Congress, industry, and others to develop ideas, solicit feedback, gather support, and ultimately move the programs from paper to reality. We also established a new forum for CDRH and our counterparts in other countries to share information about safety signals and better coordinate our actions to address them and to expand the global capacity to identify and address device safety risks.

Established the **International Medical Device Regulators Forum (IMDRF)** to harmonize the world's approach to how we oversee medical devices.	Published the **Emerging Signals Guidance** to expedite timely notification to the public about device safety issues.	Made improvements to the **Manufacturer and User Facility Device Experience (MAUDE)** database, which houses adverse medical device reports.	Launched the **Customer Collaboration Portal** to provide more information in a more accessible and user-friendly manner.
As chair of IMDRF in 2024, we hosted the largest meeting in history with over 1,200 participants to discuss harmonized approaches among regulatory authorities to facilitate and broaden patient access to safe and effective devices in the U.S. and globally.	Issued 69 safety-related communications about emerging signals since 2017.	Increased accessibility and search capabilities. Incorporated UDI information in the MAUDE database to ensure adverse event information is searchable.	Fulfills one of our MDUFA IV commitments to build a secure, industry dashboard where the Official Correspondent can see the status of a submission in near real-time. Plans to expand to other submissions in the future and create a virtual workspace with our customers.

Strengthening Medical Device Recall Program

CDRH has taken significant steps to further strengthen our medical device recall program. Over the last 15 years, CDRH has issued numerous guidance documents providing recommendations to help medical device manufacturers ensure their devices are safe and effective and comply with applicable laws and regulations. We also continued to engage with manufacturers and industry to better understand where the Center can provide additional clarity on recommendations and requirements. Patients are at the heart of our work, and we remain committed to timely and informative recall information and to using our available authorities to improve medical device recalls and protect the public health.

Modernized Policies

Issued guidances on **Product Recalls, Including Removals and Corrections**, **Initiation of Voluntary Recalls**, and **Public Warning, Notification of Recalls**.

Issued guidance to **clarify differences between a product recall and product enhancement**.

Enhanced Patient-Centered Decision-Making

Issued guidance concerning **Benefit Risk decision-making** in product availability and compliance decisions, including recalls.

Held **Patient Engagement Advisory Committee (PEAC) Meeting on Medical Device Recalls** to incorporate patient feedback into policies and practices.

Increased Recall Data Transparency

Provided public access to **recall data**.

Enhanced search and notification capabilities of enforcement report database.

Increased Efficiencies in Recall Review

Introduced SMART template for recall review and documentation.

Published a **standardized template** for industry submission of recalls.

Executing Medical Device Safety Action Plan

In 2018, we issued the **Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health** that described many of our past efforts and outlined a vision for how we can continue to enhance our programs and processes to assure the safety of medical devices throughout the Total Product Life Cycle (TPLC), to provide for the timely identification, communication, and resolution of new or increased known safety issues, and to advance innovative technologies that are safer, more effective and address unmet needs. As described below, we kept our commitment to implement the plan. In summary, our key accomplishments include:

Goal 1: Invest in the development of a Real-World Data (RWD)-based active surveillance system

- Worked collaboratively with the National Evaluation System for health Technology Coordinating Center (**NESTcc**) toward establishing a minimally viable real-world data-based (RWD) **active surveillance system**.
- Submitted request for funding the RWD-based active surveillance system in the President's FY2024 Budget to secure **consistent funding**.
- Developed multi-stakeholder **collaborations** to promote the use of real-world evidence (RWE) for evaluating health technologies, including those specifically for women.

Goal 2: Enhance Postmarket Capabilities and Mitigations

- Provided more clarity around mandated **postmarket studies** and updated plans to provide transparency to the public.
- Exercised **rarely-used authorities** to protect patients impacted by recalled devices.
- Integrated the use of **real-world data** to evaluate postmarket device safety through the development and execution of **real-world evidence studies**.

Goal 3: Spur Innovation Toward Safer Medical Devices

- Launched **programs** including the Safer Technologies Program (STeP) and the 510(k) Safety and Performance Based Pathway.
- Continued to build on the **Case for Quality** Program.

Goal 4: Advance Medical Device Cybersecurity

- Began implementation of **new authorities** and issued **updated premarket guidance**.
- Strengthened key **partnerships** across the public and private sectors to help ensure comprehensive, timely responses to medical device cyber vulnerabilities and incidents.

Goal 5: Complete CDRH's Reorganization

- Integrated CDRH's **premarket review, postmarket surveillance, and compliance** offices across functions allowing our experts to leverage their knowledge of premarket and postmarket information to optimize decision-making and inform new product approvals and clearances with the latest safety data.

Looking Forward

Medical device safety is a top priority for CDRH. We will continue working to assure the U.S. is among the first to detect and address safety signals, working closely with our domestic and international partners, to help ensure patients can depend on the devices CDRH approves, clears, and authorizes for marketing. We will continue maximizing every available approach and resource to meet our regulatory responsibilities and to achieve optimal public health outcomes; taking prompt action and communicating publicly when appropriate; and using our regulatory or enforcement authorities against those who place patients or the public health at risk. In 2024, we plan to take three actions to help ensure devices on the U.S. market are high-quality, safe, and effective and remain so over time.

Advance Improved Device Quality

- Expand participation in the Voluntary Improvement Program (VIP).
- Explore development of AI tools to better track and identify device quality issues.

Strengthen Active Surveillance

- Utilize real-world evidence, and leverage data from a combination of active and passive safety surveillance systems.
- Continue to advance the adoption and use of UDI throughout the health ecosystem to further enable accurate and efficient assessment of medical devices throughout their life cycle.

Enhance Medical Device Recall Program

- Further reduce the time of public notification once the FDA becomes aware of a recall and continue to enhance communications to the public about recalls.
- Further enhance MAUDE database and MDR tracking.

ADDITIONAL INFORMATION

U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health

Web: **Center for Devices and Radiological Health**

Trade Press:

Email: **CDRHTradePress@fda.hhs.gov**

Division of Industry and Consumer Education (DICE):

Phone: 1(800) 638-2041 or (301) 796-7100

Email: **DICE@fda.hhs.gov**

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