U.S. FOOD & DRUG ADMINISTRATION

CDRH International Harmonization Annual Assessment

Fiscal Year 2025

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Background

Our Work on Global Harmonization

The U.S. Food and Drug Administration (FDA)'s Center for Devices and Radiological Health (CDRH) has long recognized that the global device ecosystem is interconnected and requires close international collaboration to work at its best. The device industry is evolving at an unprecedented rate, improving the delivery of healthcare to patients with innovative products. Regulators worldwide keep pace with these innovations by developing new, and evolving existing, regulatory frameworks in which members of the healthcare ecosystem operate. It is critical that interested parties in the ecosystem bring their unique perspectives on the successes and challenges specific to their market to discussions informing these frameworks. With these dynamics in mind, CDRH is committed to fostering relationships globally with device parties. We are encouraging harmonized regulatory approaches among regulatory authorities, which will maximize available resources and ultimately help ensure safe, effective, and high-quality medical devices. We are also promoting opportunities to share information and build trust, ensuring that CDRH and our global partners can make the most informed regulatory decisions within the context of an interconnected ecosystem.

CDRH International Harmonization Strategic Plan

The Medical Device User Fee Amendments (MDUFA) for Fiscal Year (FY) 2023-2027 (MDUFA V) agreement includes several commitments to promote international harmonization and provides additional CDRH resources for this vital work.

To describe how CDRH will meet our MDUFA V commitments, the Center for Devices and Radiological Health International Harmonization Draft Strategic Plan (Strategic Plan) includes specific strategies to directly encourage harmonization, convergence, and reliance among medical device regulatory authorities, as applicable, and builds on CDRH's current work with international interested parties.

Annual Assessment by CDRH

As part of the MDUFA V obligation, CDRH conducts annual assessments of its international activities and publishes those findings in an annual report.

We will use the 5 strategies identified in Appendix C of the Strategic Plan as a rubric for the annual assessment.

Strategy 1	Increase engagements in international harmonization, convergence, and reliance efforts.
Strategy 2	Create a mechanism for CDRH to share best practices with trusted partners.
Strategy 3	Assess the extent of CDRH implementation of IMDRF technical documents.
Strategy 4	Support creation of a forum to engage with stakeholders to identify opportunities for regulators to leverage one another's approach to decision-making.
Strategy 5	Participate in outreach activities to encourage harmonization, convergence, and reliance.

Appendix C also provides examples of the type of activities that may be identified relative to each strategy. While the Strategic Plan includes specific strategies and activities, CDRH recognizes that international harmonization work is interdependent. As we report on the specific activities outlined in this Plan, we will highlight how they interconnect within CDRH and across the global community.

CDRH International Harmonization Annual Assessment for FY2025

Reporting Period

This Annual Assessment covers activities conducted by CDRH in FY2025 (from October 1, 2024, to September 30, 2025).

Inclusion of Information

While this Annual Assessment aims to provide a complete assessment of activities conducted under the Strategic Plan, some details cannot be provided based on confidentiality considerations between FDA and the regulatory authorities with which we share information.

Activities to Date

CDRH worked diligently throughout FY2025 with international medical device representatives to meet MDUFA V commitments with the goal of ensuring safe, effective, and high-quality medical devices. The specific activities that we accomplished in relation to each Strategic Plan strategy are listed below.

A summary of international activities prior to FY2024 is available in Appendix D of the Strategic Plan. Previous MDUFA V CDRH International Harmonization Annual Assessments can be found on the CDRH International Affairs web site.

Strategy 1: Increase engagements in international harmonization, convergence, and reliance efforts.

In FY2025, we advanced successful initiatives in harmonization, convergence, and reliance by continuing international engagement as described in this assessment.

In the context of this document, reliance refers to when the regulatory authority in one jurisdiction may consider and give significant weight to assessments performed by another or trusted institution, or to any other authoritative information, in reaching its own decision. The regulatory authority that relies on such information remains independent, responsible, and accountable regarding the decisions it makes.

Our reporting of activities and accomplishments for Strategy 1 in FY2025 reflects the categories identified in Appendix D of the Strategic Plan.

International Medical Device Regulators Forum (IMDRF)

IMDRF is the preeminent global forum for advancing international harmonization and convergence in medical device regulation. At the end of 2024, CDRH concluded its term as Chair and Secretariat of IMDRF, transitioning these responsibilities to Japan. Throughout FY2025, we continued our participation as a member of the IMDRF Management Committee while supporting IMDRF initiatives and maintaining communication with international counterparts.

In March, we participated in the 27th IMDRF Management Committee meeting; and in September, we attended the 28th meeting in Sapporo, Japan. Across these sessions, we contributed to several initiatives including a workshop on conformity assessment practices and development of new and revised IMDRF guidance. The published Outcome Statements from March and September reflected collective progress toward global regulatory convergence and reinforced FDA's role as a strategic partner in building a more cohesive international medical device ecosystem.

Recognizing the importance of stakeholder perspectives, we also facilitated discussions with the medical device industry to identify appropriate opportunities for industry input on IMDRF activities. During our tenure as Chair and Secretariat, we helped lay the groundwork for the establishment of the IMDRF Industry Group, strengthening structured industry engagement within IMDRF. We were happy to observe active industry participation, including engagement of the recently established IMDRF Industry Group in the development of New Work Item Proposals and workshop topics for IMDRF Management Committee consideration.

As of September 30, 2025, CDRH participated in all eight IMDRF technical working groups that were active during this reporting period and served as co-chair of six of them. CDRH provided technical input and subject matter expertise as necessary. During the reporting period, these working groups finalized and published four technical documents. IMDRF also published one information document in FY2025, reflecting ongoing progress toward greater international alignment in medical device regulation and promoting the availability of informational resources for regulatory use.

In April 2025, IMDRF also published the draft document Playbook for Medical Device Regulatory Reliance Programs for public comment. This work originated from a workshop convened during our tenure as Chair and Secretariat, and the Good Regulatory Review Practices Working Group—co-chaired by CDRH—led the development of this document. Once finalized, this document will offer best practices to help regulators who may wish to implement reliance approaches that streamline regulatory processes, enhance efficiency, and expand access to safe and effective medical devices.

CDRH remains committed to supporting IMDRF's strategic priorities and to advancing global collaboration in medical device regulatory practices.

Medical Device Single Audit Program (MDSAP)

MDSAP continues to advance a global approach to auditing and monitoring the manufacturing of medical devices. The MDSAP Forum, held June 13 – 19, 2025, in Amsterdam, Netherlands, served as a key platform for communicating operational and regulatory updates from the MDSAP Consortium and its Regulatory Authority Council Members—including TGA (Australia), ANVISA (Brazil), HC (Canada), PMDA/MHLW (Japan), and FDA—to external stakeholders. The forum provided insights into MDSAP operations, educated potential new regulators, compared MDSAP audit criteria to requirements in other regions, and promoted broader global acceptance of MDSAP audits, supporting consistency and collaboration among participating authorities.

CDRH remains an active participant and contributor to the program through its role on the MDSAP Regulatory Authority Council (RAC). During FY2025, the program expanded its international engagement, with Malaysia joining as a new Affiliate Member and Singapore participating as an Official Observer. By the end of the fiscal year, there were 15 participating Auditing Organizations that audit over 7,500 sites under the program. CDRH will assume the role of Chair of the RAC for the 2026–2027 term. Continued expansion is planned for 2026, with a focus on increasing engagement across the Asia region.

Asia-Pacific Economic Cooperation (APEC)

Throughout 2025, CDRH continued its role as a co-champion of the medical device priority work area (PWA), supporting regulatory convergence efforts across APEC. The APEC Regulatory Harmonization Steering Committee (RHSC) continued to advance its mission of promoting regulatory convergence for medical products—including medical devices—across the APEC region by 2030. It further reaffirmed its commitment to fostering alignment, cooperation, capacity building, and regulatory reliance among member economies, emphasizing that its role is to facilitate harmonization and education rather than develop new regulatory frameworks. Key achievements included the relaunch of the RHSC's Key Performance Indicators (KPIs) initiative to measure progress toward convergence, with Phase 1 successfully completed in 2025 and Phase 2 scheduled for expansion in 2026. Centers of Excellence supporting the medical device PWA continued to deliver targeted training programs and plan future

initiatives, aligning with the IMDRF and GHTF foundational documents and promoting participation in MDSAP.

Harmonization by Doing (HBD)

HBD is a joint effort by government, academia, and industry members in Japan and the US to align regulatory and clinical approaches for medical devices in both countries through practical project-based activities. In September 2025, CDRH participated in the HBD East 2025 Think Tank Meeting in Sapporo, Japan. The meeting focused on key areas of mutual interest, including marketing approval pathways, real-world clinical evidence, digital health technologies, pediatric and orphan device development, and strategies for global collaboration and access. Discussions emphasized advancing regulatory convergence, leveraging multi-regional clinical data, promoting innovation in digital health, and fostering sustainable global device development ecosystems.

Taking advantage of its proximity to the 28th IMDRF Management Committee meeting, the Think Tank brought together a broad audience that was not limited to US and Japanese stakeholders. CDRH presented an overview of the U.S. regulatory landscape for digital health technologies as well as initiatives to accelerate medical device access, with the goal of identifying synergies that can facilitate joint US-Japanese device development strategies. Through these efforts, we aim to reduce regulatory duplication and accelerate patient access to safe, effective, and innovative medical technologies in both the U.S. and Japan.

Bilateral & Multilateral Discussions

In FY 2025, we continued to advance alignment of medical device regulatory approaches through extensive bilateral and multilateral collaborations. These efforts supported the agency's strategic goal of fostering international regulatory convergence, promoting consistent oversight, and strengthening global public health protection.

Strengthening Bilateral Partnerships

CDRH convened multiple bilateral meetings with individual regulatory authorities across the Americas, Europe, and the Asia-Pacific region. Some topics of these discussions were exchanging information on regulatory expectations for certain device types, explaining regulatory approaches, and providing updates in emerging policy areas. These meetings served to promote alignment and efficiency in regulatory reviews and facilitate reliance on CDRH decisions.

Advancing Multilateral and Regional Harmonization

Throughout 2025, CDRH actively participated in the ongoing International Medical Device Safety (IMDS) meetings. These meetings strengthened communication on postmarket safety concerns among global regulatory partners with established confidentiality commitments. We shared several safety issues identified through postmarket surveillance and responded to inquiries from other regulators.

Strategy 2: Create a mechanism for CDRH to share best practices with trusted partners

As we aspire to support the harmonization and convergence of medical device regulation worldwide, we have committed under Section V.I.2. of the MDUFA V Commitment Letter to create a mechanism for FDA to work with regulatory partners, with whom we have appropriate confidentiality commitments, to inform and align regulatory strategies.

The field of implanted brain-computer interface (BCI) devices continues to advance rapidly, moving from fundamental neuroscience discoveries and innovations in digital health and AI/ML to translational applications. Implanted BCI devices have the potential to benefit people with severe disabilities by increasing their ability to interact with their environment but also present inherent high risks.

Given the importance and growth of this field, and the benefits of engaging with certain regulatory authorities to discuss scientific developments, we continued our international collaboration through the Multilateral BCI (MBCI) Forum. This ongoing forum includes six regulatory authorities. In FY2025, the BCI Think Tank met twice virtually to share regulatory intelligence and harmonize approaches to the review of BCI devices. Discussions focused on regional updates, approaches to clinical trials and clinical outcome assessments, and the potential development of BCI device standards.

This continued engagement demonstrates our commitment to fostering international collaboration on high-risk, innovative medical technologies, while supporting the safe and effective development of implantable BCI devices.

Strategy 3: Assess the extent of CDRH implementation of IMDRF technical documents

With the goal of improving the efficiency of the global regulatory systems for medical devices through international harmonization and convergence, we agreed in Section V.I.3. of the MDUFA V Commitment Letter to assess and publish the extent of CDRH implementation of IMDRF technical documents.

The most current IMDRF Document Implementation Report was published on September 1, 2025. This report includes self-assessments from 14 regulatory authorities, including CDRH, detailing their implementation status of all IMDRF technical documents. Of the 34 available IMDRF technical documents, CDRH reported that we have implemented 22 and have partly implemented 12.

For detailed information, the full IMDRF Document Implementation Report is available here: IMDRF Document Implementation Report – September 1, 2025.

Strategy 4: Support creation of a forum to engage with stakeholders to identify opportunities for regulators to leverage one another's approach to decision making

The device community represents many types of interested parties, including manufacturers, patients, healthcare providers, and standards development organizations. Their unique perspectives and experiences are invaluable to regulatory authorities in their decision-making processes.

With these considerations, CDRH committed under Section V.I.4. of the MDUFA V Commitment Letter to support the creation of a forum which engages interested parties to identify opportunities for regulators to leverage one another's approach to decision making. This process of leveraging can be a win-win for the entire medical device community by maximizing resources toward the goal of safe, effective and high-quality devices.

In FY2025, CDRH held two virtual MDUFA V Forum meetings with representatives from AdvaMed and other industry stakeholders. Topics of these meetings included general updates, discussion of global regulatory reliance activities, and identification of potential future projects and regional training opportunities.

Moving forward, we plan to maintain regular discussions on shared areas of interest, exchange relevant information, and explore new opportunities aligned with the MDUFA V commitments. Insights from these conversations will shape future collaboration within this forum and with additional regulators and stakeholders, helping to identify international projects and strategies that advance regulatory convergence.

Strategy 5: Participate in outreach activities to encourage harmonization, convergence, and reliance

With recognition that global regulatory alignment will only be achieved through collaboration, CDRH committed under committed under Section V.I.5. of the MDUFA V Commitment Letter to participate in

outreach to other regulatory authorities to encourage harmonization, convergence, and reliance. Outreach under this strategy includes discussion of international best practices with an international audience, including presentations, training, and meetings, and may include coordination with other parts of the U.S. government.

We held several discussions with regulatory authorities in Europe to explain U.S. premarket regulatory processes and programs. The goal of these interactions was highlighting potential opportunities for reliance on CDRH marketing authorizations, while reducing the burden for manufacturers and those involved in regulatory assessment.

A Look Ahead

As MDUFA V enters its remaining years and we look ahead to MDUFA VI, CDRH remains committed to advancing international engagement and harmonization within the global medical device ecosystem. By leveraging dedicated resources, we will continue to strengthen existing collaborations while exploring innovative approaches to cooperation in an increasingly interconnected world. Our ongoing participation in international forums such as IMDRF, MDSAP, HBD, and APEC will continue to support alignment of regulatory approaches and effective information sharing across the global regulatory community.

As medical devices become more sophisticated, we will aim to expand efforts across a broad range of topics—from training global regulators on CDRH policies, requirements, and use of IMDRF technical documents, to addressing emerging areas such as digital health technologies, artificial intelligence (AI), and BCIs.