U.S. FOOD & DRUG ADMINISTRATION

CDRH International Harmonization Annual Assessment

Fiscal Year 2024

CDRH International Harmonization Annual Assessment for Fiscal Year 2024

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 assure 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.

On September 18, 2023, the FDA issued the draft Center for Devices and Radiological Health International Harmonization Strategic Plan (Strategic Plan) to describe how CDRH will meet our MDUFA V commitments. The 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.

The Strategic Plan was posted to docket FDA-2023-N-4897 on November 7, 2023 and remains open for public comment.

Annual Assessment by CDRH

As part of the MDUFA V obligation, CDRH conducts annual assessments of the 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 interested parties 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 FY2024

Reporting Period

This Annual Assessment covers activities conducted by CDRH in FY2024 (from October 1, 2023, to September 30, 2024).

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 FY2024 with international medical device representatives to meet MDUFA V commitments with the goal of assuring safe, effective, and high-quality medical devices. The specific activities which we accomplished in relation to each Strategic Plan strategy are listed below.

A summary of prior international activities is available in Appendix D of the Strategic Plan.

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

In FY2024, we spearheaded successful initiatives in harmonization, convergence, and reliance by increasing international engagement as described in this assessment.

In the context of this document, reliance refers to when the regulatory authority in one jurisdiction may take into account 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 FY2024 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. CDRH has been a dedicated member of the IMDRF Management Committee since its launch in 2011 and had the honor of serving as Chair and Secretariat in 2024. During our term as Chair, IMDRF hosted two in-person sessions open to the public and two half-day teleconferences of the Management Committee. The 25th and 26th Session of IMDRF, held in March and September respectively, drew record attendance – over 1200 attendees from 60 nations and 500 organizations in March and over 1200 attendees from 70 nations and 750 organizations in September. With the purpose of expanding the perspectives of IMDRF, we diligently worked to add 15 regulatory authorities as Affiliate Members and one regulatory authority as Official Observer. In doing so, total membership in IMDRF increased from 25 nations and organizations in 2023 to 41 in 2024.

FDA actively participates in the eight working groups of IMDRF and serves as co-chair for six working groups, which create harmonized technical documents on key international regulatory topics. In FY2024, IMDRF published 12 technical documents for the entire medical device ecosystem to utilize. After surveying regulatory authorities on the most effective way to help them understand and ultimately adopt the foundational technical documents of IMDRF, we developed and held a two-part training for over 100

regulators on the “Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices” (IMDRF/GRRP WG/N47).

Although interested parties from the device industry are currently ineligible to join IMDRF as official members, we recognize that their perspectives are important to the success of IMDRF as the Forum works to globally harmonize and converge regulatory approaches. In 2024, we facilitated discussions with the medical device industry to identify appropriate opportunities for them to provide input on IMDRF activities.

Medical Device Single Audit Program (MDSAP)

MDSAP strives for a global approach to auditing and monitoring the manufacturing of medical devices. CDRH is a member of MDSAP and provides significant contributions to the program. As a member of the Regulatory Authority Council (RAC) of MDSAP, CDRH encouraged expansion of membership with the goal of improving the safety and oversight of medical devices on a global scale. Three regulatory authorities joined as Affiliate Members in FY2024 – Kenya’s Pharmacy and Poisons Board (PPB), Mexico’s Federal Commission for Protection from Sanitary Risks (COFEPRIS), and Chinese Taipei’s Taiwan Food and Drug Administration (TFDA). We also contributed to the planning and coordination of the annual MDSAP Forum in Essen, Germany in June 2024, which focused on increasing engagement with European interested parties.

Asia-Pacific Economic Cooperation (APEC)

CDRH continued to be one of three co-champions of the medical device priority work area of the APEC Regulatory Harmonization Steering Committee (RHSC). The medical device priority work area focuses on regulatory capacity building for countries developing a medical device regulatory framework and covers foundational documents from IMDRF, as well as international consensus standards. In July 2024, we collaborated with the RHSC to modernize the RHSC Centers of Excellence training protocol, updated the medical device core curriculum, and revised the medical device priority work area roadmap.

Harmonization by Doing (HBD)

HBD is a joint effort by government, academia, and industry in Japan and the US to harmonize regulatory and clinical approaches for medical devices in both countries through practical project-based activities. A Think Tank is held once a year to inform medical device development companies and the public about the latest activities.

In December 2023, we participated in HBD’s first in-person meeting of the Think Tank in four years in Tokyo, Japan. Agenda topics included obtaining marketing approval in the two countries, real-world clinical evidence, and software as a medical device. CDRH also organized and participated in two interventional cardiology conference sessions on clinical and regulatory convergence in the US and Japan.

Bilateral & Multilateral Discussions

In pursuit of harmonizing medical device regulatory approaches in FY2024, CDRH regularly engaged with international regulatory partners. Our notable bilateral and multilateral accomplishments included:

In October 2023, FDA released internationally the Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles with our regulatory partners Health Canada and the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA), which draws upon existing guiding principles around Good Machine Learning Practices.
In February 2024, FDA issued its Quality Management System Regulation (QMSR) Final Rule to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation (21 CFR Part 820), incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016 *Medical devices – Quality management systems – Requirements for regulatory purposes*. This final rule will harmonize the FDA's CGMP regulatory framework with that used by other regulatory authorities.
In monthly meetings of the International Medical Device Safety (IMDS) group, CDRH and ten regulatory authorities worldwide strategically collaborated on international post-market safety performance issues and pre-market activities to protect and maximize international public health and safety.
We continued to foster innovation for new and emerging digital health technologies. CDRH and other global regulatory bodies participated in the Digital Health Think Tank to discuss large language models, transparency, artificial intelligence, health at home, and bias. CDRH also helped to advance discussions internationally on brain computer interface (BCI). More information about our BCI activities in FY2024 is available in this report under Strategy 2.
Beginning in FY2023 and throughout FY2024, CDRH engaged with regulators in Europe to impart our experience on orphan products and provide technical, scientific advice as regulators develop their frameworks.
In 2024, FDA chaired the Meeting of the National Regulatory Authorities of Regional Reference (NRAr). In support of that activity, CDRH presented at the Medical Products Regulation Symposium the day prior to NRAr. We highlighted the importance of IMDRF and MDSAP as two globally recognized efforts to advance regulatory harmonization and convergence worldwide. We also encouraged regulatory authorities in Latin America to increase engagement with IMDRF and MDSAP.
In FY2024, we continued to advance understanding of how the international use of FDA's electronic Submission Template and Resource (eSTAR) can be a tool to streamline the submission and review of premarket applications. In connection with the eSTAR Pilot between FDA and Health Canada, the two nations conducted surveys and incorporated changes based on the feedback.
Reflecting our steadfast commitment to collaboration, the FDA and Kenya's Directorate of Health Products and Technologies, Medical Devices and In-Vitro Diagnostics Section (MDIVD) at the Pharmacy and Poisons Board (PPB) signed a Statement of Authority and Confidentiality Commitment.

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 BCI devices is progressing rapidly from fundamental neuroscience discoveries, pushing the boundaries of digital health and artificial intelligence/machine learning (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 are inherently high risk. Given the

importance and growth of this field, and the benefits of engaging with certain regulatory authorities to discuss scientific developments in this area, we created the Multilateral BCI (MBCI) Forum in FY2024. The MBCI Forum, comprised of six regulatory authorities, met twice in FY2024 to share insights and challenges on important topics in this field. Discussions included regional updates, approaches to clinical trials and clinical outcome assessments, and the potential for development of BCI device standards. Although the category of BCI devices includes a range of assistive devices that are not implanted, the meetings focused on implantable BCI.

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.

During CDRH's term as Chair of IMDRF in 2024, the IMDRF Management Committee agreed to conduct and publish a yearly report on the extent to which all members of the Management Committee and Official Observers are implementing the relevant elements, concepts, and principles of the IMDRF technical documents. After collecting information both internally and from the other IMDRF members, we completed and published the IMDRF Document Implementation Report on August 30, 2024.

The report includes self-assessments by 12 regulatory authorities, including CDRH, on the status of implementation of all IMDRF technical documents. The process of implementing an IMDRF technical document occurs at the discretion of each medical device regulatory authority and the implementation status falls into one of four categories: implemented, partly implemented, not implemented, and not applicable. CDRH reported that we have implemented 14 and partly implemented 17 of the 31 IMDRF technical documents.

The implementation of IMDRF technical documents by regulatory authorities worldwide is foundational to achieving global harmonization and convergence of medical device regulatory approaches. The speed with which IMDRF conducted its assessment and published its report demonstrates CDRH's commitment to leading by example in international harmonization efforts. This report will serve as a model for future assessments of the implementation of IMDRF technical documents by regulatory authorities worldwide.

Strategy 4: Support creation of a forum to engage with interested parties 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 fall 2023, CDRH convened representatives from companies and trade associations to envision this forum and continued to meet with industry throughout 2024.

Through these discussions, CDRH encouraged external interested parties to create the forum with our support and insight. As currently planned, CDRH and U.S. industry will regularly discuss topics of interest, share intelligence, and identify opportunities within the scope of the MDUFA V commitment. These discussions will inform subsequent engagement within this forum with other regulators and additional interested parties to identify potential projects and approaches that could be implemented internationally to foster greater regulatory alignment.

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 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, and may include coordination with other parts of the U.S. government.

We met our commitment to globally align in FY2024 by leading and participating in numerous initiatives throughout the world. Our notable activities included:

We developed and conducted several individualized trainings for two regulatory authorities in Europe on U.S. premarket pathways in order to promote opportunities for reliance on CDRH marketing decisions.
With the goal of building capacity on the African continent, in November 2023, we provided medical device training at a workshop of the African Medical Devices Forum (AMDF) to regulators from 22 nations in person in Nairobi, Kenya. The agenda included an overview of FDA regulations, reliance and regulatory practices, internationally recognized technical standards, and the harmonization work of IMDRF. After the meeting, we met with AMDF member countries and, from our dedicated outreach, six countries joined IMDRF as Affiliate Members.
In February 2024, we co-hosted the Artificial Intelligence (AI) and International Symposium (AIRIS) with South Korea's Ministry of Food and Drug Safety (MFDS), in Seoul, South Korea. The knowledge we gained and shared at this event will help us anticipate and prepare for the challenges of AI and better harness its potential.
In regard to device technologies with the potential for improving outcomes for people with mental health conditions, in FY2024, CDRH participated in two international workshops of the Digital Mental Health Project led by the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA). In November 2023, representatives from 14 regulatory authorities explored approaches, opportunities, and challenges. The workshop in July 2024 focused on MHRA's Digital Mental Health Technologies project. CDRH continued the productive dialogue to advance mental health technologies throughout FY2024.
In April 2024, CDRH representatives participated in person at a workshop in Delhi, India, to describe to industry the FDA premarket submission process and latest policies regarding digital health, software as a medical device (SaMD), and AI-enabled devices. As one result of our dedicated outreach, India's Central Drugs Standard Control Organization (CDSCO) joined IMDRF as an Affiliate Member in 2024.
CDRH delivered presentations across the world at conferences, trainings, roundtables, and meetings to communicate the importance of regulatory alignment to interested parties.

A Look Ahead

In the remaining years of MDUFA V, CDRH looks forward to continuing international engagement and harmonization within the global device ecosystem. With dedicated resources, we can drive current initiatives and envision new ways to collaborate in an interconnected world. Our continuing activities within forums such as IMDRF, MDSAP, HBD, APEC, and MBCI will strive to align regulatory approaches and ensure that vital information is circulated, as appropriate, to the global regulatory community. As devices grow more complex, our efforts will span the scope of device issues, from training regulators on their understanding of CDRH requirements and policies and use of IMDRF technical documents, to cutting edge topics including digital health, AI, and BCI. We also look forward to working with industry on a forum that will drive toward harmonization and convergence to international best practices. The ultimate goal of our steadfast commitment to increased harmonization, convergence, and reliance is to help assure safe, effective, and high-quality medical devices worldwide.