Center for Devices and Radiological Health International Harmonization Draft Strategic Plan

2023

Foreword

The mission of the Center for Devices and Radiological Health (CDRH) is for US patients to have timely, continued access to safe, effective, and high-quality medical devices. The increasingly global and increasingly complex nature of medical device design, manufacture, distribution, and use means that the United States must continue and strive to strengthen its long-standing work with other regulatory authorities to harmonize and converge medical device regulation policy and practices.

The Medical Device User Fee Amendments (MDUFA) for FY2023-2027 (MDUFA V) agreement includes several commitments specific to international harmonization and provide additional CDRH resources for this important work. This draft strategic plan ("the Plan") describes how CDRH will meet these MDUFA V commitments.

CDRH recognizes that successful international harmonization will require the integration of ideas and perspectives from key stakeholders, including other regulatory authorities, industry, conformity assessment bodies, patients, standards development organizations, and internal CDRH staff. CDRH appreciates that we are one of many stakeholders, with one of many perspectives. This Plan is rooted in an inquiring outlook that recognizes not only the expertise CDRH may be able to provide others, but, equally, the expertise and learnings that other stakeholders may be able to provide CDRH.

This Plan includes both inward looking and outward looking activities. Inward looking activities are aimed at understanding CDRH's current practices within the context of globally harmonized policies. CDRH staff and FDA more broadly will be a critical voice in this work. Outward looking activities are aimed at furthering globally harmonized best practice to stakeholders outside of CDRH, including other regulatory authorities.

We look forward to working on the strategies and activities outlined in this Plan over the next four years. As always, our drive will be to achieve the highest quality safe and effective medical devices for every US patient.

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Executive Summary

The Center for Devices and Radiological Health (CDRH) has long recognized the importance of and worked towards globally harmonized medical device regulatory policy and practices. Reducing redundant expectations across medical device regulatory systems means better access by patients (in the United States and globally) to safe, effective, and high-quality medical devices. The need for harmonized approaches, convergent expectations, and reliance among regulatory authorities has only become more evident and urgent as the design, manufacture, distribution, and use of medical devices has become increasingly complex and increasingly global. With this Plan, CDRH outlines our specific strategies and activities towards international harmonization, convergence, and reliance.

During the next four years, CDRH looks forward to strengthening existing diplomatic relationships which are critical to risk-based decision-making using the most up-to-date scientific and regulatory intelligence, as well as furthering broader work on harmonization, convergence, and reliance. We also welcome the opportunity to demonstrate our leadership in the international medical device landscape by hosting and chairing the International Medical Device Regulators Forum (IMDRF) in 2024.

This Plan includes specific strategies to directly encourage harmonization, convergence, and reliance among regulatory authorities. CDRH will increase engagement in global harmonization projects and initiatives, create a new mechanism to work with trusted partners, and conduct specific outreach to and with other regulatory authorities. CDRH will not only look outward, but also inward- we will examine our own implementation of international best practices and share our findings, conclusions, and next steps. And lastly, we look forward to supporting new ways to listen and learn from stakeholders on this global journey.

CDRH is committed to this Plan and to sharing our progress towards it. We will publish annual assessments of the international harmonization activities described in this Plan. We look forward to public comment and feedback to improve our approach and efforts to provide patients in the United States and globally with safe, effective high-quality medical devices in an increasingly global regulatory environment.

Mission

It is CDRH's mission to protect and promote the US public health. From an international perspective, this means integrating the United States into the international medical device ecosystem. To do so, we develop and foster relationships with other regulatory authorities and strategic partners so that we maintain a current understanding of the evolving global regulatory environment and our role within it. CDRH collaborates with the international community to develop and implement harmonized best practices and inform one another's approach to decision-making. We connect internal decision-makers with timely and relevant information to ensure US decisions are made within the context of a global world.

Vision

The United States is fully integrated into the international medical device ecosystem so that patients have timely access to high quality, safe and effective medical devices.

> The United States collaborates with international stakeholders to develop and implement harmonized best practices and meaningfully inform one another's approach to regulatory decision-making. As emerging regulatory topics are identified, we work with trusted regulatory partners to develop coordinated strategies that can be used effectively in a complex and inter-connected global medical device world.
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> The United States maintains an awareness of the true global nature of the medical device ecosystem, including an understanding of the evolving roles and priorities of stakeholders (industry, regulatory authorities, conformity assessment bodies, standards development organizations, and patients), as well as the intersection of the medical device regulatory environment with other global policies. We fully appreciate how decisions made in the United States are received and, as relevant, relied upon by others in the international medical device community. Likewise, our own decision-making is directly informed by a thorough knowledge and appreciation of the wide-ranging perspectives and considerations throughout the world.

Introduction

The medical device sector has become increasingly globalized and complex. Many different economies participate in the design, development, manufacturing, and distribution of products. Technologies are evolving at a rapid pace. Each economy may be required to develop and implement its own regulatory paradigm and path to market products based on the applicable statutory requirements, especially as emerging technologies are considered. However, resources are not maximized when regulatory authorities must administer, and industry must navigate adherence to, numerous and sometimes redundant regulatory requirements. Reducing these inefficiencies through harmonization, convergence, and reliance promotes a more effective regulatory model for medical devices. Ultimately, a more efficient and effective model means patients (in the United States and globally) have better access to safe, effective, and high-quality medical devices.

International harmonization, convergence, and reliance have always been important to CDRH. Our engagements across the world have expanded over the years as the medical device ecosystem becomes increasingly global. Figure 1 provides an overview of CDRH's involvement in harmonization programs and initiatives over the past 30 years.[1] Work in specific programs and initiatives is in addition to bilateral and multilateral engagements with our trusted partners[2] and our continued commitment to the development, recognition, and use of internationally harmonized medical device consensus standards.

With this Plan, CDRH outlines our mission and vision with respect to international harmonization. We describe the specific strategies and activities that we will use over the next four years (through FY2027) to advance international harmonization, convergence, and reliance.

[1] Details on the work of each of these initiatives and programs is provided in **Appendix A**.
[2] A trusted partner is a regulatory authority with whom the US has a strong diplomatic relationship and appropriate confidentiality commitments (see https://www.fda.gov/international-programs/international-arrangements/confidentiality-commitments).

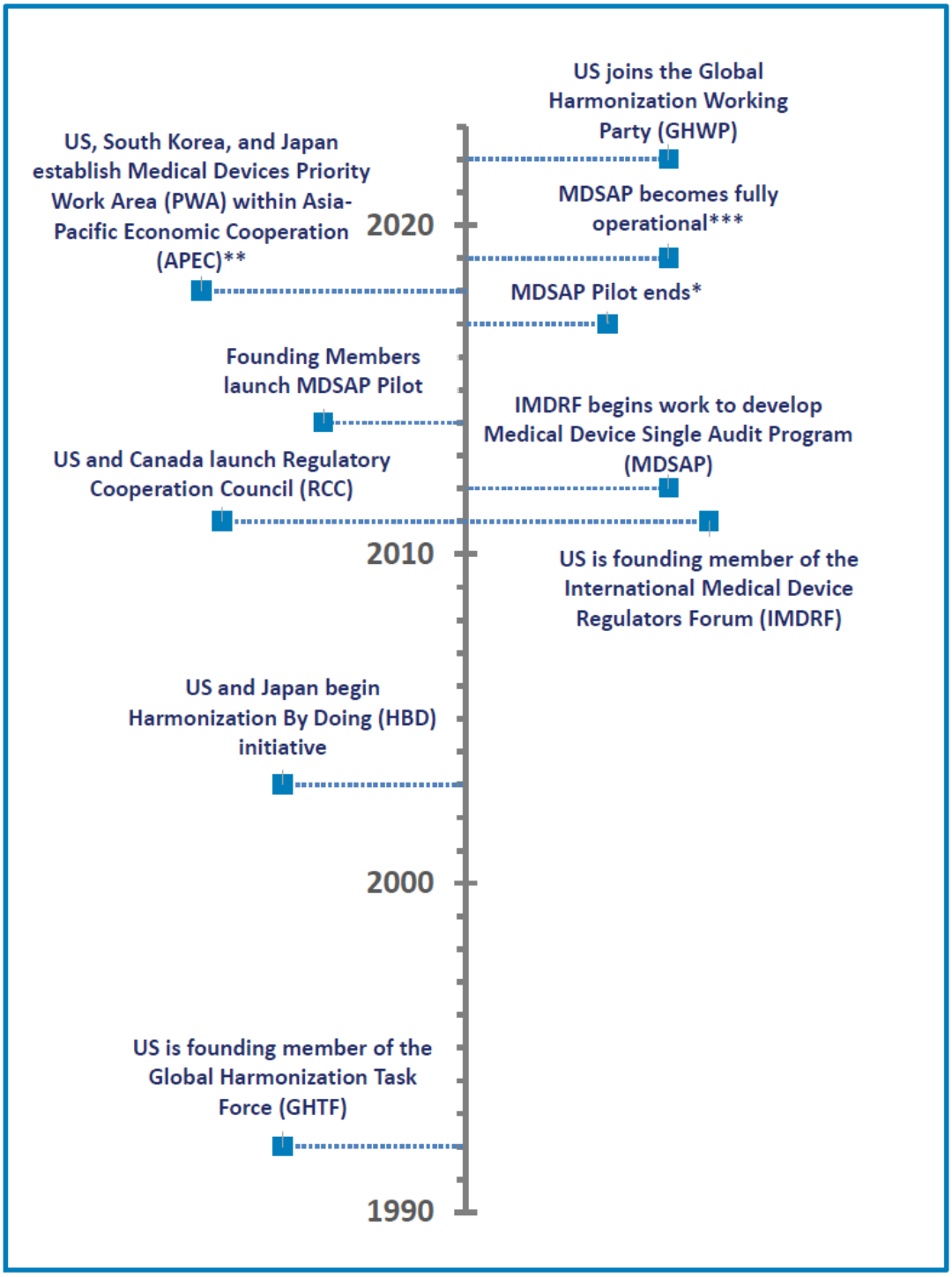

Figure 1 Timeline of CDRH engagement in international harmonization initiatives and programs between 1992 and 2022.
**Proof of Concept is reviewed to determine if program can become fully operational*
*** The Medical Device Priority Work Area (PWA) is within the Life Science Innovation Forum (LSIF) managed by the Regulatory Harmonization Steering Committee (RHSC) in the Asia-Pacific Economic Cooperation (APEC)*
****Canada transitions from the Canadian Medical Devices Conformity Assessment System (CMDCAS) to MDSAP*

The Plan

An Interdependent and Integrated Approach

While this Plan includes specific strategies and activities, CDRH recognizes that international harmonization work is interdependent. For example, the forum described in Strategy 4 may provide valuable insights into the outreach described in Strategy 5. To this end, CDRH will use an integrated approach in our work on the specific activities and strategies outlined in this Plan, always with the broader mindset and goal to ensure the availability of safe, effective, and high-quality medical devices to patients.

A Note on the Medical Device User Fee Amendments (MDUFA) V Commitment Letter

The Medical Device User Fee Amendments (MDUFA) for FY2023-2027 (MDUFA V) agreement[3] includes several specific commitments regarding international harmonization. These commitments are incorporated into this Plan and **Appendix B** links each MDUFA V Commitment to the relevant Plan element.

A Note on Timelines

Specific target dates are provided for some, but not all, activities. Where it is possible to predict CDRH workload and decision-making authority, specific targets are provided. Less concrete, iterative timelines are provided for activities that require significant input and close collaboration with stakeholders outside of CDRH (such as other regulatory authorities, industry, conformity assessment bodies, patients, and standards development organizations) and/or where international medical device policy and regulation are likely to evolve quickly. FDA believes this iterative approach appropriately balances transparency and adaptability, allowing for adjustments based on stakeholder feedback, lessons learned, and the changing global medical device landscape.

A Note on Reporting

For each year after the publication of this Plan, updates on activities specific to this Plan will be published in an annual assessment. **Appendix C** provides examples of the type of content that could be provided relative to each strategy. In many cases the amount of information that can be shared with respect to a specific strategy or activity will be limited due to the nature of the discussions. For example, many discussions are likely to fall under the protection of FDA's confidentiality commitments with trusted partners. In these cases, CDRH aims to provide quantitative and/or qualitative summaries of the interactions including, where possible, indication of the general geographies in which CDRH is interacting.

A Note on Terminology (Harmonization, Convergence, and Reliance)

Each of the terms "regulatory harmonization," "regulatory convergence," and "regulatory reliance" has a different meaning. The below terms are consistent with the World Health Organization (WHO) draft document "Good regulatory practices for regulatory oversight of medical products"[4] and will be used for the purposes of this Plan.

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[3] See https://www.fda.gov/media/158308/download

[4] See https://www.who.int/docs/default-source/medicines/norms-and-standards/current-projects/qas16-686-rev-3-good-regulatory-practices-medical-products.pdf?sfvrsn=ccb041db_2

Regulatory Harmonization refers to the process whereby technical guidelines are developed to be uniform across participating regulatory authorities in multiple countries.

Regulatory Convergence refers to a voluntary process whereby the regulatory requirements in different countries or regions become more similar or "aligned" over time. The process results from the gradual adoption of internationally recognized technical guideline documents, standards and scientific principles, common or similar practices and procedures, or the establishment of appropriate domestic regulatory mechanisms that align with shared principles to achieve a common public health goal.

Regulatory Reliance refers to act whereby 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 relying authority remains independent, responsible, and accountable regarding the decisions taken, even when it relies on the decisions and information of others.

While some of the strategies in this Plan focus more on one of the above aspects of international work than the others, we believe that all strategies and activities support harmonization, convergence, and reliance to different extents. For example, Strategy 2 describes creation of a mechanism for CDRH to share best practices with trusted partners. The discussion and information sharing through such a mechanism is expected to identify opportunities for harmonization and convergence as well as promote an understanding amongst regulators that could eventually support reliance. The language for Strategy 2 does not use the terms harmonization, convergence, or reliance, but the activities conducted under Strategy 2 are intended to support all three.

Strategies | Timeline of Activities

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

Several initiatives and projects already exist to further international harmonization, convergence and reliance. The work of CDRH in these forums has, thus far, been limited to the resources that could be devoted to engaging with the different groups. During the course of MDUFA V, CDRH is expected to receive additional funding and resources, allowing the Agency to expand engagement in international harmonization and convergence efforts.

The increase in engagement will have qualitative and quantitative aspects to consider. For example, an increase may be shown as an increase in the number of meetings of particular forums, the number of additional documents published, or (qualitatively) the complexity of work or projects undertaken and delivered. CDRH's engagement during the last year of MDUFA IV (FY 2022) is provided in Appendix D and will serve as a baseline for comparison throughout MDUFA V.

This strategy is related to Section V.I.1. of the MDUFA V Commitment Letter.

Timeline of Activities

- *Each fiscal year, CDRH will evaluate its engagement and identify opportunities to expand engagement in international harmonization, convergence and reliance efforts.*

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

Detailed discussions regarding implementation of harmonized policies and processes may require discussion under confidentiality commitments. Under this strategy, CDRH will create a mechanism to engage with trusted regulatory partners with whom the United States has confidentiality commitments to inform and align regulatory strategy.

This strategy is related to Section V.I.2. of the MDUFA V Commitment Letter.

Timeline of Activities

- *By the end of FY2023, FDA will identify and begin engaging with regulatory authorities with whom sharing information would be most supportive of harmonization and convergence efforts*
- *By the end of FY2024, CDRH will create a mechanism to share best practices in device evaluation and identify opportunities for convergence and reliance of international regulatory strategy*

** During the remainder of MDUFA V, activities undertaken as part of the implemented mechanism will be relevant to Strategy 2A*

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

IMDRF documents include harmonized policies and practices approved by all regulatory authorities that are members of the IMDRF Management Committee. By assessing CDRH's own policies as compared to IMDRF policies, CDRH demonstrates leadership and accountability in international harmonization efforts. In addition, by conducting a thorough assessment of CDRH's implementation of each IMDRF technical document, CDRH may identify opportunities to further advance this implementation. CDRH intends to capitalize on the results of this assessment and, where possible, work to further harmonize our processes and policies with internationally harmonized best practices.

This strategy is related to Section V.I.3. of the MDUFA V Commitment Letter.

Timeline of Activities

- *By the end of FY2025, CDRH intends to have published an assessment of the implementation of at least nine IMDRF technical documents*
- *By the end of FY 2026, CDRH intends to have published assessments of at least 18 IMDRF technical documents*
- *By the end of FY 2027, CDRH intends to have published assessments of all remaining IMDRF technical documents*

** These targets will be updated when CDRH's progress towards the elements of this Plan is reported.*
** Assessments will be conducted in accordance with IMDRF SOP Section 3.8*
** Assessments will be published on CDRH's International Affairs website.*

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

Stakeholders beyond CDRH (including patients, industry, conformity assessment bodies, and standards development organizations) may have better visibility to recommend opportunities for one regulatory authority to leverage another regulatory authority's approach to decision-making. Information from a broader audience may provide valuable insights for CDRH to consider in determining forms of engagements that may be most productive towards fulfilling our mission and vision.

This strategy is related to Section V.I.4. of the MDUFA V Commitment Letter.

Timeline of Activities

- *Beginning in FY2024, each fiscal year, CDRH intends to assess and report on efforts taken to support creation of a forum to engage with stakeholders and identify opportunities for regulators to leverage one another's approach to decision-making.*

** Activities may include:*

  - *Identification of potential programs or methods of engagement, including advantages and opportunities of each*
  - *Development of priorities for CDRH involvement in such a forum (e.g., targeted questions or work ideas; CDRH's role in the forum)*
  - *Understanding of level of interest and considerations of other stakeholders, including the extent to which those considerations overlap with CDRH's priorities*

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

Through technical discussions, regulatory authorities (including CDRH) may become more aware of one another's approach to decision-making and, in particular, expectations and processes around market authorizations. With a better understanding of current practices and policies, regulatory authorities may be more likely to adopt harmonized practices or rely on one another in whole or in part.

This strategy is related to Section V.I.5. of the MDUFA V Commitment Letter.

Timeline of Activities

- *Beginning in FY2024, CDRH targets participating in outreach activities to encourage harmonization, convergence, and reliance at least 6 times each fiscal year.*

** For example, to be considered outreach that contributes to this strategy, the engagement would need to include discussion of international best practices with an international audience. Where appropriate, CDRH may coordinate with other parts of the US government to participate in outreach (e.g., USAID).*

Summation

Patients throughout the world benefit from the rapid pace of innovation and increasingly global nature of medical device design, manufacture, distribution, and use. Through international harmonization, convergence, and reliance, the regulatory systems used across the globe can not only keep pace with, but also encourage and support this rapid evolution of technology while safeguarding access for patients to safe, effective, and high-quality medical devices.

CDRH welcomes feedback on this Plan. Public comment from stakeholders is critical to identifying and focusing our efforts where we can be most effective in supporting the United States and global public health. We look forward to your thoughts on this document and beginning the important work described within it.

Appendices

Appendix A: CDRH International Harmonization Engagements

Global Harmonization Task Force (GHTF)

In 1992, the United States, along with Canada, the European Union, Australia, and Japan, formed the Global Harmonization Task Force[5] (GHTF). Study groups within the GHTF developed documents on internationally harmonized best practices related to a variety of topics including premarket evaluation, post market surveillance, quality systems, auditing, and clinical safety/performance.[6] The GHTF published 29 documents,[7] many of which are still used today directly or as a reference and building block to documents published by the International Medical Device Regulators Forum (IMDRF), which replaced GHTF in 2011. [8]

Harmonization By Doing (HBD)

Through the U.S. - Japan Medical Device Harmonization by Doing (HBD)[9] initiative, US and Japanese regulators, academia, and industry have developed agreed-upon approaches for global clinical trials related to cardiovascular devices, and addressed regulatory barriers that may delay timely medical device approvals in both countries. HBD was initiated in 2003 and, since then, has continued to organize scientific sessions and conduct work specifically focused on convergence of pre-market clinical practices in emerging product areas such as pediatric devices,[10] standardizing information available in post-market data registries, and moving Japanese and US clinical study sponsors and regulatory agencies toward the use of single global clinical trial protocols[11] for evaluating cardiovascular devices rather than parallel country-specific protocols.

International Medical Device Regulators Forum (IMDRF)

In 2011, representatives from the medical device regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan and United States, as well as the WHO, met to establish the IMDRF.[12] The newly-formed organization aimed to build on the strong foundational work of the GHTF and to further accelerate international medical device regulatory harmonization and convergence.[13] As of the date this Plan was published, the forum has published 40 technical documents in topics ranging from machine learning and cybersecurity to regulatory authority competence and training requirements.[14] Further information about the work and operations of IMDRF is available in its Terms of Reference[15] and Strategic Plan 2021-2025.[16]

[5] See https://www.imdrf.org/ghtf
[6] *Ibid*
[7] List of documents available at https://www.imdrf.org/documents/ghtf-final-documents
[8] See https://www.imdrf.org/
[9] See https://www.fda.gov/medical-devices/cdrh-international-programs/usjapan-regulatory-collaboration
[10] See https://pubmed.ncbi.nlm.nih.gov/32238666/
[11] See https://pubmed.ncbi.nlm.nih.gov/29962385/
[12] Meeting outcome statement available at imdrf-meet-111101-ottawa-outcome-statement.doc (live.com)
[13] History and purpose of IMDRF available at https://www.imdrf.org/about
[14] List of documents available at https://www.imdrf.org/documents/library?f%5B0%5D=type%3Atechnical_document
[15] See https://www.imdrf.org/documents/imdrf-terms-reference
[16] See https://www.imdrf.org/documents/imdrf-strategic-plan-2021-2025

Regulatory Cooperation Council (RCC)

Launched in 2011, the United States-Canada Regulatory Cooperation Council[17] (RCC) brings together regulators from both United States and Canadian departments with health, safety, and environmental protection mandates to reduce unnecessary differences between their regulatory frameworks. Under the 2019-2020 RCC Medical Device Work Plan, the United States and Canada have been and continue to work bilaterally to harmonize premarket technical review where possible.[18]

Medical Device Single Audit Program (MDSAP)

At its inaugural meeting in Singapore in 2012, the IMDRF identified a work group to develop specific documents for advancing a Medical Device Single Audit Program (MDSAP).[19] The MDSAP allows an MDSAP-recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements for the regulatory authorities participating in the program.[20] A pilot of the MDSAP was conducted with participating regulatory authorities (Australia, Brazil, Canada, Japan, and the United States) from 2014 to 2016.[21] The pilot demonstrated viability of the program, which continues to expand in use over time. Since the program became fully operational, over 16,000 audit reports have been submitted to the MDSAP consortium. The United States continues to accept MDSAP audit reports as a substitute for routine Agency inspections.[22]

Asia-Pacific Economic Cooperation (APEC)

The Asia-Pacific Economic Cooperation (APEC)[23] is a regional economic forum established in 1989. The group aims to create greater prosperity for the people of the region by promoting balanced, inclusive, sustainable, innovative, and secure growth by accelerating regional economic integration.[24] The leaders of APEC established the Life Sciences Innovation Forum (LSIF) in 2002 to lead APEC initiatives related to health and health science innovation.[25] Within LSIF, the Regulatory Harmonization Steering Committee (RHSC) was formed in 2009 to promote strategic approach to regulatory harmonization.[26] The RHSC has several Priority Work Areas (PWAs), including one for medical devices.[27] The Medical Devices PWA was established in 2018 and is being led by the regulatory authorities of Japan, South Korea, and the United States. The aim of this work is encouraging regulatory convergence and harmonization via training and promoting implementation of IMDRF and GHTF guidance documents throughout the region.[28] The PWA regulatory leads coordinate the work and approve Centers of Excellence (CoEs) to conduct such training using the medical device core curriculum.[29]

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[17] See https://www.trade.gov/rcc
[18] The 2019-2020 Medical Devices Work Plan is available at https://legacy.trade.gov/WP_MedicalDevices.pdf
[19] See https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap
[20] *Ibid*
[21] *Ibid*
[22] See https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap
[23] See https://www.apec.org/about-us/about-apec
[24] *Ibid*
[25] Information about the LSIF is available at https://www.apec.org/groups/committee-on-trade-and-investment/life-sciences-innovation-forum
[26] Information about RHSC is available at https://www.apec.org/RHSC/About-us
[27] A listing of all PWAs is available at https://www.apec.org/RHSC/About-us/Organization
[28] Information about the Medical Devices PWA available at https://www.apec.org/RHSC/RHSC-Priority-Work-Areas/Medical-Devices
[29] See https://www.apec.org/-/media/Satellite/RHSC/PWA-Documents/Medical-Devices/APEC-RHSCMDCore-Curriculum-2020-Oct.pdf

World Health Organization (WHO) and Pan American Health Organization (PAHO)

The United States is an active participant in medical device working groups established by the World Health Organization[30] (WHO) and the Pan American Health Organization[31] (PAHO). Activities have included providing expertise, along with other WHO Member States, to the authors of various WHO publications targeted at providing guidance and up to date information about medical device regulations and recommended best practices for regulatory authorities. CDRH works closely with WHO's Prequalification of In Vitro Diagnostics and Male Circumcision Devices[32] to understand appropriate performance considerations regarding in vitro diagnostics.

Global Harmonization Working Party (GHWP)

The Global Harmonization Working Party[33] (GHWP), originally termed the Asia Harmonization Working Party (AHWP), focuses on global medical device harmonization. Membership to the group was initially targeted to the Asia region, but has recently become more global. The United States joined in October 2021 to better understand the group's work, work towards alignment between IMDRF and GHWP, and expand outreach to additional global regulatory and industry partners.

Bilateral and Multilateral Discussions

CDRH maintains strategic relationships with trusted regulatory partners throughout the world. CDRH may interact with other regulators bilaterally on issues that pertain only to one other jurisdiction or may convene a larger group to discuss a certain matter. For example, in 2021, CDRH initiated recurring, multilateral discussions regarding safety issues and (separately) digital health. These discussions accelerate harmonization and convergence of regulatory approaches for current and evolving topics. CDRH is also always looking for regulatory partners who may not have a developed regulatory framework, but are willing and motivated to work with FDA to explore approaches that are harmonized with international best practices.

[30] See https://www.who.int/
[31] See https://www.paho.org/en
[32] See https://extranet.who.int/pqweb/in-vitro-diagnostics
[33] See http://www.ahwp.info/

Appendix B: Linking MDUFA V Commitments to Specific Strategies within this Plan

Commitment Letter Heading	Commitment Letter Language	Strategy
V.I.1	Expand engagement in international harmonization and convergence efforts through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees to promote alignment with international best practices and internationally developed policies, including exploring the development of harmonized premarket review processes.	1
V.I.2	Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners with whom we have appropriate confidentiality commitments to inform and align international regulatory strategy. This may include, for example, sharing of scientific, clinical, or other technical information, or policies and practices, as needed and consistent with applicable disclosure law and policy.	2
V.I.3	Commencing in FY 2023, assess the extent of CDRH implementation of International Medical Device Regulators Forum (IMDRF) technical documents and make this information publicly available to enhance clarity and transparency.	3
V.I.4	Support the creation of a forum to engage with relevant stakeholders, including industry representatives and other regulators, to identify opportunities for regulators to leverage one another's approach to decision-making.	4
V.I.5	Participate in outreach activities to other regulatory authorities that encourage harmonization and may also encourage such authorities to rely in whole or in part on FDA marketing authorizations	5
V.I.6	By the end of FY 2023, issue for public comment a draft strategic plan with additional details and timelines associated with achieving the international harmonization objectives described above.	This document
V.I.7	Commencing with FY 2024, publish an annual assessment of the international harmonization activities described the strategic plan above, including the progress assessment described in V.I.3..	future publications

Appendix C: Initial Considerations for Information to Include in Annual Assessments

Strategy	Example Information to Include in an Annual Assessment
Strategy 1 Increase engagements in international harmonization, convergence, and reliance efforts	List of engagements with comparison to the baseline of the last year in MDUFA IV (FY2022).[34]
Strategy 2 Create mechanism for CDRH to share best practices with trusted partners	Activities completed and planned regarding creating a mechanism for CDRH to share best practices with trusted partners. Once the mechanism is created, reports on use of the mechanism will be provided under Strategy 1.
Strategy 3 Assess the extent of CDRH implementation of IMDRF technical documents	• Status of review of each IMDRF technical document in that year (e.g., "not started," "in progress," "published") • Where appropriate and publicly available, updates to CDRH practices based on the review 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	Steps taken to support creation of a forum and/or the work done within the forum.
Strategy 5 Participate in outreach activities to encourage harmonization, convergence and reliance	Number and type of engagements under this strategy.

[34] See **Appendix D** for baseline MDUFA IV information

Appendix D: CDRH Engagements in International Harmonization, Convergence, and Reliance Efforts During Fiscal Year 2022[35,36]

- IMDRF
  - CDRH participated in seven IMDRF working groups.[37] Of these working groups, CDRH co-chaired five.[38] Three documents were published in draft[39] and no documents were published in final by these working groups.
- GHWP
  - CDRH was accepted into GHWP and onto seven of the nine GHWP working groups.
- MDSAP
  - MDSAP extended use of extraordinary measures pertaining to use of remote/hybrid audits, with the intent of implementing post-pandemic remote audit practices long-term by 2024.[40]
- HBD
  - CDRH participated in HBD Think Tank held on January 13 and 20, 2022.
  - CDRH participated in monthly HBD-wide and working group-specific teleconferences.
- RCC
  - CDRH and Health Canada jointly reviewed two submissions to understand similarities and differences in approach that could inform reliance, convergence, and harmonization activities.
- APEC
  - Under APEC LSIF RHSC Medical Devices PWA, two trainings were reviewed by CDRH and conducted by the Centers of Excellence.
- WHO and PAHO
  - CDRH participated in working groups and provided feedback on draft WHO documents and proposals including the now published Global Atlas of Medical Devices[41] and the Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices.[42] In addition, CDRH worked with OGPS to develop the US government position regarding medical device topics (e.g., nomenclature, pandemic preparedness with respect to in vitro diagnostics) discussed at the World Health Assembly, WHO Executive Board meetings, and other engagements.
- Bilateral and Multilateral Discussions

[35] This list includes publicly available information, but is not inclusive of activities and engagements under confidentiality commitments.
[36] Fiscal Year 2022 runs from October 1, 2021 through September 30, 2022.
[37] IMDRF Working Groups included Adverse Event Terminology, Artificial Intelligence Medical Devices, Good Regulatory Review Practices, Medical Device Cybersecurity, Personalized Medical Devices, Regulated Product Submission, and Software as a Medical Device. For a complete listing of IMDRF working groups see https://www.imdrf.org/working-groups.
[38] IMDRF Working Groups co-chaired by the US included Adverse Event Terminology, Good Regulatory Review Practices, Medical Device Cybersecurity, Regulated Product Submission, and Software as a Medical Device.
[39] Documents published in draft include IMDRF/GRRP WG/N71, IMDRF/CYBER WG/N70, and IMDRF/CYBER WG/N73.
[40] See https://www.fda.gov/media/165653/download
[41] See https://www.who.int/publications/i/item/9789240062207
[42] See https://www.who.int/publications/i/item/9789241512350

- CDRH worked with industry, conformity assessment bodies, and other regulatory authorities to develop a project plan and building block for a Medical Device Single Review Program.[43]
- CDRH worked with trusted regulatory partners to establish a group to discuss digital health issues and best practices. The group met three times[44] to discuss topics ranging from bias to predetermined change control plans.
- CDRH and Health Canada worked towards an eSTAR[45] pilot in which submissions developed through a single eSTAR would meet the needs of both CDRH and Health Canada.
- CDRH published a guiding principles discussion paper[46] on Good Machine Learning Practice for Medical Device Development with Health Canada and the United Kingdom's Medicines and Healthcare products Regulatory Agency.
- In FY2021, CDRH and five other regulatory authorities began engaging on a bimonthly basis to share policies and best practices regarding post market surveillance. In FY2022, the group increased the frequency of engagements (from bimonthly to monthly) and increased the number of participating regulatory authorities (from six total to nine total).
- CDRH established routine calls regarding mPox in vitro diagnostic best practices among trusted regulatory partners.

[43] MDSRP is not being actively pursued at this time due to statutory changes needed to effectively support the program in the United States.
[44] Meetings held in FY2022 included Nov 2021, Feb 2022, and June 2022.
[45] See https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program
[46] See https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles