CDRH Vision for Future of Medical Device Oversight: Global Engagement

Kenneth J. Cavanaugh Jr, PhD
Associate Director, International Policy and Strategy
Center for Devices and Radiological Health
U.S. Food and Drug Administration

June 15, 2026

Patients are at the Heart of What We Do

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

Global Device Development Challenges

- Each country is typically required to develop and implement its own regulatory framework and path to market products based on the applicable statutory requirements
  - Consideration of emerging technologies presents additional challenges
- Resources are not maximized when regulatory authorities must administer, and industry must navigate adherence to, numerous and sometimes redundant or conflicting regulatory requirements globally
  - These inefficiencies can be reduced through harmonization, convergence, and reliance efforts which can promote a more effective regulatory model for medical devices

International Harmonization Benefits

- Reduces technical barriers to trade and performing unnecessary, redundant work
- Streamlines development processes and deliver products faster
- Elevates regulatory frameworks and builds global competency to international best practice
- Stimulates innovation
- Ultimately, a more efficient and effective model means patients have better access to safe, effective, and high-quality medical devices

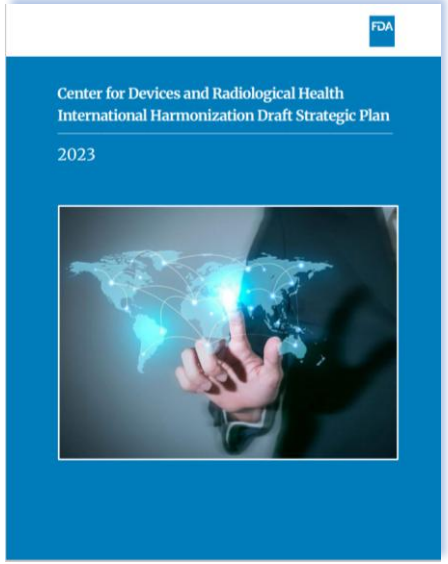
CDRH International Harmonization Commitments (FY2023 – 2027)

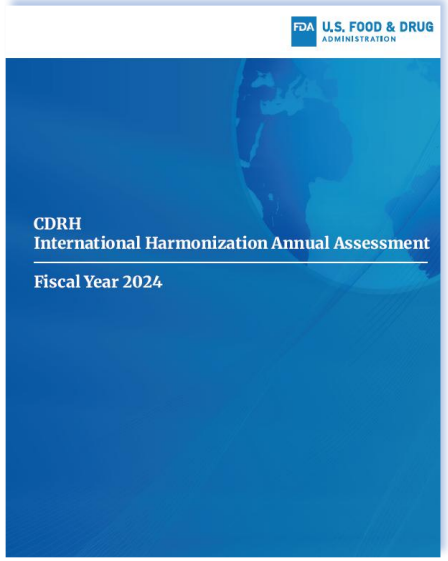
- Five broad commitments related to international harmonization efforts:
  1. Expand engagement in international harmonization and convergence efforts through participation with international regulators and other key stakeholders in **forums, working groups, projects, and committees**
  2. Further support regulatory convergence by creating a mechanism for **FDA to work with regulatory partners**
  3. Assess the extent of **CDRH implementation of IMDRF technical documents** and make this information publicly available
  4. Support the **creation of a forum** to engage with relevant stakeholders to identify opportunities for regulators to leverage one another's approach to decision making
  5. Participate in **outreach activities** to other regulatory authorities that encourage harmonization

- Requires the issuance of a **strategic plan** with additional details and timelines associated with achieving these international harmonization objectives

CDRH International Harmonization Strategic Plan

- Issued September 19, 2023
- Recognizes the importance of globally harmonized medical device regulatory policy and practices
- Builds on our existing international work and serves as a foundation for our work to come
- Outlines specific strategies and activities towards international harmonization, convergence, and reliance over the next 4 years
- Commits to publishing annual assessments of CDRH's international harmonization activities
  - Reports for FY24 and FY25 activities are published





International Harmonization: CDRH Approach

- Use of international consensus standards
- Use of minimal country-specific deviations, if any
- Implementation of internationally harmonized documents such as those developed by IMDRF
- Participation in international programs such as MDSAP
- Use of Least Burdensome Principles
- Additional staff dedicated to international harmonization activities

International Partnerships

- Collaboration with global regulatory authorities through multilateral and bilateral efforts such as:
  - International Medical Device Regulators Forum (IMDRF)
  - Medical Device Single Audit Program (MDSAP)
  - Pan-American Health Organization (PAHO)
- Key to success is building confidence and trust among regulators

IMDRF Strategic Plan 2026 - 2030


IMDRF International Medical Device Regulators Forum

Final Document

IMDRF/MC/N91 FINAL: 2025

IMDRF Strategic Plan 2026-2030

AUTHORING GROUP

IMDRF Management Committee

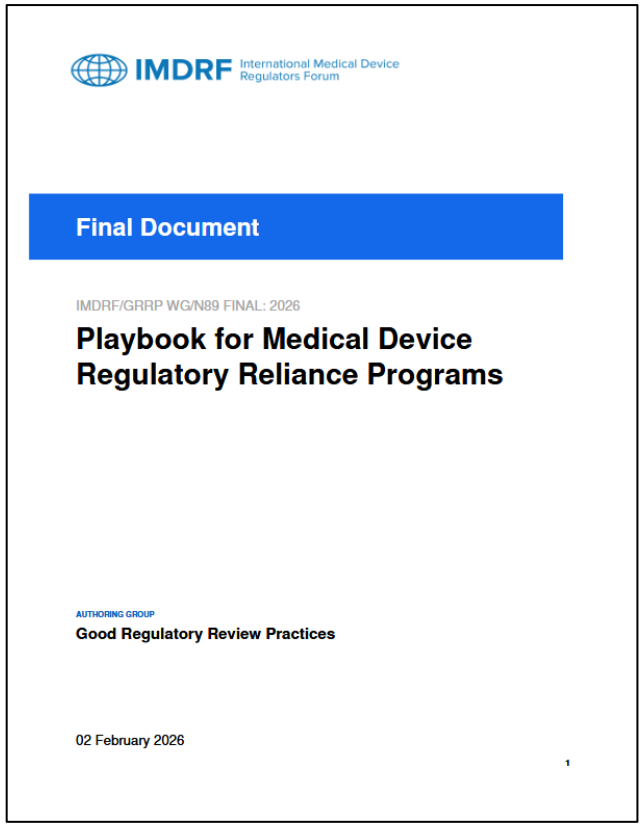
19 December 2025

- Sustainable leadership and growth
- Sufficient foundational guidance
- Innovative technical documents
- Broad stakeholder engagement
- Guidance implementation/training

Regulatory Reliance – A Potential Tool for All

Reliance: *The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.*

- IMDRF reliance playbook published in February 2026
  - Resource for developing reliance programs designed to best meet the needs of all stakeholders
  - Can include recognition, abridged review, or work-sharing



CDRH Reliance via Work-Sharing: Medical Device Single Audit Program (MDSAP)

Chair & Secretariat
2026-2027

MDSAP
Medical Device Single Audit Program

7,650+
MANUFACTURING SITES

81
COUNTRIES

30K+
Audits

2026 MDSAP FORUM

KYOTO, JAPAN
JUNE 15-19, 2026

CDRH Harmonization:
Quality Management System Regulation (QMSR)

Final QMSR rule published on February 2, 2024

*QMSR effective date is **February 2, 2026** (two-year transition)*

QMSR Core Actions

- Replaces the long- standing CGMP regulation: Quality System regulation
- Directly incorporates requirements from international quality management system standards (ISO 13485:2016)
- Embeds risk-based quality requirements and globally harmonizes device quality expectations

QMSR Major Impacts

- Aligns FDA expectations more closely with international practice and risk-based lifecycle approach
- Harmonization that can simplify global quality system management expectations

Considerations for the Future

- Successful regulatory convergence, harmonization, and reliance in accordance with Good Regulatory Practices takes time
- Not everything can be fully aligned...
- …but understanding and accounting for any differences is also valuable
- Important not to add to (or complicate) existing regional requirements
- Consensus may increase stability in a changing global regulatory environment
  - Regional changes
  - Emerging technology