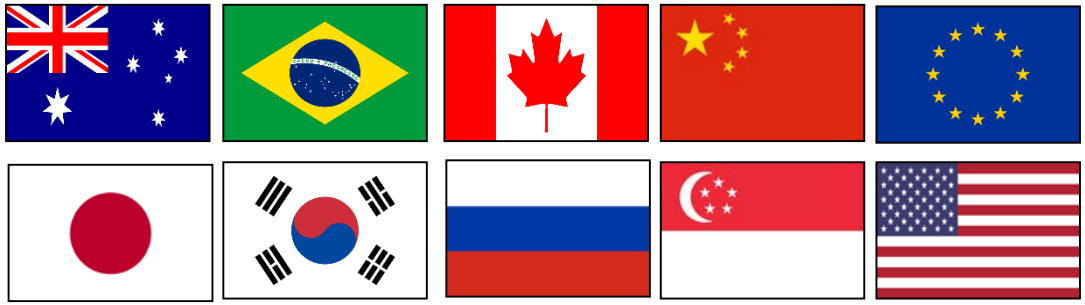
Medical Device Regulatory Harmonization: IMDRF and MDSAP

Melissa Torres
Associate Director for International Affairs
Office of the Center Director
Center for Devices and Radiological Health
US Food and Drug Administration

International Medical Device Regulators Forum (IMDRF)



Management Committee (MC) Members

IMDRF International Medical Device Regulators Forum

Official Observer

World Health Organization

Regional Harmonization Initiatives

Pan American Health Organization

Life Sciences Innovation Forum (LSIF)

APEC

Regulatory Harmonization Steering Committee (RHSC)

AHWP

ASIAN HARMONIZATION WORKING PARTY

IMDRF Overview

- Launched in February 2012
- Successor to the Global Harmonization Task Force (GHTF)
- Chair and secretariat rotate on annual basis
  - Australia (2012), EU (2013), US (2014), Japan (2015), Brazil (2016), Canada (2017), China (2018), Russia (2019), Singapore (2020), S. Korea (2021)
- Decisions are made by consensus, not voting
- Two 3 day meetings per year (March and September)
  - Includes public stakeholder session which provides updates from MC members, IMDRF working groups, RHIs, industry associations, etc.

IMDRF Mission and Goals

Mission:

To strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.

Goals:

- Accelerate international medical device regulatory harmonization and convergence building on the work of GHTF
- Address common public health regulatory challenges to convergence due to the globalization of medical device production and the emergence of new technologies
- Accelerate innovation by clear and practical regulatory expectations

IMDRF Working Groups

- Working groups are formed to address particular emerging topics.
- Currently 8 active working groups:
  - Adverse Event Terminology
  - Good Regulatory Review Practices
  - Standards
  - Regulated Product Submission (RPS)
  - Personalized Medical Devices
  - Clinical Evaluation
  - Cybersecurity
  - In Vitro Diagnostics
- Working groups develop harmonized documents, procedures, or programs

Medical Device Single Audit Program (MDSAP)

- Development of program began in 2012 by IMDRF
- Participation:
  - Members: Australia, Brazil, Canada, Japan, US
  - Affiliate Members: Argentina and S. Korea
  - Official Observers: EU and WHO
- Allows recognized Auditing Organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of 5 participating Regulatory Authorities
- Pilot program 2014-2016, full implementation 2017 – present
- Over 5,100 medical device manufacturing sites participate in the program

MDSAP Mission, Objectives, and Benefits

- Mission:
  - To "…jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers"

- Objectives:
  - Appropriate regulatory oversight while minimizing regulatory burden on industry
  - Efficient and flexible use of regulatory resources
  - Promote a greater global alignment of regulatory approaches and technical requirements
  - Promote consistency, predictability, and transparency

- Benefits:
  - Reduction of the number of audits for manufacturers
  - Clear regulatory audit expectations
  - Improvement in predictability of audit outcomes

Thank You