Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

Policy Session with Regulators: U.S. FDA

June 15, 2020

If you would prefer to join over the telephone in listening mode, please select “Phone Call” in the Audio pane and the dial-in information will be displayed.

Inter-American
Coalition for
Regulatory Convergence

MEDICAL TECHNOLOGY SECTOR

Questions?

Please use the Questions/Chat pane of the GoToWebinar Control Panel

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

Agenda

TIME (min)	AGENDA
5	**Introductions & Session Objectives** *Facilitated by: Steven Bipes, Vice President – Global Strategy & Analysis, AdvaMed*
60	**Presentation by U.S. Food and Drug Administration** *Presented by: Patricia Pineda, International Regulatory Analyst* • FDA Latin America Office • Overview of IMDRF Structure, WGs, and Priorities • FDA Medical Device Division (CDRH) & LatAm Activities • Overview of FDA Engagement with IMDRF and use of international standards for medical device regulatory convergence (FDA Standards & Conformity Program/Policy) • MDSAP & ISO13485
20	**Q&A** *Facilitated by: Sandra Ligia González, Executive Secretary*
5	**Conclusions and Closing Remarks** *Facilitated by: Steven Bipes*

Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

U.S. Food and Drug Administration

Ana Patricia Pineda,
International Regulatory Analyst, USFDA

U.S. FOOD & DRUG ADMINISTRATION

Medical Devices Regulatory Convergence

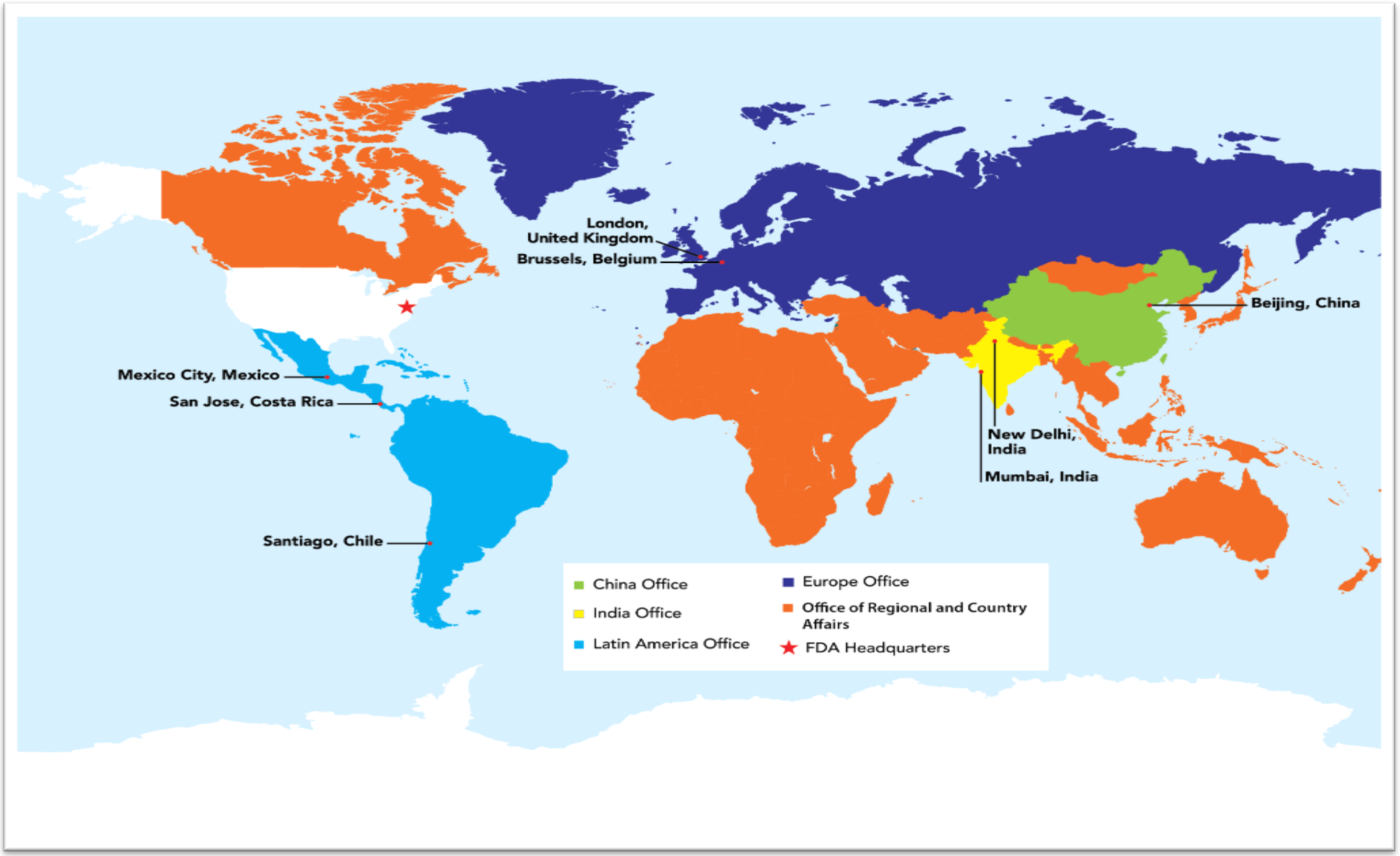
Patricia Pineda
International Regulatory Analyst
Latin America Office
Office of Global Operations
US Food and Drug Administration

Disclaimer

The content here is intended only to provide a summary and general overview. It is not intended to be comprehensive nor does it constitute legal advice

FDA Latin America Office

FDA Foreign Offices



LAO's activities related to Medical Devices

- Participate in the National Regulatory Authorities of Regional Reference (NRAr).
- Steering Committee of the Pan American Drug Regulatory Harmonization Network (PANDRH).
- Outreach activities in countries in the region to industry and government, aimed to promote understanding of the medical device regulations in order to improve the compliance level of the products exported to the US.
- Promote active participation and engagement on regulatory convergence intiatives such as IMDRF and MDSAP.

International Medical Devices Regulators Forum
IMDRF

Management Committee (MC) Members

IMDRF International Medical Device Regulators Forum

Official Observer

World Health Organization

Regional Harmonization Initiatives (RHIs)

Pan American Health Organization

Life Sciences Innovation Forum (LSIF)

APEC

Regulatory Harmonization Steering Committee (RHSC)

AHWP

ASIAN HARMONIZATION WORKING PARTY

IMDRF

- Launched in February 2012
- Successor to the Global Harmonization Task Force (GHTF)
  - Broader membership than GHTF
- Chair and secretariat rotate on annual basis, beginning with 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

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.

Strategic Plan

- Enhance Post-Market Surveillance
- Improve the Effectiveness and Efficiency of Pre-Market Review

IMDRF Working Groups

- Active Working Groups – Comprised of regulators only or regulators and stakeholders depending on the topic.
  - Adverse Event Terminology
  - Good Regulatory Review Practices
  - Regulated Product Submission (RPS)
  - Personalized Medical Devices
  - Clinical Evaluation
  - Cybersecurity
  - In Vitro Diagnostics

U.S. FOOD & DRUG ADMINISTRATION

Standards and Conformity Assessment Program (S-CAP)

Value of Standards' Use

- Promotes international trade
- Expeditious to rely upon consensus-driven standards rather than lengthy legal or rule-making approaches
- Encourages innovation and competition among product developers
- Reduces burdens on device companies by harmonizing expectations across international jurisdictions
- Introduces efficiencies into the pre-marketing review process
- Standardized conformity assessments and test reporting
- Promotes regulatory science at national and international levels
- Ensures that patients have access to innovative devices that are also safe and effective

S-CAP Vision

The Standards and Conformity Assessment Program (S-CAP) enhances consensus standards and their use in the design, development and evaluation of medical devices across their lifespans. Relying upon a collaborative approach to standards development and application, S-CAP draws upon expertise from across the medical device and standards communities to advance regulatory science, promote patient safety and support a least burdensome regulatory framework.

S-CAP Mission

S-CAP supports CDRH's mission by driving the development, recognition, and appropriate use of regulatory-ready standards for medical devices throughout their lifecycles. S-CAP:

- Produces and implements clear policies to promote the appropriate use of standards in regulatory processes
- Anticipates the need for and leads development of national and international consensus standards
- Advances initiatives to enhance confidence in conformity assessment activities
- Fosters innovation and standardization in technologies that facilitate patient access to novel devices
- Provides leadership in standards quality and utilization through outreach and global harmonization

S-CAP priorities:

- Encouraging the appropriate use of standards
- Active participation in national and international standards development
- Recognition program

15

S-CAP numbers:

- 17 internal advisory Specialty Task Groups (STGs) in 23 device/scientific areas
- 400+ CDRH staff participating in 600+ national and international standards committees across 29 Standards Developing Organizations
- 1385 currently recognized standards (1268 complete and 117 partial recognitions)
- 5-10% typical increase in requests for new standards development activities each year
- Average of 7 (range of 1-35) standards cited in each 510(k)

Medical Devices Single Audit Program
MDSAP

MDSAP

The Medical Device Single Audit Program (MDSAP) is a regulatory audit program that was jointly developed by five jurisdictions.

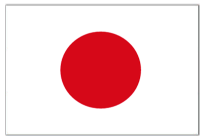
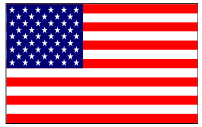
It allows a medical device manufacturer to have a single quality management system audit to satisfy the requirements of all participating regulatory authorities.

Members, Observers and Affiliates

Members

- Australia: Therapeutic Goods Administration (TGA)
- Brasil: Agência Nacional de Vigilância Sanitária (ANVISA)
- Canadá: Health Canada
- Japón:
  - Ministry of Health, Labour and Welfare (MHLW)
  - Pharmaceuticals and Medical Devices Agency (PMDA)
- USA: Food and Drug Administration (FDA)



Observers

- World Health Organization (WHO)
- European Union (EU)


Affiliate Member

- Argentina: National Administration of Drugs, Foods and Medical Devices (ANMAT)
- South Korea: Ministry of Food and Drug Safety (MFDS)


Objectives / Benefits of the program

For the Regulatory Authorities

- Appropriate oversight of the medical device industry
- Efficient and flexible use of regulatory resources
- Promote a greater global alignment of regulatory approaches and technical requirements
- Enable each Regulatory Authority to use the outcomes of the program (i.e. audit reports and certification documents) according to their own processes

For the medical device industry

- Reduced number of audits
- Greater predictability of audit outcomes
- Choice of MDSAP Auditing Organization
- Required to access the Canadian market; support access to other markets

Affiliate Membership

- New Membership Option for Regulatory Authorities
- Criteria for Membership includes:
  - Laws and regulations in place for evaluating a medical device manufacturer's QMS based on GHTF and IMDRF foundations and principles
  - Other laws and regulations that build on GHTF and IMDRF foundations and principles (ex: pre-market evaluation, post-market surveillance/vigilance, clinical safety/performance)
  - Completion of MDSAP on-line training modules
  - Objectives for becoming an Affiliate Member
  - Contributions to MDSAP
  - Implementation of MDSAP documents
- Application submitted to MDSAP RAC for review

Affiliate Membership

- Regulatory requirements of the Affiliate Member are not included in the audit model
- Reports will need to be requested from the medical device manufacturer
- Benefits:
  - Training on MDSAP
  - Receive MDSAP audit/site information
  - Listed on MDSAP website as an Affiliate Member
  - Participate in yearly MDSAP Forum meetings
  - Collaboration and capacity building with MDSAP RAs

ISO 13485:2016

ISO 13485:2016
Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

- ISO 13485 outlines QMS requirements for the lifecycle of medical devices
- Used globally by many Regulatory Authorities as the requirement for GMPs for medical device manufacturers
  - Canada, Japan, S. Korea, EU, Australia, etc.
- Foundation of the Medical Device Single Audit Program (MDSAP) audit model

Why Require a QMS?

- Quality system requirements are the base requirement for medical device life cycle. Not ONLY Manufacturing
- Quality systems assure that products are designed, manufactured and provided consistently by focusing on safety, performance and regulatory requirements.
- Quality system requirements are designed with flexibility to accommodate the diversity and complexity of medical devices, manufacturing processes, supply chains, etc

8 Clauses of ISO 13485

1 Scope
Meeting customer requirements & regulatory requirements
Exclusions & Applicability

2 Normative References
ISO 9000:2015

3 Terms and Definitions

4 Quality Mgmt. System
General
Requirement
Documentation Requirements

5 Management Responsibility
Mgmt. Commitment
Mgmt. review

6 Resource Mgmt.
Human Resources
Work Environment and Contamination Control

7 Product Realization
Design & development
Purchasing
Production & Service Provision **Process Validation

8 Measurement, Analysis & Improvement
Corrective action
Preventive action

It is all about interactions and processes!

FDA AND ISO 13485

FDA's Intention

FDA intends to harmonize and modernize the Quality System regulation for medical devices. The revisions will supplant the existing requirements with the specifications of an international consensus standard for medical device manufacture, ISO 13485:2016. The revisions are intended to reduce compliance and recordkeeping burdens on device manufacturers by harmonizing domestic and international requirements. The revisions will also modernize the regulation.

Rationale for Use of ISO 13485: 2016

- Many similarities between the requirements of the QS regulation (21 CFR 820) and the clauses of ISO 13485:2016
  - Differences between the QS regulation and standard are minor
- ISO 13485:2016 is already used in many countries to meet jurisdictional QMS requirements
- Moving to ISO 13485 allows for:
  - More opportunities to work closer with regulatory authorities around the globe and facilitate regulatory convergence on QMS.
  - Opportunities for medical device manufacturers to have a more globally harmonized QMS system.

Thank You!

ana.pinedazavaleta@fda.hhs.gov

Q & A

Closing Remarks