IMDRF International Medical Device Regulators Forum

RHI Update - Secretariat of the Pan American Network for Drug Regulatory Harmonization (PANDRH)

March 2025 - September 2025

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IMDRF International Medical Device Regulators Forum

Agenda

PANDRH

State of the Region

RHI Activities

IMDRF Guidance

IMDRF International Medical Device Regulators Forum

CONFERENCE

STEERING COMMITTEE

SECRETARIAT

TECHNICAL STRUCTURES

MEMBERS

NRA from PAHO countries

PARTICIPANTS

Regional regulatory initiatives
Producers' associations
FIFARMA (founder)
ALIFAR (founder)

OBSERVERS

Civil society
Academia
Professional societies
Scientific institutions
Experts
Authorities from other regions
Harmonization initiatives

The Pan American Network for Drug Regulatory Harmonization (PANDRH)

GENERAL OBJECTIVES

1. Strengthen the **regulatory functions and systems** of the countries in the Region
2. Develop common proposals for the regulation of **health technologies**
3. Develop **competencies** in the use of **regulatory science/good practices**
4. Encourage **NRAs** to develop and maintain **well-structured organizations**

IMDRF International Medical Device Regulators Forum

State of the Region

Development of New Regulatory Frameworks

Updating Existing Regulatory Frameworks

Public Consultations Underway

Development and Issuance of Technical Guidance

Capacity-Building Initiatives

Knowledge Harmonization Initiatives

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RHI Activities [March – September, 2025]

(March 2025) **WORKSHOP ON STRENGTHENING THE REGULATORY FRAMEWORK FOR MEDICAL DEVICES IN IBERO-AMERICA**
Organized by the EAMI Network

(May 2025) **INFORMATION SESSION ON THE IMDRF N89 PLAYBOOK**
In collaboration with the USFDA, Chair of the IMDRF GRRP Working Group.

(June 2025) **5th WHO GLOBAL FORUM ON MEDICAL DEVICES**
Plenary panel on *Regulations of Medical Devices*

(July 2025) **VIRTUAL MEETING ON THE NEW NRAr EVALUATION AND DESIGNATION SYSTEM**
Framework for evaluating and designating NRAr based on WHO GBT

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(September 2025)

WORKSHOP ON MEDICAL DEVICE REGULATION & THE WHO GBT+MD

Objectives:

- Overview of WHO Regulatory System Strengthening (RSS) Program,
- WHO Global Benchmarking Tool Plus for Medical Devices (GBT+MD),
- Global Model Regulatory Framework for Medical Devices,
- WHO guidance on post-market surveillance and market surveillance.

Modality: 4 virtual sessions of 1.5 hours each, scheduled for **September 22, 23, 24, and 25**.

Languages: English, with simultaneous interpretation to Spanish and Portuguese.

Outputs will contribute to the REGTEC learning itinerary available on the PAHO Virtual Campus for Public Health (VCPH).

IMDRF International Medical Device Regulators Forum

IMDRF Guidance

Regional Representation in the Working Groups

ARTIFICIAL INTELLIGENCE/MACHINE LEARNING-ENABLED

- Argentina, ANMAT
- Chile, ISP
- Cuba, CECMED

SOFTWARE AS A MEDICAL DEVICE

- Argentina, ANMAT

PERSONALIZED MEDICAL DEVICES (PMD)

- Argentina, ANMAT
- El Salvador, SRS
- Paraguay, DINAVISA

QUALITY MANAGEMENT SYSTEMS

- Argentina, ANMAT
- Colombia, INVIMA
- Cuba, CECMED
- El Salvador, SRS
- Venezuela, INHRR

ADVERSE EVENT TERMINOLOGY

- El Salvador, SRS

CLINICAL EVIDENCE FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

- Argentina, ANMAT
- Cuba, CECMED
- El Salvador, SRS

GOOD REGULATORY REVIEW PRACTICES

- Argentina, ANMAT

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IMDRF Guidance

Public Consultation

PUBLIC CONSULTATION ON THE IMDRF N89 PLAYBOOK

In addition to comments submitted by the PANDRH Secretariat, **eight countries** from the Region also provided feedback on the:

"IMDRF N89 Playbook for Medical Device Regulatory Reliance Programs"

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IMDRF Guidance

Feedback

PAHO and PANDRH have undertaken the **translation of IMDRF documents into Spanish and Portuguese**, ensuring that national regulatory authorities across the region can make practical use of this guidance. However, these efforts face sustainability constraints, particularly without a clear mechanism for assessing their long-term impact.

By facilitating access to IMDRF standards and fostering the exchange of knowledge among countries, PANDRH is helping to **advance regional convergence and harmonization** in medical device regulation, laying the groundwork for more equitable and effective oversight.

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IMDRF Guidance

Sustaining Progress

Strengthening synergies among initiatives to

- Maximize resource utilization
- Collaborate on priority and emerging technologies
- Strengthen regulatory decisions via shared information
- Accelerate IMDRF guidance adoption & reduce duplication
- Support sustainable, competency-based capacity building
- Enable IMDRF Management Committee knowledge exchange

Thank you/Questions