IMDRF International Medical Device Regulators Forum

PAHO Update

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IMDRF Meeting

14 September 2021

Regional Working Group on Medical Device Regulation

24 countries are currently members

Argentina	Belize	Bolivia	Brazil	Canada
Chile	Colombia	Costa Rica	Cuba	Dominican Republic
Ecuador	El Salvador	Guatemala	Guyana	Honduras
Jamaica	Mexico	Nicaragua	Panama	Paraguay
Peru	Trinidad & Tobago	Uruguay	Venezuela	

Activities of the Regional Working Group

- Annual Face to Face Meetings
  - Open Session with stakeholders
- Virtual Meetings

Regional Meetings

Training

- Annual virtual courses in collaboration with CECMED and INVIMA
- Face to face workshops on defined priority topics

- Regional Meetings in conjunction with the IMDRF Meetings
- Participation in the Working Groups
- Mirror Working Groups
- Translation of technical documents

Collaboration with IMDRF

Technical Groups

- Reuse and reprocessing of Medical Devices
- National Implant Registry

- Development of Basic Indicators
- Advanced Indicators draft
- Participation in the Global Benchmarking Tool + Medical Devices

Medical Device Indicators

Community of Practices

- Regulation of Medical Devices
- REDMA Program

Collaboration with IMDRF

PARTICIPATION IN THE FOLLOWING IMDRF WORKING GROUPS			
Medical Device Clinical Evaluation	Personalized Medical Devices	Good Regulatory Review Practices	Principles of IVD Medical Devices Classification
• ANMAT	• ANMAT	• INVIMA	• ANMAT • CECMED • MoH Uruguay

On August 24, 2021, ANMAT (Argentina) became an OFFICIAL OBSERVER of the IMDRF

Collaboration with IMDRF

TRANSLATIONS

Six documents translated into Spanish

Collaboration with IMDRF

T R A N S L A T I O N S

The following documents are currently being translated into Spanish:

1. Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
2. Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews
3. Personalized Medical Devices - Regulatory Pathways
4. Clinical Investigation
5. Clinical Evaluation
6. Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making
7. Common Data Elements for Medical Device Identification
8. Software as a Medical Device (SaMD): Key Definitions

Program on exchange of reports on adverse events of Medical Devices - REDMA Program

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Associate Members

BOL | ECU | HND | NIC | PRY | ELS | URY | PAN | DOR | VEN

6

Full Members

ARG | BRA | COL | CUB | CHL | MEX

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Reports

20 Confidential

13 Non-confidential

NRA	*Medical Device*	*Confidentiality*
COFEPRIS	Breast implant	Yes
	Breast implant	Yes
INVIMA	Mechanical ventilator	Yes
	Mechanical ventilator	No
CECMED	Non-sterile hydrophilic white gauze	Yes
	Plastic Tracheostomy Cannula (PVC)	Yes

- 71% of the total reports are confidential
- Health institutions reported 67% of the events while the manufacturers reported 33%
- Reported equipment risk-based classification: 50% Moderate-High; 33% High; and 17% Low
- Most represented medical specialties: General medicine and plastic surgery with 33% respectively; anesthesia and general hospital 17%
- China was the manufacturing country with the highest percentage of reports 33%

REDMA Program

Capacity building activities

Virtual course on **Regulation of Medical Devices**

- Spanish version was fully translated into English
- In collaboration with CECMED, PAHO/WHO Collaborating Centre for the *Regulation of Health Technologies*
- Hosted on CECMED's Virtual Classroom platform
- English versión of the course will be offered to the Caribbean countries in 2022

Meeting of the Regional Working Group on Medical Devices Regulation

- Held on 27 May 2021
- 41 participants from 16 countries

TOPICS
Global Benchmarking Tool + Medical Devices
Medical Devices Nomenclature
Collaboration with IMDRF
Collaboration opportunities
Next steps of the Regional Working Group
Regulation of Assistive Products

IMDRF International Medical Device Regulators Forum

NEW PROJECT on Regulation of assistive products in the Americas

Main components

1. **Assessment of the regulatory situation of APs in the Region**
2. **Development of a guidance tool on AP regulation**
3. **Development of a virtual course hosted at PAHO's Virtual Campus for Public Health**

Assistive technology (AT)
Is the application of organized knowledge and skills related to assistive products, including systems and services. AT is a subset of health technology.

Assistive products (AP)
Any external product that maintain or improve an individual's functioning and independence, and thereby promote their well-being. APs are also used to prevent impairments and secondary health conditions.

Quality assurance of Medical Devices in response to the COVID-19

REQUIREMENTS

Eligibility criteria	• Product included in the *List of Priority Medical Devices in the context of the COVID-19 (LPMD)* • Regulatory compliance (**IMDRF Members,** WHO SRAs for IVDs, manufacturing country) • Documentation to demonstrate compliance with standards (as specified in the LPMD)
For the manufacturer	• Manufacturing license issued in the country of origin • Certified Quality Management System. (e.g. ISO 13485, ISO 9001 or equivalent) • Application of risk management to medical devices, if applicable (e.g. ISO 14971)
For the product safety and performance	• Quality Assurance process based on technical requirements and applicable standards, (according to the Medical Device) • Evidence to demonstrate compliance with the applicable standards (e.g. *official test reports*)
For the labelling	• Instructions for use, service manual, user manual, technical specifications. • Label contains essential requirements (e.g. storage and distribution conditions) • Compliance with the principles of the document **IMDRF/GRRP WG/N52 FINAL:2019**

Quality assurance of Medical Devices in response to the COVID-19

Biomedical Equipment	In Vitro Diagnostics	Personal Protective Equipment
140 evaluations	**15** evaluations	**209** evaluations
Examples: ICU **v**entilator, transport ventilador, portable ultrasound, defibrillator, pulse oximeter, BiPAP, patient monitor	**Examples:** diagnostic kits, analyzers	**Examples:** particulate respirator, surgical masks, sterile surgical gloves, examination gloves, gowns

January-June 2021

Thank you!