IMDRF International Medical Device Regulators Forum

PAHO Update

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IMDRF Meeting

13 September 2022

Regional Working Group on Medical Devices Regulation

Established in 2012 with the objective of strengthening the regulatory capacity of medical devices in the Americas - **25 NRA** 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**	**USA**	**Venezuela**

Activities of the Regional Working Group

Regional Meetings

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

Training

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

Collaboration with IMDRF

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

Technical Groups

- Reuse and reprocessing of Medical Devices
- National Implant Registry

Medical Device Indicators

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

Community of Practices

- Regulation of Medical Devices
- REDMA Program

IMDRF International Medical Device Regulators Forum

X Regional Meeting of Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Americas

1 - 3 June 2022

In collaboration with the *Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector*

TOPICS

- Regional Working Group on Medical Devices Regulation
- Good Regulatory Practices for Medical Devices
- The Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector and its work in support of advances in the Region
- Good Reliance Practices in Emergency Use Authorizations for Medical Devices

Sesion recordings and material can be consulted at: https://www.paho.org/es/temas/dispositivos-medicos

VIRTUAL MODE

Open Session	Closed Session
	Regulators
1-2 June	2-3 June
250 participants	100 participants

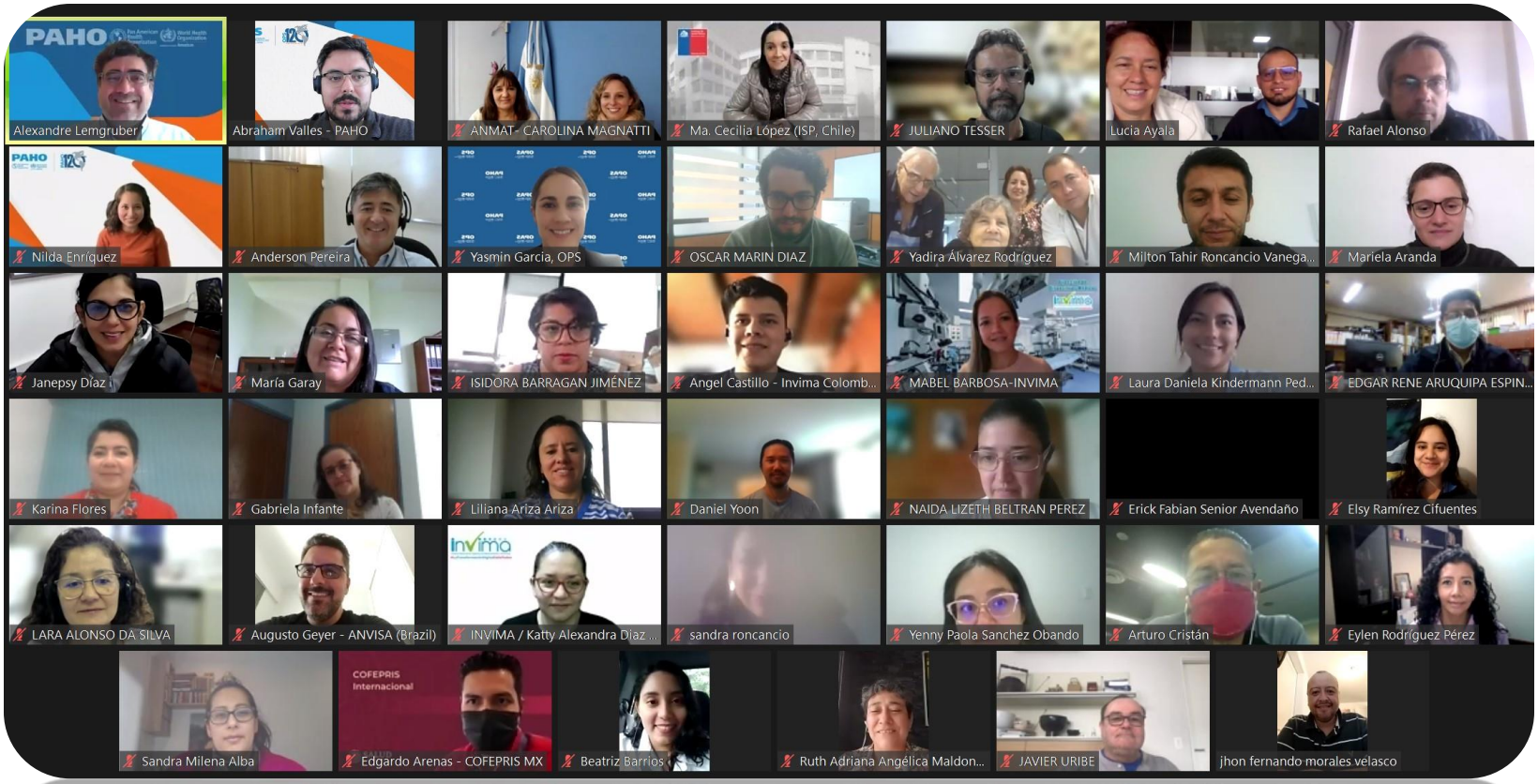
TOPICS

- Capacity-building activities
- REDMA Program
- Regulation of In Vitro Diagnostics
- HEARTS Initiative
- PAHO/WHO WHO Collaborating Centre for the Regulation of Health Technologies
- Medical Device Nomenclature
- Global Benchmarking Tool + Medical Devices
- WHO Collaborative Registration Procedure
- Global Model Regulatory Framework
- IMDRF Activities
- Assistive Products

IMDRF International Medical Device Regulators Forum

X Meeting of Regulatory Authorities for the Strengthening of the Regulatory Capacity of Medical Devices in the Americas

3 June 2022 – Closed session



Policy to Strengthen Regulatory Systems for Medicines and other Health Technologies

POLICY PROPOSAL

To promote **efficient regulatory systems** with maturity level 3 or higher **in all Member States**, tailored to the **needs of** their **health systems** and **ensuring** the **quality, safety, and efficacy** of **health technologies** in accordance with WHO recommendations

In addition, where established by national policies and where the context permits, regulatory systems should **encourage the production of health technologies** that promote health and well being, as well as economic and social development.

Next Steps:

- Consultation sessions with MS were held in February-March;
- PAHO internal review process;
- Edition and publication in all official languages;
- 20-24 June 2022, the Executive Commmittee was invited to review the Policy, adopt the proposed Resolution, and recommend its adoption at the 30th Pan American Sanitary Conference, to be held on 26-30 September 2022.

Capacity building activities in 2021/2022

Virtual module on post-market surveillance

In collaboration with **INVIMA**

2021 Edition

Spanish

125 participants

14 **beneficiary countries**

Bolivia, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Paraguay, Peru, Uruguay, Venezuela

Main **TOPICS**

- Introduction to Medical Devices and international overview of technovigilance
- Progress, challenges and projection of the Colombian technovigilance program
- Steps to implement a technovigilance program in Colombia
- Strengthening technovigilance in the context of COVID-19

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Collaboration with IMDRF

12 documents translated into Spanish (1)

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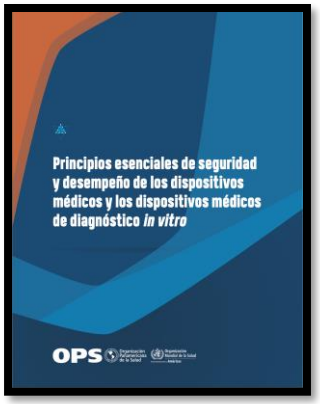

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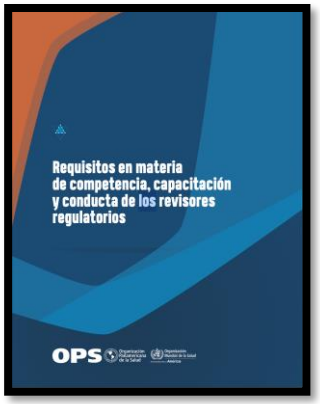

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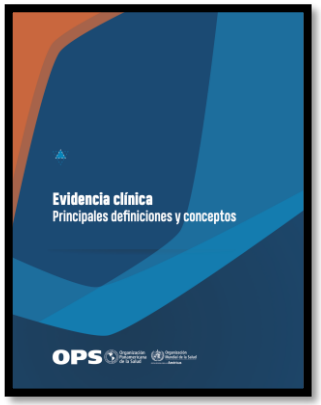

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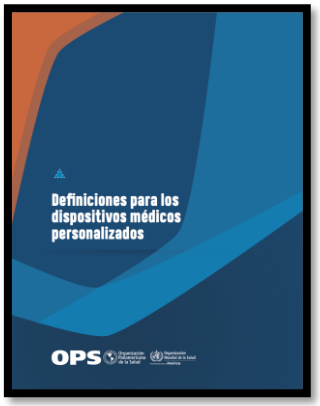

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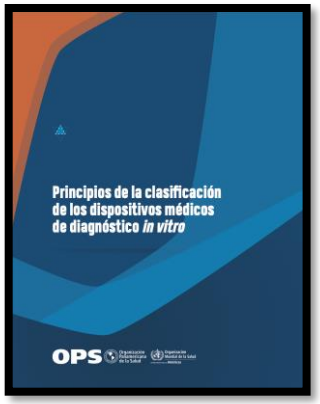
Collaboration with IMDRF

12 documents translated into Spanish (2)



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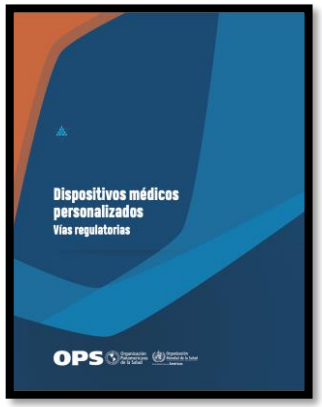

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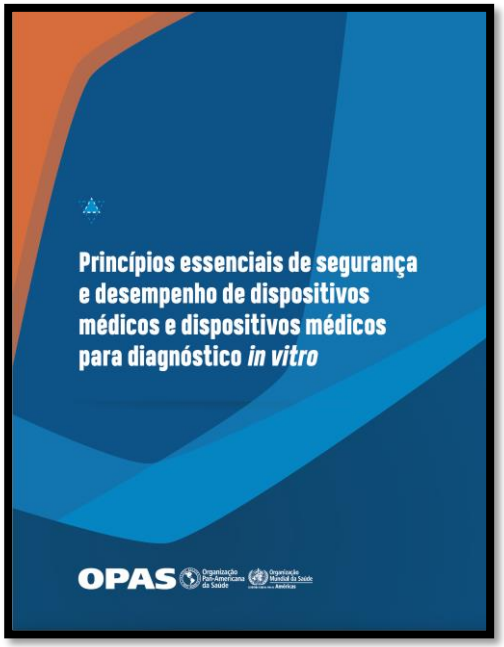
Collaboration with IMDRF



3 documents translated into Portuguese

Collaboration with IMDRF

6 new translations (into Spanish) under development:

1. Clinical Evaluation
2. Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making
3. UDI Guidance. Unique Device Identification (UDI) of Medical Devices
4. Principles of International System of Registries Linked to Other Data Sources and Tools
5. Unique Device Identification system (UDI system). Application Guide
6. Post-Market Clinical Follow-Up Studies

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

11
Associate Members

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

6
Full Members

ARG | BRA | COL | CUB | CHL | MEX

37
Reports
24 Confidential - 13 Public

- 86% of the reports are confidential.
- Health institutions reported 50% of the events, manufacturers 37%, and users 13%.
- Risk level of the reported devices: 38% Low-Moderate; 29% High; 21% Moderate-High; 12% Low.
- The most reported medical specialty was cardiovascular health with 21%.

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Project to strengthen testing capacity for PPE quality control laboratories

COVID-19 Pandemic

Lessons learned:

- The regional production capacity for health technologies is insufficient
- Access to medical products depends on supply chains that are vulnerable

- The shortage of PPE was one of the first consequences
- The importance of improving the analytical capacity of laboratories was highlighted

Project proposal

Objetive	How	Scope
Strengthen the analytical capacity of NRA Quality Control Laboratories (QCL) in the Region	Purchasing laboratory equipment for quality control of PPE	▪ Respirators ▪ Medical masks ▪ Gloves

specific objective: support two QCLs to work as *subregional hubs* (Central and South America)

Milestones

- 31 pieces of equipment were procured for the NRA QCL in El Salvador and Colombia
- Total amount invested: USD$1.1 million

Quality assurance of medical devices in the context of the COVID-19 response

REQUIREMENTS

Eligibility criteria	• Regulatory compliance (**IMDRF Members,** WHO SRAs for IVDs, manufacturing country) • Documentation to demonstrate compliance with technical requirements
Manufacturer	• Manufacturing license issued in the country of origin • Certified Quality Management System • Application of risk management to medical devices, if applicable
Product safety and performance	• Evaluation process based on the technical specifications and applicable international standards (recommended to each medical device) • Evidence to demonstrate compliance with applicable standards
Labelling	• Instructions for use, service manual, user manual, technical specifications. • Compliance with the principles of the document **IMDRF/GRRP WG/N52 FINAL:2019**

Technical support related to Medical Devices

Quality assurance assessment

149

medical devices

Technical support related to local procurement of MD

444

medical devices

19

benefited countries

Information from Jan-Aug, 2022

Regulation of Assistive Products (APs) in the Americas

Main components	Activities
Assessment of the regulatory situation of APs in the Region	**Indicators on APs** • Pilot to be implemented later this year
Development of a virtual course	**Introductory course on AT** • 324 certified professionals, 26 countries • Topic on strengthening regulation of APs is included https://bit.ly/CVOPS-TecnologiaApoyoAmericas
Development of a guidance tool on regulation	**Under development**

Thank you!