10th Session Inter-American Coalition for Regulatory Convergence, Medical Technology Sector

INTER-AMERICAN COALITION FOR
REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

14.11. 24

Technical Secretariat Update

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Executive Secretary

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MDRC

Final Report

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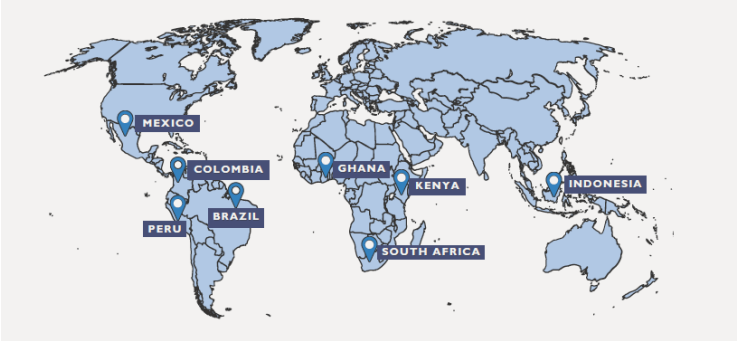
MDRC Scope and objectives:



01. Build capacity of partner countries for international standards and conformity assessment procedures for medical devices;

02. Remove countries' technical barriers to trade for medical devices;

03. Increase access to needed high-quality personal protective equipment (PPE) and other medical technologies to respond to and recover from COVID-19 and future global health crises; and

04. Foster private sector engagement and co-responsibilities in public consultations and WTO notifications of draft technical regulations and standards regarding medical technologies.

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Top Outcomes

In order to build resilient health systems, the MDRC led capacity building activities advancing regulatory reliance, encouraging health and trade authorities – with support from industry – to:

01.

Implement GRP as established by the WTO, World Health Organization (WHO) for health products, and implement globally harmonized reference documents of the International Medical Device Regulators Forum (IMDRF)

02.

Base national medtech technical regulations, standards and conformity assessment procedures upon relevant international standards with the objective of aligning with international best practices

03.

Leverage reliance pathways to streamline market authorization processes and reduce the duplication of regulatory efforts, ultimately increasing efficiency and patient access to medical technologies

Year	Workshops	Participants	Person Hours
2021	24	4,746	11,692
2022	26	3,587	12,195
2023	23	3,507	16,520
Total	**73**	**11,840**	**40,407**

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Top Outputs - Brazil

ACTIVITIES AND OUTPUTS - CAPACITY BUILDING

Activities focused on capacity building for Brazilian Ministry staff; in total, 3 events were held between 2021 and 2023 on the following thematic areas:

- GRP and international trade
- Conformity assessment for medical devices
- Post-market surveillance

ACTIVITIES AND OUTPUTS - REVIEW AND ANALYSIS

- Dissemination of GRP/Conformity Assessment Checklist (U.S.-Brazil ATEC Protocol Annex II GRP implementation)
- Incentive to improve the INMETRO/ANVISA workstream (including through contribution to the MDIC public consultation on regulatory costs)
- Support to INMETRO to review the TBT/Conformity Assessment Checklist as benchmarking for an internal standard operating procedure (SOP)

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Top Outputs - Colombia

ACTIVITIES AND OUTPUTS - CAPACITY BUILDING

- Workshop on GRP
- Workshop on Standard Operating Procedures for Implementation of GRP
- Workshop on Ex-Post Analysis
- Workshop on Ex-Ante Analysis
- Workshop on the GRP "Problem Tree"
- Workshop on Good Manufacturing Practices of Medical Devices

ACTIVITIES AND OUTPUTS - REVIEW AND ANALYSIS

At the start of the project, the MDRC agreed to support the development of a U.S.-Colombia PPE Guide with NIST to facilitate trade and exports and promote transparency.

As MDRC supported the guide's development, the Colombian Institute of Technical Standards and Certification (ICONTEC) worked with both INVIMA and the Ministry of Health to incorporate the guide into an inter-agency guide to PPE requirements for COVID-19 and other national PPE requirements. NIST also completed a reciprocal guide to PPE requirements in the workplace in the United States, excluding nuclear and medical settings.

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Top Outputs - Mexico

ACTIVITIES AND OUTPUTS - CAPACITY BUILDING

- GRP and medical device regulation (GRP & CA Checklists)
- Utilization of International Standards and Conformity Assessment
- Quality Management Systems for MDs Manufacturing: ISO 13485 & MDSAP
- Stability studies for medical devices
- Software as a medical device and unique device identification (UDI)

ACTIVITIES AND OUTPUTS - REVIEW AND ANALYSIS

- GRP Checklist
- CA Checklist
- COFEPRIS applied to become an IMDRF Affiliate Member
- COFEPRIS applied for "Affiliate Member" status at MDSAP
- Strategy for Regulatory Certainty of the Medical Devices Sector and commitment to publish a broader recognition agreement for medical devices
- Position paper on Good Manufacturing Practice (GMP) regulation

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Top Outputs - Peru

ACTIVITIES AND OUTPUTS - CAPACITY BUILDING

- GRP Workshop engaging public and private sector stakeholders
- Capacity building workshop on GRP for the private sector

ACTIVITIES AND OUTPUTS - REVIEW AND ANALYSIS

- Medical Device Procedures Triannual Update

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Top Outcomes

MDRC ECONOMIC OUTCOME

Non-Aligned Medical Device Technical Regulatory Requirements and Delays (World)	50B
Non-Aligned Medical Device Technical Regulatory Requirements and Delays (MDRC Countries)	2.35B
MDRC Policy Change Economization (if Colombia GRP model extended to all MDRC countries)	1.75B
MDRC Policy Change Economization (policies implemented to date)	235M

numbers in USD

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What is next?

- **Standards Alliance 2.5 (January 2025 – May 2026)**
  - IMDRF Affiliate Members and Applicants – Capacity Building, March 2025

  - Colombia:
    - INVIMA:
      - GRPs Implementation & IMDRF/MDSAP Affiliation
    - DNP:
      - Implementation of GRPs SOP: tool kit & capacity building
      - Processes simplification and “clear language”

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Working Groups

- Regulatory Reliance: Strategies to leverage resources available via GMTA & IACRC
- eCFG / eCFG/CFS / Apostilles – Strategies to eliminate the requirement
- GMPs: Strategies to increase NRA affiliation to MDSAP
- Open public consultations: Industry active participation
- Participation in National Standard Bodies Technical Committees
- eIFU: Strategies to implement as general practice

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Countries

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Key Highlights

Argentina

- eCFG

Brazil

- Human Resources – ANVISA
- Reliance Implementation
- Good Regulatory Practices – INMETRO / ANATEL
- Reclassification of Products – RDC nº. 830/2024
  - Class or II to Class III or IV
- eIFU for MDs
- Implementation of Reliance

Chile

- Ley de Fármacos 2 – Regulatory Framework for MDs & IVDs
- Utilization of International Standards
- Public Consultations

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Priorities - Country

Colombia

- Reliance Policy
- Reprocessing
- Decrees: 4725, 3770, Clinical Trials
- Further GRP implementation
- GMP Regulation
- IMDRF / MDSAP Membership

Ecuador

- UDI for public procurement
- Post-market surveillance regulation

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Priorities - Country

Mexico

- Good Manufacturing Practices NOM-241
- Reliance Policy – Expanded Equivalence Agreement
- Labeling – NOM-137
- Post-Market surveillance – NOM-240
- Back log

Peru

- Regulatory Framework for IVDs
- Regulatory Framework for MDs
- Customized devices – proposal to develop an ad-hoc regulation

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Priorities – Regional

IACRC Publishing of Timelines: Approvals, changes and renewals

- 2024 – 1st edition

2025

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Key Activities

5th. Anniversary – Celebration

Coalition Action 2025 – 2030 - preparations for March 2025 meeting:

- Action Plan on Health and Resilience in the Americas
- Declaration on Good Regulatory Practices

Executive Committee - Elections

In person meeting: November 2025

- **Sidelines of the X Summit of the Americas**
- **Punta Cana, Dominican Republic**

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THANK YOU

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