Implementation of Good Regulatory Practices – Regulatory Impact and Effectiveness

INTER-AMERICAN COALITION FOR
REGULATORY
CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

MDRC Update on GRP related activities in Latin America Region

INTER-AMERICAN COALITION FOR
REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

11.14.23

Miembros Principales

abimed
Associação Brasileira da Indústria de Alta Tecnologia de Produtos para Saúde

abraidi

AdvaMed
Advanced Medical Technology Association

ADIMECH
INNOVACIÓN AL SERVICIO DE LA SALUD

amid®
Asociación Mexicana de Industrias Innovadoras de Dispositivos Médicos.

ANDI
Cámara de Dispositivos Médicos e Insumos para la Salud

APIS
Asociación Proveedores Industria de la Salud

ASEDIM

ABIIS | Aliança Brasileira da Indústria Inovadora em Saúde

AVEDEM

CADIEM

CAPRODI
CÁMARA ARGENTINA DE REACTIVOS PARA DIAGNÓSTICO

cbdl
DIAGNÓSTICO PARA A VIDA

Comité Mixto de Dispositivos Médicos

ALAFARPE

AMCHAM
CAMARA DE COMERCIO AMERICANA DEL PERU

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COMITÉ DE PRODUCTOS PARA LA SALUD

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Miembros Normalizadores

AAMI
Advancing Safety in Health Technology

CLSI

MITA
MEDICAL IMAGING & TECHNOLOGY ALLIANCE
A DIVISION OF NEMA

Cooperación con Organismos Normalizadores

ISO

IEC

ASTM

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Vision

The Vision of the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector is **one standard, one test, accepted everywhere for any medical technology scope**. This Vision implies that medical technology regulators across the Western Hemisphere base their national medical device regulations, standards and conformity assessment criteria on the relevant international standards for medical technology.

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Mission

Our Mission is to lead the coordination of all materially affected stakeholders to achieve this Vision. This includes promoting regulatory cooperation across the Western Hemisphere to achieve **internationally aligned medical technology regulations, standards and conformity assessment requirements** within a continual process of convergence to maximize patients access to innovative, effective, life-saving and life-improving medical technologies.

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Compromise

Support the countires in the Americas to achieve:

- **Institucionalization of Good Regulatory Practices:**
  - Quality Management System – SOPs
    - Utilization of International Standards
    - Regulatory Impact Assessment
    - Public Consultation and International Notification

- **Implementation of Reliance and Recognition**
  - Processes to take theory to practice

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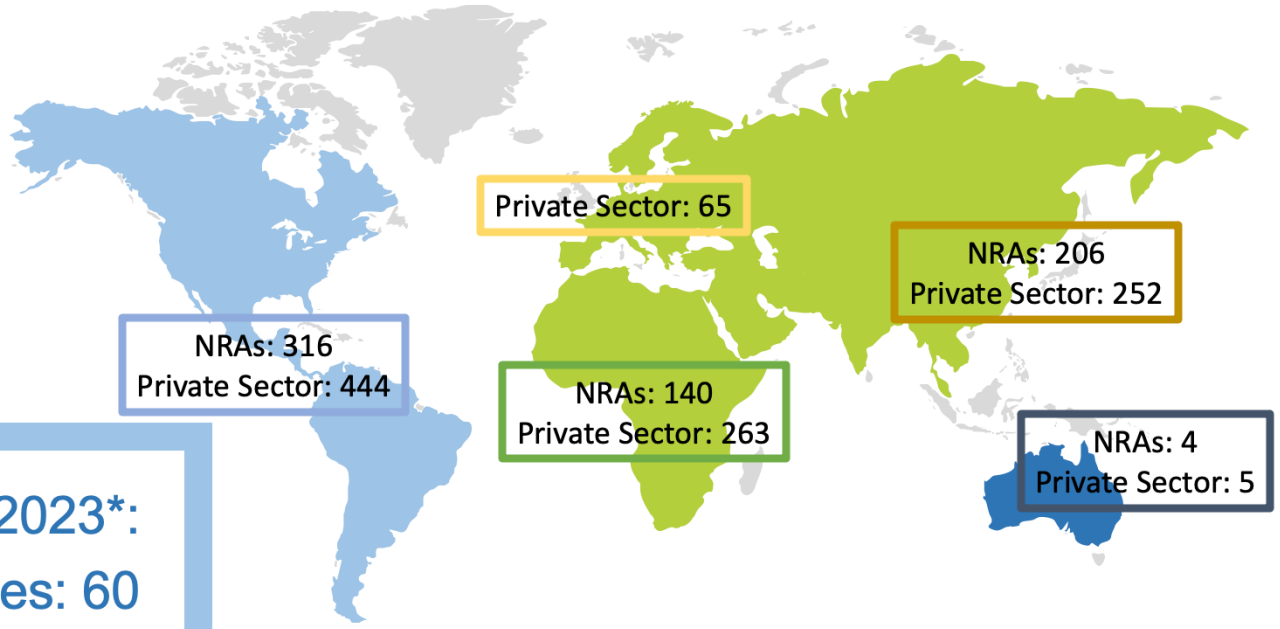
Regulatory Convergence Project of Medical Devices COVID-19 (MDRC)



The Numbers 2023*:

Countries: 60

NRAs: 662

Private Sector:1029

*August 2023

Americas

Argentina	Bolivia
Brazil	Canada
Chile	Colombia
Costa Rica	Ecuador
El Salvador	Estados Unidos
Honduras	Mexico
Nicaragua	Panama
Paraguay	Peru

Capacity Building

- **Webinar on Stability Studies for Medical Devices**
  - 1 June 2023
  - Recordings and materials available here
- **Good Regulatory Practices – Peru**
  - 18 May 2023
- **Good Regulatory Practices - Mexico**
  - 5 October 2023
  - Materials are available here in Spanish

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Upcoming event

Stability Studies for Medical Devices: Industry Perspective

- 30 November 2023
- Virtual

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MDRC – Progress up to date

- **Brazil**
  - Regional Support
  - Conformity Assessment – ANVISA. INMETRO, NIST, FDA

- **Colombia:**
  - MinSalud – SOP on GRP – Check lists
  - DNP – SOP on GRP with national and territorial scope
  - MinComercio – Technical Regulations and Processes – alignment on interpretation of definitions
  - Premio al Ministerio de Salud: Evaluación ex-post Decretos 4725 y 3770

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Support to Members

- **Chile:**
  - IVDs – HIV Regulation
  - IVDs – Immunohematology Regulation
  - Traceability Regulation

- **Ecuador**
  - Third Parties for Certification on GWDTP

- **Peru**
  - Input to registration procedures
  - Capacity building

MDRC – Progress up to date

- **Mexico**
  - COFEPRIS
    - MDSAP Afilliate Member
    - Strategy for Regulof the Medical Device Sector
      - GRP Committee
      - Check list
    - Legal analysis
    - Commitment to update Official Mexican Norm – Good Manufacturing Practices: 2024
  - REGULATED SECTOR:
    - Capacity Building – How to apply GRP in Mexico?

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Sitio Web

COALICIÓN INTERAMERICANA PARA LA CONVERGENCIA REGULATORIA
SECTOR DE TECNOLOGÍA MÉDICA

https://www.interamericancoalition-medtech.org/regulatory-convergence/?lang=es

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Gracias

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