Working Group: Regulatory Reliance

14-NOV-2024

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

WG OBJECTIVES

RELIANCE

Strategies to leverage resources available at

GMTA & Coalition

One standard , One test, accepted everywhere
for any medical technology scope

– EXECUTIVE COMMITTEE

CAPABILITIES

- Be the expert in Regulatory Reliance, using the WHO & GMTA international references.
- Align the terms to simplify the understanding of Regulatory Reliance.
- Educate, train and standardize criteria and knowledge about regulatory reliance among agencies and stakeholders from the region.
- **Define the scope per stages according to the pain points identified to apply reliance.**
- Create a toolkit with examples, guides, case studies, good reliance practices, etc. to facilitate the practical application of reliance.

STAKEHOLDERS

- Map all initiatives from the different LatAM regulatory authority.
- Try to use of reliance within LatAm countries.
- Enhance regulatory capacity promoting and starting the use of reliance.

REGULATORY FRAMEWORK

- Advocacy activities to create a regulatory framework to clarify and define the criteria and acceptance of reliance in our region / countries.
- Modernize regulatory systems to create efficiencies, avoid redundancies and reduce unnecessary complexity.

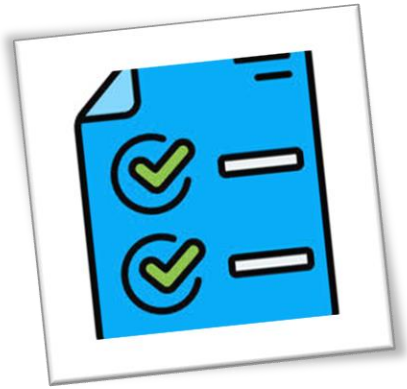
INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Key ACTIVITIES

Start = Q1/2024…

- ✓ **Regulators mapping and pathways;**
- ✓ **Classify regulators to prioritize advocacy activities;**
- ✓ **Identify different ways to advocate.**
- ✓ **Share/train GMTA position paper & WHO guideline with NRAs (MDRC/PAHO/WHO as trainers).**
- ✓ **Include: different forms for reliance (different from recognition);**
- ✓ **Reinforce that Reliance is not losing authority**

"Good Policy should benefit all stakeholders"



INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Key ACTIVITIES

Train target date: 2025

- → Collect examples of Reliance such us MDSAP.
- → Exchange groups material/ documents.
- → Toolkit for the industry.
- → Regulators training.
- → Gradual approach for Reliance.

"Good Policy should benefit all stakeholders"

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

WHO Guideline

Promoting Good Regulatory and Reliance Practices

Good regulatory practices

Set of principles and practices applied to the development, implementation and review of regulatory instruments in order to achieve a public health policy objectives in the most efficient way

Addressing responses to **common gaps in regulatory practices** identified during benchmarking of national regulatory systems

Relevant to all regulators, irrespective of resources, maturity or regulatory models (national, supranational and multiple institutions)

Annex 11: Good regulatory practices in the regulation of medical products (March 2021)

Good reliance practices

The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision.

Importance of **international cooperation** to ensure the safety, quality and efficacy or performance of locally used medical products

Make best use of available resources and expertise, avoid duplication and concentrate regulatory efforts and resources where most needed

Annex 10: Good reliance practices in the regulation of medical products (March 2021)

World Health Organization

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE MEDICAL TECHNOLOGY SECTOR

IMDRF LATAM Participation

Management Committee	Official Observer	Affiliate Members
• Brazil	• Argentina	• Chile • Costa Rica • Cuba • Dominican Republic • El Salvador • Mexico • Paraguay • Peru

IMDRF seeks to maintain working relationships with regional organizations and other international entities that have a **mutual interest in medical device regulatory activities** which are directly related to the common goals of fostering global **convergence, leveraging resources** and making available safe and effective medical devices globally.

IMDRF International Medical Device Regulators Forum

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE MEDICAL TECHNOLOGY SECTOR

LATAM STATUS

2021
Thirteen regulatory authorities (Argentina, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Mexico, Panama, Paraguay, Peru, Uruguay, and the unique Caribbean Regulatory System for 15 Caribbean States) explicitly accept relying on marketing authorizations issued by the European Medicines Agency, United States Food and Drug Administration, and Health Canada.

https://journal.paho.org/en/articles/regulatory-reliance-approve-new-medicinal-products-latin-american-and-caribbean-countries

2024
Argentina: ANMAT accepts reliance on approvals from recognized authorities like EMA and FDA.
Brazil: ANVISA has a robust independente regulatory system, it also consider international standards and approvals in its evaluation process.
Colombia: INVIMA accepts reliance on approvals from authorities such as EMA, FDA and Health Canada
Mexico: COFEPRIS recognizes approvals from EMA, FDA, Health Canada and others.
Paraguay: DINAVISA accepts reliance on approvals from major international bodies like EMA and FDA
Peru: DIGEMID also relies on approvals from recognized international authorities.
Uruguay: MSP accepts reliance on approvals from EMA, FDA and Other trustes regulatory bodies.

Copilot

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

LATAM STATUS

ROADMAP

Q4 2023
Q1 2024

- WG Objective, Scope
- Ranking of Priorities
- Regulators mapping

Q2 2024

- Share GMTA position paper & WHO Guidelines
- Classify regulators to prioritize advocacy activities.
- Identify different ways to advocate.

Q3 2024

- Training activities
- Use Reliance Practical Examples such as MDSAP

Q4 2024

- Training activities
- Use Reliance same document from CFG/FSC group to support regulators to find approvals.

Q1 2025

- Regulatory Framework
- Monitor Milestones & Define new actions

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Benefits – Outcome

- Improve knowledge about NRA regulatory processes to facilitate reliance mechanisms and optimize resource use
- Strengthening the regulatory capacity of authorities in the region.
- Promote participation in global initiatives and use of international standards which improves access to innovative medical products.
- Rapid response to emergency situations.
- More agile regulatory processes in the region through alignment while maintaining a high level of regulatory oversight.

Slide from Patricia Pineda - FDA

THANK YOU

SANDRA LIGIA GONZÁLEZ

Executive Secretary

STEVEN BIPES

Vice President, Global Strategy and Analysis, AdvaMed

LETICIA SEIXAS

Deputy Executive Secretary
Executive Secretary Brazil

ANDREW BLASI

Director, C&M International

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR