REGULATORY RELIANCE

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE

MEDICAL TECHNOLOGY SECTOR

5 ANNIVERSARY

10-Dec-2025

Working Group:
Regulatory Reliance

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RELIANCE

Strategies to leverage resources available at GMTA & Coalition

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

– EXECUTIVE COMMITTEE

WG OBJECTIVES

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 authorities
- 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 the region / countries.
- Modernize regulatory systems to create efficiencies, avoid redundancies and reduce unnecessary complexity.

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Key Activities – 2024 / 2025

Collect examples of Reliance such as MDSAP	• Brazil, Mexico, Argentina, Colombia, Paraguay are accepting the reports. • Some countries are still pending formalization
Exchange material/ documents	• A shared folder has been created to centralize Reliance materials (Playbook drafts, white papers, training slides, case studies, regulatory references). • This ensures all stakeholders have one authoritative source of Reliance documentation.
Toolkit and training industry	• Reliance Playbook (Draft, IMDRF/GRRP WG/N89, 2025) and White Paper have been deeply discussed in working groups. These documents serve as toolkits for regulators and industry to understand reliance frameworks.
Regulators training	• Ongoing training programs are being provided to regulatory authorities. • Focus on how to operationalize reliance, MDSAP reports adoption and IMDRF principles.
Gradual approach for Reliance	• Reliance is being introduced progressively. • Discussed in all regulator meetings, with best practices shared across jurisdictions.

"Good Policy should benefit all stakeholders"

Playbook for Medical Device Regulatory Reliance Programs

IMDRF 27 – Tokyo

IMDRF International Medical Device Regulators Forum

Looking Ahead…

IMDRF Management Committee Recommendations

- Complete and refine the Reliance Playbook to:
  - Include practical information and real-world examples to help operationalize reliance
  - Ensure it meets the needs of regulatory authorities
  - Allow for flexibility
- Adopt WHO definitions for Reliance and Product Sameness[1]
- Reinforce Good Regulatory Practices and use of the WHO Good Reliance Practices[1]

IMDRF International Medical Device Regulators Forum

Looking Ahead…

Industry Recommendations

- Support regulators as they operationalize reliance pathways and with determination of product sameness
- Share examples of reliance in practice by regulatory authorities
- **Use the Reliance pathway!**

1 Annex 10, WHO Technical Report Series, No.1033, 2021: Good reliance practices in the regulation of medical products: high level principles and considerations

[IMDRF presentation deck]

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Playbook for Medical Device Regulatory Reliance Programs

IMDRF 28 – Sapporo

IMDRF International Medical Device Regulators Forum

Opportunities and Challenges

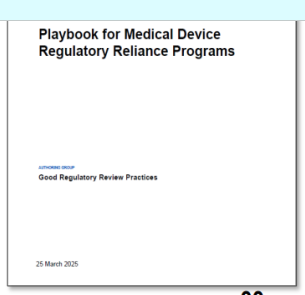
- IMDRF recognizes the value in developing robust regulatory reliance programs that can benefit all stakeholders, along with the challenges associated with such programs
- Guidance from GRRP and other IMDRF WGs, along with appropriate use of international consensus standards, can serve as trusted, globally recognized building blocks for reliance
- GRRP WG welcomes feedback on real-world lessons learned from developing and implementing reliance programs, and on additional opportunities for IMDRF to contribute in this area

IMDRF International Medical Device Regulators Forum

Ongoing work

Playbook for Medical Device Regu

- Outlines general strategies and s considerations for developing an regulatory reliance programs with regulatory jurisdictions
- Initiated *June 2024*
- Draft playbook available for public consultation *April – May 2025*



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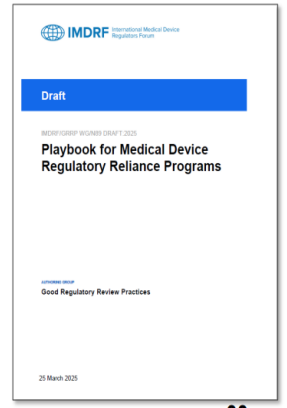
e Regulatory Reliance Programs

s of reliance

- Identifying/resolving potential barriers to reliance

- Publication of final playbook planned for *early 2026*



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Microsoft Word - IMDRF Reliance playbook draft (final).docx]

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LATAM – Reliance Status

Country	Regulation	Reliance Scope
Argentina	If a product has a Free Sale Certificate (FSC) from a recognized regulatory authority, ANMAT waives additional tests, trial repetitions, and inspections. The product must be registered and marketed in the issuing country.	Reliance vision stated; Not yet formalized.
Brazil	Normative Ruling 290/2024: Establishes reliance pathway for Class III/IV devices	Abbreviated analysis for high-risk devices if already approved by “equivalent foreign regulatory authorities” – MDSAP ones.
El Salvador	Decree No. 891, Article 36, authorized the practice of reliance for all products they oversee. They have a public facing regulation on reliance for drugs and vaccines but the reliance policy for MD and IVDs is only an internal document at SRS (Superintendencia de Regulación Sanitaria).	Recognition as GMP certificates: MDSAP, ISO 13485, CE, NRA CGMP/CoFS with explicit GMP compliance. Expedited review for marketing authorization: This pathway applies to applications for products that already hold prior authorization from regulatory authorities that are members of the IMDRF Management Committee or the MDSAP Regulatory Authority Council
Mexico	DOF (Diario Oficial de la Federación) Agreement July 18, 2025: Creates reliance pathway for medicines and devices classes I-III. (IMDRF and EU).	Explicit reliance framework; devices must be identical to RRA-approved versions.
Panama	Law 419/2024: Regulates medicines and devices	Expedited registration for products from “High Standard Countries” (e.g., US/EU)
Paraguay	Resolution DINAVISA No. 226/2024	Simplified registration for Class II–IV if approved by recognized authorities;

Ongoing and Future Effort

- **Support for Emerging Regulators:** Many authorities are still learning how to operationalize reliance, they need our guidance!

- **Expansion:** The next step is to bring other mature regulators into the circle of recognized authorities, strengthening global convergence.

- **Global Convergence:** Sustaining this group ensures reliance pathways continue to grow and align with IMDRF principles.

- **Knowledge Continuity:** The group keeps reliance materials alive, updated, and relevant.

THANK YOU

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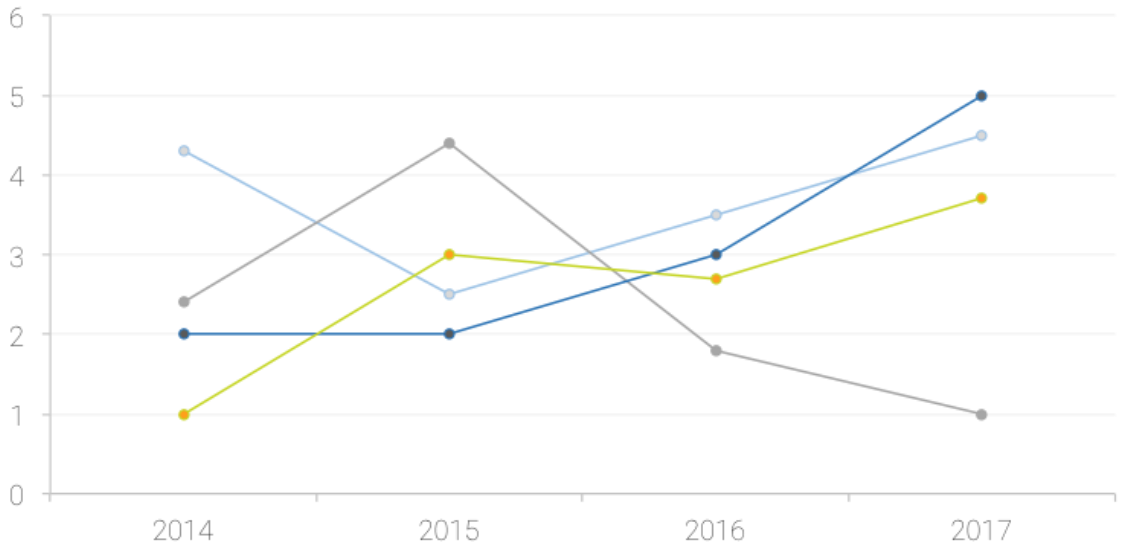

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THE DATA REVEALS research subjects and data were gathered from several sources to confirm that the programs and data have been effective as shown on all projects in North and South America.

Milestones Achieved

Following IMDRF principles, regulators can confidently adopt Reliance to streamline processes and align with international best practices:

- Good Regulatory Review Practices (GRRP-N47): Encourages regulators to rely on trusted authorities to avoid duplicative evaluations.
- Medical Device Single Audit Program (MDSAP): A single audit conducted by a recognized auditing organization is accepted by multiple countries, replacing redundant certificates and audits.
- Regulated Product Submission (RPS-N13): Provides harmonized submission formats (Table of Contents) that reduce duplicative requirements across jurisdictions.
- Principles of Convergence (2013): Establishes the foundation for regulatory convergence, promoting efficiency and reducing unnecessary burdens.

MAP DIAGRAM SLIDE

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