



IMDRF International Medical Device
Regulators Forum

29th IMDRF 2026

Day 1 IMDRF Industry Joint Workshop | 09 March 2026



THE RELIANCE PLAYBOOK

Igniting a lamp of hope

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Health Sciences Authority, Health Products Regulation Group



PLAYBOOK BENEFITS

During Covid-19, one manufacturer reported reducing their **global approval timeline from 18 months to 8 months by leveraging reliance pathways**



PATIENTS

Faster access to innovative medical technologies



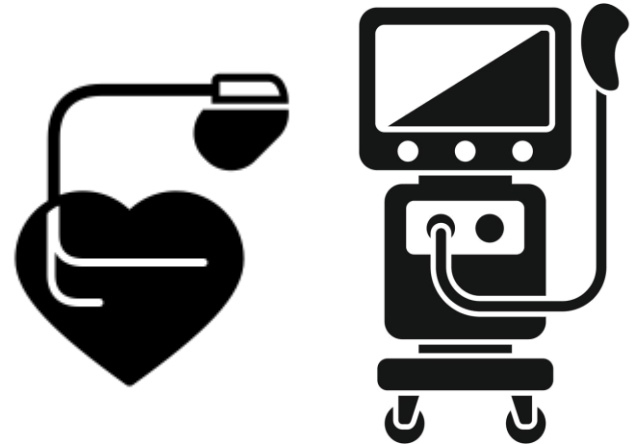
INDUSTRY

Reduce regulatory burdens and costs



REGULATORS

Optimise resource allocation while maintaining rigorous oversight



REVEALING THE PLAYBOOK SECRET INGREDIENTS

01

**Definitions
Matter**

02

**Build Trust
Through
Transparency**

03

**Regulatory
Agility**

04

**Global
Collaboration**

Execution Excellence with robust Legal Frameworks



HSA
Health Sciences Authority



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A BEACON OF HOPE *FOR THE FUTURE*

“

The IMDRF Playbook represents more than guidance.

It represents **hope**. *Hope* for a future

where **innovative medical technologies can reach patients more quickly,**

where **regulatory resources are optimised for maximum impact,**

and where **international collaboration drives continuous**

improvement in global health outcomes.

”



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Thank You!





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Applying frameworks for reliance: From principles to practice and feedback integration

Kenneth Cavanaugh, PhD

Associate Director for International Policy and Strategy

US FDA Center for Devices and Radiological Health



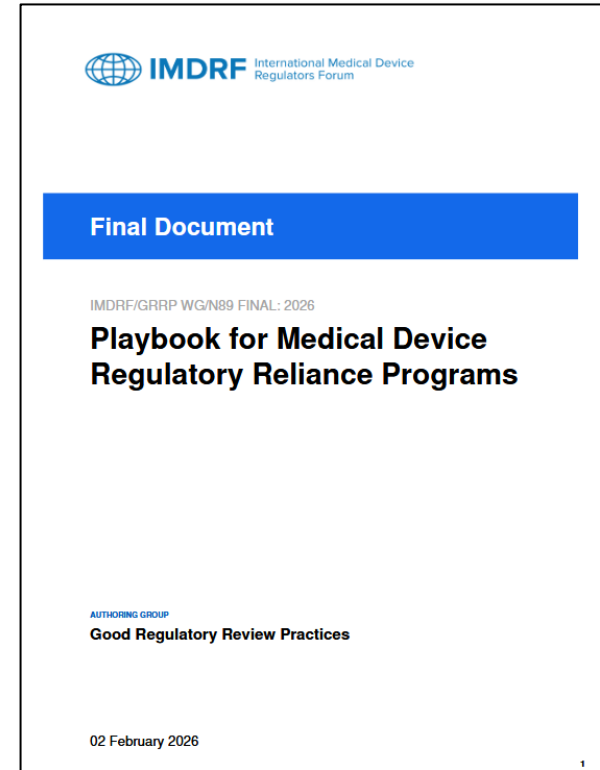
The IMDRF Reliance Journey

- March 2024: IMDRF Industry Workshop on Reliance
- May 2024: Publication of IMDRF White Paper on Reliance
- June 2024: Approval to start work on reliance playbook
- March 2025: Draft playbook open for public comment
- February 2026: Reliance playbook publication
- Today!



IMDRF Reliance Playbook Now Available!

- General strategies and specific considerations for reliance program development and implementation
- Flexible yet structured framework for reliance practices
- Intended to drive reliance program adoption, increase regulatory efficiency, and enhance patient safety worldwide
- IMDRF's reliance work is the right?



Key Factors Impacting Playbook Development (and Reliance Implementation)



Building on previously established practices



Using language that promotes clear and consistent interpretation



Best use of real-world vs hypothetical examples



Proposing reliance “considerations” vs “requirements”



Key Playbook Considerations for Reliance Implementation

- 🧠 Fit-for-purpose for **medical devices**
- 📋 Permissible under **regulatory framework**
- 🔒 Need for **confidential vs public** information
- 📈 Opportunities throughout **device lifecycle**
- 🌱 OK to “**start small**”
- 👤 Maintain individual **autonomy**
- 👥 Internal & external **stakeholder engagement**



Public Feedback

- **468 public comments** received from wide range of industry members and regulators
- Key themes and improvements based on comments:
 - Clearer and more consistent use of terms
 - More varied and useful examples
 - Additional discussion of information-sharing and agreement considerations
 - Overall improved readability and organization
- Not every comment results in a visible change to the document, yet they all have an impact

THANK YOU!

5. Overview of Medical Device Regulatory Reliance Programs

5.1. Role of regulatory reliance

Reliance programs are designed to streamline and expedite regulatory processes by leveraging assessments performed by other trusted partners. Adopting reliance approaches helps reduce duplication and facilitates access to safe and effective medical devices while maintaining sufficiently rigorous oversight. It also minimizes the regulatory burden on industry, particularly for small and medium-sized enterprises. In addition, reliance programs promote the ability of regulatory authorities to allocate resources to other priority areas. Furthermore, reliance programs should be designed to offer a concrete incentive to participation, such as shorter review time frames that could facilitate market access. In order to best realize the benefits of a reliance program, it should be voluntary in nature and not be the only possible pathway for a given regulatory process.

It is important to note that reliance, convergence, and harmonization are distinct but interconnected concepts in regulatory practices. Reliance refers to the process where one regulatory authority leverages another organization's assessment or decisions as part of reaching its own decision. In contrast, convergence refers to efforts to align regulatory practices and requirements among different regulatory authorities, aiming for more streamlined processes, though it does not necessarily entail acceptance or recognition of decisions made by other institutions. Harmonization goes a step further to aim for a higher level of uniformity by creating consistent standards and requirements across multiple jurisdictions, striving for global regulatory consistency.

While reliance focuses on utilizing existing approvals or decisions, convergence and harmonization are geared towards achieving broader alignment and uniformity across different regulatory systems. They each play a different role in regulatory practices. By understanding these various concepts and using reliance together with other types of programs, regulatory authorities can better design and implement strategies to enhance efficiency and cooperation in medical device regulation.

5.2. Types of regulatory reliance

This section explores some types of reliance mechanisms that regulatory authorities can use to develop a reliance program tailored to their specific needs. To illustrate the thought process involved in developing a specific reliance program, actual examples of each type of reliance program are also listed along with a discussion of why that particular form of reliance was implemented. Other forms of reliance can also be adopted and may utilize some of the characteristics listed below.



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The Reliance Journey Continues



- Our journey is just beginning!
- Our varied experiences and continued engagement will guide our next steps
- How can we help each other along the way?
- Let's make this journey **together**



Thank You!





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IMDRF/Industry Joint Workshop
Reliance Playbook Release and Implementation
Monday, March 9, 2026

**Global foundations: Good reliance practices and
synergy with IMDRF Reliance Playbook**





Mandated under Resolution WHA 67.20 (2014)

- Identified strong regulatory systems as essential to a well-functioning healthcare system and the attainment of health-related SDGs and UHC.

WHO provides technical support to Member States in regulatory systems strengthening for effective and efficient regulatory oversight of medical products



Objectives of the RSS programme

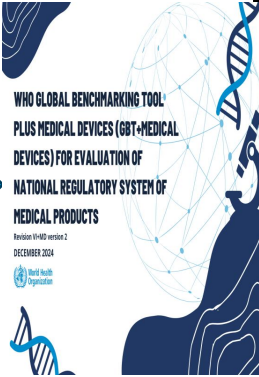
- *Build capacity in Member States consistent with good regulatory practices*
- *Promote regulatory cooperation, convergence and transparency through networking, work-sharing and **reliance***



Ultimate goal

- *Promote access to quality assured medical products (medicines, vaccines, medical devices)*

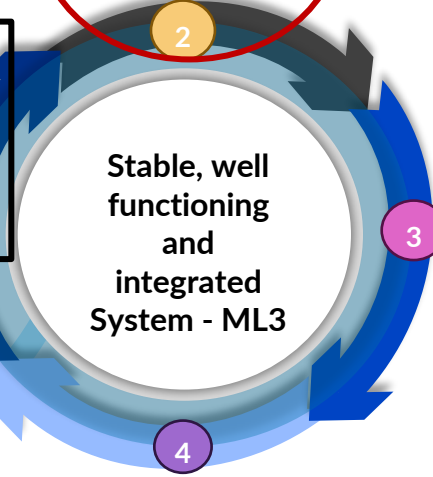
The critical role of GMRF and WHO GBT + medical devices



WHO GMRF & GBT + medical devices

System strengthening in regulation of medical device including IVDs

Convergence of regulatory requirements



Reduce variability in the regulatory requirements

Capacity building



- International collaboration
- Information sharing
- Protect public from substandard devices

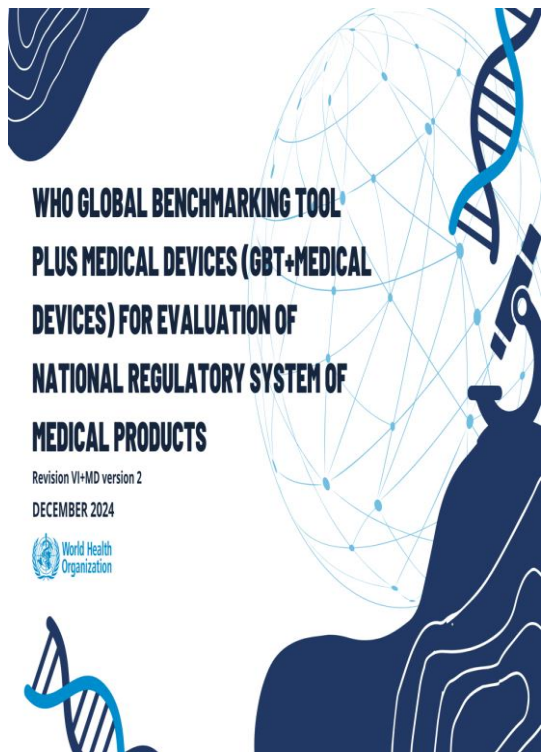


- Reliance
- Access to safe and effective medical devices
- Strengthen public health



- Access to innovative medical devices
- Facilitate response to public health emergencies

GBT plus medical devices – 8 sub indicators related to reliance



WHO GLOBAL BENCHMARKING TOOL
PLUS MEDICAL DEVICES (GBT+MEDICAL
DEVICES) FOR EVALUATION OF
NATIONAL REGULATORY SYSTEM OF
MEDICAL PRODUCTS

Revision VI+MD version 2

DECEMBER 2024



National Regulatory System

RS

RI01.05: Legal provisions and regulations

RS03.04: Documented policies, procedures and mechanisms, including written criteria

RS03.05: The NRA is promoting good regulatory practices (GRPs)

Registration and Marketing Authorization

MA

MA01.08: Legal provisions or regulations

Post-market surveillance, market surveillance and controls

PS

PS01.06: Legal provisions and regulations

Regulatory
Inspection
RI

RI01.05: Legal provisions and regulations

Laboratory Testing

LT

LT01.02: Legal provisions and regulations

Clinical Trials oversight

CT

CT01.10: Legal provisions or regulation



Good Reliance Practices (GReIP) and synergy with IMDRF Reliance Playbook

Concepts, principles, and considerations

Annex 10

Good reliance practices in the regulation of medical products: high level principles and considerations

Background

WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to: vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance facilitates timely access to safe, effective, quality-assured medical products (see section 3. Scope) and can support regulatory preparedness and response, particularly during public health emergencies.

Good reliance practices (GReIP) are anchored in overall good regulatory practices (GRP) (1), which provide a means for establishing sound, affordable, effective regulation of medical products as an important part of health system strengthening. If implemented effectively, GRP can result in consistent regulatory processes, sound regulatory decision-making, increased efficiency of regulatory systems and better public health outcomes. NRAs are encouraged to adopt GRP to ensure that they are using the most efficient regulatory processes possible.

WHO is establishing and implementing a framework for evaluating regulatory authorities and designating those that meet the requirements as "WHO-listed authorities" (WLA) (4). Using the WHO Global Benchmarking Tool (5) and performance evaluation, WHO will assess the maturity and performance of a regulatory authority to determine whether it meets the requirements of a WLA and thereby provide a globally recognized, evidence-based, transparent system that can be used by NRAs as a basis for selecting reference regulatory authorities to practise reliance. A list of reference regulatory authorities is available on the WHO website (6).

In September 2019, WHO held a consultation to solicit input on the nature, structure and overall content of a document outlining GReIP. The meeting concluded that the concept note and recommendations on regulatory reliance principles of the Pan American Health Organization (PAHO) and the Pan American Network for Drug Regulatory Harmonization (7) should be used as a basis for the WHO document on GReIP. The high-level document would be complemented by a repository of case studies, practice guides and examples of practical application of GReIP.

Shared Objective: Promote efficient, transparent, and risk-based regulatory decision making, evidence-base assessments, and capacity building.

Shared aim: Improve timely access to quality-assured medical devices and IVDs.

Synergy: GReIP provides foundational principles; IMDRF operationalizes them into concrete actions.

Outcome: Stronger regulatory convergence, reduced duplication, faster access to quality-assured products.

Reference to the WHO Good Reliance Practice and Good Regulatory Practice guidelines

- Key concepts (risk -based approach and types)
- Principles (sovereignty, transparency, competence,)
- Legal framework
- Stakeholders engagement
- Regulatory analysis
- Targeting potential regulatory partner

Drive reliance program adoption



Final Document

IMDRF/GRPP WG/N89 FINAL: 2026

Playbook for Medical Device Regulatory Reliance Programs

AUTHORING GROUP

Good Regulatory Review Practices

02 February 2026



Complementary documents that aim to strengthen regulatory systems through reliance approaches. Their synergy can be understood across four main dimensions: principles, operationalization, scope, and capacity building

Sources of information on reliance

WHO Good Reliance Practices

Annex 10

Good reliance practices in the regulation of medical products: high level principles and considerations

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Adopted by WHO Expert Committee on Specification for Pharmaceutical Products in October 2020, published in March 2021 <https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations>

Short eLearning Module of main principles and examples of reliance (Oct 2022)

<https://openwho.org/courses/good-reliance-practices>

Reliance repository and Questions & Answers

<https://www.iprp.global/news/iprp-good-reliance-practices-repository-now-published>
https://admin.iprp.global/sites/default/files/2022-11/IPRP_RelianceQ%26As_2022_0930.pdf



When birds weave their nests using other bird`s feathers, they create something far stronger than the individual feather they carry. Likewise, when Member States, regulators and WHO work together; sharing evidence, aligning requirements, and supporting reliance; NRAs build systems that are stronger, more resilient and more capable of protecting public health.

Thank you



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Back to Basics: Reliance Playbook's Principles, Objectives and Practical Benefits

Tammy Steuerwald

Global Head of Regulatory Policy, Foundational Principles & Supranational Organizations

Roche

GMATA

Fatemeh Razjouyan

Senior Director, Regulatory Policy, International and Harmonization

Medtronic

DITTA



IMDRF Reliance Playbook

- An **international methodology** to guide regulators with **all levels of maturity**
- Design a convergent reliance program that is **jurisdiction appropriate** & maintains sovereignty
- Delivers **tangible patient benefits**
- The result of innovation, **collaboration**, learning & sharing



Remarkable & Unique

- **First** international reliance guidance written by **regulators for regulators**
- Specifically **designed for MD/IVDs**
- Provides a **trusted method**, key considerations, and case studies to **implement** & evolve a globally **convergent reliance program**



Reliance Journey at a Glance

- **Step by step** process
- Engage with **stakeholders** early and often
- Complete with case studies

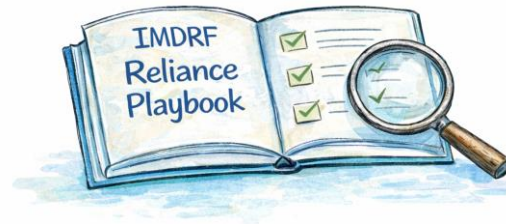
... to implement a **sustainable** reliance program that is **jurisdiction appropriate** & results in tangible **patient benefits**



Using the Playbook: Tailored Implementation

Establish:

- Reliance management plan
- Process & procedures
- Plan for training staff
- Communication plan
- Documentation needs



To enable effective use of reliance pathways and establish **clear, transparent implementation** guidelines based on **criteria appropriate for MD/IVDs**

**Harmonization & convergence
facilitate reliance**

but

**their absence doesn't negate
reliance**

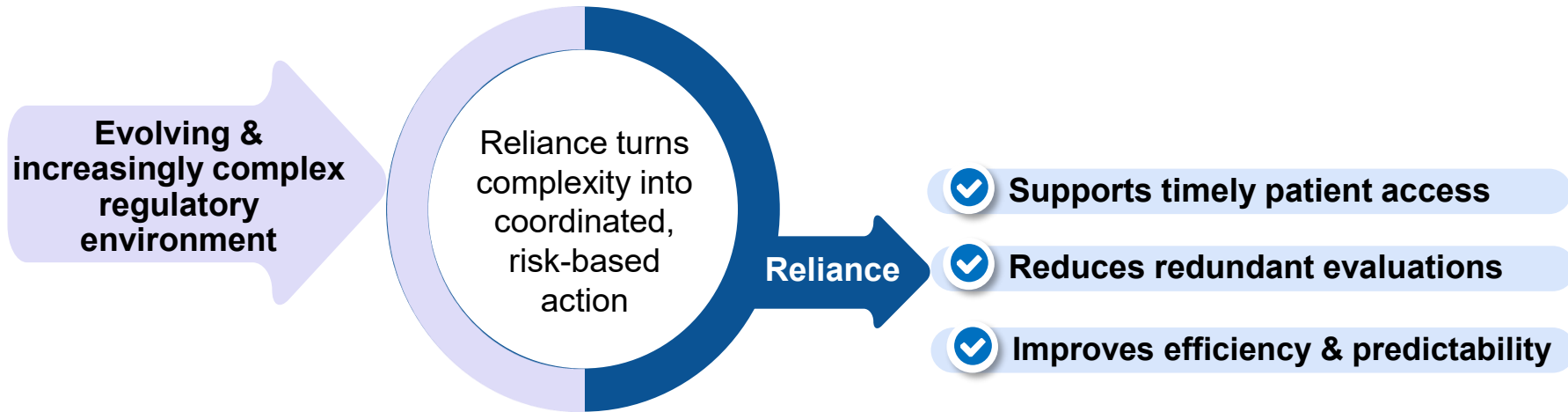
**Reliance can be implemented today even in
heterogeneous regulatory environments!**



Principles & Objectives of the Playbook



Reliance Programs Should Deliver Concrete Benefits



Operationalizing Reliance: Success Criteria & Practical Steps



Design Smart:

- Prioritize publicly available regulatory information over CFG/CFS
- Leverage trusted work products
- Align to IMDRF international best practices & TOC



Engage Early & Often:

- Cross-functionally within government
- External stakeholders
- Dialogue with RA to support mutual understanding & trust
- Clear criteria & timelines



Start Small, Scale:

- Start with pilots: define scope, learn fast
- Measure performance + stakeholder feedback
- Refine & mature program



Looking to the Future



To expand **timely patient access** worldwide through:

- A shared commitment to lifecycle-based oversight, grounded in **international best practices**.
- **Aligning conformity assessment** and streamline regulatory processes while maintaining scientific rigor & sovereignty.



Thank You!

