



**IMDRF** International Medical Device  
Regulators Forum

# 29<sup>th</sup> IMDRF 2026

Day 1 IMDRF Industry Joint Workshop | 09 March 2026



# Reliance in the real world: What enables and what hinders it

**Markus Wälti**

**Head of Department Medical Devices Vigilance**

**Swissmedic, Swiss Agency for Therapeutic Products**



## Where Switzerland stands today on reliance (devices & wider context)

Controlled pathway for US-FDA-authorized medical devices (not automatic recognition): On 30 Apr 2025 the Federal Council set guidelines to implement Motion 20.3211 so that US-authorized devices can be placed on the Swiss market via private assessment bodies under Swiss oversight, to ensure Swiss safety requirements are met.

Swiss reliance principle and international harmonization: Swissmedic embeds reliance in its strategy in line with WHO/ICMRA (the relying authority remains responsible), and it participates actively in IMDRF, since March 2025 as a Management Committee member.

Broader reliance footprint in medicines (GMP MRA): A Switzerland–USA GMP Mutual Recognition Agreement for medicinal products entered into force on 27 Jul 2023, enabling each side to rely on the other's routine GMP inspections, thereby reducing duplication and strengthening supply chains (note: scope = medicines, not medical devices).



## What enables reliance for Switzerland (Enablers)

IMDRF integration as a practical enabler: Swissmedic's active role in IMDRF, including Management Committee membership since Mar 2025, supports harmonization of definitions and regulatory expectations, which is particularly valuable for Switzerland as a non-EU country.

Structured blueprint for building reliance: The IMDRF Reliance Playbook (draft) lays out steps on scope, processes, agreements, management systems, and stakeholder engagement, useful for targeted resource use at authorities such as Swissmedic.

Federal Council guidance clarifies the Swiss route for US devices: The April 2025 decision defines roles for private bodies and safety pre-conditions, allowing Switzerland to benefit from foreign decisions while keeping Swiss oversight.

Legal convergence at home: MedDO and IvDO are aligned to EU MDR/IVDR → predictable requirements that support reliance.



## What still hinders reliance for Switzerland (Barriers)

Legal/organizational pre-conditions still required: For devices, Switzerland must adapt its framework to enable the proposed US pathway while safeguarding Swiss requirements, hence the non-automatic route via private bodies.

EU–Switzerland context (MRA chapter not updated): Since May 2021 (devices) and May 2022 (IVDs), Switzerland is treated by the EU as a third country because the MRA medical-devices chapter was not updated; the Federal Council and FOPH have implemented mitigation measures to secure supply and surveillance.

Divergent adoption/interpretation of standards and conformity routes: Although Switzerland has aligned its legislation to MDR/IVDR, the absence of an updated MRA device chapter means additional frictions around recognition and conformity assessment persist.

Capacity & implementation workload: Establishing the new procedures and supervision of private bodies foreseen by the Federal Council requires up-front resources across FOPH, Swissmedic and SECO.



## Source List (by authority)

### FOPH/BAG (Federal Office of Public Health):

- Federal Council guidelines (30 Apr 2025) on enabling US-authorized devices via private assessment bodies (press release | Published on 30 April 2025) [\[Link\]](#).
- Public page on US devices access & context. [\[Link\]](#)
- Medical devices legislation (MDR/IVDR alignment, third-country status & mitigation). [\[Link\]](#)

### Swissmedic:

- IMDRF role & Management Committee membership (news, 3 Apr 2025). [\[Link\]](#)
- IMDRF page (harmonization work & participation). [\[Link\]](#)
- ICMRA/WHO statement on reliance (principles). [\[Link\]](#)
- Legal framework page (MDR/IVDR alignment). [\[Link\]](#)

### SECO / FDA / Swissmedic (GMP MRA — medicines):

- SECO page — Switzerland–USA GMP MRA overview & objectives. [\[Link\]](#)
- Swissmedic news — MRA with USA (GMP) in force 27 Jul 2023. [\[Link\]](#)



# Thank You!





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**Lucas Duarte**  
International Affairs Analyst  
**ANMAT** 



## COMMON BARRIERS AND ENABLERS

BARRIERS	ENABLERS
▶ Differences in national regulatory requirements and evidentiary standards	▶ Trust
▶ Lack of a common language	▶ Convergence and harmonization of requirements
▶ Lack of accessible information and confidentiality of information	▶ Cooperation and dialogue among regulators
▶ Insufficient knowledge of the reference regulatory authority and how it operates	▶ Flexible regulatory framework
▶ Lack of regulatory alignment of product risk classifications	▶ Engagement of stakeholders

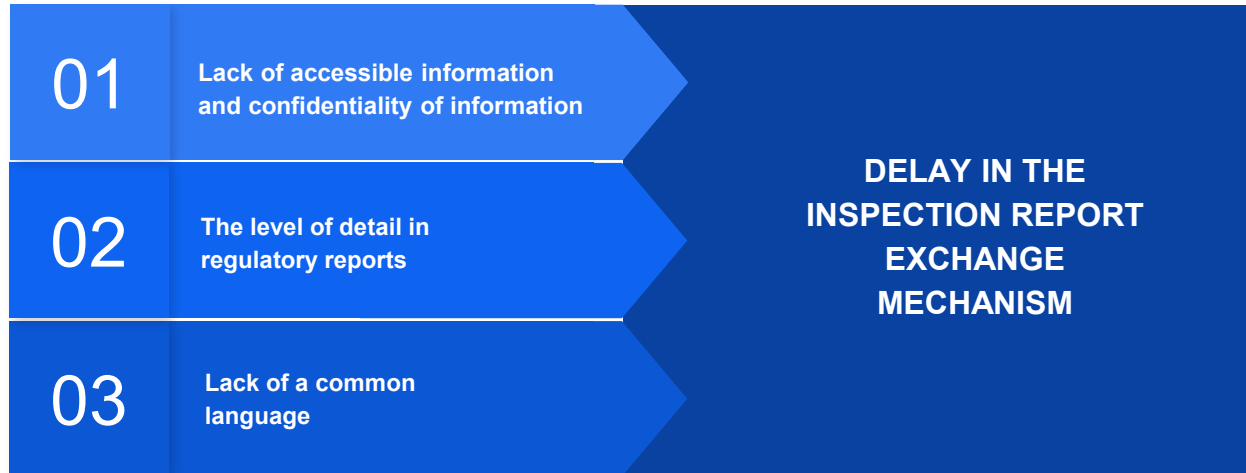


## BARRIERS THAT MAKE IT IMPOSSIBLE TO ADOPT RELIANCE

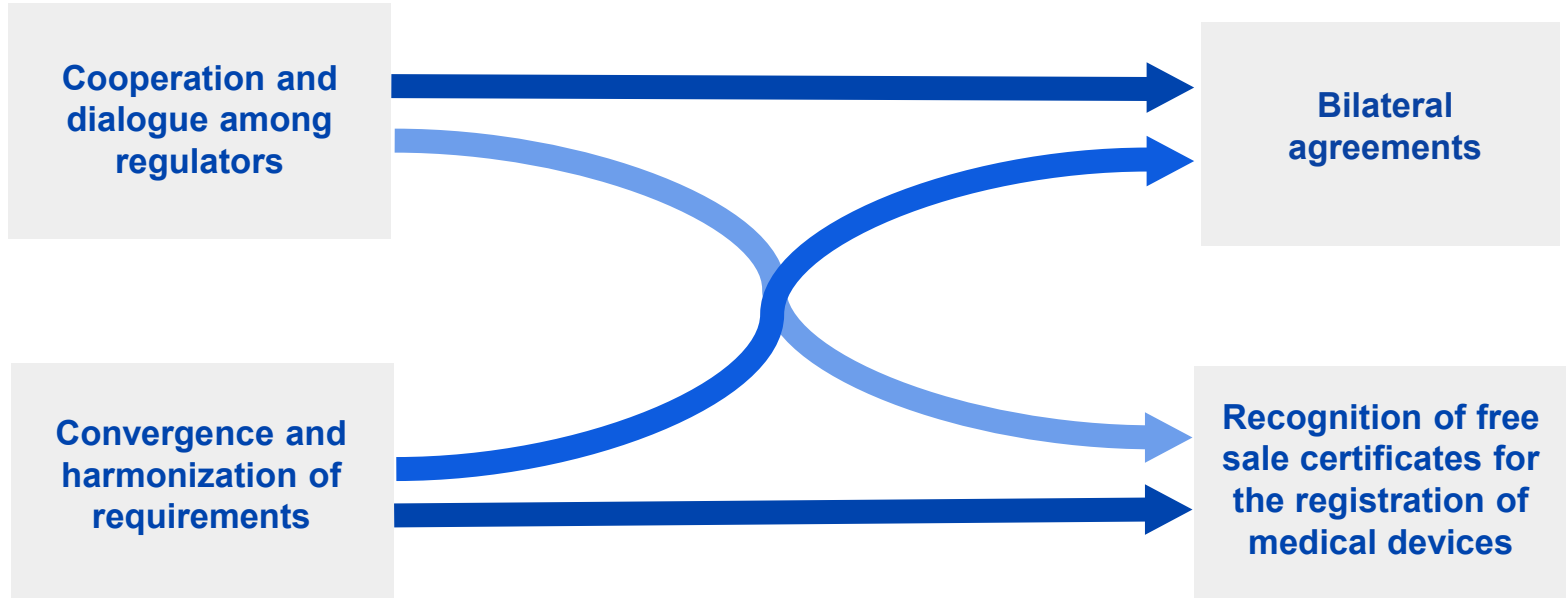
- ▶ **Differences** in national regulatory requirements and evidentiary standards
- ▶ **Lack** of regulatory alignment of product risk classifications



## BARRIERS HINDERING CURRENT RELIANCE MECHANISMS



## ANMAT RELIANCE ENABLERS



## ANMAT RELIANCE ENABLERS

TRUST

FLEXIBLE  
REGULATORY  
FRAMEWORK



Executive order N° 892/25 and ANMAT  
Regulation N° 236/2026



Australia



European Union



USA



Japan



Norway



United Kingdom



Switzerland



Iceland



Liechtenstein



Israel







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**Session 2: Enablers and barriers to reliance adoption, implementation, and use**  
**“Reliance in the real world: What enables and what hinders it”**

**Naoki MOROOKA**

**BoD member of DITTA**

**Vice Chair, Regulatory and Safety Division of JIRA**



## How can "the implementation timing and transition periods for international standards" be harmonized across jurisdictions?

### Key factors:

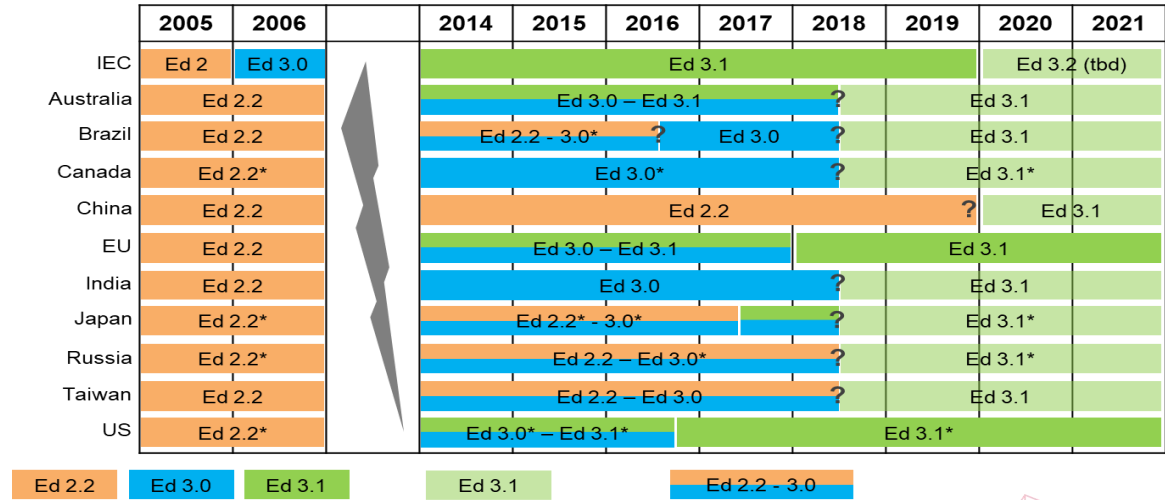
- 1) Implementation for International Standards into National Standards
- 2) Regulatory recognition of National Standards

E.g.;  
<Transition Problem>

Significant challenges during the transition from the 2nd to the 3rd edition of IEC 60601-1 (2015) for manufacturers.

Ref; Maurizio Andreano's presentation in DITTA Workshop with IMDRF 2015

\* National deviations may apply  
Information without guarantee



# Challenges in Regulatory Transitioning: Varying Implementation Timelines Across Jurisdictions

Significant challenges may arise during the transition from IEC 60601-1 Edition 3 to Edition 4.

In particular, the associated compliance requirements could increase the burden on manufacturers in the following areas:

## 1. Regulatory Alignment Across Markets

- Manufacturers may need to **navigate multiple compliance path ways across different jurisdictions.**
- Some devices may require **dual certification to comply with both editions** for different jurisdictions.
- There is a potential risk of market access **delays where compliance with new edition** is required before approval.

## 2. Re-Certification Costs & Increased Compliance Burdens

- **Increased financial burden** for companies distributing to multiple regions.
- **Regulatory delays** due to waiting for approvals from various countries.
- **Increased resource allocation** to manage different sets of compliance obligations.

## 3. Documentation & Submission Complexity

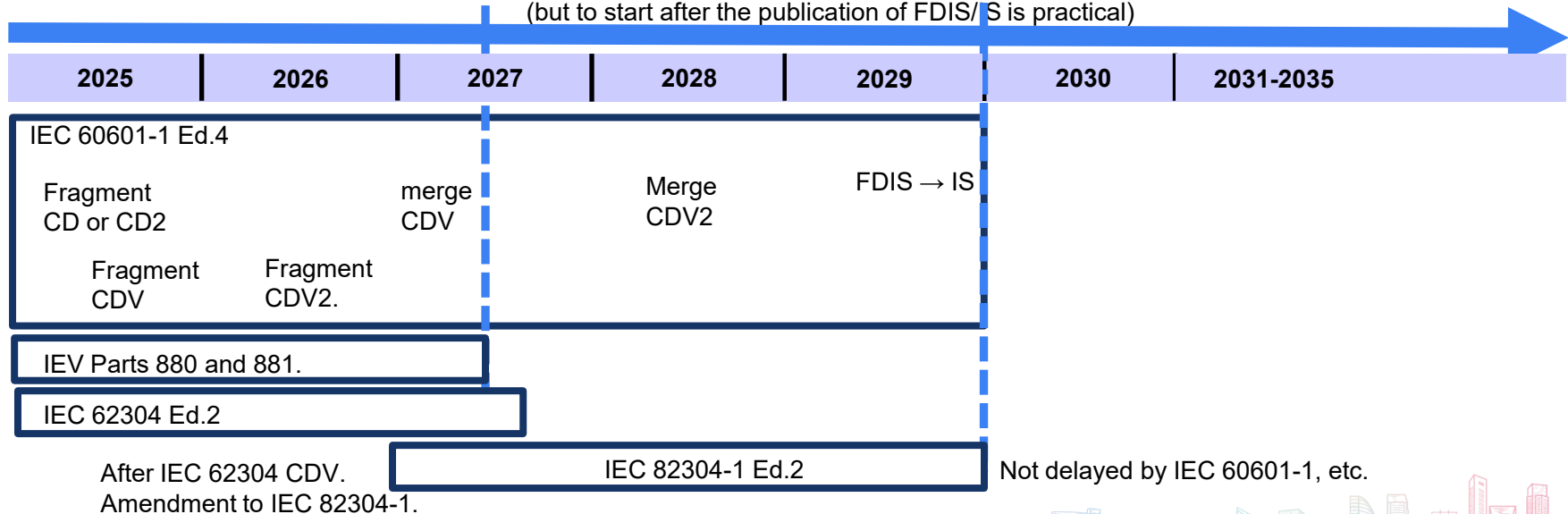
- Divergent implementation timelines may increase **the complexity of technical documentation and regulatory submissions.**
- Companies may need to allocate **additional regulatory affairs personnel to manage varying submission requirements** across jurisdictions.



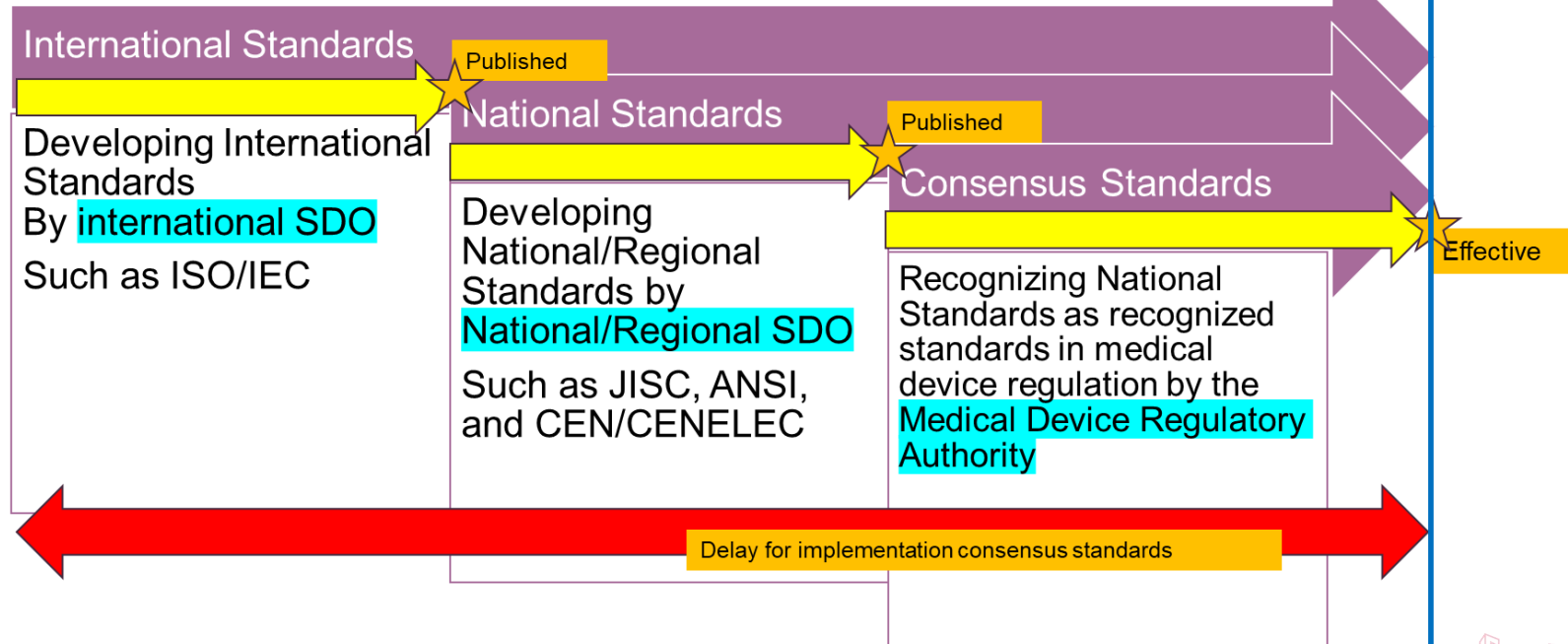
## Timeline of IEC 60601-1 Ed.4 (4th edition).

**More than 80 particular standards**

Start development of particular standards after the publication of merged CDV (but to start after the publication of FDIS/IS is practical)



# Process for Implementing International Standards into Medical Device Regulatory Frameworks Across Jurisdictions



## Recommendation/Suggestion

- Promote timely recognition of international standards across jurisdiction.
- Enhance alignment of implementation timelines across jurisdictions to reduce regulatory fragmentation.
- Strengthen coordination in development and adoption process of international standards and their corresponding national or regional standards



# Thank You!





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# GMTA Regulatory Reliance Dataset – Insights

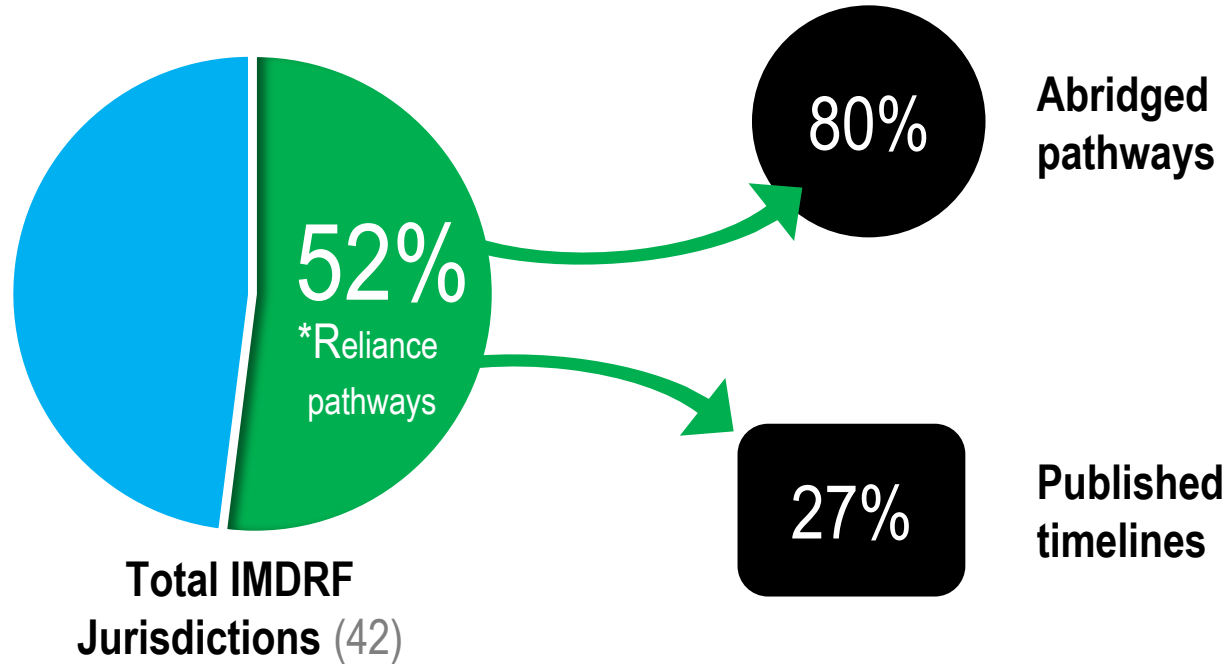
**Nataly Trejos**

**Assoc. Director, Regulatory Policy LATAM**

**Johnson & Johnson Medtech**



# GMTA Regulatory Reliance Dataset - Key Figures

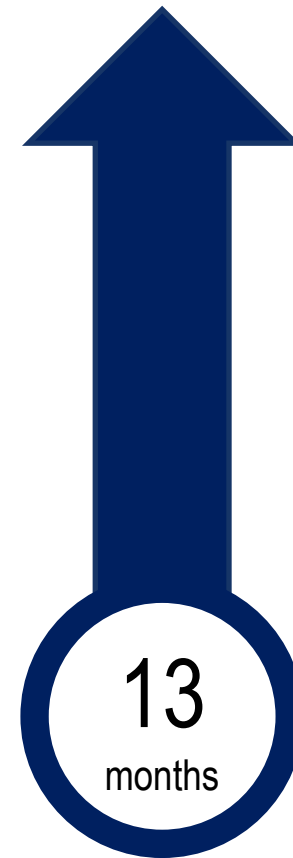


\*As of date

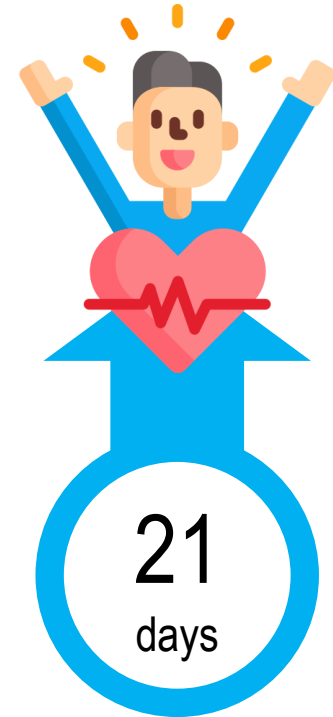


## Case Study

- Life-sustaining cardiac mapping catheter
- Same product, with identical data and manufacturing
- Authorization in one IMDRF jurisdiction through a reliance pathway: **21 days**
- In a neighboring jurisdiction with no reliance required: **13-months**



Regular Conformity  
Assessment



Reliance  
Pathway



# Actionable steps to address barriers which hinder reliance



# Thank You!





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# Standards Development Organizations Perspectives on Reliance

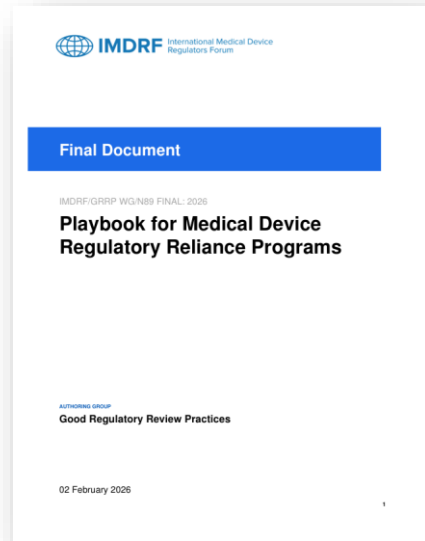
**Nicole Taylor Smith, JD**

**Vice President, Patient Safety & Quality Regions;  
Regulatory Science & Policy**

**Philips**



# IMDRF Playbook for Medical Device Regulatory Reliance Programs

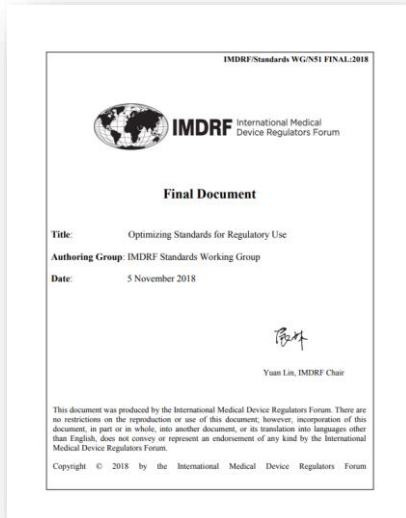


“[Y]ou can **maximize your reliance program’s benefits** by leveraging existing approaches developed using consensus-based processes...,” for example “**using globally-adopted consensus standards for medical devices.**”

“The approaches discussed in IMDRF/Standards WG/N51 – Optimizing Standards for Regulatory Use - may be helpful in adopting a **reliance program that leverages consensus standards**, as well as developing new standards that would be most suitable for such a program.”



# IMDRF/Standards WG/N51 – Optimizing Standards for Regulatory Use Device Regulatory Reliance Programs

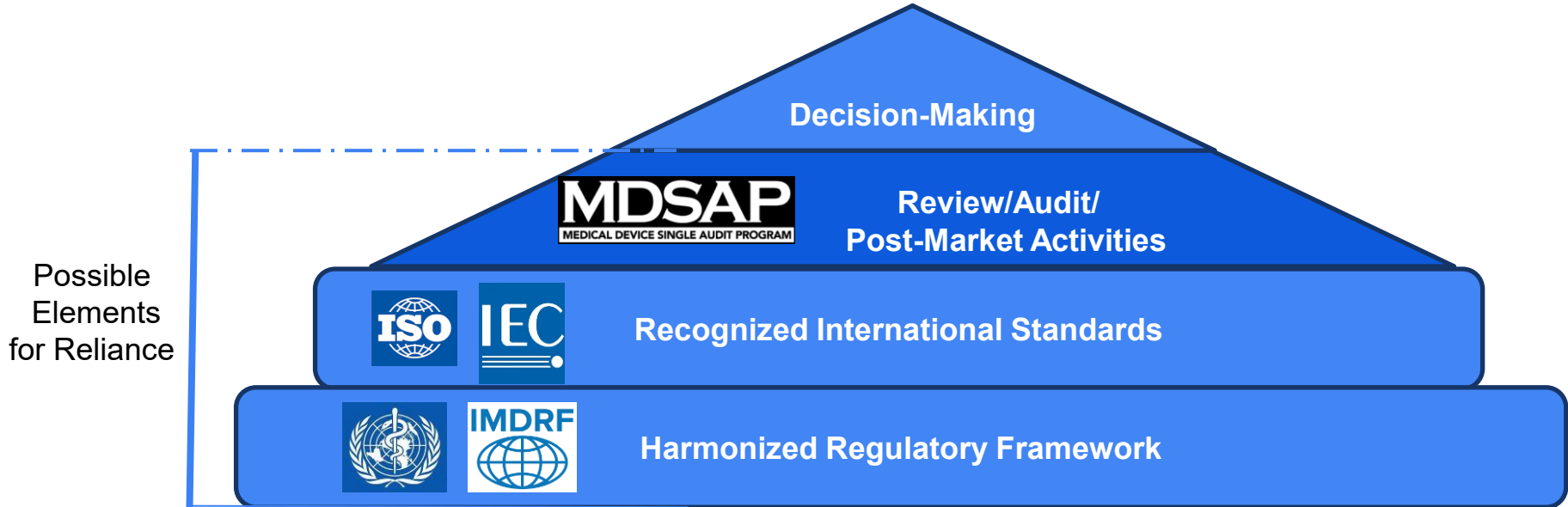


“With wider acceptance of standards among regulators comes **harmonization**, which supports IMDRF’s mission: ...to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.”

“Adoption of the recommendations in this guidance will lead to important benefits for all stakeholders. For manufacturers, **harmonization will help speed products to market and promote international trade**. RA [(Regulatory Authorities)] will **value the advances in regulatory science and practices**. Ultimately, **patients will benefit from expanded access to life-saving and life-enhancing treatments.**”



## Reliance and International Standards



# Role of International Standards in Supporting Reliance



## Streamline the device review process

Shared standards narrow variability and reduce duplicative assessment efforts among countries.

## Improve the efficiency of regulations

International standards establish unified safety, performance, and quality expectations across jurisdictions.

## Builds trust and confidence in acceptance of others' assessment

Transparent and consensus-driven development and productive dialogue among regulatory authorities, manufacturers, clinicians, patients, and the public builds trust in the process and outcomes, enabling authorities to rely on others' assessments.





## World Health Organization

*“Reliance does not weaken regulatory authority —  
it actually strengthens it.”  
Dr Agnes Sitta Kijo, WHO*



# Standards Development Organizations (SDOs) as Key Enablers for Trust, Transparency, and Efficiency



## Common Technical Language

SDOs provide globally accepted technical language to support clear communication and consistent regulatory interpretation.

## Rigorous Consensus Process

Consensus-based standards build trust by involving diverse stakeholders and ensuring scientific reliability.

## Support for Good Regulatory Practices

SDOs promote standardized methodologies and data expectations to enhance regulatory efficiency and resource use.

## Global Capacity Building

SDOs enhance global regulatory capacity and scalability by enabling reliance on trusted standards and frameworks.





## International Standards Organization

*“International Standards mean that consumers can have confidence that their products are safe, reliable and of good quality.”*

*“Regulators and governments count on ISO standards to help develop better regulation, knowing they have a sound basis thanks to the involvement of globally-established experts.”*

*“International Standards help to harmonize technical specifications of products and services, making industry more efficient and breaking down barriers to international trade.”*





## International Electrotechnical Commission

*“IEC International Standards represent the globally agreed way of doing things and are used as the basis for national or regional standards.”*

“IEC work promotes equal access to technology and state-of-the art expertise.”



HSA  
Health Sciences Authority



IMDRF

International Medical Device  
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# The Barriers: Deviations and Fragmentation

## Fragmentation of Standards

Partial adoption and local modifications fragment the technical foundation, causing uncertainty in regulatory reliance.

## Lack of Transparency

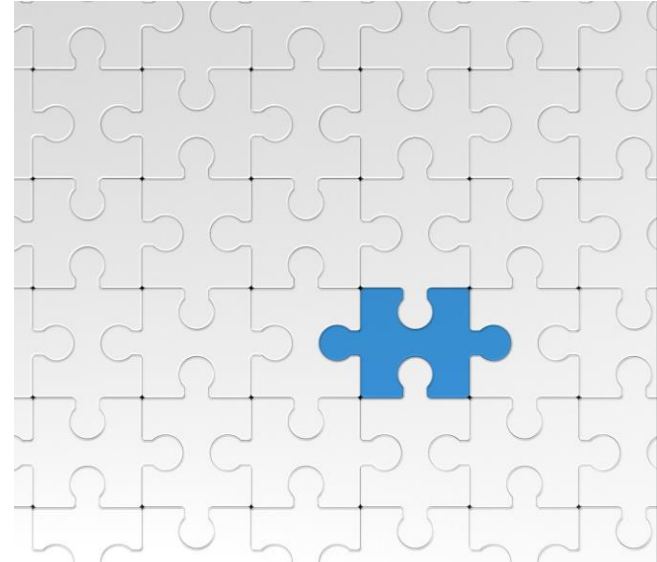
Undocumented deviations require regulators to repeat assessments, reducing reliance efficiency and increasing workload.

## Divergent Conformity Expectations

Variations in testing protocols and acceptance criteria complicate evaluations and cause duplicative efforts.

## Impact of Uncoordinated Updates

Frequent unsynchronized standards updates slow global regulatory convergence and undermine reliance pathways.



## Steps Forward



### Addressing Local Deviations

Local deviations are the single greatest barrier to reliance. It often results in redundant testing and delay or prevent patient access. It may create the need for different product versions to meet local requirements, thereby dramatically increasing development costs and complexity. This could increase the risk of production errors, endangering product quality and safety.

### Predictability = Efficiency

When a regulator anchors their process in global consensus standards, like ISO/IEC standards, industry can more accurately prepare and predict the outcome. This predictability is what allows us to scale innovations globally.

### Future Proofing (AI & Cyber)

Tech is moving faster than law. Using SDO working groups to develop risk-based requirements for AI and Digital Health, for example, before jurisdiction-specific rules are adopted into law supports stronger alignment globally, confidence in developed regulatory science requirements, and facilitate efficient patient access to new therapies.



## What the SDOs are saying...



*“International Standards help to harmonize technical specifications of products and services, making industry more efficient and breaking down barriers to international trade.” [Link](#)*



*IEC International Standards represent the globally agreed way of doing things and are used as the basis for national or regional standards. [Link](#)*



*ASTM standards are developed through consensus and are used globally to improve product quality, enhance safety, facilitate market access and trade, and build consumer confidence. [Link](#)*



*Harmonized standards reduce redundant testing and certification, lower costs, and facilitate international trade. [Link](#)*



*“AAMI’s adoption of ISO standards provides clarity for U.S. medical device manufacturers and healthcare delivery organizations and promotes the harmonization of best practices around the world.” [Link](#)*



## Regulator Perspectives



“Standards need to be purposed for an intended need that ends with **confidence in the competence of its conformity assessment in practice**. We need to be clear on what documents are designed to be instructive/educational vs. produced to support testing/regulatory needs.”

-Scott Colburn



“[W]hen multiple jurisdictions recognize the same standards as valid routes to demonstrate conformity, manufacturers avoid redundant testing and duplicable submissions. This not only reduces cost and time-to-market but also encourages innovation by freeing resources that can be reinvested into research and development. In fact, **international standards function as a common language – a bridge across borders that fosters trust between regulators, manufacturers, healthcare providers, and patients**. They reduce technical barriers to trade, support the opening of global markets, and accelerate patient access to safe, effective, and innovative technologies worldwide. **Without them, harmonization would remain an aspiration rather than a practical reality.**”

- Woei Jiuang Wong







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# Lessons learned on the path to implementation

**Dr Elaine Grimes**

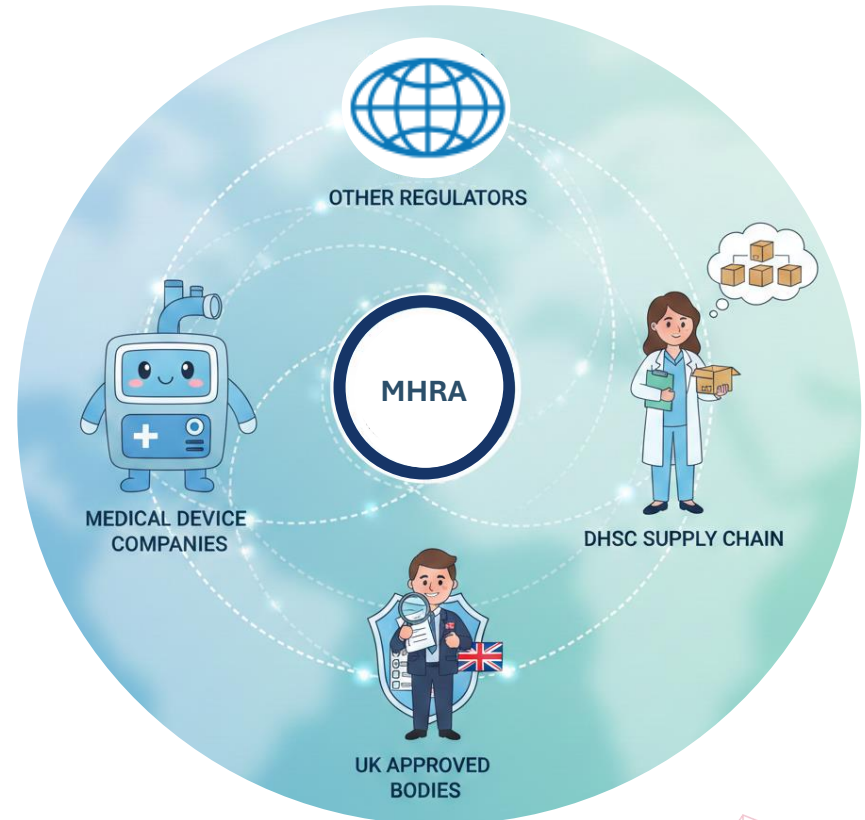
**Devices Regulatory Specialist**

**MHRA**



## Pilot project - summer 2024

- Tested the proposed reliance framework with devices across all classifications and types
- Collaborated with industry, approved bodies, DHSC supply chain and regulators
- Iterative process with > 50 trusted advisors and internal technical experts





## Trusted advisor principles

- All meetings will be **confidential**, and any information shared will be **kept in confidence** by all members.
- Confidential dissemination of the information discussed with the Groups is permitted only to **employees within their organisation, where this is appropriate for providing meaningful input to meeting discussions.**
- Members will **not** use the Groups to lobby on behalf of their host organisation.
- The Groups have no authority to make decisions for or on behalf of the MHRA and are only constituted to enable **seeking informal opinion.**
- The Groups will be comprised of individuals from across the Health and Life Sciences sector including patients and the public, industries, academia/clinical academia and charities to inform the development of policy, legislation and guidance.
- The Groups should meet on an as **needed basis** to deliver against specific projects/activities and will be 'stood down' after this has been completed.
- Attendees will be those people who can **contribute personally and professionally** without binding their host organisation.



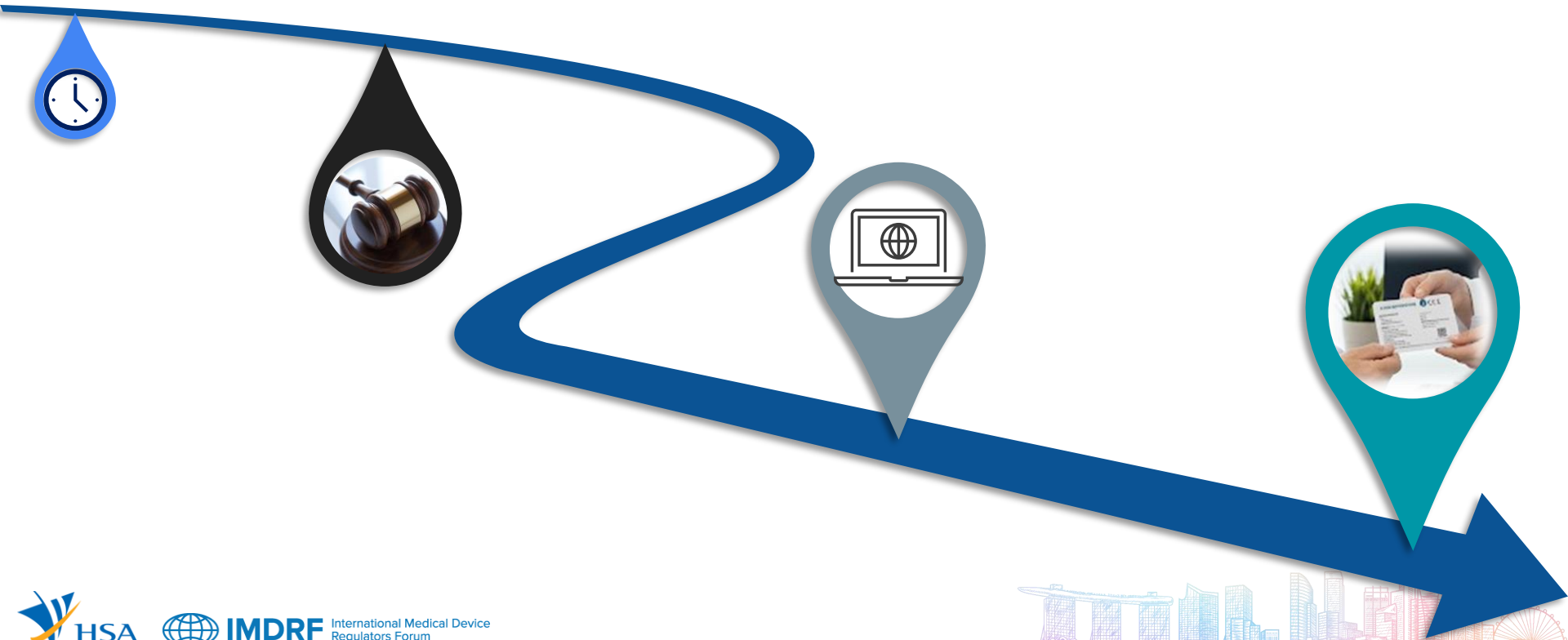
## Why did we do this?

Pilot aimed to:

- Finalise policy for public consultation and legal drafting
- Determine the role of approved bodies in delivering international reliance under the direction of MHRA
- Create a list of key topics for guidance needed to support stakeholders

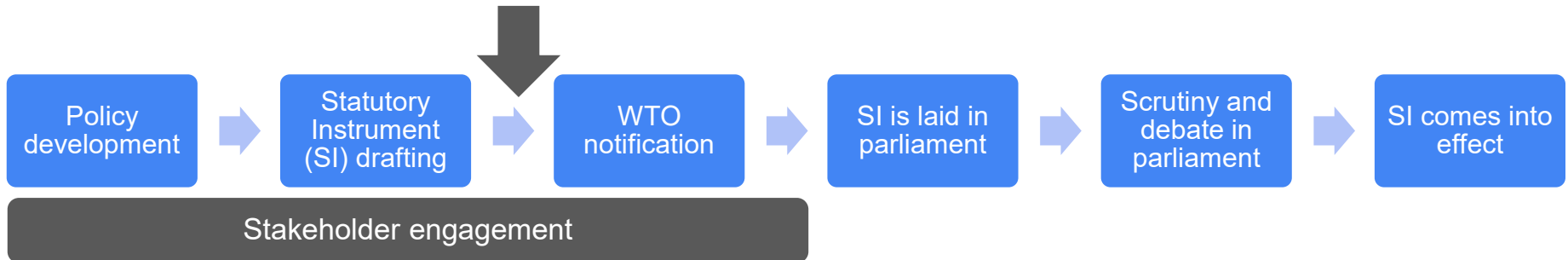


## Lessons learned



## What have we done since?

- November 2024 – Consulted on the [proposals for international reliance](#) from November to January 2025
- Spring 2025 – 287 responses received and analysed
- July 2025 – Published [government response](#) to consultation



# Thank You!



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# Lessons learned on the path to reliance implementation

**Mario Ernesto Vega Valenzuela**




**Head of the Medical Devices Registration Unit**

**Sanitary Regulation Superintendency**



## Implementing Reliance: The Experience and Perspective of El Salvador

For emerging regulatory systems, reliance is not merely a procedural shortcut; it is a progressive and capacity-building strategy while maintaining regulatory sovereignty. In the case of El Salvador, reliance represents an opportunity to:

-  Optimize expertise
-  Reduce duplication of efforts
-  Strengthen decision-making through structured collaboration with trusted regulatory authorities

Our pathway toward the implementation of reliance is just beginning; however, along the way, we have already learned valuable lessons.



## Lesson 1: Harmonization of basic regulatory aspects is essential



### Basic terminology

SRS has formally adopted the harmonized terminology for medical devices provided by IMDRF:

- Medical device, IVD Medical device and accessory definitions.
- Manufacturer, Distributor and Importer definitions
- Labelling definition
- Among others.



### Risk classification

SRS has formally adopted the medical device risk classification rules system and its nomenclature A, B, C, and D, established by IMDRF :

- The rules established by IMDRF in the GHTF/SG1/N77, IMDRF/IVD WG/N64 and IMDRF/SaMDWG/N12 documents were taken as a basis.
- Additional rules established by the European Union were added.



### Technical requirements

While the national regulatory framework establishes specific requirements, which may differ in structure or terminology from the IMDRF-proposed ToC, it is important to emphasize that:

- All technical requirements requested by the SRS are encompassed within the ToC
- The SRS maintains flexibility regarding document titles and formats, provided that the required content is adequately addressed.



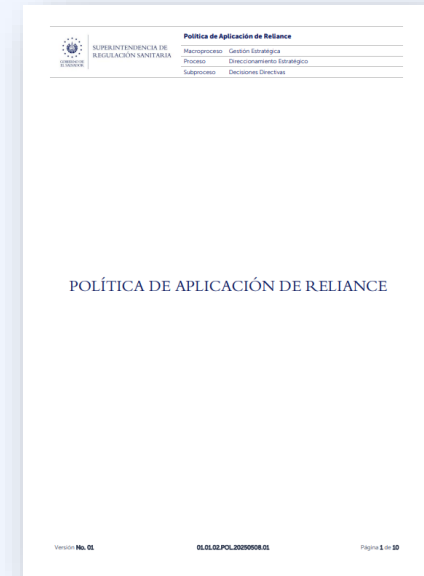
## Lesson 2: Good practices are fundamental for successful implementation

The implementation of reliance must be based on good regulatory practices and good reliance practices promoted by the World Health Organization, which implies:

- Having clear and predefined criteria for selecting reference authorities.
- Establishing specific aspects in which reliance applies.
- Making a descriptive document available to the public.

Reliance based on good regulatory practices strengthens institutional credibility.

### SRS Reliance Implementation Policy



Available at the following link: [https://www.srs.gob.sv/wp-content/uploads/2025/09/01.01.02.POL.\\_20250508.01.pdf](https://www.srs.gob.sv/wp-content/uploads/2025/09/01.01.02.POL._20250508.01.pdf)



## Criteria for selecting reference authorities:

The SRS will periodically review and update these considerations in accordance with the defined criteria.



**WHO Listed  
Authorities (WLA,  
tWLA and ML3)**



**PAHO recognized  
regional authorities**



**IMDRF Management  
Committee members**



**Regulatory  
information must be  
available and  
traceable**



**Demonstrated  
technical performance**



**Transparency of  
regulatory processes**



**Specific regulatory  
framework for medical  
devices**



**Reference institutions  
(NB, ISO, etc.)**



## Lesson 3: Pilot tests are a valuable tool

Pilot initiatives can generate valuable evidence and a broader strategic perspective, while preserving the integrity of routine regulatory processes.

In 2022, the SRS implemented a pilot exercise to assess the extent to which marketing authorization applicants were able to provide UDI codes for medical devices.

The findings highlighted important considerations for the progressive implementation of this type of identifier within a regulatory system undergoing institutional strengthening, particularly in jurisdictions where the medical device market is predominantly composed of importers.

- Most applicants did not have the device's UDI code available.
- UDI structures vary, as devices are manufactured in multiple countries and issued by different entities.
- As the regulated sector is primarily composed of importers, implementation requires balancing national requirements with diverse international UDI frameworks.
- The SRS continues to review this issue and consult with other jurisdictions to determine the most appropriate approach for implementing this identifier.



## Lesson 4: Digital submission portals are key enablers

Digital submission portals are essential not only to facilitate reliance, but to enable effective regulatory management. Their value lies fundamentally in the ability to generate, structure, and analyze data to support decision-making.

SRS electronic portal: <https://ventanilla.srs.gob.sv/>

- Automatically captures review timelines and generates measurable performance indicators.
- Enables real-time workload monitoring and specialty-based case allocation.
- Reduces submission errors through structured and standardized application forms.
- Allows fast retrieval of device-specific data for vigilance and traceability.
- Enhances the ease of data exchange with other regulatory authorities: generation of automated reports, reports sharing, public marketing authorizations, etc.



## Lesson 5: Continuous engagement with other NRAs is essential

Participation in international platforms such as the International Medical Device Regulators Forum and PAHO Medical Devices Regional Working Group strengthens convergence and builds confidence in shared technical standards.



## Final thoughts

Technical and digital enablers are mutually reinforcing elements. When implemented together, they can transform reliance into a sustainable regulatory strategy.

For emerging regulatory systems, reliance is not a secondary option, it is an essential instrument for building resilient and internationally connected regulatory frameworks.

One of the most valuable enablers for countries with emerging regulatory systems is access to regulatory information issued by trusted authorities in order to apply unilateral reliance as a first approach.



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