IMDRF International Medical Device Regulators Forum

# IMDRF Training

## N78: Conformity Assessment
## N89: Reliance Playbook

Collated training slides

13 September 2026

| Time | Title | Slide Deck Title | Speakers | Link to slide (ctrl + left click) |
|---|---|---|---|---|
| **9-910** | Course overview & logistics | Nil slides | •Wong Woei Jiuang, **Singapore HSA (**on behalf of the **IMDRF Chair and Secretariat**)<br>•Tracey Duffy, **Australia TGA, IMDRF TOSC Co-Chair** | Nil |
| **910-1015** | N78: Conformity assessment | Conformity Assessment (CA) for Medical Devices & IVDs | •Moe Ohashi, **Japan MHLW/PMDA**<br>•Kang-Hyun KIM, **South Korea MFDS**<br>•Fatemeh Razjouyan, **Medtronic** | Conformity Assessment (CA) for Medical Devices & IVDs |
| **1015-1115** | N78 Case Studies | • Training on GHTF N78 and IMDRF/GRRP WG/N89 Session: N78 Case Studies<br>• Training on GHTF N78 and IMDRF/GRRP WG/N89 Session: N78 Case Studies (US)<br>• Training on GHTF N78 and IMDRF/GRRP WG/N89 Session: N78 Case Studies (EU) | •Erin Cutts, **US FDA**<br>•Nada Alkayat, **European Commission** | • Training on GHTF N78 and IMDRF/GRRP WG/N89 Session: N78 Ca…<br>• Training on GHTF N78 and IMDRF/GRRP WG/N89 Session: N78 Ca…<br>• Training on GHTF N78 and IMDRF/GRRP WG/N89 Session: N78 … |
| **1115-1130** | BREAK | Nil slides | | Nil |
| **1130-1230** | N89: Reliance Playbook | Training on N98: IMDRF Reliance Playbook | •Debbie Ko, **Singapore HSA**<br>•TBD, **WHO** (recording)<br>•Tammy Steuerwald**, Roche** | Training on N98: IMDRF Reliance Playbook |
| **1230-130** | LUNCH | Nil slides | | Nil |
| **130-215** | Reliance Playbook Case Study: QMS evidence & audit reliance ISO | Reliance Playbook Case Study: QMS Evidence & Audit Reliance | •Thiago Rezende P. Cunha, **Brazil ANVISA**<br>•Melissa Torres, **AdvaMed** | Reliance Playbook Case Study: QMS Evidence & Audit Reliance |
| **215-245** | Reliance Playbook Case Study: Certificates, CFGs, apostilles, and alternatives | Reliance Playbook Case Study: Certificates, CFG/CFS, apostilles and practical verification | •John Jamieson, **Australia TGA**<br>•Sandra Ligia González**, IACRC** | Reliance Playbook Case Study Certificates, CFG/CFS, apos… |
| **245-320** | Group exercise | Opportunities for Reliance within the Elements of Conformity Assessment and Ensuring Sovereignty | •Rob Reid and Francisco Delgardo, **UK MHRA**<br>•Markus Wälti, **Switzerland Swissmedic**<br>•Razan Asally**, Saudi Arabia, SFDA**<br>•Sharad Shukla**, J&J** | Opportunities for Reliance within the Elements of Confor… |
| **320-330** | Concluding remarks | Nil slides | •Erin Cutts, **US FDA, IMDRF TOSC Co-Chair** | Nil |

# Conformity Assessment (CA) for Medical Devices & IVDs

# Speakers



**Fatemeh Razjouyan**

Senior Director, Regulatory Policy, International and Harmonization

Medtronic



**Kanghyun Kim**

Deputy Director, Medical Device Management Division

Ministry of Food and Drug Safety



**Moe OHASHI**

Reviewer, Office of Medical device I

Pharmaceutical and Medical Device Agency (PMDA)

# Learning Objectives

By the end of this session, participants will be able to:



**Explain the purpose and principles of conformity assessment** within a risk-based regulatory framework for medical devices and IVDs.

Describe the five **conformity assessment elements** and how **evidence expectations** vary according to device risk.

Recognize when existing conformity assessment evidence may be leveraged to **avoid unnecessary duplication**.

**Apply internationally recognized principles** from GHTF/IMDRF to design or strengthen conformity assessment processes that are proportionate, efficient, and appropriate for your jurisdiction.

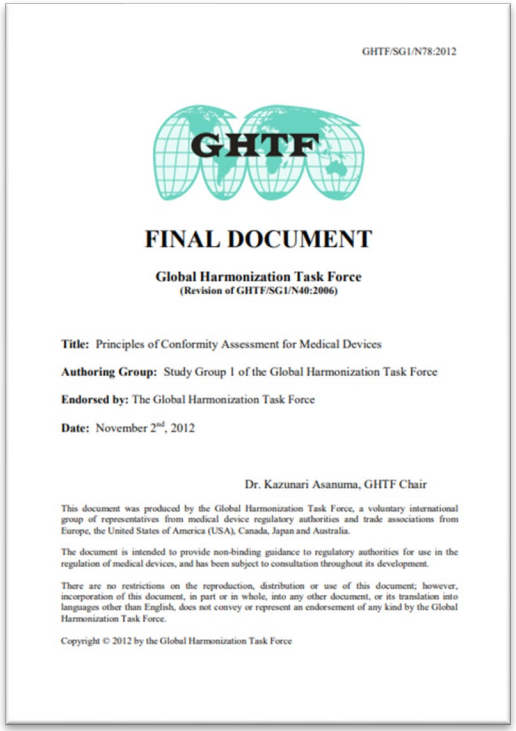
# Agenda

1. Introduction to CA | 10 mins
2. Overview of QMS element of CA | 15 mins
3. Overview of the remaining CA elements | 20 mins
4. Key takeaways | 5 mins
5. Q & A | 15 mins

# Foundational international guidance

These guidance documents establish internationally recognized principles for CA by describing:

- **The evidence & procedures** manufacturers use to demonstrate MD/IVDs are safe & perform as intended.
- **The CA elements** applied according to device risk, ensuring that regulatory oversight is proportionate to the potential hazard.
- **The role of Regulatory Authorities (RAs) & Conformity Assessment Bodies (CABs)** in verifying that the appropriate CA elements have been applied.
- **The Declaration of Conformity**, through which the manufacturer attests that all applicable CA requirements have been met.



GHTF/SG1/N78:2012

GHTF

FINAL DOCUMENT

Global Harmonization Task Force
(Revision of GHTF/SG1/N40:2006)

**Title:** Principles of Conformity Assessment for Medical Devices

**Authoring Group:** Study Group 1 of the Global Harmonization Task Force

**Endorsed by:** The Global Harmonization Task Force

**Date:** November 2nd, 2012

Dr. Kazunari Asanuma, GHTF Chair

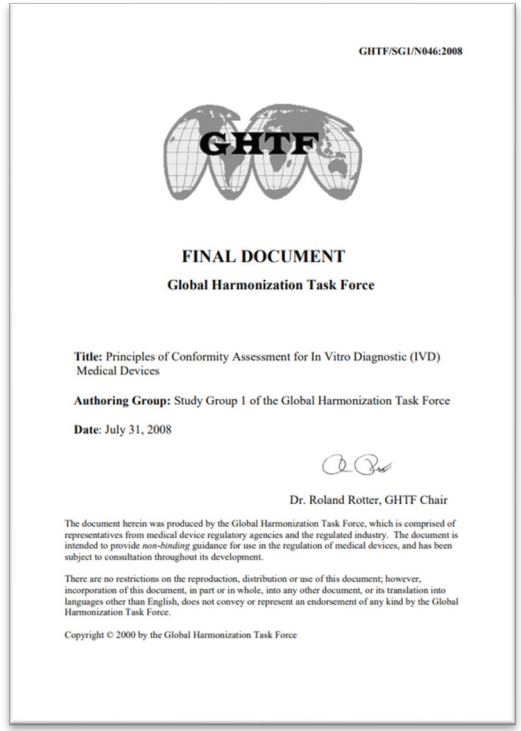
This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide non-binding guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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**Principles of CA for MD:** GHTF SG1/N78:2012



GHTF/SG1/N046:2008

GHTF

FINAL DOCUMENT

Global Harmonization Task Force

**Title:** Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices

**Authoring Group:** Study Group 1 of the Global Harmonization Task Force

**Date**: July 31, 2008

Dr. Roland Rotter, GHTF Chair

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**Principles of CA for IVD:** GHTF SG1/N046:2008

Medical Devices and IVDs follow the same principles for conformity assessment

# Conformity assessment provides confidence in safety, performance & quality throughout MD/IVD lifecycle



- MD/IVDs are:
  - ✓ Safe
  - ✓ Perform as intended
  - ✓ Conform to the Essential Principles of Safety and Performance of MD/IVDs

# What is Conformity Assessment?

- The **systematic examination of evidence** and **procedures undertaken by the manufacturer**, under **requirements established by the Regulatory Authority**, to determine whether a MD/IVD is safe and performs as intended by the manufacturer and, therefore, conforms to the Essential Principles of Safety and Performance of Medical Devices.

- Manufacturers of all classes of device are expected to demonstrate conformity of the device to the Essential Principles of Safety and Performance of Medical Devices.

True or False? Conformity assessment is completed before an MD/IVD is placed on the market.

A. True

B. False



# All 5 conformity assessment elements are required for each device class, but there is flexibility in the manner of their application

1. Quality management system (QMS)
2. System for postmarket surveillance
3. Technical documentation
4. Declaration of conformity
5. Registration of manufacturers and their MD/IVD by regulatory authority to provide visibility of devices on the market



# Which element(s) apply to all MD/IVD classes?

A. QMS & registration of manufacturers and their MD/IVD

B. System for postmarket surveillance

C. Declaration of conformity & technical documentation

D. All of the above



# The rule of risk-proportionality




- All five conformity assessment elements are **required for every device class; however,**
- As device risk increases, regulators require **greater confidence**.
- That confidence is achieved through **increasing evidence** and **regulatory oversight**.
- **Note:** While N78/N46 & these slides are based on a four-level classification system, the underlying principles are applicable across different classification systems.

# According to the IMDRF/GHTF principles, which element is considered the “most basic level” of regulatory control of medical devices in a market?

A. Registration of manufacturers and their MD/IVD by regulatory authority

B. Premarket submission of technical documentation

C. Quality Management System (QMS) implementation

D. Third-party certification by a notified body



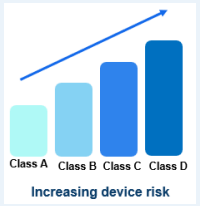
# Conformity assessment is not one-size-fits-all: the level of assessment should be proportionate to device risk

| Conformity Assessment Element | Class A | Class B | Class C | Class D |
|---|---|---|---|---|
| Quality Management System | Maintain Basic QMS | Satisfied QMS in place or audit prior to authorization | | |
| System for postmarket surveillance | Constant across all classes (RA verifies during audit) | | | |
| Technical documentation | Upon request | Normally no premarket review | Premarket review | In-depth premarket review |
| Declaration of Conformity | Maintain on file | Upon request | Submitted & reviewed | |
| Registration of manufacturers & their MD/IVD | Constant across all classes | | | |

# Classification, conformity assessment, essential principles & reliance are connected

## Classification

**Risk-based classification sets Foundation and downstream oversight, evidence depth, and specific review pathways**




## Conformity Assessment




## Essential Principles

**Essential Principles of Safety and Performance is the benchmark for safety, performance & quality, and defines what the MD/IVD must conform to**

## Reliance

**Reliance leverages existing decisions & oversight from trusted regulators/institutions to:**

1. **Reduce redundant evaluations**
2. **Improve efficiency & predictability**
3. **Support timely patient access**

Classification determines the level of scrutiny. Conformity assessment generates evidence that MD/IVD conforms to Essential Principles. Reliance leverages trusted decisions so regulators can focus their resources where risk is greatest.

Right level of confidence.
Right use of resources.
Better regulatory outcomes.

# Element #1: QMS

# QMS provides the foundation for effective conformity assessment

- **Quality Management System**

  - Establishes the organizational processes needed to consistently design, manufacture, and maintain MD/IVD that conform to the Essential Principles of Safety and Performance **throughout its lifecycle**

**01** **Consistent processes**

Establishes controlled design, manufacturing, supplier, and change management processes throughout the lifecycle

**02** **Consistent conformity**

Generates objective evidence that devices consistently meet the Essential Principles of Safety and Performance

**03** **Regulatory confidence**

Provides regulators with confidence that the manufacturer can consistently produce & maintain MD/IVDs that conform to requirements

# QMS integrates all activities needed to maintain conformity throughout the MD/IVD lifecycle

**Why QMS matters?**

- Integrates all critical activities that influence MD/IVD safety and performance
- Generates objective and verifiable evidence of conformity
- Enables consistent decisions and effective regulatory oversight
- Supports continuous conformity throughout the MD/IVD lifecycle




These interconnected processes work together within the QMS to ensure MD/IVDs consistently conform to the **Essential Principles**.

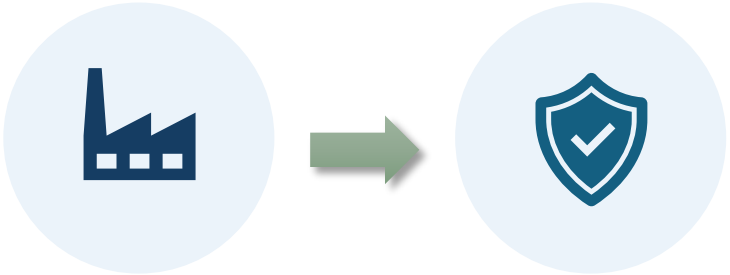
# International guidance provides a harmonized framework for implementing QMS

| | |
|---|---|
| GHTF/SG3/N99-10:2004 | **Process Validation**<br>Provides guidance on establishing objective evidence and strictly controlling process variables to consistently meet predetermined requirements |
| GHTF/SG3/N15R8:2005 | **Risk Management**<br>Integrates risk management principles into the QMS to actively identify, evaluate, and control hazards throughout the lifecycle |
| GHTF/SG3/N17:2008 | **Control of Suppliers**<br>Provides a risk-based approach for evaluating, selecting, controlling and monitoring suppliers |
| GHTF/SG3/N18:2010 | **Corrective Action & Preventive Action**<br>Provides guidance on measurement, analysis, corrective action, preventive action and related improvement processes |

**Each document addresses a critical aspect of an effective quality management system**

Together they support manufacturers in establishing **effective QMS processes** that enable conformity throughout the MD/IVD lifecycle

# QMS has become the internationally harmonized term for MD/IVD quality systems




- **GMP – Good Manufacturing Practice**
  - ➢ Originated from **pharmaceutical** manufacturing process control
  - ➢ Still used by some MD/IVD regulators
  - ➢ Generally, focuses on manufacturing controls

- **QMS – Quality Management System (ISO 13485- based)**
  - ✓ Preferred terminology by **GHTF/IMDRF**
  - ✓ Covers the entire MD/IVD lifecycle
  - ✓ An enterprise-wide system covering design, development, and risk management
  - ✓ Ensures consistent processes and evidence of conformity to the Essential Principles

# Why do regulators audit the QMS instead of inspecting every single device?

01

### Process, not inspection

Regulators assess the system because quality is built into the process, not inspected into the product.

02

### Consistent outcomes

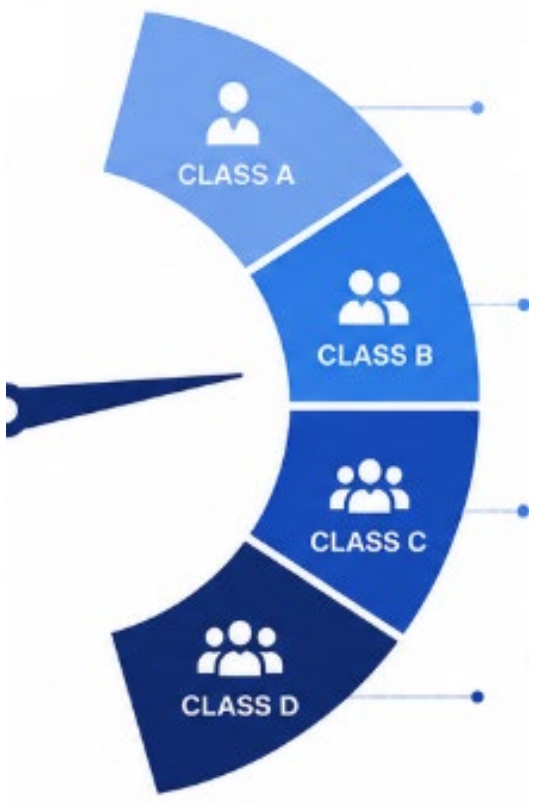
An effective QMS ensures consistent outcomes and provides objective evidence of conformity.

03

### Sustained conformity

A robust QMS is the most effective way to achieve and sustain conformity.

# QMS applies to every device class, but regulatory oversight increases with risk




**Low Risk**
Regulator audit normally not required

**Low-moderate Risk**
Regulator-satisfied QMS in place or audit prior to authorization

**Moderate-high Risk**
Regulator-satisfied QMS in place or audit prior to authorization

**High Risk**
Regulator-satisfied QMS in place or audit prior to authorization

- Every manufacturer **must** implement a QMS
- The depth of regulatory oversight is **risk-proportionate**
- The objective remains the same for every class:
  - Provide confidence that MD/IVDs **conform to the Essential Principles**

# Trusted QMS assessments enable regulatory reliance



**Manufacturer**
Implements an ISO 13485-based QMS

**QMS in Place**
Operates controlled processes across the MD/IVD lifecycle

**Trusted QMS Assessment**
Conducted by a trusted assessment authority (e.g., MDSAP audit, ISO 13485 audit)

**Objective Evidence of QMS Conformity**
Audit/inspection report and findings provide objective evidence

**Leveraging Regulatory Authority**
Relies on the existing assessment to support its regulatory decisions

**Key Takeaway**

Trusted QMS assessments are a cornerstone of regulatory reliance, enabling regulators to make confident decisions while minimizing duplication, increasing efficiency, and strengthening global regulatory convergence.

# Which statement best describes the role of a QMS in conformity assessment?

A. It focuses only on manufacturing activities.

B. It provides confidence that devices consistently conform to the Essential Principles throughout their lifecycle.

C. It replaces technical documentation requirements.

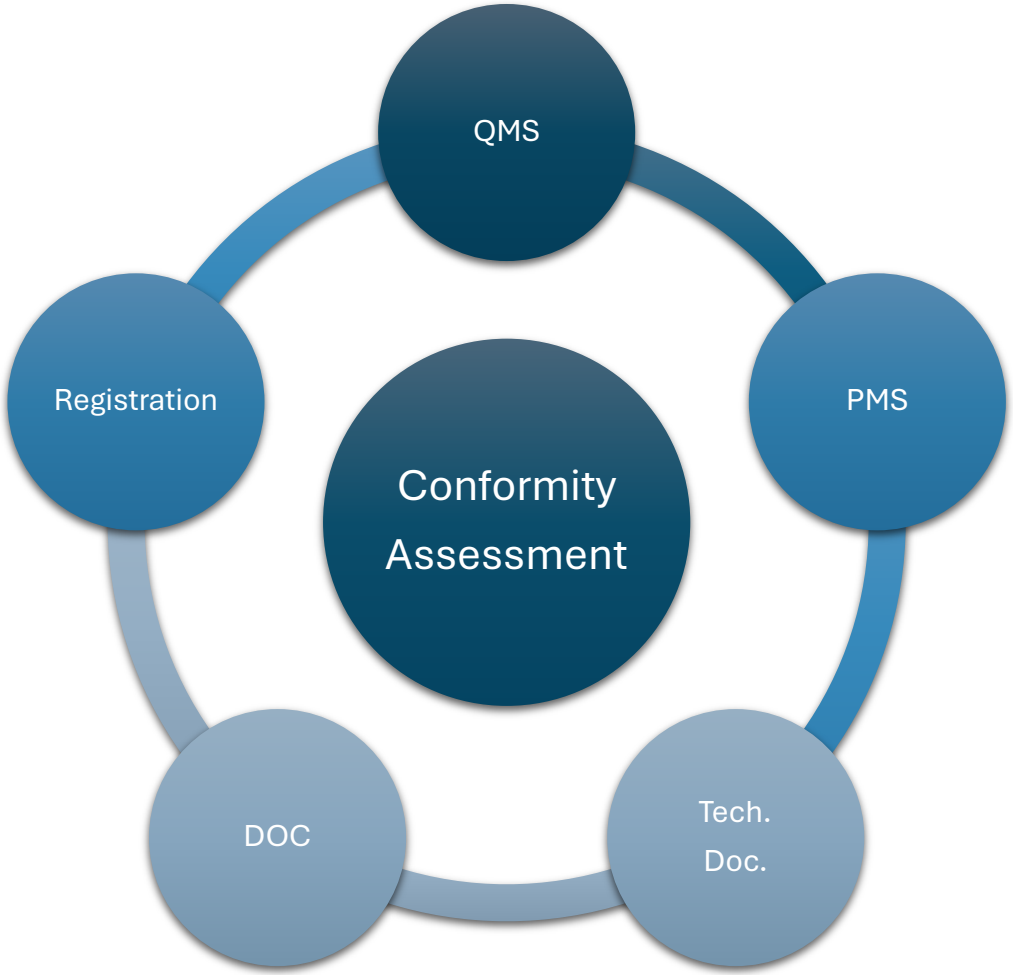
D. It applies only to high-risk devices.



# Element #2: System for postmarket surveillance

# Other Elements of Conformity Assessment

1. Quality management system (QMS)
2. System for postmarket surveillance
3. Technical documentation
4. Declaration of conformity
5. Registration of manufacturers and their MD/IVD by regulatory authority



# What is System for postmarket Surveillance （PMS） ?

**Regulatory confidence is not built only before market authorization.**

- The manufacturer will establish, as part of its QMS, a process to assess
- the continued conformity of the device to the Essential Principles
- of Safety and Performance through the post-marketing phase.

This process will include・・・

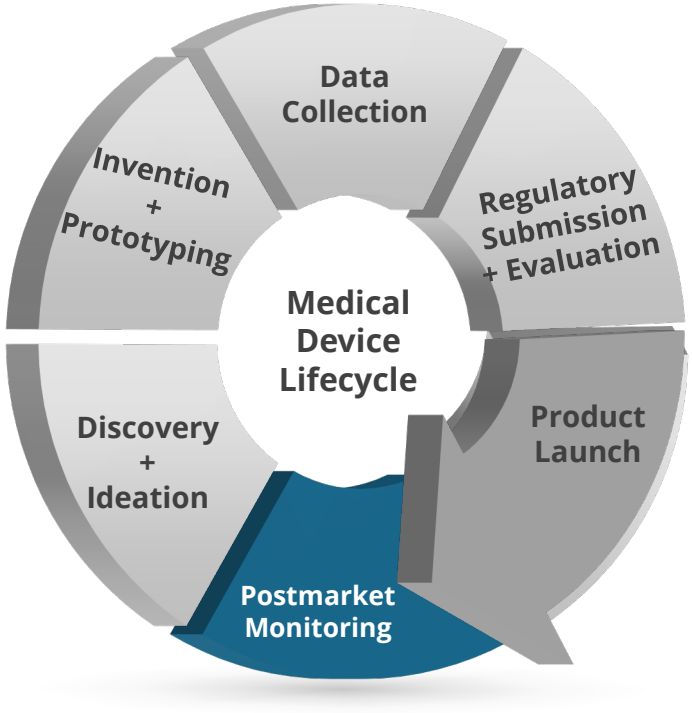
✓ complaint handling
✓ post-market vigilance reporting
✓ any subsequent corrective & preventive actions (CAPA)

# PMS: monitoring MD/IVD performance in real world

Continuous postmarket surveillance is **vital** for safety and generates learning to **improve** current and future products

Manufacturers are required to **document complaints** and determine if an investigation is needed and **determine reportability** in each jurisdiction

**TPLC* approach** ensures **vigilant tracking** of product performance from launch through postmarket activities

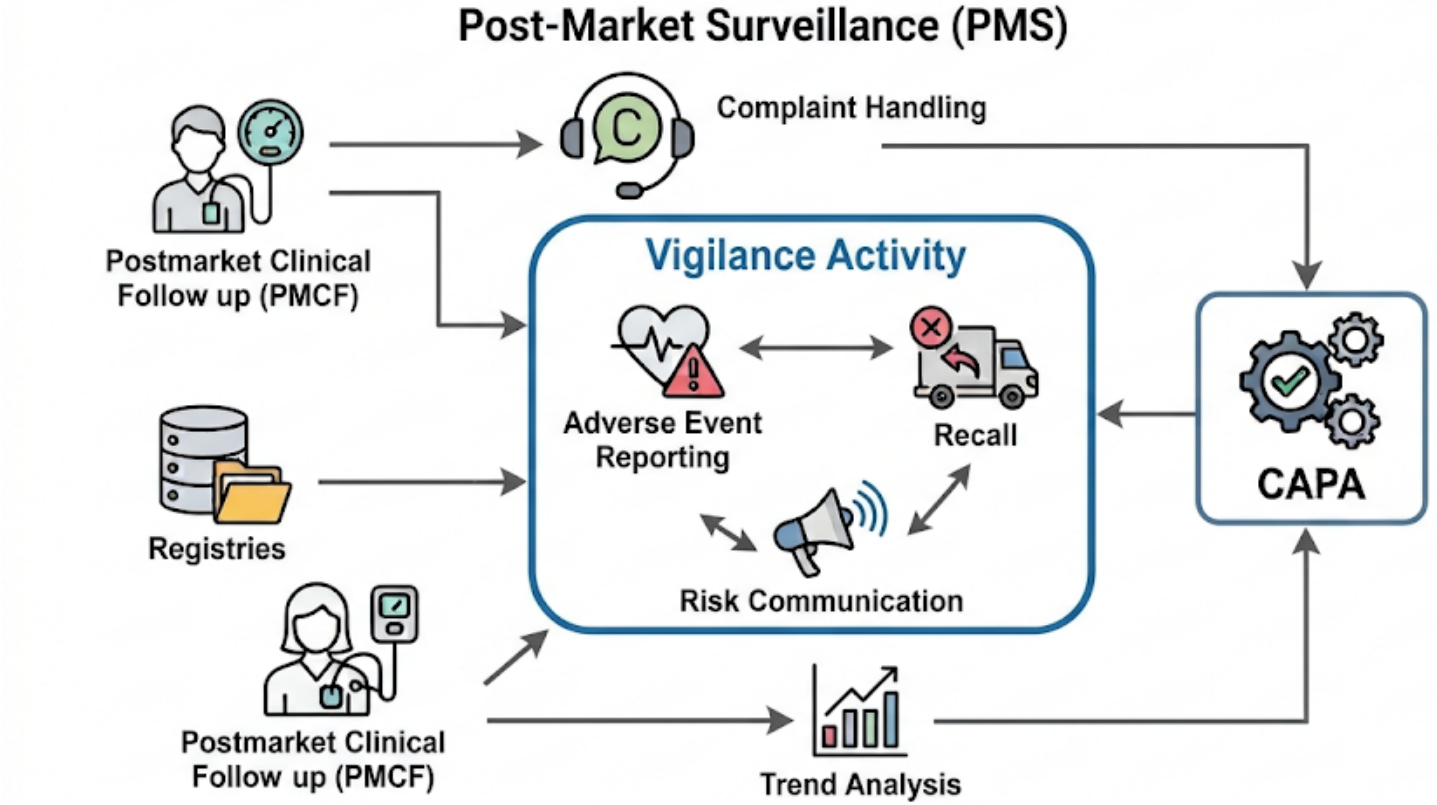



*TPLC : Total Product Life Cycle

# PMS Comprises Multiple Interconnected Activities

**PMS**

A comprehensive system of interconnected activities designed to continuously monitor the performance of a medical device throughout its post-market lifecycle.



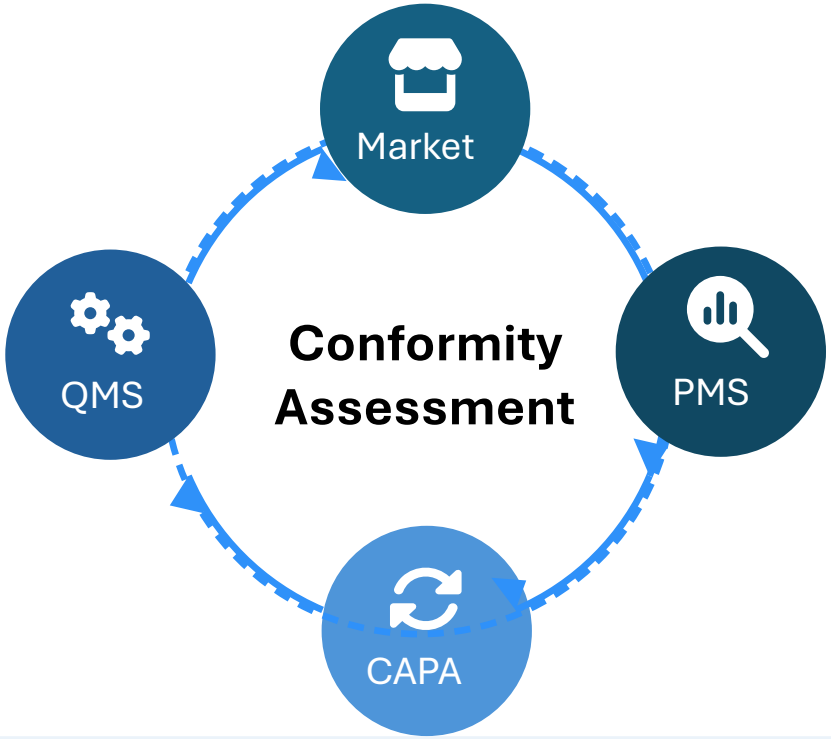

**Each element is interconnected, contributing to the continuous monitoring and improvement of product performance.**

# PMS strengthens the QMS through a continuous improvement loop

**The continuous improvement is achieved through Corrective Action and Preventive Action (CAPA).**

## CAPA Process

- Identify the issue
- Assess risk and impact
- Investigate the Root cause
- Develop corrective and preventive actions
- Implement the actions
- Verify effectiveness




**Key Takeaway**

PMS generates real-world evidence. Through CAPA, that evidence is incorporated into the QMS, helping ensure MD/IVDs continue to conform to the Essential Principles of Safety and Performance throughout their lifecycle.

# When does conformity assessment end?

- A. After obtaining ISO 13485 certification
- B. After market authorization
- C. After registration
- D. It continues throughout the product lifecycle



# Element #3: Technical documentation

# What is Technical Documentation?

**Documented evidence of compliance with safety & performance requirements**

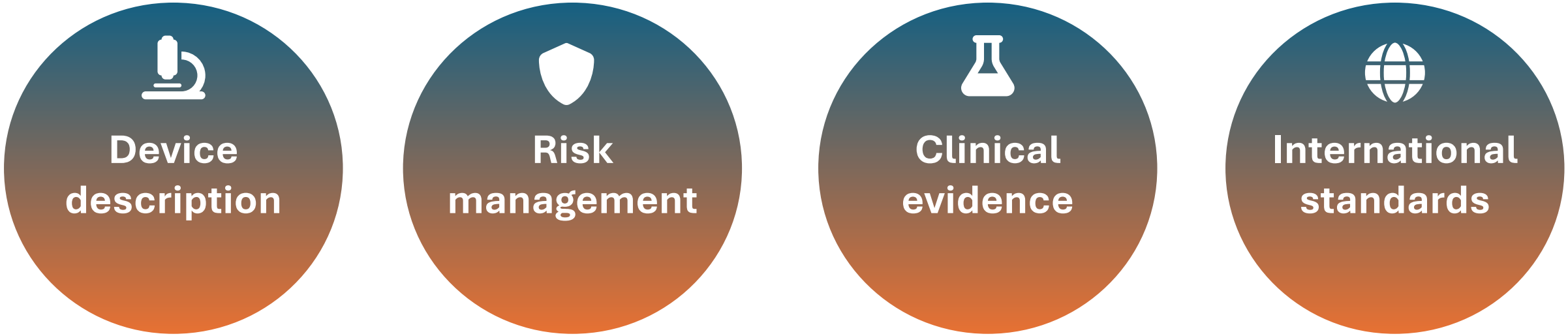
- Manufacturers of all classes of device are expected to demonstrate conformity of the device to the Essential Principles of Safety and Performance of Medical Devices through the preparation and holding of technical documentation that :

✓ shows how each medical device was developed, designed and manufactured together

✓ with the descriptions and explanations necessary to understand the manufacturer's determination with respect to such conformity

# What is Technical Documentation?

**Documented evidence of compliance with safety & performance requirements**




NRA/CABs review to assess whether documented evidence supports claims of conformity for its intended use & environment

# International Standards Support the Entire process

## International Standards = Common Language / Direction to the Goal

**Supporting the Conformity Assessment Infrastructure**

ISO 19011 – Guidelines for Auditing management systems
ISO/IEC 17021-1– Requirements for bodies providing audit and certification of management systems
ISO/IEC 17065 – Requirements for bodies certifying products, processes and services
ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories
ISO/IEC 17011 –Requirements for accreditation bodies accrediting conformity assessment bodies
ISO/IEC 17000 –Vocabulary and general principles

**Supporting Device Safety and Performance**

ISO 13485 – Quality management systems
ISO 14971 – Risk Management
IEC 60601 series – Electrical safety
ISO 10993 series – Biological evaluation
ISO 14155 – Clinical investigation
ISO 62366-1 – Usability engineering



# What is the primary role of International standards in conformity assessment?

A. To replace technical documentation

B. To replace regulatory review

C. To generate objective evidence supporting conformity

D. To replace PMS



# Element #4: Declaration of conformity

# Declaration of Conformity （DOC）

**The declaration has value because it is supported by evidence.**

- Is manufacturer’s formal attestation that MD/IVDs meet applicable standards and regulatory requirements
- Includes information on device identification, classification, compliance with safety and performance principles, and labeling instructions

# The Declaration of Conformity derives its value from the _____ that supports it

A. regulator's approval

B. objective evidence generated through conformity assessment

C. manufacturer's marketing claims

- D. product labeling



# Element #5: Registration of manufacturers & their MD/IVD

# Registration

- Is the regulatory control for medical devices
- Manufacturers must provide necessary information for registration and listing before placing MD/IVD on the market
- Guidance on the information to be provided may be found in the document entitled Registration of Manufacturers and other Parties and Listing of Medical Devices （GHTF/SG1/N065:2010） *

RAs are encouraged to establish an internet-based system for collection of registration information.

Update the information provided within 30 calendar days of the occurrence of any change.

*https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n065-listing-of-medical-devices-100827.pdf

# Why is it important for registration information to be accurate and kept up to date throughout the product lifecycle?

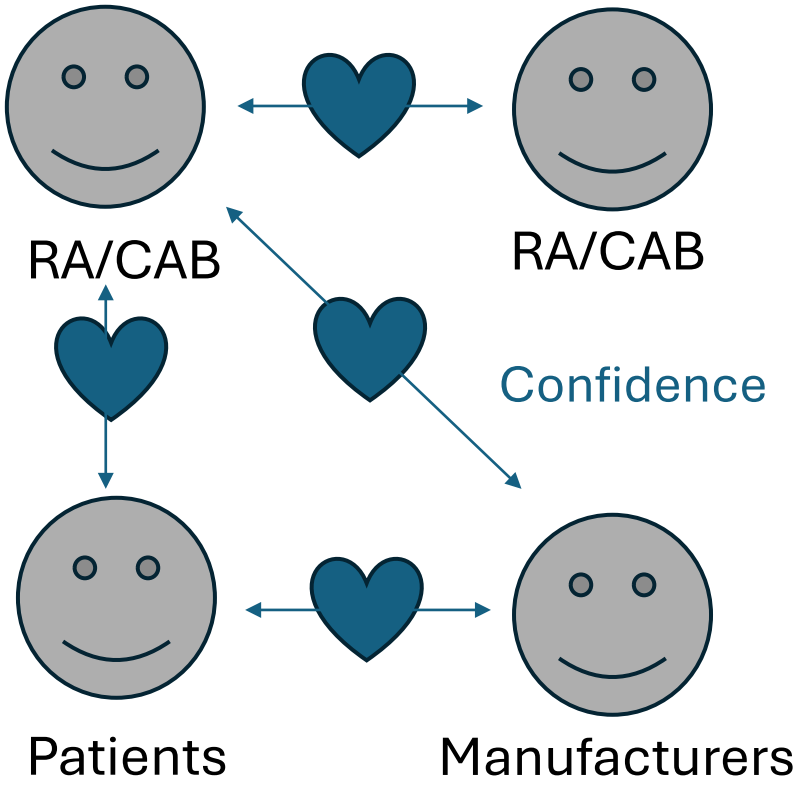
- Ensures regulatory oversight.
- Facilitates communication between manufacturers and regulators.
- Supports traceability and post-market activities.
- Helps maintain an accurate regulatory database.



# Key Takeaways

**These common principles provide the foundation for regulatory cooperation and information sharing among regulatory authorities.**

1. Quality management system (QMS)
2. System for postmarket surveillance
3. Technical documentation
4. Declaration of conformity
5. Registration of manufacturers and their MD/IVD by regulatory authority

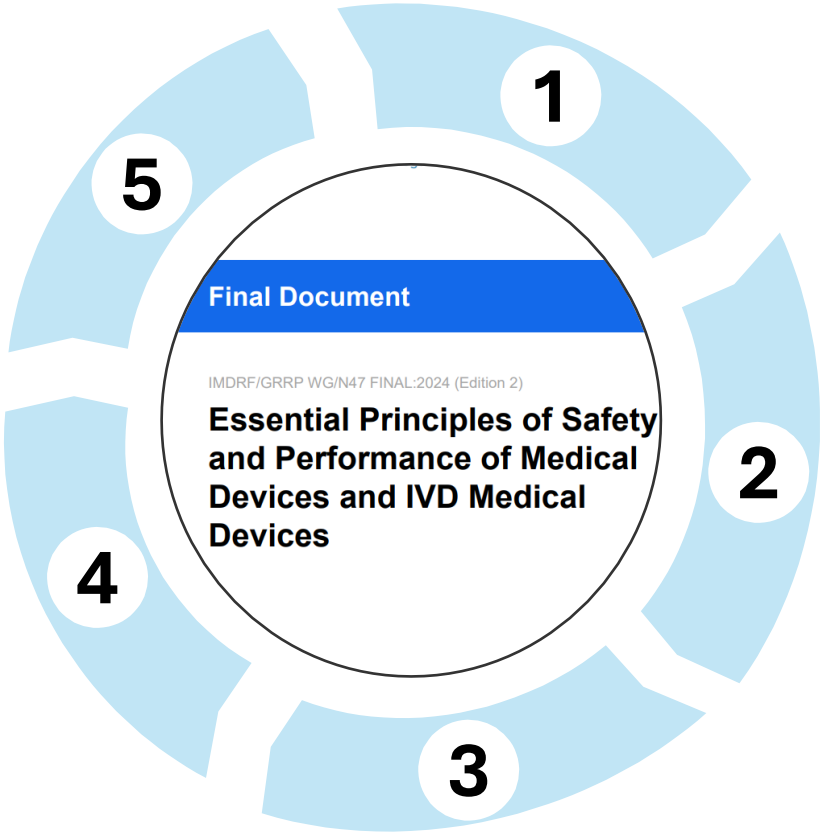


# Key takeaways



# The 5 elements of conformity assessment work together

To demonstrate conformity with the Essential Principles throughout the device lifecycle




1 **Quality Management System**
Provides assurances that manufacturers will perform every activity to keep MD/IVD safe & effective over its lifecycle

2 **Technical Documentation**
Provides robust objective evidence demonstrating that the device meets the Essential Principles of Safety and Performance prior to market entry

3 **Declaration of Conformity**
Manufacturer's formal attestation confirming all applicable CA activities are fully complete & certifies MD/IVD complies with applicable regulatory requirements

4 **Registration**
Provides regulatory visibility of manufacturers and MD/IVD within the jurisdiction, supporting market oversight and traceability

5 **Postmarket Surveillance**
Monitors device performance in real-world use and feeds back info to drive corrective actions & continuous improvements

**Key Takeaway:**
Together, these five elements function as an integrated system to provide confidence that MD/IVD continues to conform to the Essential Principles of Safety and Performance throughout its lifecycle.

# Fundamental principles of conformity assessment

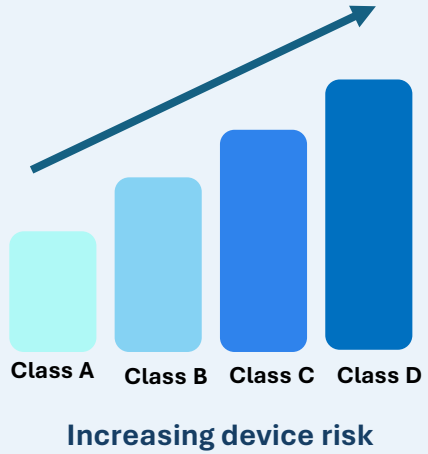
- QMS
- Tech doc
- PMS
- DoC
- Registration

**Applies across all device classes**

Manufacturers are responsible for demonstrating & maintaining conformity with EP throughout MD/IVD lifecycle

**Applied Proportionately**

The manner in which these elements are applied and the level of regulatory oversight are **proportionate to device risk**



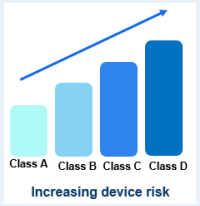

Same five conformity assessment elements.
Different evidence expectations & regulatory oversight.

Goal: The right level of confidence for the level of device risk.

# Classification, conformity assessment, essential principles & reliance are connected

## Classification

**Risk-based classification sets Foundation and downstream oversight, evidence depth, and specific review pathways**




## Conformity Assessment




## Essential Principles

**Essential Principles of Safety and Performance is the benchmark for safety, performance & quality, and defines what the MD/IVD must conform to**

## Reliance

**Reliance leverages existing decisions & oversight from trusted regulators/institutions to:**

1. **Reduce redundant evaluations**
2. **Improve efficiency & predictability**
3. **Support timely patient access**

Classification determines the level of scrutiny. Conformity assessment generates evidence that MD/IVD conforms to Essential Principles. Reliance leverages trusted decisions so regulators can focus their resources where risk is greatest.

Right level of confidence.
Right use of resources.
Better regulatory outcomes.

**Regulators provide oversight, but**

**manufacturers hold the primary responsibility for demonstrating & maintaining conformity**



# Thank you

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# Training on GHTF N78 and IMDRF/GRRP WG/N89
# Session: N78 Case Studies

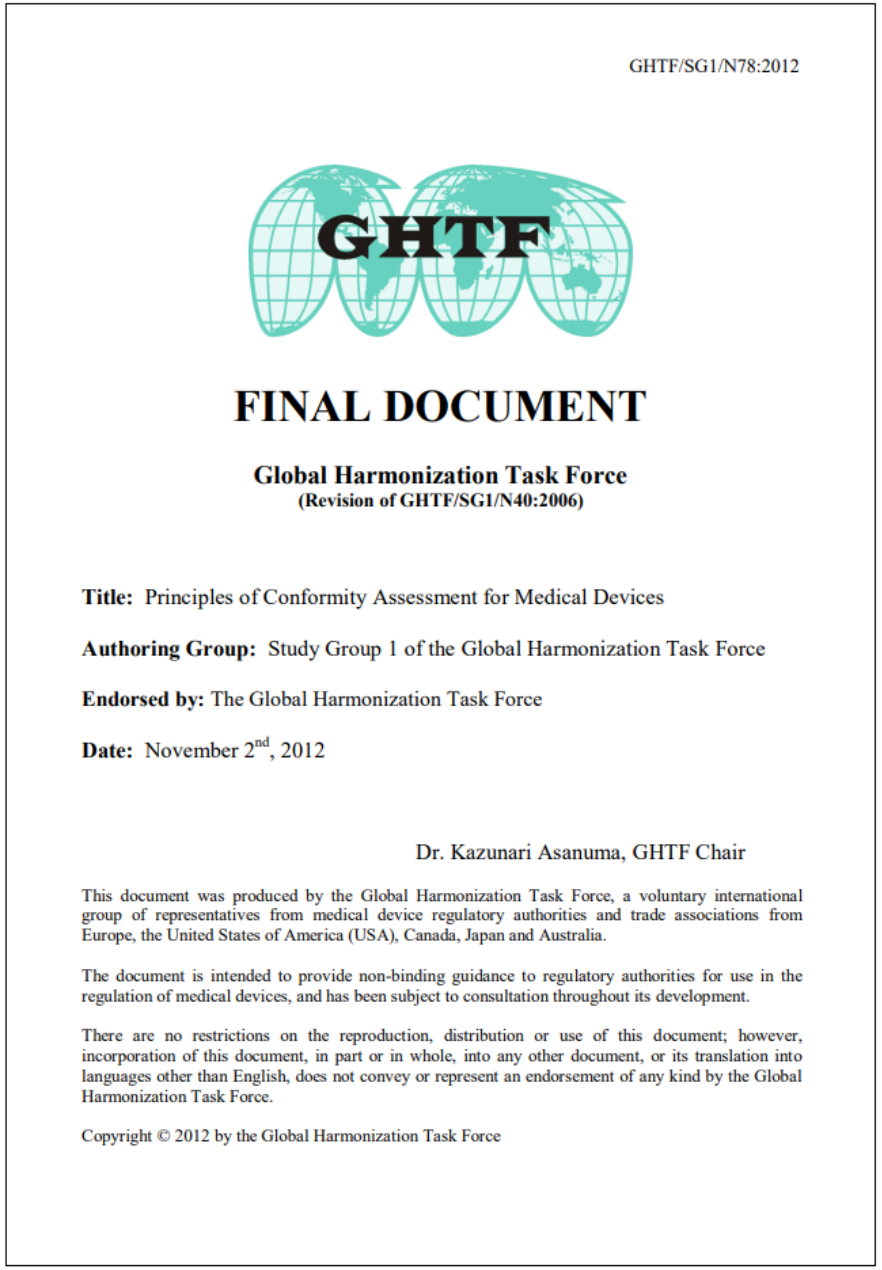

- Erin Cutts, Assistant Director for Medical Device International Harmonization and Reliance, US FDA/CDRH
- Nada Alkhayat, Policy Officer, European Commission/Directorate-General for Health and Food Safety

# Learning Objective

- By the end of this session, participants will
  - Understand how the US and the EU apply the five conformity assessment elements described in GHTF/SG1/N78:2012, and
  - Be able to identify challenges and considerations for implementing conformity assessment of medical devices.

# From Principles to Practice

- **You've just learned about GHTF/SG1/N78**
  - Now let's see how a real jurisdiction applied these elements in practice
- **N78 as the foundation**
  - N78 establishes the core framework for regulating medical devices
  - Reliance frameworks, covered later, depend on first understanding how devices are regulated
  - Once this foundation is clear, you can determine how best to incorporate reliance for your jurisdiction's needs
- **Why harmonization and reliance matter**
  - Greater harmonization and reliance supports faster, more consistent patient access to safe, effective, and high-quality medical devices



GHTF/SG1/N78:2012

GHTF

**FINAL DOCUMENT**

**Global Harmonization Task Force**
**(Revision of GHTF/SG1/N40:2006)**

**Title:** Principles of Conformity Assessment for Medical Devices

**Authoring Group:** Study Group 1 of the Global Harmonization Task Force

**Endorsed by:** The Global Harmonization Task Force

**Date:** November 2nd, 2012

Dr. Kazunari Asanuma, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide non-binding guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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# Quick knowledge check

- **Before we continue, let's see what's stuck from the last session.**
- Can you name the five elements of conformity assessment under N78?

# The five conformity assessment elements:

1. Quality management system (QMS)
2. System for post-marketing surveillance
3. Technical documentation
4. Declaration of conformity
5. Registration of manufacturers and their medical devices by the Regulatory Authority

# Training on GHTF N78 and IMDRF/GRRP WG/N89
# Session: N78 Case Studies (US)


- Erin Cutts, *Assistant Director for International Harmonization and Reliance*, *US FDA/CDRH*




## Erin Cutts

Assistant Director for International Harmonization and Reliance

US FDA

Erin.Cutts@fda.hhs.gov

# N78 Case Study: The United States

- CDRH oversees roughly 257,000 different types of medical devices on the U.S. market made by approximately 22,000 facilities worldwide
- CDRH authorizes about a dozen new or modified devices every business day



# CDRH's Responsibilities

- Oversee the full lifecycle of medical devices: premarket review, quality systems, labeling, and post-market safety
- Oversee registration of manufacturers and listing of devices
- Monitor real-world performance and respond to safety signals
- CDRH staff, including biologists, chemists, physicists, engineers, physicians and nurses, statisticians, epidemiologists, veterinarians, and lawyers, directly review submissions, facilitate inspections, and monitor devices already on the market



# CDRH's Mission

To protect and promote public health by ensuring medical devices on the U.S. market are high-quality, safe, and effective, and that patients and providers have timely and continued access to these devices.

# Key Concepts in US Medical Device Regulation

- A risk-based approach
- A least burdensome approach

# A Risk-Based Approach

- With a risk-based approach, regulatory oversight and prioritization increase as the risk of a device or activity increases.
- For example,
  - Medical device classification and regulatory controls





  - Selection of sites and processes for inspection

# A Least Burdensome Approach

- Since 1997, Congress has directed FDA to take a **least burdensome approach** to device evaluation
- This approach eliminates unnecessary burdens that could delay beneficial products while still meeting statutory requirements
  - → a manufacturer may propose an alternative approach to generating or providing information, as long as it still meets the underlying regulatory requirement
- The concept applies across the total product lifecycle, not just at premarket submission



# Agenda

- Quality management system (QMS)
- System for post-marketing surveillance
- Technical documentation
- Declaration of conformity
- Registration of manufacturers and their medical devices by the Regulatory Authority

# Agenda

- **Quality management system (QMS)**
- System for post-marketing surveillance
- Technical documentation
- Declaration of conformity
- Registration of manufacturers and their medical devices by the Regulatory Authority

# N78 indicates

- The **manufacturer** should **implement**, **document** and **maintain** a **QMS** that ensures the medical devices it **designs**, **manufactures** and **supplies** to the market are **safe, perform as intended** and **comply** with the relevant provisions of the **regulations**.

# In the US, consistent with N78,

- The Quality Management System Regulation includes requirements regarding the methods used in, and the facilities and controls used for, all finished devices intended for humans.


design


manufacture


packaging


labeling


storage


installation


servicing

The Quality Management System Regulation incorporates by reference materials from several other sources, including ISO 9000 and ISO 13485:2016.






The Quality Management System Regulation also specifies requirements for complying with other applicable regulatory requirements

| 21 CFR Part | Title |
|---|---|
| 830 | Unique Device Identification (UDI) |
| 821 | Medical Device Tracking Requirements |
| 803 | Medical Device Reporting |
| 806 | Medical Devices; Reports of Corrections and Removals |

# Inspectional approach

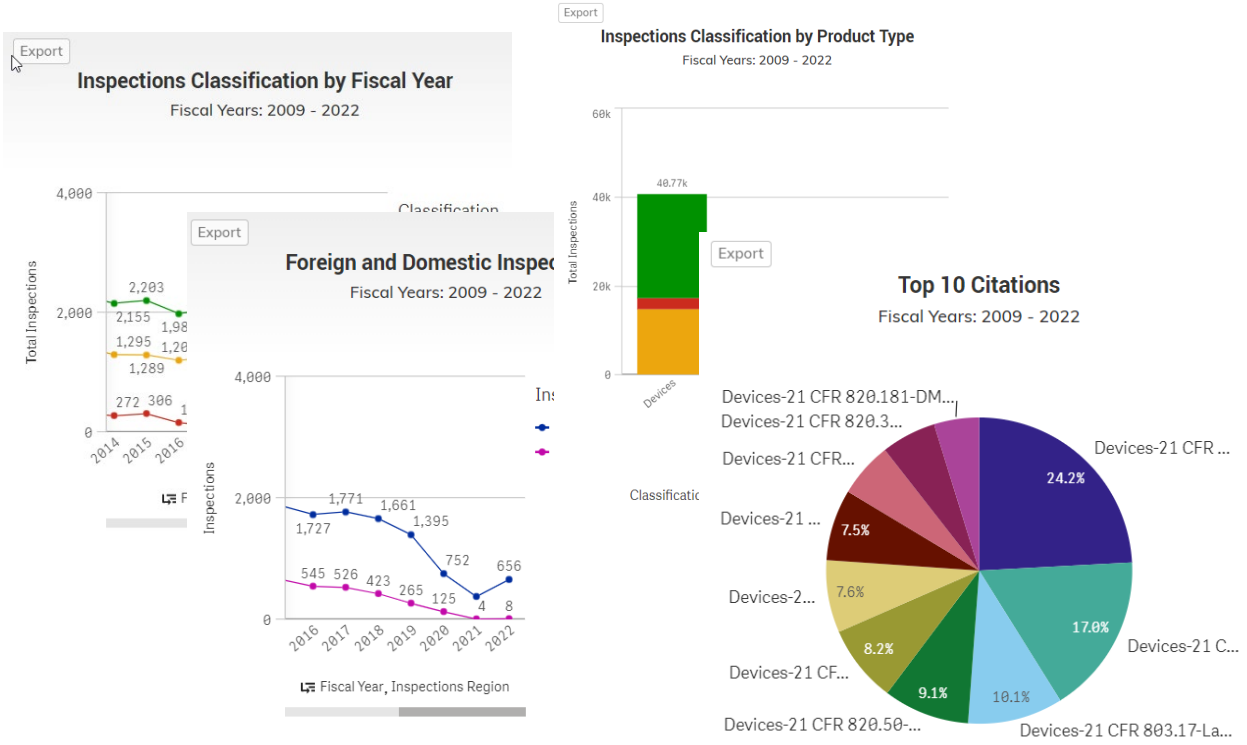
- Compliance Program Manual 7382.850 *Inspection of Medical Device Manufacturers* provides instructions to FDA field and Center staff for inspection and administrative/enforcement activities.




Diagram 1: FDA Medical Device Risk-Based Inspections

# FDA updates a “Data Dashboard” with information about some completed inspections.

See [FDA Dashboards – Inspections]




**Inspections Details** Help

Download Inspections Dataset

Record Count: 40,766

Select Inspection ID(s) to view corresponding Inspections Citations.

| FEI Number | Legal Name | City | State | Zip | Country/Area | Fiscal Year | Inspection ID | Posted Citations | Inspection End Date |
|---|---|---|---|---|---|---|---|---|---|
| 3002516162 | Myriad Fiber Imaging Technologies, Inc. | Dudley | Massachu... | 01571 | United States | 2022 | 1175802 | Yes | 07/29/ |
| 3002516162 | Myriad Fiber Imaging Technologies, Inc. | Dudley | Massachu... | 01571 | United States | 2022 | 1175802 | Yes | 07/29/ |
| 3010667677 | Dvl-Op Medico | Valencia | California | 91355 | United States | 2022 | 1176028 | No | 07/28/ |

**Inspections Citations Details**

CFR Reference | FDCA Reference

Download Citations Dataset

Record Count: 44,907

Citations data include Form FDA 483 citations and may not necessarily represent citations on final classification letters.

| Inspection ID | FEI Number | Legal Name | Inspection End Date | Program Area | Act/CFR Number | Short Description | Long Desc |
|---|---|---|---|---|---|---|---|
| 1175802 | 3002516162 | Myriad Fiber Imaging Technologies, Inc. | 07/29/2022 | Devices | 21 CFR 820.70(g)(1) | Maintenance schedule, Lack of or inadequate schedule | Schedules equipment |
| 1175802 | 3002516162 | Myriad Fiber Imaging Technologies, Inc. | 07/29/2022 | Devices | 21 CFR 820.198(a) | Lack of or inadequate complaint procedures | Procedures formally de |
| 1175079 | 3015733038 | Advanced Facialdontics LLC | 07/22/2022 | Devices | 21 CFR 803.17 | Lack of Written MDR Procedures | Written MI |
| 1175079 | 3015733038 | Advanced Facialdontics LLC | 07/22/2022 | Devices | 21 CFR 820.20(e) | Quality System Procedures | Quality sys |

# FDA accepts Medical Device Single Audit Program (MDSAP) audit reports as a substitute for routine Agency inspections.

- MDSAP allows an MDSAP recognized Auditing Organization to conduct a **single regulatory audit** of a medical device manufacturer that **satisfies** the relevant **requirements** of the **regulatory authorities** participating in the program.

MDSAP
Medical Device Single Audit Program

# Knowledge Check

- **Poll question**: How does the US implement N78's QMS requirement?
- **Options:**
    - **A.** The US maintains its own fully independent QMS regulation, separate from any international standard
    - **B.** The US incorporates ISO 13485:2016 by reference as the QMS baseline, with a small number of supplemental US-specific requirements
    - **C.** The US has no formal QMS requirement for medical device manufacturers
    - **D.** The US requires manufacturers to follow whichever QMS standard their home country uses

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# Agenda

- Quality management system (QMS)
- **System for post-marketing surveillance**
- Technical documentation
- Declaration of conformity
- Registration of manufacturers and their medical devices by the Regulatory Authority

# N78 indicates

- Prior to placing the product on the market, the **manufacturer** will **establish**, as part of its QMS, a process to **assess the continued conformity** of the device to the Essential Principles of Safety and Performance through the post-marketing phase. This process includes:
  - complaint handling,
  - post-market vigilance reporting,
  - and any subsequent corrective & preventive actions
- The **RA** or **CAB** will **confirm** that appropriate **processes are in place**, usually at the time of the **QMS audit**
- An RA may require manufacturers to perform a specific **postmarket study** and report the outcome to the RA. The RA will monitor any post-marketing study and consider whether any additional regulatory action is needed.

# In the US, consistent with N78,

- Manufacturers are required to conduct proactive market surveillance.
- FDA may also require completion of a specific post-marketing study.
- Manufacturers are required to submit specific market surveillance information to FDA for review and analysis.
- FDA confirms the required processes are in place during inspections.
- FDA then uses multiple sources of information to determine whether additional regulatory action is needed.

# In the US, consistent with N78,

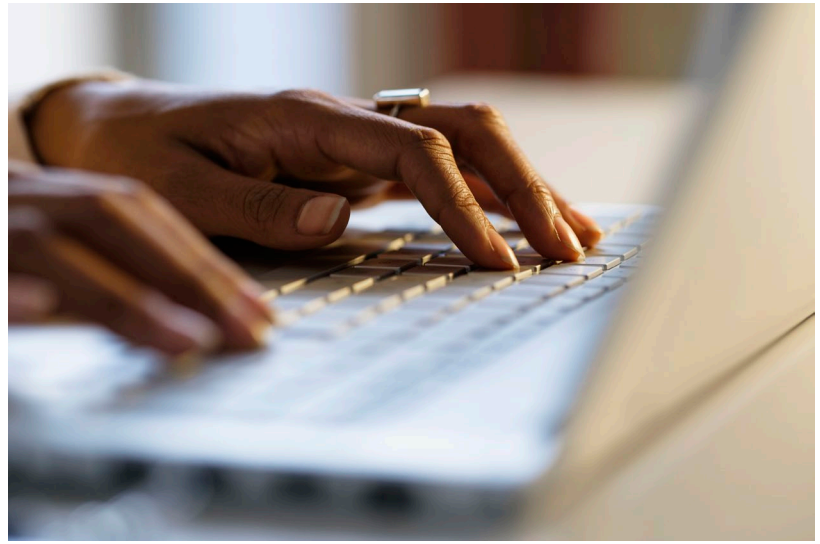
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- FDA confirms the required processes are in place during inspections.
- FDA then uses multiple sources of information to determine whether additional regulatory action is needed.

# Proactive market surveillance requirements are included in the Quality Management System Regulation.

- The Quality Management System Regulation incorporates ISO 13485 by reference, including clauses related to complaint handling, post market vigilance reporting, and corrective and preventive actions
- Beyond ISO 13485, the Quality Management System Regulation also
  - Provides FDA-specific requirements for what complaint records must contain, including unique device identification (UDI) for the device or batch involved, and treatment of confidential information
  - Specifies the timelines for adverse event reporting

Manufacturers, importers, and device user facilities are required to submit certain information about suspected device-associated deaths, serious injuries, and malfunctions.

- **Mandatory reporting** from manufacturers, importers, and device user facilities
- **Voluntary reporting** from health care professionals, patients, and consumers



# Manufacturers

| Event Type | Report to | Timeframe |
|---|---|---|
| Deaths, serious injuries and reportable malfunctions | FDA | • 30 calendar days - standard<br>• 5 working days - at FDA request or when remedial action is required to prevent unreasonable risk/harm |

# Importers

| Event Type | Report to | Timeframe |
|---|---|---|
| Death/serious injury | FDA and Manufacturer | 30 calendar days |
| Reportable Malfunction | Manufacturer only | 30 calendar days |

- Importers must also maintain complaint files and adverse event records

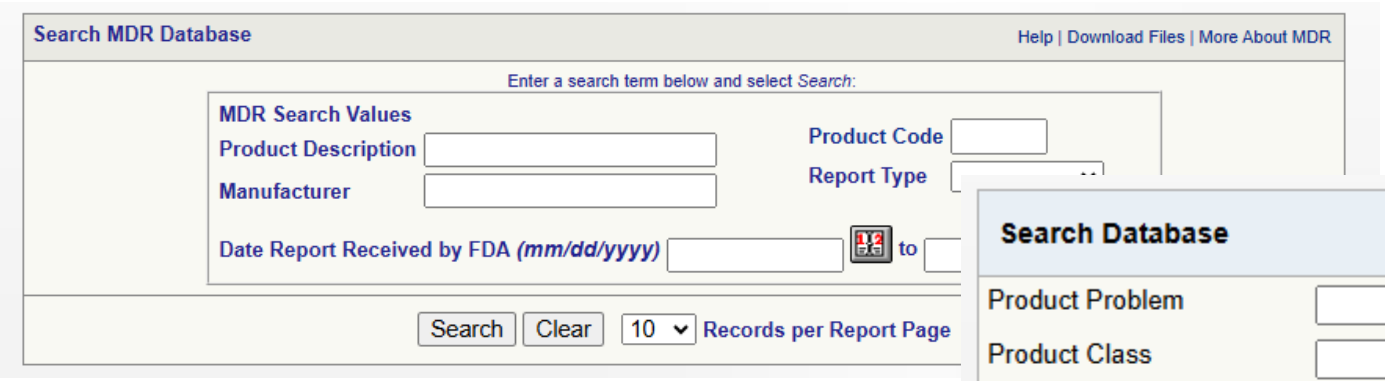
# Device User Facilities

- Hospitals, ambulatory surgical centers, nursing homes, outpatient treatment facilities, etc., but **not physician offices**

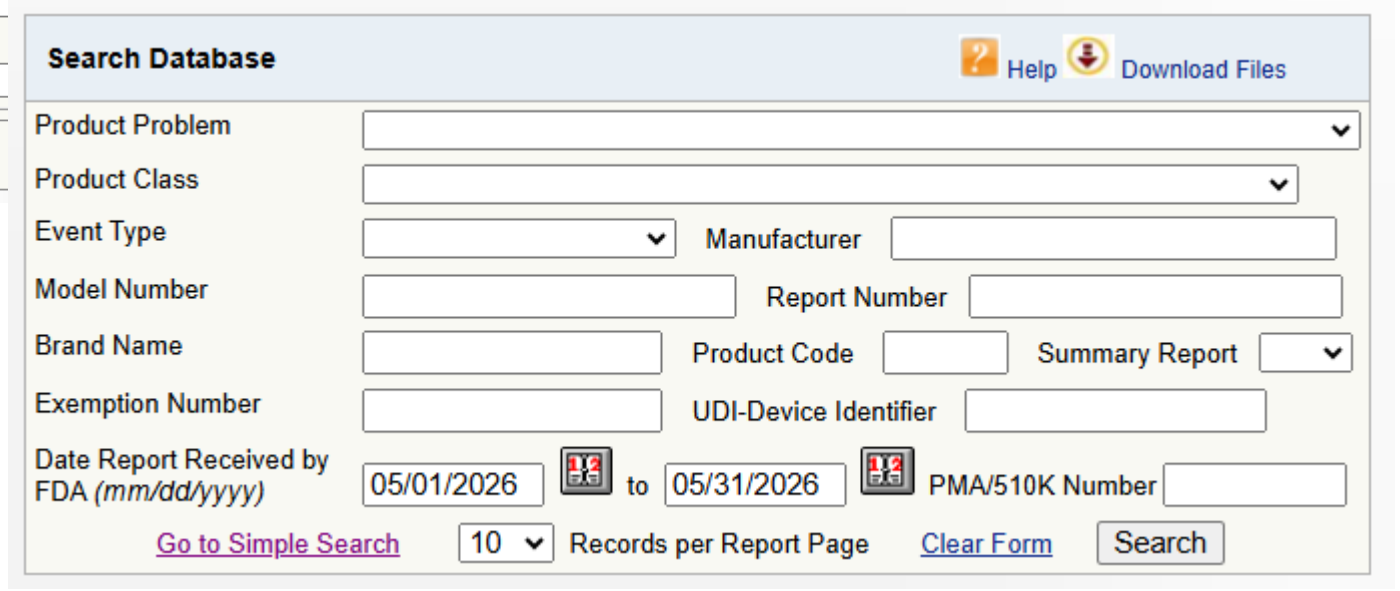
| Event Type | Report to | Timeframe |
|---|---|---|
| Device-related death | FDA and Manufacturer | 10 working days |
| Device-related serious injury | Manufacturer or, if manufacturer is unknown, FDA | 10 working days |

Not required to report device malfunctions unless they involve a reportable death or serious injury

# Adverse event reports are available to the public.




MDR Database Search (fda.gov)




MAUDE - Manufacturer and User Facility Device Experience (fda.gov)

# In the US, consistent with N78,

- Manufacturers are required to conduct proactive market surveillance.
- **FDA may also require completion of a specific post-marketing study**.
- Manufacturers are required to submit specific market surveillance information to FDA for review and analysis.
- FDA confirms the required processes are in place during inspections.
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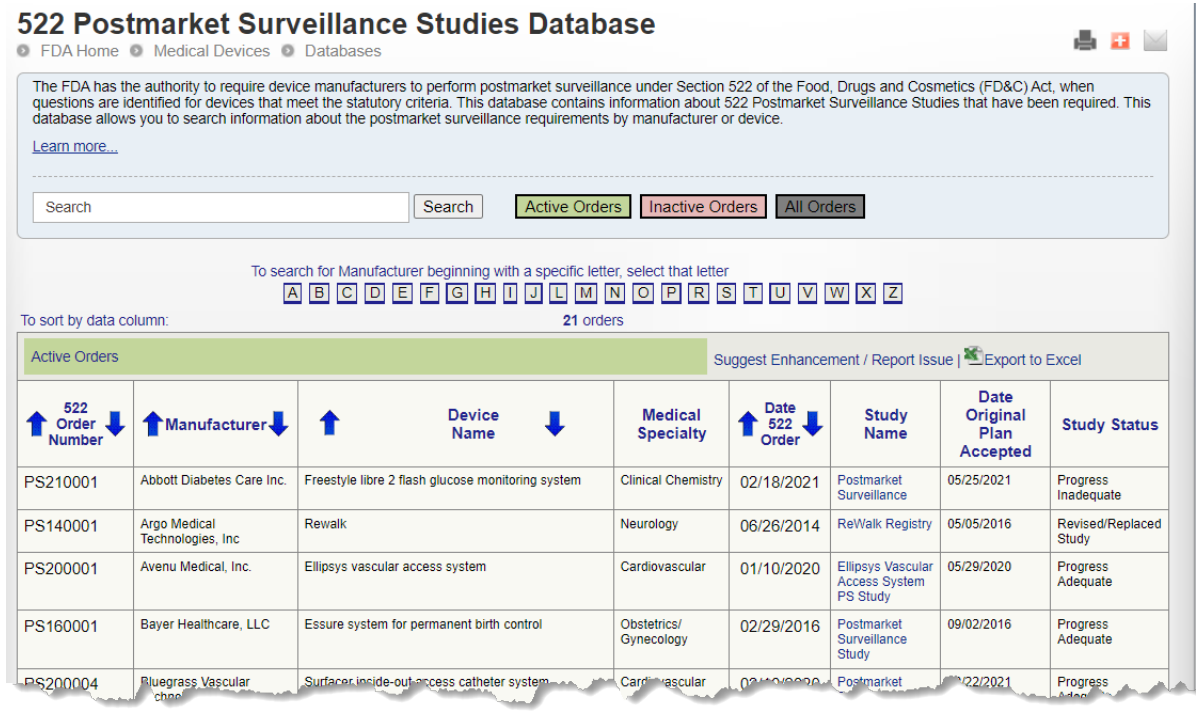
# To provide reasonable assurance, or the continued assurance, of safety and effectiveness of an approved device, FDA may require a post approval study.

- A Post Approval Study is
  - usually a clinical or non-clinical study
  - specified in the PMA approval order
  - intended to gather specific data to address questions about the postmarket performance of or experience with an approved medical device.

FDA also has authority to require manufacturers to conduct a 522 postmarket surveillance study at the time of approval or clearance or at any time thereafter of certain class II or class III devices.

- Data collected under a surveillance order helps to address important public health questions on the safety and effectiveness of a device.
- Issues may be identified through a variety of sources including analysis of adverse event reports, a recall or corrective action, post-approval data, review of premarket data, reports from other governmental authorities, or review of scientific literature.

# Information on 522 postmarket surveillance studies and post approval studies are available to the public.



## 522 Postmarket Surveillance Studies Database

FDA Home › Medical Devices › Databases

The FDA has the authority to require device manufacturers to perform postmarket surveillance under Section 522 of the Food, Drugs and Cosmetics (FD&C) Act, when questions are identified for devices that meet the statutory criteria. This database contains information about 522 Postmarket Surveillance Studies that have been required. This database allows you to search information about the postmarket surveillance requirements by manufacturer or device.

Learn more...

Search | Search | Active Orders | Inactive Orders | All Orders

To search for Manufacturer beginning with a specific letter, select that letter

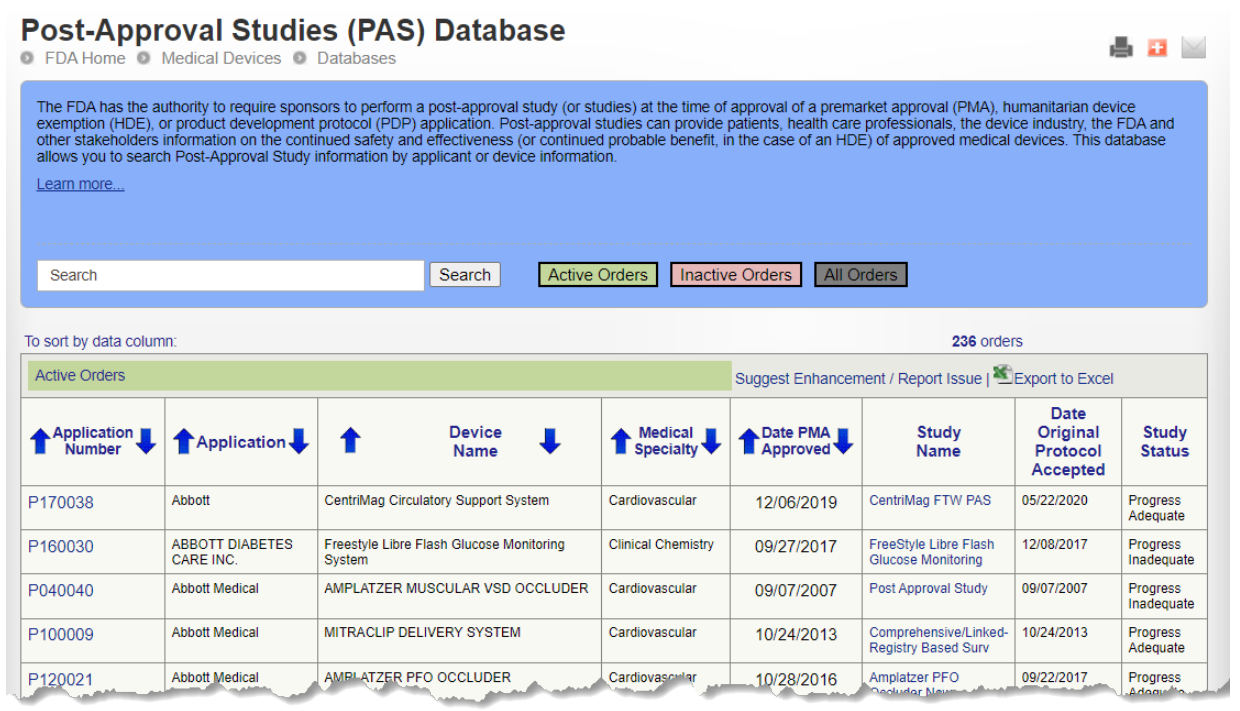
A B C D E F G H I J L M N O P R S T U V W X Z

To sort by data column: 21 orders

Active Orders | Suggest Enhancement / Report Issue | Export to Excel

| 522 Order Number | Manufacturer | Device Name | Medical Specialty | Date 522 Order | Study Name | Date Original Plan Accepted | Study Status |
|---|---|---|---|---|---|---|---|
| PS210001 | Abbott Diabetes Care Inc. | Freestyle libre 2 flash glucose monitoring system | Clinical Chemistry | 02/18/2021 | Postmarket Surveillance | 05/25/2021 | Progress Inadequate |
| PS140001 | Argo Medical Technologies, Inc | Rewalk | Neurology | 06/26/2014 | ReWalk Registry | 05/05/2016 | Revised/Replaced Study |
| PS200001 | Avenu Medical, Inc. | Ellipsys vascular access system | Cardiovascular | 01/10/2020 | Ellipsys Vascular Access System PS Study | 05/29/2020 | Progress Adequate |
| PS160001 | Bayer Healthcare, LLC | Essure system for permanent birth control | Obstetrics/ Gynecology | 02/29/2016 | Postmarket Surveillance Study | 09/02/2016 | Progress Adequate |
| PS200004 | Bluegrass Vascular | Surfacer inside-out access catheter system | Cardiovascular | | Postmarket | /22/2021 | Progress |

[522 Postmarket Surveillance Studies Database (fda.gov)]



## Post-Approval Studies (PAS) Database

FDA Home › Medical Devices › Databases

The FDA has the authority to require sponsors to perform a post-approval study (or studies) at the time of approval of a premarket approval (PMA), humanitarian device exemption (HDE), or product development protocol (PDP) application. Post-approval studies can provide patients, health care professionals, the device industry, the FDA and other stakeholders information on the continued safety and effectiveness (or continued probable benefit, in the case of an HDE) of approved medical devices. This database allows you to search Post-Approval Study information by applicant or device information.

Learn more...

Search | Search | Active Orders | Inactive Orders | All Orders

To sort by data column: 236 orders

Active Orders | Suggest Enhancement / Report Issue | Export to Excel

| Application Number | Application | Device Name | Medical Specialty | Date PMA Approved | Study Name | Date Original Protocol Accepted | Study Status |
|---|---|---|---|---|---|---|---|
| P170038 | Abbott | CentriMag Circulatory Support System | Cardiovascular | 12/06/2019 | CentriMag FTW PAS | 05/22/2020 | Progress Adequate |
| P160030 | ABBOTT DIABETES CARE INC. | Freestyle Libre Flash Glucose Monitoring System | Clinical Chemistry | 09/27/2017 | FreeStyle Libre Flash Glucose Monitoring | 12/08/2017 | Progress Inadequate |
| P040040 | Abbott Medical | AMPLATZER MUSCULAR VSD OCCLUDER | Cardiovascular | 09/07/2007 | Post Approval Study | 09/07/2007 | Progress Inadequate |
| P100009 | Abbott Medical | MITRACLIP DELIVERY SYSTEM | Cardiovascular | 10/24/2013 | Comprehensive/Linked-Registry Based Surv | 10/24/2013 | Progress Adequate |
| P120021 | Abbott Medical | AMPLATZER PFO OCCLUDER | Cardiovascular | 10/28/2016 | Amplatzer PFO | 09/22/2017 | Progress |

[Post-Approval Studies (PAS) Database (fda.gov)]

# In the US, consistent with N78,

- Manufacturers are required to conduct proactive market surveillance.
- FDA may also require completion of a specific post-marketing study.
- **Manufacturers are required to submit specific market surveillance information to FDA for review and analysis.**
- FDA confirms the required processes are in place during inspections.
- FDA then uses multiple sources of information to determine whether additional regulatory action is needed.

# In addition to adverse event reporting, manufacturers must also submit the following to FDA to inform understanding of a product's postmarket performance.

- Within 10 working days from initiation of a correction or removal, the party initiating the action (i.e., manufacturer, importer) must report to FDA. FDA then classifies the recall based on the probability of harm.
- For PMA products specifically, manufacturers must submit annual reports that identify changes made to the product and provide a summary and bibliography of both published and unpublished literature concerning the device. Additional requirements may be included in the approval order (e.g., cumulative survival and a breakdown of reported deaths and explants for pacemakers).

# In the US, consistent with N78,

- Manufacturers are required to conduct proactive market surveillance.
- FDA may also require completion of a specific post-marketing study.
- Manufacturers are required to submit specific market surveillance information to FDA for review and analysis.
- **FDA confirms the required processes are in place during inspections.**
- FDA then uses multiple sources of information to determine whether additional regulatory action is needed.

# As discussed earlier, FDA inspects manufacturers to confirm the required processes are in place and being followed.

- Inspections may be routine or for cause.
- The frequency and focus of these inspections is determined using a risk-based approach.



# In the US, consistent with N78,

- Manufacturers are required to conduct proactive market surveillance.
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- FDA confirms the required processes are in place during inspections.
- **FDA then uses multiple sources of information to determine whether additional regulatory action is needed.**

Using its TPLC approach, FDA regularly combines information from a variety of sources to get a better understanding of performance of a specific device and/or device areas.

- Sources of data include:
  - Adverse event reports
  - Postmarket studies
  - PMA annual report contents
  - Literature sources
  - Results from inspections
  - Communications with other regulators under confidentiality commitments
- Based on its review, FDA may take a variety of actions to protect the public health including, for example, issuing safety communications, recall of products, warning letter, requirement for additional study, etc.
- Failure to comply with requirements may results in Warning Letters, injunctions, civil monetary penalties, or other regulatory actions under the FD&C Act.

# Knowledge Check

- **Poll question:**
- Beyond passively waiting for complaints or adverse event reports to come in, how does FDA require manufacturers to proactively monitor their devices?
- **Options:**
  - **A.** Manufacturers must proactively monitor devices, but only if FDA specifically designates the device as high-risk at the time of clearance or approval
  - **B.** Manufacturers are only required to monitor devices during the first 30 days on the market
  - **C.** Through several mechanisms, such as Section 522 postmarket surveillance studies, post-approval studies, PMA annual reports, adverse event reporting, and reports of corrections and removals, as applicable
  - **D.** Proactive monitoring is optional and left to each manufacturer's discretion

# Knowledge Check

- **Poll question:**
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    - **C. Through several mechanisms, such as Section 522 postmarket surveillance studies, post-approval studies, PMA annual reports, adverse event reporting, and reports of corrections and removals, as applicable**
    - **D.** Proactive monitoring is optional and left to each manufacturer's discretion

# Knowledge Check

- **Poll question:**
- What does FDA do with the information gathered through this proactive monitoring?
- **Options:**
    - **A.** Nothing; the studies are for the manufacturer's internal use only
    - **B.** FDA reviews the information, monitors for emerging signals, and considers whether additional regulatory action is needed
    - **C.** FDA only reviews the results if the manufacturer voluntarily shares them
    - **D.** FDA automatically issues a recall whenever a Section 522 study is ordered

# Knowledge Check

- **Poll question:**
- What does FDA do with the information gathered through this proactive monitoring?
- **Options:**
    - **A.** Nothing; the studies are for the manufacturer's internal use only
    - **B. FDA reviews the information, monitors for emerging signals, and considers whether additional regulatory action is needed**
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    - **D.** FDA automatically issues a recall whenever a Section 522 study is ordered

# Agenda

- Quality management system (QMS)
- System for post-marketing surveillance
- **Technical documentation**
- Declaration of conformity
- Registration of manufacturers and their medical devices by the Regulatory Authority

# N78 indicates:

- **Manufacturers of all classes of device** are expected to **demonstrate conformity** of the device to regulatory requirements through the **preparation** and **holding** of **technical documentation** that:
    - shows **how** each medical device was **developed, designed and manufactured**
    - includes **descriptions** and **explanations** necessary to understand the manufacturer's determination of conformity
- The RA or CAB determines the **adequacy of the documented evidence** in support of the manufacturer's attestation of conformity to the essential principles of safety and performance, and other regulatory requirements

# In the US, consistent with N78,

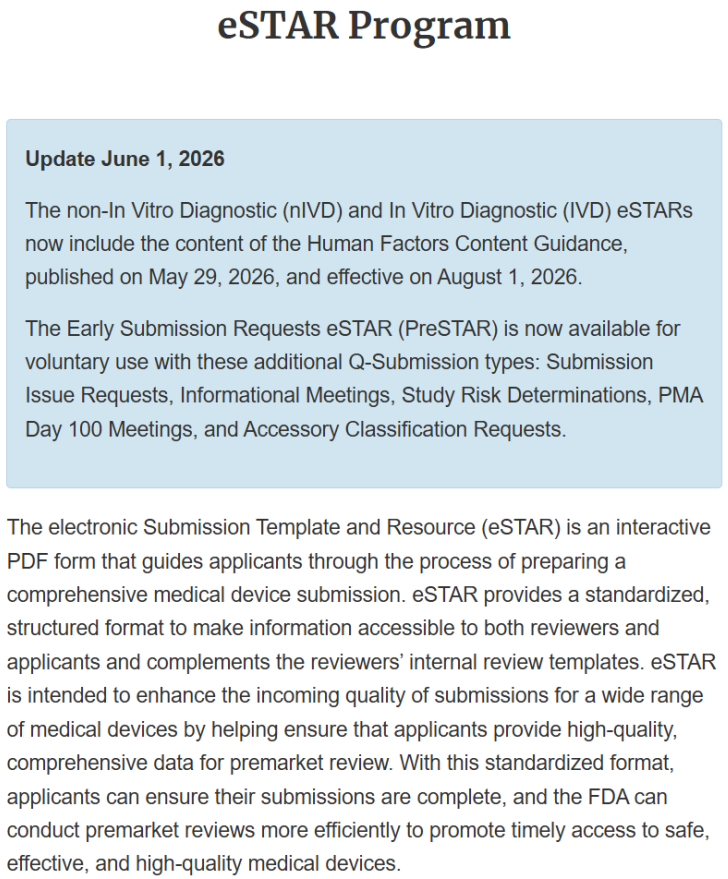
- Manufacturers are required to maintain specific technical documentation per the Quality Management System Regulation (which references ISO 13485), and
- FDA conducts assessments of the acceptability of that documentation during inspections and during premarket review.
  - Inspections have been covered in previous slides
  - Premarket review will be covered in the following slides

In order to market a medical device in the US, a manufacturer may need to submit a premarket submission.



# FDA uses the eSTAR program.

- The eSTAR program provides an interactive PDF form that guides applicants through the process of preparing a comprehensive medical device submission
- eSTAR is built from the IMDRF Table of Contents documents (IMDRF/RPS WG/N9 and N13), which provide an **internationally harmonized**, modular, format for use when filing medical device submissions to regulatory authorities for market authorization.



**eSTAR Program**

**Update June 1, 2026**

The non-In Vitro Diagnostic (nIVD) and In Vitro Diagnostic (IVD) eSTARs now include the content of the Human Factors Content Guidance, published on May 29, 2026, and effective on August 1, 2026.

The Early Submission Requests eSTAR (PreSTAR) is now available for voluntary use with these additional Q-Submission types: Submission Issue Requests, Informational Meetings, Study Risk Determinations, PMA Day 100 Meetings, and Accessory Classification Requests.

The electronic Submission Template and Resource (eSTAR) is an interactive PDF form that guides applicants through the process of preparing a comprehensive medical device submission. eSTAR provides a standardized, structured format to make information accessible to both reviewers and applicants and complements the reviewers' internal review templates. eSTAR is intended to enhance the incoming quality of submissions for a wide range of medical devices by helping ensure that applicants provide high-quality, comprehensive data for premarket review. With this standardized format, applicants can ensure their submissions are complete, and the FDA can conduct premarket reviews more efficiently to promote timely access to safe, effective, and high-quality medical devices.

# The three most common types of premarket submissions are:

## 510(k)

- Demonstrates that the new device is **"substantially equivalent"** to a predicate device in terms of intended use, technological characteristics, and performance testing
- See https://www.fda.gov/premarket-notification-510k
- For **low to moderate risk** devices (some Class I and most Class II devices)

## PMA

- Demonstrates **reasonable assurances of safety and effectiveness** for the device's intended use
- See https://www.fda.gov/premarket-approval-pma
- For **higher risk** devices (Class III devices)

## De Novo classification

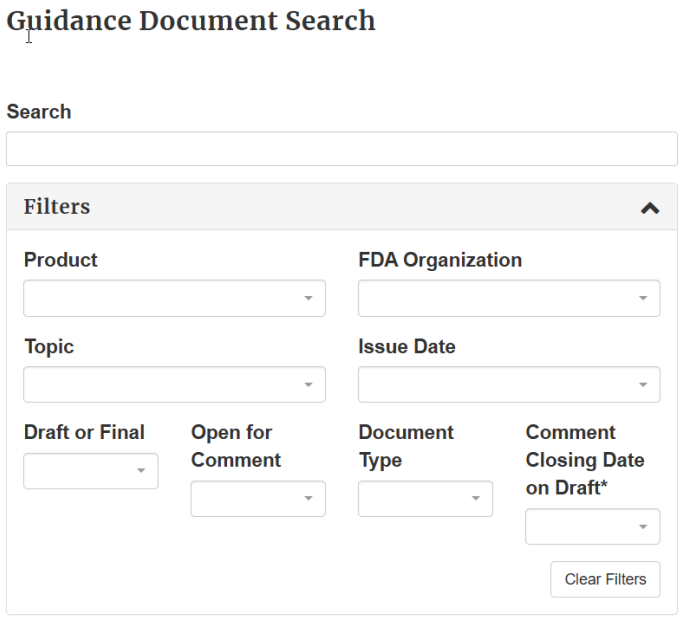
- Pathway for certain **novel types of devices** without a predicate to obtain marketing authorization as **class I or class II devices**
- See De Novo Classification Request | FDA

# FDA requires and reviews valid scientific evidence to determine whether the probable benefits outweigh any probable risks.

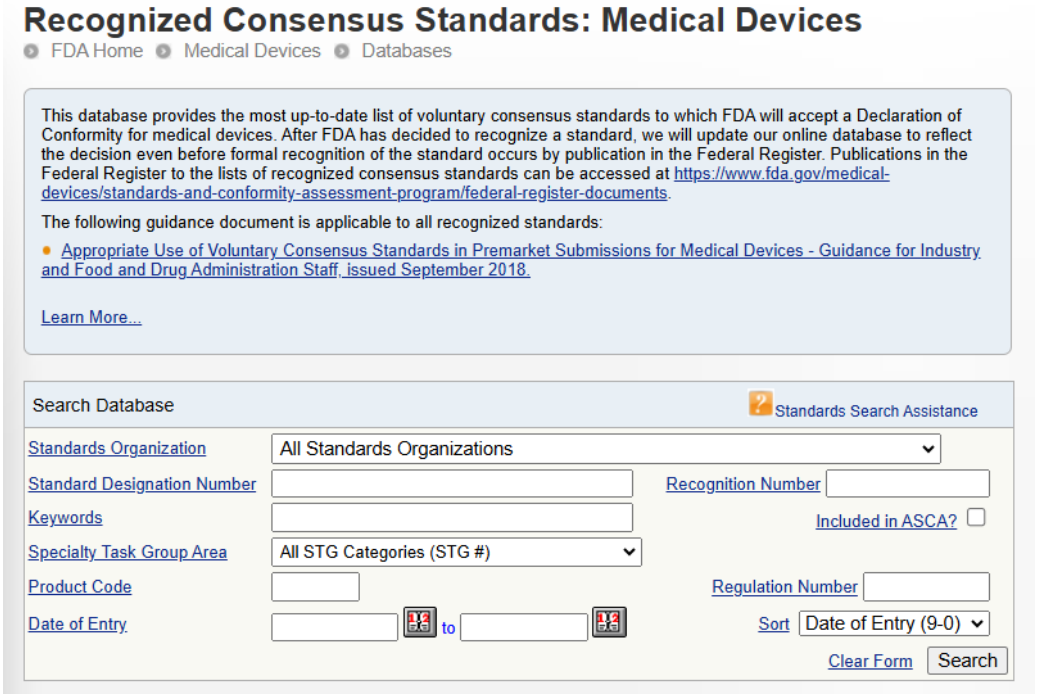
- Valid scientific evidence includes
  - investigations using laboratory animals,
  - investigations involving human subjects,
  - nonclinical investigations, and
  - analytical studies for in vitro diagnostic devices.



# Guidance documents and voluntary consensus standards are valuable tools in developing technical documentation and regulatory submissions.




Search for FDA Guidance Documents | FDA




Recognized Consensus Standards: Medical Devices

# A few notes on FDA's approach to the use and review of clinical data to support regulatory decision-making.

- FDA applies a risk-based and least burdensome approach to clinical data in marketing submissions
  - The need for clinical data is considered for all devices in a manner proportionate to the risk of the device.
  - The need for data depends on the device's intended use, device design, and novelty of materials, components, use case, etc.
- FDA considers many types of clinical data
  - results of pre- and post-market clinical investigation(s) of the device (i.e., traditional clinical trials);
  - results of pre- and post-market clinical investigation(s) or other studies reported in the scientific literature of a comparable device;
  - published and/or unpublished reports on clinical experience of either the device in question or a comparable device;
  - real world data (electronic health records (EHRs), registries, administrative claims data, device-generated data, patient-generated data, public health surveillance data, clinically annotated biobanks, medical device data repositories, and chargemaster and/or billing data.) and
  - other sources of clinical experience such adverse event databases.

# FDA publishes detailed information on the regulatory submissions for which a positive decision is made.

## 510(k)

- Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- Information available for each cleared 510(k):
  - Device and manufacturer
  - Decision date
  - Classification information
  - Clearance Letter
  - 510(k) summary describing the device, the included evidence, and the basis for the regulatory decision

## PMA

- Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
- Information available for each approved PMA:
  - Device and manufacturer
  - Decision date
  - Classification information
  - Approval order
  - (for original PMAs) Summary of Safety and Effectiveness describing the device, the included evidence, and the basis for the regulatory decision

## De Novo classification

- Database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm
- Information available for each granted De Novo:
  - Device and manufacturer
  - Decision date
  - Classification information
  - Classification order
  - Decision Summary describing the device, the included evidence, and the basis for the regulatory decision

# Knowledge Check

- **Poll question:**
- Since the 510(k) pathway is based on demonstrating "substantial equivalence" to an existing device, which statement best describes FDA's approach to clinical data for 510(k) submissions?
- **Options:**
    - **A.** Clinical data is never required for 510(k)s, since substantial equivalence relies only on comparison to a predicate device
    - **B.** Clinical data is always required for every 510(k) submission, regardless of device type or risk
    - **C.** Clinical data is only required if the device is later found to have safety problems after clearance
    - **D.** Whether clinical data is needed depends on the specific device and the regulatory question being asked; many 510(k)s rely on bench or non-clinical testing, but clinical data may be necessary where those methods can't adequately answer the safety or performance question

# Knowledge Check

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# Knowledge Check

- **Poll question:**
- Once FDA clears or approves a device, is any part of the underlying technical documentation made available to the public?
- **Options:**
    - **A.** Yes — FDA publishes a 510(k) summary, a PMA Summary of Safety and Effectiveness Data (SSED), and a De Novo decision summary; FDA also maintains public, searchable databases of clearances and approvals
    - **B.** No, all technical documentation remains fully confidential indefinitely
    - **C.** Only competitors can request access, through a formal legal petition
    - **D.** Technical documentation is only made public if the device is later recalled

# Knowledge Check

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# Agenda

- Quality management system (QMS)
- System for post-marketing surveillance
- Technical documentation
- **Declaration of conformity**
- Registration of manufacturers and their medical devices by the Regulatory Authority

# N78 indicates:

- **Manufacturer attests** that its medical device **complies fully with all regulatory requirements** and draws up a **written "Declaration of Conformity"** containing specific information
  - An **attestation** that each device that is subject to the declaration **complies with the applicable Essential Principles for Safety and Performance** and the **applicable requirements of Label and Instructions for Use for Medical Devices**
  - Information sufficient to identify the device/s to which the Declaration of Conformity applies
  - The Global Medical Device Nomenclature (GMDN) code for the device
  - The classification of the device/s after following the guidance found in Principles of Medical Devices Classification
  - The date on which the Declaration of Conformity is issued
  - The name and address of the device manufacturer
  - The name, position, and signature of the responsible person who has been authorized to complete the Declaration of Conformity upon the manufacturer's behalf
- The **RA or CAB** may **review and confirm** the adequacy of the Declaration of Conformity and, if required, examine the supporting documents or other evidence

# In the US, the FDA itself makes the determination on regulatory conformance.

- Consistent with FDA's risk-based and least burdensome approach, FDA carefully considers which regulatory controls are needed to reasonably assure the safety and effectiveness of each device type.
- Regulatory controls are related to adulteration, misbranding, labeling, adverse event reporting, establishment registration, device listing, premarket notification and/or review, and quality management system. Additional controls may also apply based on the specific device type.

# FDA’s premarket review is based on the evidence the manufacturer submits.

- The manufacturer is not required to draft and sign a separate written statement attesting to compliance with applicable Essential Principles and requirements of Label and Instructions for Use
- Instead, the manufacturer's role is to submit truthful, accurate, and complete supporting information to support FDA’s review and determination.
- *Note that a manufacturer may submit a Declaration of Conformity to a specific standard as one of many pieces of evidence to support FDA’s review. In all cases, FDA makes the determination on regulatory conformance.



**Premarket Notification Truthful And Accurate Statement**

**[As Required by 21 CFR 807.87(l)]**

I certify that, in my capacity as (*the position held in company*) of

*(*company name), I believe to the best of my knowledge, that all data

and information submitted in the premarket notification are truthful and

accurate and that no material fact has been omitted.

_____

(Signature)

# Agenda

- Quality management system (QMS)
- System for post-marketing surveillance
- Technical documentation
- Declaration of conformity
- **Registration of manufacturers and their medical devices by the Regulatory Authority**

# N78 indicates:

- **Prior** to placing a medical device on the **market**, the **manufacturer**, or **distributor**, or **importer**, or **authorized representative** should **provide the RA** with the information it needs in respect of **registration** and medical device **listing** requirements.
- The **RA** will **implement** and **maintain** the **register**

# In the US, consistent with N78,

- Owners or operators of establishments that are involved in the production and distribution of medical devices intended for use in the U.S. are required to register within 30 days of beginning distribution and re-register annually thereafter with the FDA. This process is known as *establishment registration* (21 CFR Part 807).
- Generally, device establishments that are required to register with the FDA are also required to *list the devices* that are made there and the activities that are performed on those devices.
- A complete listing of who must register, list, and pay the annual fee to do so is provided at Who Must Register, List and Pay the Fee | FDA.

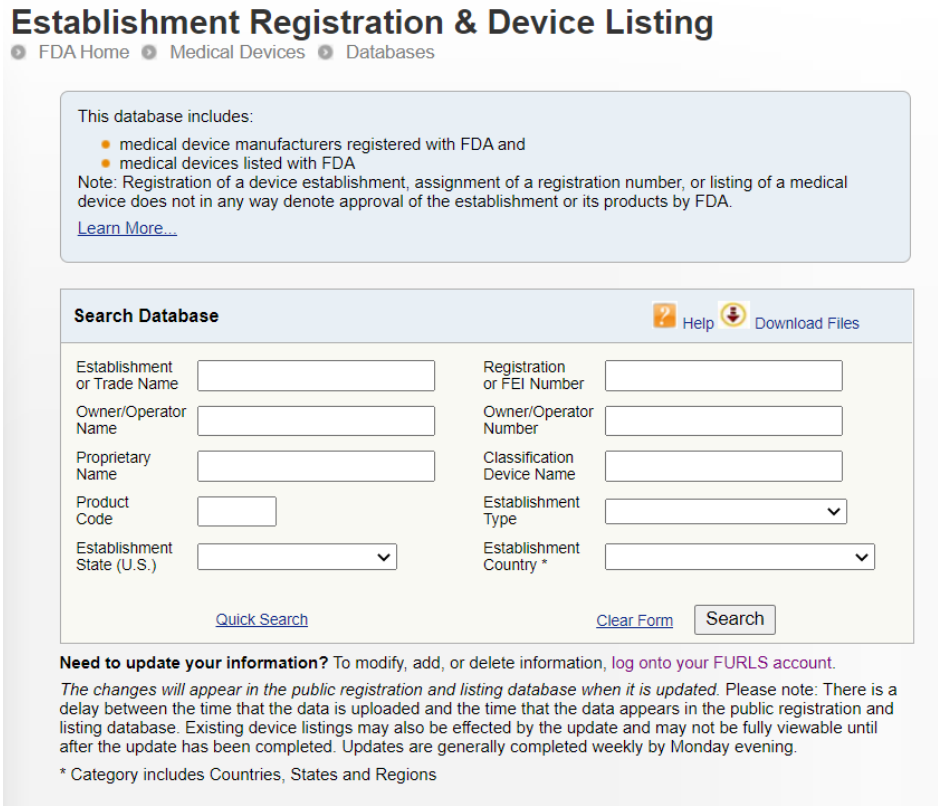
# Registration and listing provide the FDA with the location of medical device establishments and the devices manufactured at those establishments.

- Knowing where devices are made increases the ability to **prepare for** and **respond to public health emergencies**.
- See Device Registration and Listing | FDA



# Most information regarding Registration and Listing is available to the public.

- Firm's registration or owner/operator number can be found in the **Public Registration and Listing database**
- Medical device listing number(s) are not available publicly
- See How to download listing information from FURLS (fda.gov)



# Registration and listing do NOT denote approval of the establishment or its products by FDA.

- **FDA does not certify registration and listing** information for firms that have registered and listed.
- **FDA does not issue Registration Certificates** to medical device establishments.

# Challenges and Considerations

- **No jurisdiction implements N78 from scratch in isolation.**
  - Every regulatory authority translates the same core elements into its own legal and administrative structures, as we just saw with the US case study
- **International harmonization matters.**
  - The more jurisdictions align their interpretation and application of these elements, the easier it becomes for manufacturers to bring safe, effective devices to more patients without duplicating effort at every border
- **Trainings like this one are part of the solution.**
  - Seeing how other jurisdictions have implemented the same framework helps identify practical approaches, shared challenges, and opportunities to align rather than diverge
- **Resource constraints are a real and honest challenge.**
  - No regulatory authority, however well-resourced, can build and staff every capability needed to evaluate every device on its own. This is precisely the gap that reliance mechanisms are designed to address, which will be explored this afternoon
- **Terminology doesn't always translate cleanly.**
  - Some US-specific concepts, such as substantial equivalence, have proven difficult to explain or map onto other jurisdictions' frameworks, since they reflect a particular legal and regulatory history rather than a universal concept

# Key Takeaways: In the US, consistent with N78,

| | |
|---|---|
| Quality management system (QMS) | • Manufacturers are required to establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. |
| System for post-marketing surveillance | • The US requires manufacturers to conduct proactive market surveillance. FDA uses this information in its own regulatory decision-making. |
| Technical documentation | • Manufacturers are required to maintain specific technical documentation, and FDA conducts assessments of the acceptability of that documentation |
| Declaration of conformity | • The FDA itself makes the determination on regulatory conformance. Where premarket review is required, FDA's review is based on the evidence the manufacturer submits |
| Registration of manufacturers and their medical devices by the Regulatory Authority | • Owners or operators of establishments that are involved in the production and distribution of medical devices are required to register and list in databases maintained by FDA |

# Thank you


- Erin Cutts, *Assistant Director for International Harmonization and Reliance*, *US FDA/CDRH*
- **Email** erin.cutts@fda.hhs.gov



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# Training on GHTF N78 and IMDRF/GRRP WG/N89
# Session: N78 Case Studies (EU)


- Nada Alkhayat, *Policy Officer*, *European Commission/Directorate-General for Health and Food Safety*

# How this deck is structured

N78 is the organising logic; EU MDR/IVDR is the implementation example.

## 1 Reliance architecture

EU 27 Member States, 50+ NBs, NANDO/EUDAMED, trust in certificates and ongoing oversight

## 2 Premarket conformity

Risk class determines evidence, QMS audit, technical documentation review and certificate type

## 3 Lifecycle control

CE marking is not a one-off: PMS, vigilance, UDI, EUDAMED, changes and surveillance maintain confidence

# N78 in one slide: the five conformity assessment elements

Every jurisdiction specifies how the manufacturer demonstrates conformity; EU law turns those elements into binding MDR/IVDR obligations.




| QMS | PMS | Technical documentation | Declaration of conformity | Registration / listing |
|---|---|---|---|---|
| MDR Art. 10(9); IVDR Art. 10(8) | MDR Arts. 83–86; IVDR Arts. 78–81 | MDR Annexes II–III; IVDR Annexes II–III | MDR Art. 19 + Annex IV; IVDR Art. 17 + Annex IV/V | MDR Arts. 29–31; IVDR Arts. 26–28; EUDAMED |

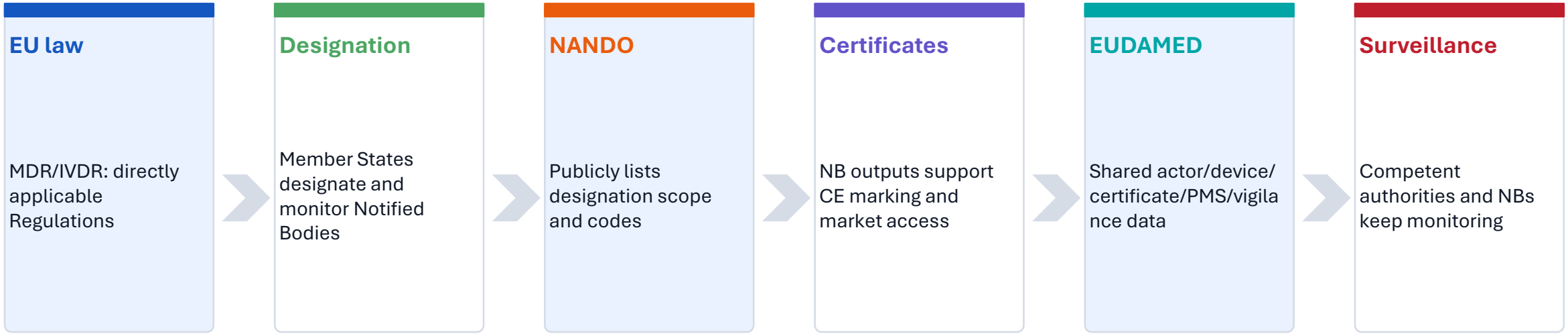
*N78: all five elements apply to every device class, but the depth and timing of RA/CAB involvement scales with risk.*
*EU: manufacturer responsibility remains central, but Notified Body involvement increases for higher-risk MDR/IVDR classes.*
*The EU model adds a strong public-interest layer: designation and monitoring of NBs, EUDAMED transparency, expert panels/EURLs, and market surveillance.*

# EU reliance architecture

Before conformity assessment details, the EU system relies on a distributed but legally harmonised network: 27 Member States, designated Notified Bodies, common rules, common databases, and continuous oversight.

# EU 27 Member States + 50+ Notified Bodies: how reliance works

The single market operates through mutual trust in a common legal framework, designated bodies, public registers and market surveillance.




**Reliance is not blind recognition. It is structured trust in a system: designation criteria, scope codes, audits, certificate conditions, surveillance, vigilance and public data.**

Current landscape: Commission/NANDO remains the authoritative source for NB designations;
*53 NBs designated under MDR and/or IVDR in early 2026.

# EU reliance is a governance chain, not a single decision

N78 speaks of RA/CAB confirmation. In the EU, those functions are split and supervised.

| | |
|---|---|
| **Manufacturer** | Designs, manufactures, maintains QMS, TD, PMS, DoC and registration obligations |
| **Notified Body** | Independent CAB: assesses QMS and/or technical documentation; issues, limits, suspends, withdraws certificates |
| **Designating Authority** | National authority responsible for designation, notification and monitoring of NBs |
| **Commission + MDCG + JAT** | Joint assessment, coordination, NANDO/EUDAMED infrastructure, guidance and consistency |
| **Competent Authorities** | Vigilance, market surveillance, enforcement and coordinated corrective action |

**Training point**

In EU discussions with global partners, a CE certificate should be read together with certificate scope, device classification, NB designation scope, DoC, PMS status and EUDAMED/NANDO information.

# Risk-class based conformity assessment

N78’s central logic is risk-proportionate conformity assessment. EU MDR and IVDR implement that logic through classification rules, conformity assessment routes and differentiated Notified Body involvement.

# N78 risk logic mapped to MDR and IVDR

Oversight, evidence and reporting become more demanding as risk and potential harm increases.

| N78 | MDR | IVDR | Oversight |
|---|---|---|---|
| **A** | Class I | Class A | Self-declaration / limited NB exceptions |
| **B** | Class IIa | Class B | QMS + sampling / targeted review |
| **C** | Class IIb | Class C | QMS + TD review stronger |
| **D** | **Class III** | **Class D** | **In depth review + special mechanisms** |

MDR Annex VIII contains medical device classification rules.
IVDR Article 47 and Annex VIII classify IVDs by public health and patient risk.
N78 tables describe a generic A–D model; EU terminology differs but the proportionality principle is the same.

# The conformity assessment journey

A device moves from qualification to CE marking through a chain of evidence, assessment and lifecycle obligations.




## N78 principle

Manufacturer demonstrates conformity; RA/CAB confirms that the relevant elements are properly applied, with intensity linked to class, complexity and technology.

## EU expression

A manufacturer affixes CE only after applicable MDR/IVDR obligations are fulfilled; for most devices an NB is involved before market access and throughout certification validity.

# Conformity assessment routes: MDR Annexes and NLF modules

The EU keeps a modular structure: QMS assessment, type examination and product verification can be combined depending on class.

| | | |
|---|---|---|
| **MDR Annex IX** | Full QMS + assessment of technical documentation | Closest to Module H |
| **MDR Annex X** | EU type-examination | Closest to Module B |
| **MDR Annex XI Part A** | Production quality assurance | Closest to Module D |
| **MDR Annex XI Part B** | Product verification | Closest to Module F |
| **Article 19 + Annex IV** | EU Declaration of Conformity | Manufacturer attestation / Module A logic |

## Important

Routes are not interchangeable labels. The certificate type tells you what the NB assessed: QMS, TD for a device/category, type examination, production quality assurance or product verification.

# MDR classes and NB involvement

The higher the class, the more direct device-specific assessment is expected.

| | | |
|---|---|---|
| **Class I** | **Manufacturer self-declaration** | NB only for sterile / measuring / reusable surgical aspects |
| **Class IIa** | **Annex IX or X+XI** | NB QMS and representative technical documentation sampling |
| **Class IIb** | **Annex IX or X+XI** | NB QMS + TD; per-device review for some categories |
| **Class III** | **Annex IX or X+XI** | NB QMS + device-level TD; special procedures for implants / medicines / animal tissue |

Legal references: MDR Article 52; Annexes IX, X, XI; Annex VIII classification rules.

# IVDR classes and NB/additional body involvement

IVDR mirrors N78's A–D logic but adds specific checks for high public-health-risk IVDs.

**Class A**

**Self-declaration**

NB only for sterile aspects

**Class B**

**NB QMS + TD sampling**

Large share of routine tests; more NB involvement than under IVDD

**Class C**

**NB QMS + TD; stronger sampling/per product as appropriate**

Genetic tests, companion diagnostics, self-tests

**Class D**

**Fullest NB + EURL + sometimes expert panel**

Blood grouping, HIV/HBV/HCV, high public-health risk tests

Legal references: IVDR Article 47 and Annex VIII; Article 48 and Annexes IX, X, XI; Article 100 on EU reference laboratories.

# What Notified Bodies do

N78 uses RA/CAB language. In the EU, Notified Bodies are the independent CABs for most medium and high-risk devices, but they operate under designation, monitoring and legal constraints.

# Notified Body role across the lifecycle

Notified Body work is not just a premarket “approval” step.

## Before certification

Application review, quotation/contracting, verification of device scope and classification, assessment route, code coverage.

## Initial assessment

QMS audit, technical documentation review, clinical/performance evaluation assessment, resolution of non-conformities and CAPA.

## Certificate decision

Independent final review, certificate issuance with scope, validity, conditions and surveillance requirements.

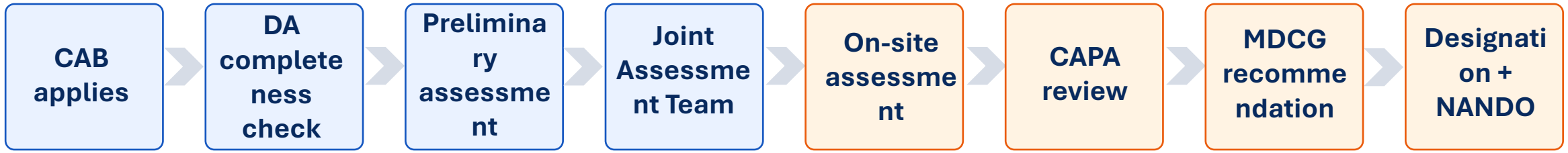
## Ongoing oversight

Surveillance audits, unannounced audits, review of PSUR/PMS/PMCF/PMPF data, changes, vigilance signals and certificate maintenance.

**NBs do not “take over” manufacturer responsibility. They provide independent conformity assessment and surveillance within their designation scope.**

# How Notified Bodies are designated and monitored

A key reliance safeguard: only bodies assessed against MDR/IVDR requirements and notified by a Member State appear in NANDO.




Designation Authorities in Member States set up and carry out assessment, designation and notification procedures and monitor NBs.
Commission experts and experts from other Member States participate through the Joint Assessment Team process.
Designation scope is code-based; a certificate is meaningful only if the NB is designated for the relevant product/technology scope.

Legal references: MDR Arts. 35–50 and Annex VII; IVDR Arts. 31–46 and Annex VII; Commission Implementing Regulation (EU) 2017/2185 on codes.

# NB assessment of the Quality Management System

N78: the QMS is the backbone; EU: the NB assesses whether the QMS can consistently produce compliant devices.

## What the NB checks

- Regulatory strategy and classification
- Design and development controls
- Supplier and subcontractor control
- Manufacturing, validation and sterilisation
- Risk management and GSPR linkage
- PMS, vigilance, CAPA and change control
- PRRC and regulatory processes

## How it is evidenced

- QMS documentation and procedures
- Audit trails and objective evidence
- Process validation records
- Complaints, CAPA and trend files
- Supplier agreements and controls
- Internal audits and management review
- Sampling of files and records

## Outputs

- Audit report
- Non-conformity reports
- CAPA assessment
- QMS certificate, where positive
- Surveillance audit plan
- Unannounced audit expectations
- Possible suspension/withdrawal if unresolved

# NB review of technical documentation

N78 uses STED as a summary of evidence; EU MDR/IVDR require full technical documentation under Annexes II and III.

### Device identity
Description, variants, accessories, UDI, intended purpose

### GSPR evidence
Annex I checklist, standards/CS/solutions, test evidence

### Risk-benefit
Risk management file, benefit-risk determination, residual risk acceptability

### Clinical / performance
CER/PER, investigations/studies, literature, PMCF/PMPF

### Verification & validation
Biocompatibility, electrical safety, software if relevant, packaging, shelf-life, usability

### Labelling & IFU
Labels, IFU, claims, warnings, translations, UDI carrier

### PMS technical file
PMS plan, PMCF/PMPF plan, PSUR/PMS report, vigilance signals

**NB output may include a technical documentation assessment report, clinical/performance evaluation assessment report, and — for certain routes/classes — a certificate linked to device or category.**

# Different reports: what each one is for

One frequent misunderstanding is to call every document a “certificate”. Many key outputs are assessment reports, not certificates.

| | |
|---|---|
| **Audit report** | NB records QMS audit scope, evidence reviewed, findings and conclusions. |
| **Non-conformity report** | NB identifies unmet requirements; manufacturer must respond with correction/CAPA. |
| **Technical documentation assessment report** | NB conclusion on device evidence against MDR/IVDR requirements. |
| **Clinical evaluation assessment report / performance evaluation assessment report** | NB assessment of clinical/performance evidence and conclusions. |
| **PSUR evaluation / surveillance record** | NB review of post-market evidence for certified devices, especially higher-risk classes. |
| **Final review / certification decision record** | Independent NB decision supporting certificate issue, maintenance, limitation, suspension or withdrawal. |

# Different types of certificates and what they actually prove

Cert : QMS coverage is not the same as device-specific TD assessment

| | | |
|---|---|---|
| **QMS certificate** | **Annex IX / XI Part A** | NB assessed the manufacturer's QMS and defined device categories or technologies within scope. |
| **EU technical documentation assessment certificate** | **Annex IX Ch. II** | NB assessed TD for a device or device category; often required for higher-risk devices. |
| **EU type-examination certificate** | **Annex X** | NB assessed a representative type and TD; paired with product conformity route. |
| **EU product verification certificate** | **Annex XI Part B** | NB verifies conformity of products/batches/lots where applicable. |
| **Production quality assurance certificate** | **Annex XI Part A** | NB assessed production QA for product conformity. |

## DoC vs certificate

The Declaration of Conformity is issued by the manufacturer and ties CE marking to the specific product. NB certificates confirm the independent assessment(s) that support it.

# Why a device may have only a QMS certificate: the sampling logic

This is compatible with N78: all TD exists; not all TD is reviewed premarket with the same intensity.

## The logic

For MDR Class IIa and some Class IIb, and IVDR Class B/C in appropriate circumstances, the NB may assess representative technical documentation from a device category or generic group. The QMS certificate then covers a broader scope than the sampled devices.

## What this does NOT mean

It does not mean the manufacturer has no technical documentation. It does not mean no NB has assessed the QMS. It does not mean there is no regulatory control. It means the depth and timing of device-specific TD review is risk-proportionate.

**Portfolio → categories / generic groups → representative TD sample → QMS certificate scope → DoC identifies specific devices**

# EU Declaration of Conformity: the product-level legal link

N78: the manufacturer's written attestation. EU: legally required before CE marking.

- Manufacturer name and address
- Product and device identification
- Risk class and conformity route
- Applicable Regulation(s), CS and standards
- NB name/number and certificate references where applicable
- Statement of conformity with GSPR
- Signature, place and date

### Manufacturer-issued

The DoC is not issued by the NB. It is issued under the manufacturer's responsibility and must be kept up to date.

### Certificate cross-reference

Where NB involvement applies, the DoC links the specific product to NB certificate number(s).

### Legal references

MDR Article 19 and Annex IV; IVDR Article 17 and Annex IV/V; CE marking under MDR Article 20 and IVDR Article 18.

# Evidence: GSPR, standards, clinical evidence and guidance

The conformity assessment system is only credible if the evidence base is structured, traceable and proportionate.

# GSPR: the EU equivalent of N78 “Essential Principles”

N78 asks for evidence of conformity to Essential Principles; MDR/IVDR Annex I makes this a legal requirement.

### Safety and performance

Benefits must outweigh risks; device performs as intended.

### Risk management

Risks reduced as far as possible and acceptable against benefits.

### Design/manufacturing

Materials, biological safety, infection, substances, electrical/mechanical safety.

### Information supplied

Labels, IFU, warnings, UDI carrier and user/patient information.

### Clinical/performance evidence

Evidence must support intended purpose and claims.

**Evidence must be traceable: each GSPR → applicable standard/CS/technical solution → test or rationale → conclusion in technical documentation.**

# Common specifications, harmonised standards and MDCG guidance

These tools support conformity demonstration; they do not replace manufacturer responsibility.

## Common specifications (CS)

Where adopted, CS may provide legally recognised technical requirements for certain devices or topics. They can be highly relevant where harmonised standards are insufficient or absent.

## Harmonised standards

Use of harmonised standards cited in the OJEU can provide presumption of conformity with requirements covered by those standards, if applied correctly.

## MDCG guidance

MDCG guidance supports harmonised application of MDR/IVDR. It is not legislation, but it is highly influential for expectations of manufacturers, NBs and authorities.

**N78 also recognises standards as a way to justify proportionate conformity assessment: well-established technology + recognised standards may support less burdensome review; novelty or public-health concern may justify deeper review.**

# Clinical / performance evidence: proportionate but central

EU MDR/IVDR raised the evidence bar; N78 expects objective evidence of safety, performance and benefit-risk.

## MDR: clinical evaluation

Clinical evaluation is planned, conducted and updated throughout the lifecycle. It may rely on clinical investigations, scientific literature, equivalent device data where permitted, and post-market clinical follow-up. For implantable and Class III devices, stronger expectations apply.

## IVDR: performance evaluation

Performance evaluation combines scientific validity, analytical performance and clinical performance. PMPF updates evidence post-market. Class D and CDx devices may trigger additional EU mechanisms.

Legal references: MDR Article 61 and Annex XIV; IVDR Article 56 and Annex XIII; PMS/PMCF/PMPF linkage in MDR Annex III and IVDR Annex III.

# Expert panels and EU reference laboratories: additional oversight layers

These mechanisms are outside the generic N78 model but reinforce EU reliance for high-risk/special devices.

## Expert panels

Under MDR Article 106, expert panels provide scientific opinions and advice. For certain Class III implantable and Class IIb active devices intended to administer/remove medicinal products, the clinical evaluation consultation procedure may apply. NB deviations from expert panel opinion must be justified.

## EU reference laboratories (EURLs)

Under IVDR Article 100, EURLs support Class D IVD oversight, including verification of performance claimed by manufacturers and batch testing, where applicable. A negative EURL opinion can prevent certificate issuance for a Class D device.

**Special mechanisms are risk-based additions; they do not replace the manufacturer's QMS, technical documentation, DoC or PMS obligations.**

# Total product lifecycle approach

N78 explicitly links premarket conformity assessment and post-market surveillance. EU MDR/IVDR operationalise this as a continuous lifecycle system.

# TPLC / lifecycle approach: CE marking is a milestone, not the finish line

Conformity assessment before and after market placement are complementary controls.



# Post-market surveillance system

N78 requires a post-marketing surveillance system as part of conformity assessment; EU makes it a proactive, systematic lifecycle obligation.

## PMS system

Proactive and systematic collection, recording and analysis of relevant data on device quality, performance and safety throughout the entire lifetime of the device.

## What it feeds

Risk management, benefit-risk determination, clinical/performance evaluation, PMCF/PMPF, corrective actions, updates to TD and instructions for use.

## Key outputs

PMS plan, PMS report for lower risk classes, PSUR for higher classes, PMCF/PMPF evaluation reports and inputs to vigilance or FSCA decisions.

Legal references: MDR Articles 83–86 and Annex III; IVDR Articles 78–81 and Annex III.

# PMS reports and PSURs: different reporting intensity by class

The reporting obligation itself is risk-based; evidence must be updated and made available to NBs/authorities as applicable.

| | | |
|---|---|---|
| **PMS plan** | **All classes** | Defines methods, indicators, sources, PMCF/PMPF, complaints and trend analysis. |
| **PMS report** | **MDR Class I / IVDR Class A-B** | Summarises results and conclusions; updated when necessary and made available to authorities. |
| **PSUR** | **MDR IIa/IIb/III; IVDR C/D** | Periodic Safety Update Report: conclusions of benefit-risk, PMS findings, sales/population data, CAPA. |
| **PMCF/PMPF evaluation report** | **Where required** | Updates clinical/performance evidence using post-market data. |

# Vigilance reporting: incidents, FSCAs and trend reporting

N78 refers to adverse event reporting; EU MDR/IVDR create detailed timelines and coordinated authority action.

## Serious incidents

Manufacturers report serious incidents to competent authorities via the electronic system. Indicative timelines include immediately for serious public-health threats, short timelines for death/unanticipated serious deterioration, and generally no later than 15 days.

## Field safety corrective actions

FSCA is reported and usually accompanied by a Field Safety Notice. It may include recall, modification, exchange, destruction, advice, software update, or IFU/labelling changes.

## Trend reporting

Significant increase in non-serious incidents or expected undesirable side effects that could affect benefit-risk must be reported and acted upon.

Legal references: MDR Articles 87–90; IVDR Articles 82–85. Vigilance links to PMS, risk management, CAPA and market surveillance.

# UDI obligations: device identity across the lifecycle

UDI is the practical infrastructure that connects device identity, traceability, vigilance, EUDAMED and market surveillance.

### Basic UDI-DI

Regulatory identifier for device model/family; anchors certificates and DoC

### UDI-DI

Device identifier: specific device/version/configuration

### UDI-PI

Production identifier: lot, serial, software version, expiry/manufacture date

### Carrier

Human and machine-readable code on label/packaging/device as applicable

### EUDAMED

UDI/device data registered and searchable according to module obligations

Legal references: MDR Article 27 and Annex VI; IVDR Article 24 and Annex VI. UDI is not only labelling — it is a data architecture for lifecycle oversight.

# EUDAMED: transparency and shared regulatory infrastructure

EUDAMED supports N78's registration/listing concept and goes beyond it by linking actors, devices, certificates and post-market data.

### Actors

Manufacturers, authorised representatives, importers

### UDI / Devices

Core UDI data and device registration

### NB & Certificates

Certificates, scope, validity and status

### Market Surveillance

Authority coordination and market surveillance data

### Vigilance

Serious incident/FSCA workflows

### Clinical / Performance Studies

Clinical investigations and performance studies

**As of 28 May 2026, the Actor, UDI/Device, Notified Bodies & Certificates, and Market Surveillance modules are mandatory to use; the Vigilance module timeline depends on audit results.**

# Substantial changes: targeted assessment, not complete re-review

N78 allows modification of conformity assessment where justified; EU change control should focus on what changed and what the change affects.

## What can be substantial?

- Intended purpose or claims
- Design, raw materials or critical components
- Manufacturing, sterilisation or supplier changes
- Software algorithm or control logic, where relevant
- Risk profile, clinical/performance evidence or GSPR compliance
- QMS processes or sites affecting conformity

## How it should be assessed

The manufacturer evaluates impact under QMS change control and informs the NB where required. The NB performs a supplementary assessment to the extent needed. A full initial certification review is not automatically repeated unless the change undermines the basis of certification.

**a valid CE certificate after a change should be read together with the manufacturer's DoC, change history, NB correspondence/supplementary assessment and updated PMS/TD evidence.**

# Registration of actors and devices: N78 basic regulatory control

N78: RA maintains a register. EU: registration obligations are embedded in EUDAMED and UDI architecture.

## Actors

Manufacturer, authorised representative and importer registration; Single Registration Number; economic operator responsibilities and traceability.

## Devices

Basic UDI-DI, UDI-DI, device attributes, risk class, certificate linkages, intended purpose and status. Device registration reinforces traceability and transparency.

## Certificates

NB certificates, scope and validity in EUDAMED/NANDO ecosystem. Useful for reliance, but must be interpreted with the DoC and device-specific context.

Legal references: MDR Articles 29–31; IVDR Articles 26–28; EUDAMED Article 33 MDR / Article 30 IVDR.

# N78 class-by-class approach: EU interpretation

The exact labels differ, but the pattern is the same: higher risk = fuller QMS, deeper TD review, more independent oversight and stronger PMS reporting.

| | |
|---|---|
| **N78 A / MDR I / IVDR A** | Basic QMS + TD held; DoC; registration; NB only for limited aspects such as sterile/measuring/reusable or sterile IVD. |
| **N78 B / MDR IIa / IVDR B** | QMS confidence; TD usually sampled or requested; DoC available; PMS/reporting scaled to risk. |
| **N78 C / MDR IIb / IVDR C** | Full QMS; TD review becomes more systematic; clinical/performance evidence stronger; PSUR and NB surveillance important. |
| **N78 D / MDR III / IVDR D** | Fullest oversight: full QMS + in-depth TD, expert panels/EURLs where applicable, rigorous PMS/PSUR and vigilance. |

# One slide on MDSAP: a reliance complement, not a CE substitute

MDSAP is relevant to N78 because it strengthens confidence in QMS audits across participating jurisdictions.

### What MDSAP is

A programme allowing recognised auditing organisations to conduct a single QMS audit that can satisfy participating regulatory authorities' QMS audit needs.

### Where it helps

It can support reliance on QMS evidence and reduce duplicate audits. It aligns with N78's idea that RA/CAB may review relevant existing certification and regulatory audit reports.

### Where it does not replace EU CA

MDSAP does not replace MDR/IVDR CE marking, EU technical documentation assessment, DoC, EUDAMED obligations, NB certificates or EU-specific PMS/vigilance requirements.

**Positioning: useful for international convergence and regulatory cooperation, but EU conformity assessment remains governed by MDR/IVDR and NB designation scope.**

# Key takeaways

A concise script for explaining the EU model to global partners.

1. **N78 is a lifecycle model: QMS, PMS, TD, DoC and registration work together.**
2. **EU MDR/IVDR implement N78 through legally binding rules, risk classes and NB involvement.**
3. **CE marking is manufacturer responsibility, supported by NB certificates where applicable.**
4. **A QMS certificate alone can be normal under risk-proportionate sampling; it is not proof that TD does not exist.**
5. **NBs produce reports as well as certificates; each output has a different reliance value.**
6. **EU oversight continues after market placement through PMS, vigilance, UDI, EUDAMED and substantial change controls.**

# Core source base

Primary materials used to anchor the deck.

GHTF/SG1/N78:2012, Principles of Conformity Assessment for Medical Devices
Regulation (EU) 2017/745 on medical devices (MDR)
Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)
European Commission public health pages: Notified Bodies, NANDO and EUDAMED overview/roadmap
Commission / user-provided training screenshots on EU MDR/IVDR conformity assessment and FDA post-market approach
N78-related IMDRF/GHTF guidance: Essential Principles, classification, STED/ToC, PMS/adverse event reporting, standards guidance

# Training on N98: IMDRF Reliance Playbook

- September 2026

# Presenters



**Agnes S. Kijo**
Technical Officer
Regulatory System Strengthening
Regulation and Safety Unit
Regulation and Prequalification Department
World Health Organization



**Debbie Ko, PhD**
Regulatory Consultant
Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority



**Tammy Steuerwald, JD**
Global Head of Regulatory Policy,
Foundational Principles & Supranational Organizations
Global Regulatory Policy and Intelligence
Roche Diagnostics

# Learning Objectives

By the end of this session, participants will be able to:



Understand how various WHO and IMDRF guidances work in synergy to create optimized and internationally convergent regulatory oversite for MD/IVDs.

Understand the various types of reliance IMDRF Playbook and their alignment to the WHO Good Reliance Practices Guidance.

Understand the contents and concepts of the IMDRF Reliance Playbook and how reliance can be applied across the product lifecycle.

Apply the IMDRF Reliance Playbook concepts to case studies and identify opportunities for reliance in your jurisdiction.

# Agenda

- 1 Overview: WHO Good Regulatory Practices (GRP), Good Reliance Practices (GRelP), Global Benchmarking Tools (GBT+), Global Model Regulatory Framework (GMRF) and types of reliance | 15 mins
- 2 Overview of the IMDRF Reliance Playbook and key elements | 20 mins
- 3 The relationship between IMDRF Guidances & the Playbook | 10 mins
- 4 Key takeaways | 5 mins
- 5 Q & A | 10 mins

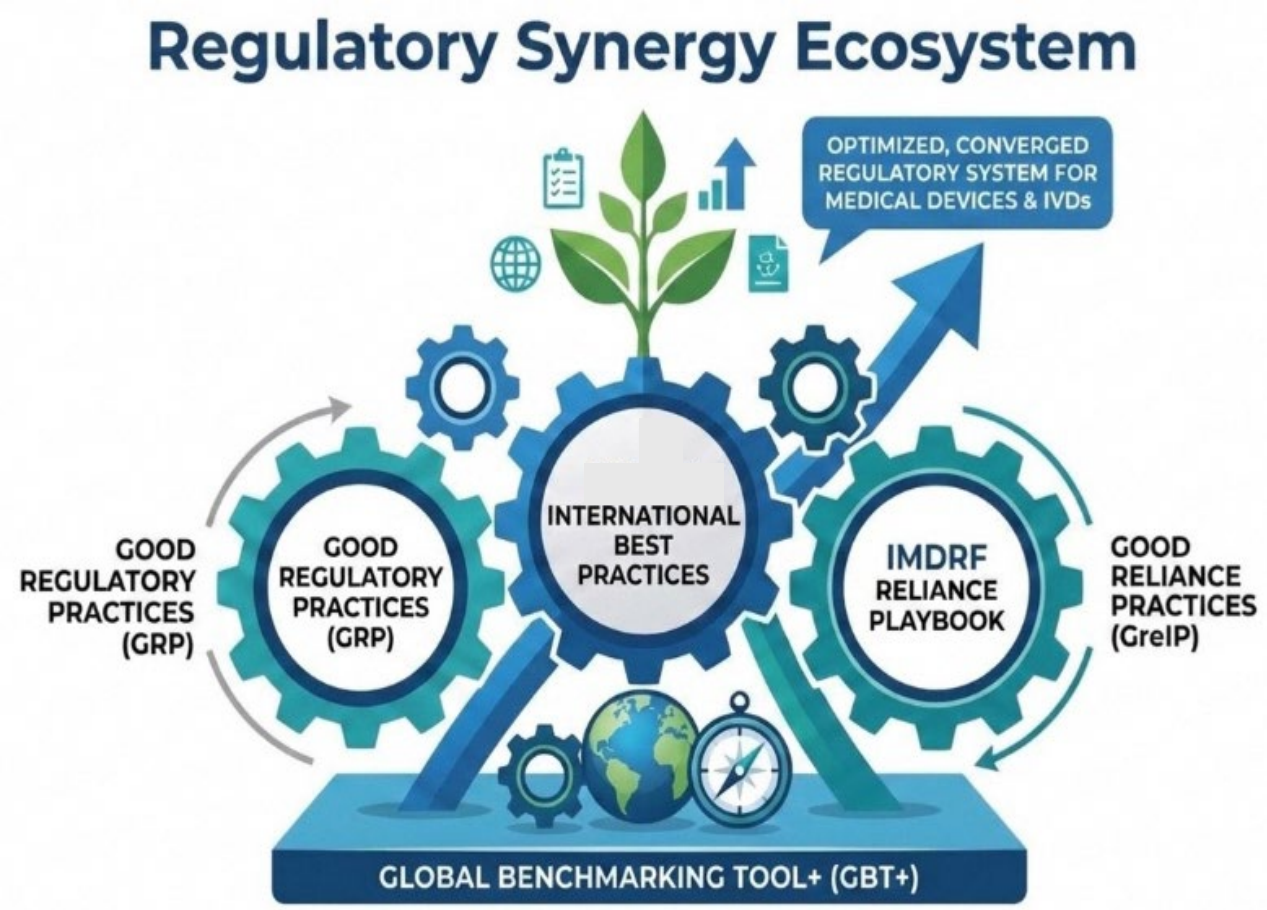
# Overview: WHO GRP, GRelP, GBT+, GMRF and types of reliance


- **Agnes S. Kijo**
- Technical Officer
- Special Access Programme
- Regulation and Safety Unit
- Regulation and Prequalification Department
- World Health Organization

# Key Frameworks & Guidances

## Regulatory Oversight & Reliance

| | |
|---|---|
| **IMDRF Reliance Playbook** | Establishes a method to develop the reliance program that is right for you. |
| **WHO GRP** | Presents the high-level principles of GRP intended to serve as benchmarks and thereby guide Member States in applying good practices in regulation of medical products. |
| **GBT+** | Provides a standardized framework for assessing the performance and maturity of National Regulatory Authorities |
| **WHO GMRF** | Provides recommendations to help regulators implement a strong and sustainable regulatory framework. |



# What are GRPs & why are they so important?



Annex 11

**Good regulatory practices in the regulation of medical products**

**Background**

A fundamental role of government is to protect and promote the health and safety of the public, including by delivering health care. A well-functioning health care system requires available, affordable medical products that are safe, effective and of assured quality. As medical products are essential in the prevention, diagnosis and treatment of disease, the consequences of substandard and falsified medical products can be life threatening. This is a concern, as users of medical products are not usually in a position to judge their quality. The interests and safety of the public must therefore be entrusted to a regulatory body or bodies that ensure that only products in legal trade are available and that marketed products are safe, perform as claimed and are of assured quality.

The regulation of medical products has become increasingly complex with the globalization of product development, production and supply and the rapid pace of technological and social change in the context of limited financial and human resources.The importance of robust regulatory systems was recognized by the Sixty-Seventh World Health Assembly when it endorsed resolution WHA 67.20, Regulatory system strengthening for medical products. The resolution notes that "effective regulatory systems are an essential component of health system strengthening and contribute to better public health outcomes", that "regulators are an essential part of the health workforce" and that "inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products" (23).

A sound system of oversight requires that regulatory authorities be supported by an effective framework of laws, regulations and guidelines and that they have the competence, capacity, resources and scientific knowledge to deliver their mandate in an efficient and transparent manner. The extent to which a regulatory framework fulfils its policy objectives depends on the quality of its development and implementation. GRP are critical to efficient performance of a regulatory system and, consequently, to the public's confidence in the system, while also setting clear requirements for regulated entities. A sound regulatory framework, including international norms and standards, and the recruitment and development of competent staff are necessary but not sufficient conditions to ensure "good oversight". All individuals in regulatory authorities should be guided by GRP in setting appropriate requirements and formulating decisions

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## Promoting Public Health

GRP is the **quality control mechanism** for the development of regulations, ensuring on a continuous and systematic basis, that government rules are relevant, of the highest quality, cost-effective, internationally aligned and least economically restrictive.

## Accelerated Access

GRPs accelerate access to safe and effective MD/IVDs by allowing manufacturers to follow a **predictable, transparent and repeatable** process to design, develop, and maintain products globally to the same high standard.

## Global Harmonization

Helps ensure technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.

GRPs help regulators implement regulation that is consistent to international best practices thereby helping convergent regulation develop worldwide.

# GRP High-level principles and key enablers for effective implementation

## 9 High-Level GRP Principles

| | | |
|---|---|---|
| Legality | Consistency | Independence |
| Impartiality | Proportionality | Flexibility |
| Clarity | Efficiency | Transparency |

## GRP Principles Enablers

- ✓ Political and government-wide support
- ✓ Effective organization and good governance supported with leadership
- ✓ Inter- and intra-organizational communication, collaboration & coordination
- ✓ A robust and well-functioning quality management system (QMS)
- ✓ Sufficient and sustainable financial resources
- ✓ Competent human resources
- ✓ Pre-set organizational ethics and values
- ✓ Science- and data-driven decision-making process

GRPs help ensure international best practice, are implemented as the basis of local regulation.

# WHO Global Model Regulatory Framework for medical devices and IVDs (GMRF)

- ✓ Provides a **stepwise approach** to developing/advancing regulatory systems for medical devices.
- ✓ Encourages **convergence with international practices** (IMDRF guidance, ISO standards).
- ✓ A **global reference** on medical devices regulation.
- ✓ Published in 2017, developed in 2015-2016 and reviewed in 2022.
- ✓ GMRF is the main reference document in the **GBT+ tool**.



# GMRF Stepwise Approach to Regulation

The GMRF advances a **stepwise approach** from basic-level to expanded-level regulatory controls, with basic controls forming a critical foundation for success.

## Foundation for Growth

Basic-level controls form the foundation of the expanded-level regulatory controls.

**Without effective implementation, expanded elements will be of limited value and difficult to manage.**

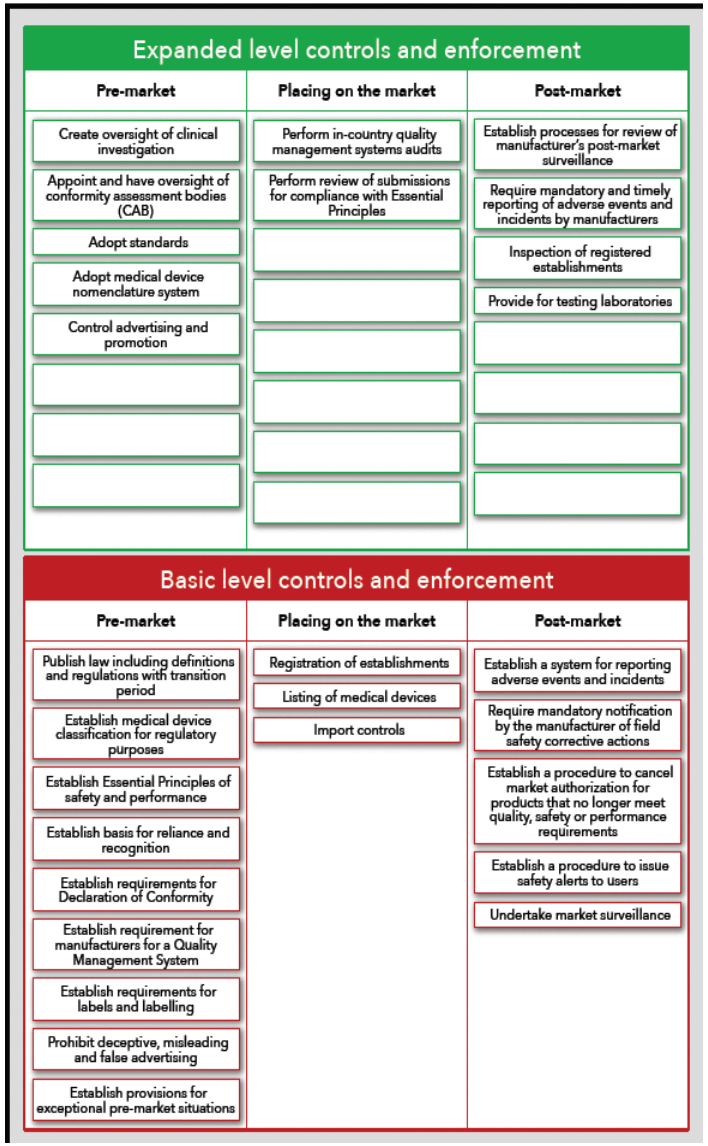
## Continuity of Reliance

Implementation of **expanded-level** pre-market controls **does not mean a regulator should discontinue existing reliance practices.**

*— Source: GMRF, page 223*

## Harmonization

GMRF **encourages countries to adopt internationally harmonized technical guidance** to promote global convergence and harmonization.



# What is the WHO GBT+ and why is it important?




**The GBT+ tool**:

- Allows countries to leverage work of trusted regulators, improve efficiency, avoid duplication, and accelerate access to quality-assured medical devices.
- Promotes harmonization and convergence; making it easier for regulators to recognize and use each other's work.

✓ Published December 2024 to measure regulatory maturity for the regulatory oversight of MDs and IVDs.

✓ Represents the primary means by which the WHO objectively evaluates regulatory systems (Resolution WHA 67.20)

✓ Identifies strengths, areas of improvement and best practices

✓ Facilitates the formulation of institutional development plan (IDP) to build upon strengths and address the identified gaps,

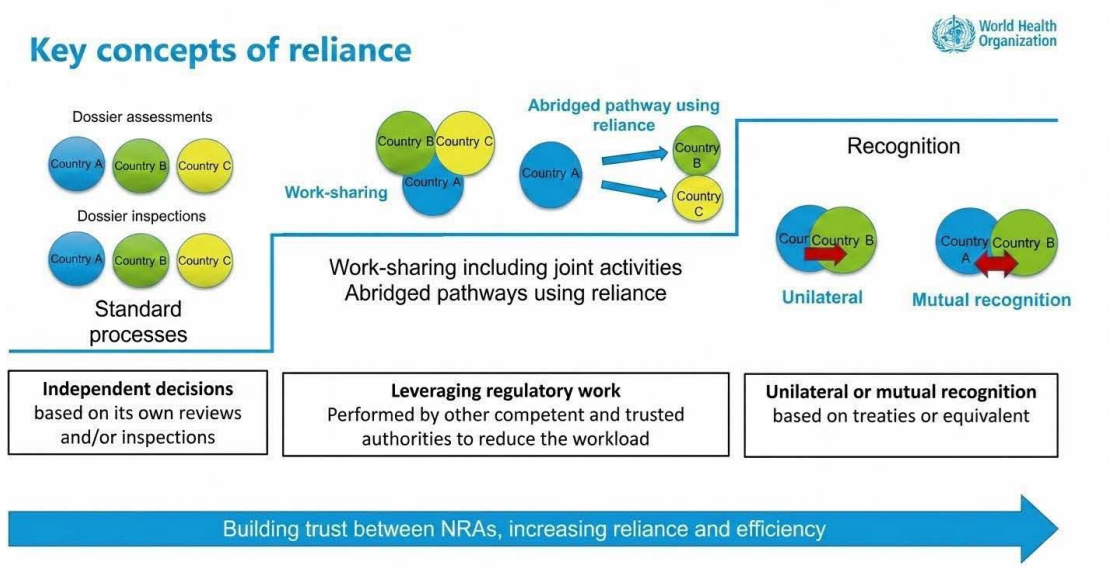
✓ Prioritize IDP interventions and

✓ Monitors progress.

✓ Measures of evidence that a National Regulatory Authorities (NRA) has implemented reliance and whether the NRAs system is robust enough to be trusted.

# WHO GRelP

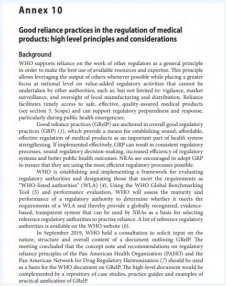
Builds a strong foundation for the IMDRF Reliance Playbook




**Official Reference**

## Annex 10 Guidelines

*"Good reliance practices in the regulation of medical products: high level 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 (GRelP) 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 GRelP. 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 GRelP. The high-level document would be complemented by a repository of case studies, practice guides and examples of practical application of GRelP.

### Expected Outcomes & Benefits

**Accelerate Access**
Accelerate global access to safe and quality health technology.

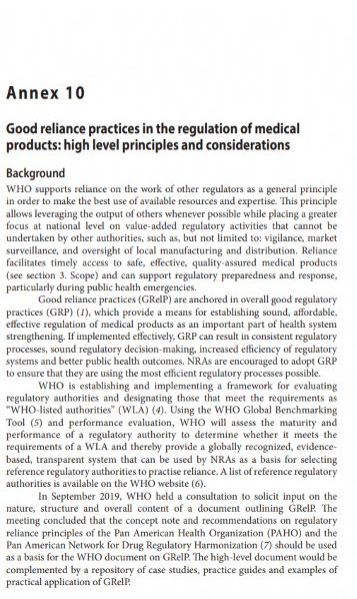
**Resource Efficiency**
Increase efficient use of resources and avoid duplication of efforts.

**Reduce Uncertainty**
Reduce uncertainties for innovators and improve regulatory harmonization.

**Robust Response**
Promote a more consistent and robust response to healthcare crises.

# WHO & IMDRF Reliance Playbook Synergy

## WHO REFERENCE



Annex 10

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

Background

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**Annex 10 Guidelines**

*Good Reliance Practices*

### Shared Objective & Aim

Promote efficient, transparent, and risk-based regulatory decision making, evidence-based assessments, and capacity building to improve timely access to quality-assured medical devices and IVDs.

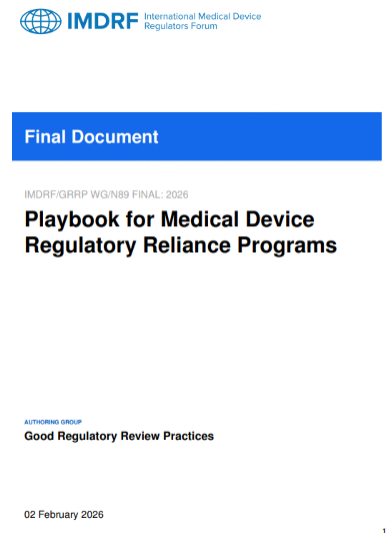
### Synergy & Outcomes

**WHO** provides the foundational principles, while **IMDRF** operationalizes them into concrete actions. This convergence reduces duplication and accelerates access to quality-assured products.

### Reference Pillars (WHO GRP & GRelP)

- Legal Framework
- Stakeholders Engagement
- Regulatory Analysis
- Targeting Potential Partners

## IMDRF PLAYBOOK



IMDRF International Medical Device Regulators Forum

Final Document

IMDRF/GRRP WG/N89 FINAL: 2026

Playbook for Medical Device Regulatory Reliance Programs

AUTHORING GROUP

Good Regulatory Review Practices

02 February 2026

**Medical Device Reliance**

*Operational Playbook*

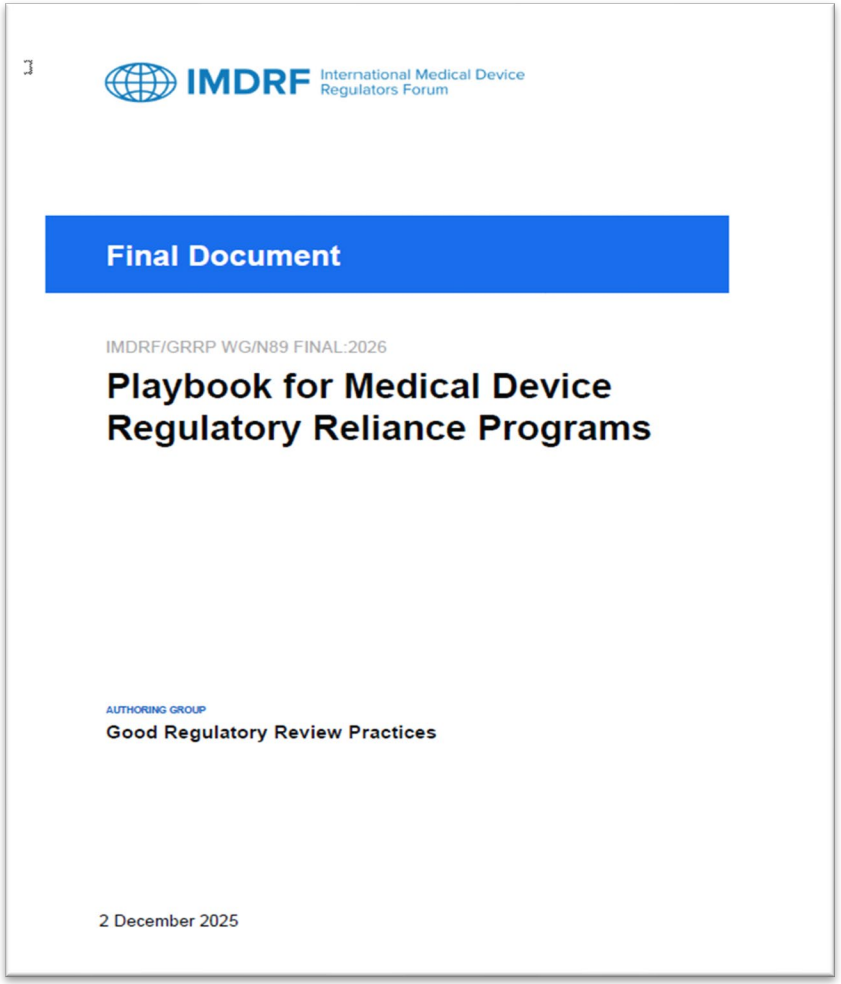
# Overview of the IMDRF Reliance Playbook and key elements


- **Debbie Ko, PhD**
- Regulatory Consultant
- Medical Devices Cluster
- Health Products Regulation Group
- Health Sciences Authority

# What is the IMDRF Reliance Playbook?

- 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.

It is not a set of requirements.



# Principles & Objectives of the Playbook

- **Retain** sovereign decision-making and accountability
- **Apply** reliance in a risk-based, proportionate manner
- **Build** trust through clarity, communication & confidentiality
- **Enable** lifecycle use (premarket + postmarket)
- **Increase** efficiency and predictability without lowering rigor
- **Engage** stakeholders across the reliance lifecycle

# Regulatory Convergence & Types of Reliance

| Concept | Definition & Scope |
| --- | --- |
| **Reliance** | A Regulatory Authority (RA) considers the assessments made by a reference RA when making its own decisions, optimizing resource utilization. |
| **Convergence** | Voluntary and gradual alignment of regulatory frameworks through the shared use of guidance and principles (e.g. IMDRF guidance). |
| **Harmonisation** | Formal unification of technical requirements among multiple RAs (e.g., the CE-marking system established within the EU). |

| Reliance Type | Mechanism | Examples |
| --- | --- | --- |
| **Work-sharing** | Collaboration among authorities to jointly perform regulatory tasks or evaluations | MDSAP: Single audit for mutiple jurisdictions. |
| **Abridged Pathway** | Partial review relying on prior assessments from a trusted authority | HSA (Singapore), ANVISA (Brazil) |
| **Recognition** | Direct acceptance of another authority's decision with minimal or no review | EU CE Marking across all EU Member States. |

# Reliance Playbook Overvie



# Legal Framework

## Establishing the Program

### Critical First Step

Assessing your jurisdiction's current legal framework is vital when establishing a regulatory reliance program.

### Review statutes

Evaluate existing statutes and common law to determine if reliance can be implemented by interpreting current regulations, or if formal legislative revisions are required.

### Medical Device & IVD

Ideally, the reliance program should be rooted in legal frameworks specific to medical devices rather than other regulated products like pharmaceuticals.

### Flexible Implementation

If regulations do not explicitly provide for reliance, adopt it through policy changes and interpretation, provided current laws do not explicitly prohibit it.

## Strategy

### Map your options

Regulators should proactively map and identify any limitations for various reliance aspects such as specific product types, regulatory decisions, or types of reliance programs.

### Target "Early Wins"

Because comprehensive legislative change can be difficult, authorities are highly encouraged to identify "early wins".

### Optimize Resource Investment

Focus on practical approaches that require less initial resource investment and fit within current legal constraints.

# Identifying Reference Regulatory Authorities

## Key Elements for Consideration

**Assess and identify** potential reference RA(s) by comparing frameworks through review of guidance, policy and legal documents. Some factors to consider:

- Relevance of the regulatory framework
- Availability of publicly accessible assessment information
- Relevance of the regulatory framework
- Existing agreements / work relationship

**Engagement is encouraged** especially when there are differences in frameworks that would result in a more complicated or challenging reliance program.

## Program Flexibility & Partnership

### Multiple Reference RAs

A reliance program can be flexible; a regulator may choose to work with multiple reference authorities, using different partners for different regulatory activities to optimize their program's reach and effectiveness. Regardless of the number of RAs, the relying agency should ensure their local laws and regulations are still being met when relying on others.

### Trust & Collaboration

Given the importance of trust in a reliance program, select reference RA(s) with whom you already work closely or have existing partnerships. Also consider how frequently other RAs rely on them, choosing reference RAs whose decisions you trust.

# Determine Agreements & Information Sharing

## Agreements

### Assessing Agreement Necessity

Once you understand another regulator's framework and decide on a reliance mechanism, you can assess whether agreements are needed and what agreement type is appropriate.

Formal information-sharing agreements **can add time and complexity**

- **Prioritize use of public information** such as published regulatory decision (especially for unilateral reliance)
- Manufactures can also be required to notify you of changes/actions by other RAs.

Formal agreements may be best in some cases:

- When non-public information (e.g. audit reports) is needed for decision-making.
- Establishing processes, such as data handling and any mutual recognition or work-sharing terms.

## Information Sharing

### Assessing Information Sharing Necessity

Consider:

- Sensitivity and type data
- Internal resources required to make these expectations and make this information available.

**Providing only the information necessary to support a reliance-based decision helps reduce processing time, workload, and legal exposure.**

# Establishing the Scope of Reliance

## Defining the Boundaries

### Plan Early

Defining the scope of your reliance activities should be done early in the development process, as these boundaries will significantly impact how the program is implemented.

### Retain Independence

A reliance program should not be imposed on any authority by another external authority or institution. You should retain independence in choosing reliance-based models and making changes when warranted to meet your needs and those of your population.

### Aspects to consider in the scope

- Regulatory activities (e.g, audits, premarket review, post-market surveillance)
- Reference RAs
- Type of reliance (e.g. work-sharing or recognition)

### Identify Influencing Factors

The scope is generally influenced by key internal factors, including available resources, existing partnerships, and constraints identified within your legal framework.

### Build in Flexibility

An effective reliance scope should not be entirely rigid. Regulators should build in flexibility to allow for future scope changes, ensuring that the program can adapt as new options emerge or environments shift.

# Establish Reliance Processes and Procedures

## Considerations

### Eligibility Criteria

Define eligibility criteria for your reliance program including for example medical device types, including risk classification and category/nomenclature and regulatory activities.

### Process Steps

- Determine how reference RA decisions are obtained (e.g. public sources),
- How extensive the review should be, including any role of third parties in relation to the reliance program
- Establishing a process to confirm that the device under review and intended use is essentially identical to the version on which the reference RA's decisions were based on.

### Communication Plan

- Training staff on procedural steps and program benefits
- Provide a description of the reliance plan to the public to include regulatory processes, criteria to participate and the process the manufacturer will need to follow.
- Provide sufficient transparency to the public so they understand the purpose, benefits and outcomes to minimize the risk of losing public trust.

## Documentation and resources

### Identify information needed for a sufficient informed decision

Technical documents and other resources used to support reliance-based decision-making (e.g. Standards, regulatory guidance)

### Maximise benefits of reliance

Adopt consensus-based processes invested in by multiple jurisdictions to reduces ambiguity, build confidence, increase reliance related efficiency (e.g., ISO 13485, MDSAP, IMDRF Regulated Product Submission Working Group (RPS WG) documents, Good Regulatory Review Practices Working Group (GRRP WG) document and Adverse Events (AE) reporting.

# Establish a Management System for Reliance

**Establishing a robust management system is critical for ensuring that a reliance program meets its long term intended goals and the needs of all stakeholders.**

## Management System Section

Minimum Requirements Include:

- **Process Monitoring & Key Performance Indicators (KPIs)**: Continuously evaluate process effectiveness and establish target KPIs (e.g. time and cost savings, rate of program update by industry, reduction in turnaround time)
- **Feedback & Change**: Systematically gather stakeholder feedback and establish formal change controls.
- **Suitability & Alignment**: Track decision differences with reference RAs and monitor their ongoing suitability.



# Engaging with Stakeholders

## Stakeholders

### Internal Stakeholders

Staff within the regulatory organization (e.g. management, legal team, reviewers) driving the program

Transparent and well-timed communication is critical. Clearly explain the intent, timeline, scope, and anticipated impact to address internal concerns early.

### External Stakeholders

Medical device & IVD industry members, patients, healthcare providers, and other government agencies. Target outreach appropriately to both large and small/medium enterprises, as they are highly sensitive to market impacts.

- Explain expected benefits (e.g. shorter timelines, improved resource allocation, expanded market access)
- Solicit feedback via public consultations and provide updates

## Engagement Strategy

### Early & Frequent Engagement

Builds trust, transparency, and predictability. Allows regulators to understand diverse perspectives, secure vital support, and gather early feedback.

### Two-Way Communication

Ensures the program benefits from diverse insights, resulting in a more robust design and highly effective execution.

### Key Success Factor

Stakeholder participation is crucial; partners are far more likely to support and correctly implement a program they helped develop.

# Key Considerations for Reliance Implementation

## 01 Permissible framework

**What does your legal framework allow?**

Ensure the establishment of clear legal parameters and authority supporting reliance pathways within the existing local regulatory architecture. When regulations do not make explicit provision reliance can be adopted through interpretation so long as it is not explicitly prohibited.

## 02 Maintain autonomy

**Are decisions independent?**

Ensure local regulatory sovereignty and independent statutory decision-making are fully preserved while utilizing RA work.

## 03 OK to "start small"

**Can you begin phased approaches?**

Design and launch with targeted pilot scopes, leveraging initial success indicators and quick wins to gain momentum.

## 04 Information access

**What data do you need?**

Distinguish confidential vspublic insights. Define practical exchange mechanisms to secure necessary documentation securely.

## 05 Monitoring

**Are there checks in place?**

Do you have established processes and procedures to measure the overall reliance program and ensure its meeting its stated goals?

## 06 Stakeholder trust

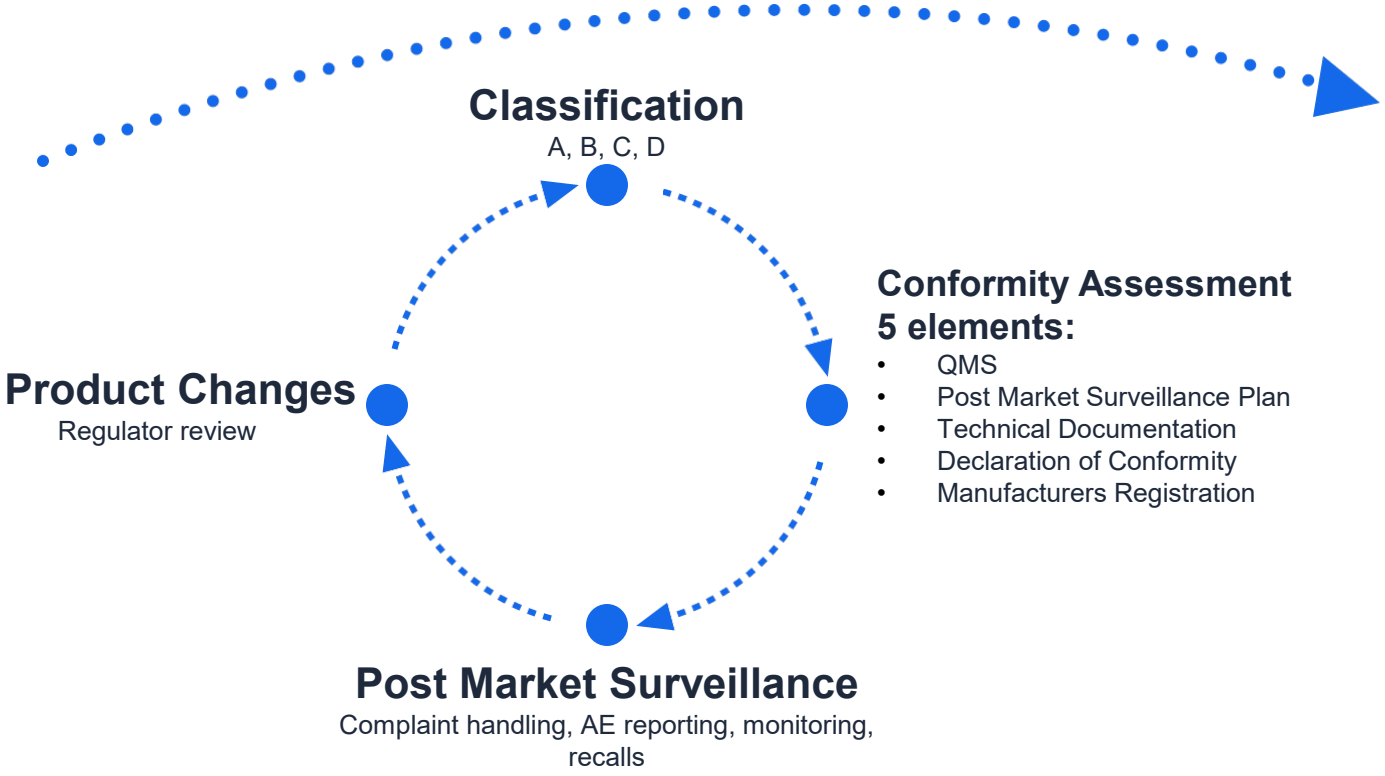
**Who is involved & when?**

Establish ongoing dialogue with internal teams, local & multi-national industry partners, reference agencies, and related government agencies.

# The relationship between IMDRF Guidances & the Playbook

**Tammy Steuerwald, JD**
Global Head of Regulatory Policy, Foundational Principles & Supranational Organizations
Global Regulatory Policy and Intelligence
Roche Diagnostics

# Linking Important Concepts from Today









# Question you might have or how you might feel



### Where do I begin?

Feeling unsure about the strategic entry points and how to launch your initial program setup.

### Am I on track?

Wondering if your current regulatory pathways align perfectly with reference authority frameworks.

### Feeling Overwhelmed

Navigating limited personnel, budgets, and tight statutory timelines while managing expectations.

### Which tool is right?

Not sure what the best digital tool is to use to securely exchange files and technical insights.

### What are next steps?

Looking for immediate, clear-cut processes to advance and scale your regional pilot projects.

### Need quick help?

Seeking targeted expert support, training modules, or reference materials when feeling stuck.

# Getting Unstuck




### Initial Steps

Start talking to agencies you have established relationships with. Learn from their experiences. Meet with industry, see how they use reliance.

### There is no perfect way

Regulatory pathways don’t have to line up perfectly to practice reliance. Start small & scale up.

### Don’t reinvent the wheel

You don’t have to start from scratch. Many regulators have implemented reliance and manufacturers use reliance.

### Tools are on their way

While a single database doesn’t yet exist, this may be the next big leap for reliance & we invite you to be part of it!.

### Refer to IMDRF Reliance Playbook

The Playbook gives you a step-wise approach to implement an effective and sustainable reliance program.

### You are not alone!!

The only place where success comes before work is in the dictionary. The initial lift will pay off for years to come.

# What opportunities still exist?



## Growing Global Momentum

Even though reliance pathways have significantly increased over the last 5 years, much work remains to be done.

## Operational Barriers

Significant barriers to operationalize reliance still prevail, hindering clear and efficient implementation.

## Process & Regulatory Challenges

**MD/IVD Retrofitting.**
Reliance programs for MD/IVD retrofitted into drug and vaccine regulation.

**No Criteria or Timelines.**
Lack of established MD/IVD criteria, traceability of submissions, and established timelines.

**Process Consistency.**
GRP not used to ensure appropriate planning to include necessary tools and resources.

## Engagement & Infrastructure

**Stakeholder Engagement.**
Increase transparency, involve stakeholders early, notify World Trade Organization and allow 60-day comment periods.

**Common Database Needed.**
Implement a shared submissions database using IMDRF TOCs for multi-regulator access and tracking.

**Post-Market Reliance.**
Build robust and scalable reliance pathways through post-market changes.

# Operationalizing Reliance: Success Criteria, Practical Steps & Sustainability



## Design Smart:

- Prioritize publicly available regulatory information
- Align to IMDRF international best practices & Table of Contents (TOC)
- Leave flexibility in reliance program and monitor effectiveness



## Engage Early & Often:

- Engage cross-functionally within government & external stakeholders
- Establish a dialogue to support mutual understanding & trust
- Have clear criteria based on MD/IVD needs & establish reliance timelines



## Start Small & Scale:

- Ask for industry feedback (e.g. 60 day consultation)
- Utilize pilots: define scope, learn fast
- Ensure performance indicators are established & met & review stakeholder feedback
- Refine & mature program

**Use performance-based indicators to track reliance progress and report to the public and legislature**

# Key Takeaways: Principles of Reliance

### 01 STARTING POINT

**Start simple and scale**

Find "early wins" and "start small". Launch with targeted pilot scopes and build momentum.

### 02 LIFECYCLE

**Apply across full lifecycle**

Utilize reliance from pre-market authorization to product changes, inspections, and surveillance.

### 03 ENGAGEMENT

**Build trust & engage**

Connect early and often with internal teams, industry, and reference authorities.

### 04 INTEGRITY

**Maintain sovereignty**

Leverage trusted partners while retaining independent decision-making and accountability.

### 05 TRANSPARENCY

**Prioritize public info**

Minimize administrative burden by utilizing online databases and public registries.

### 06 SAMENESS

**Ensure product sameness**

Verify that the device is sufficiently similar to the reference authority's approved version.

### 07 SUSTAINABILITY & MONITORING

**Continuous evaluation is required to ensure long-term program health**

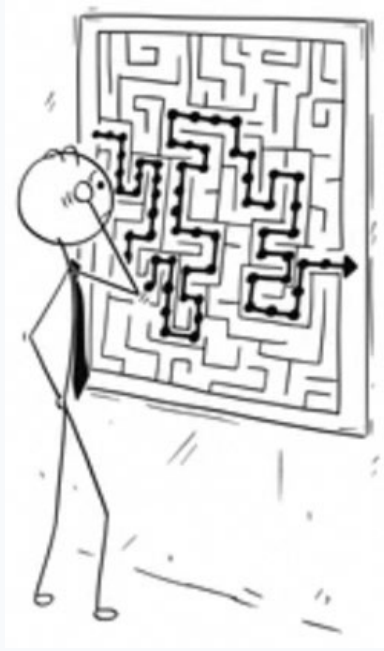
Establish robust management systems to track KPIs, collect systematic stakeholder feedback, and monitor reference partners.

# Knowledge check: Which image best depicts how reliance programs should be developed?

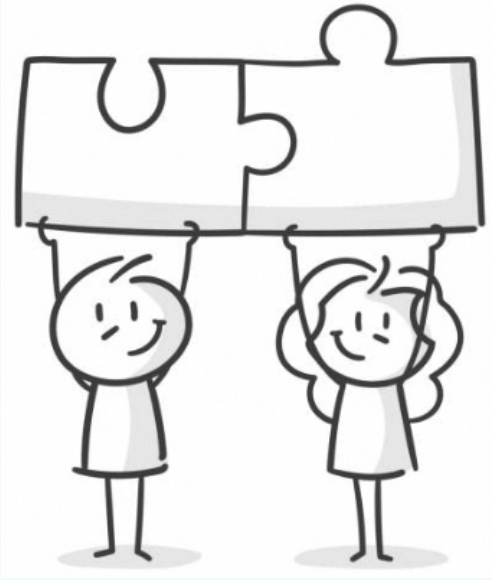
**A.** Design a reliance program by going blindly into the unknown without any guidance.



**B.** Develop an overly complex program that manufacturers cannot figure out.



**C.** Establish clear criteria, timelines, processes, procedures, and monitoring with stakeholders



# Knowledge check: Which type of reliance is preferred when designing a reliance program?

(a) Recognition

(b) Abridged Assessment

(c) Mutual Review

(d) All of the above

# Answer

All of the above.  To be fair, there really is no perfect answer. A reliance program should be tailored to the needs of the jurisdiction. Use the type of reliance or any combination of reliance that best suits your framework and needs.

# Knowledge check: Which part of the medical device life-cycle does reliance apply to?

(a) Premarket evaluation

(b) Post-market – Changes to a medical devices

(c) Post-market Surveillance

(d) All of the above

# Answer

Reliance can be applied across the total product lifecycle. How a reliance program is designed is to be determined by each jurisdiction.

# Further Information

- N89: Reliance Playbook
- WHO Good regulatory practices in the regulation of medical products, Annex 11, WHO Technical Report Series, No. 1033, 2021
- WHO Good reliance practices in the regulation of medical products: high level principles and considerations, Annex 10, WHO Technical Report Series, No.1033, 2021
- WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical device, Annex 3, Technical document, 2023
- WHO Global Benchmarking Tool + Medical Devices (GBT + medical devices) for evaluation of national regulatory systems of medical devices including in-vitro diagnostics

# Thank you

Debbie Ko, debbie_ko@hsa.gov.sg
Agnes Kijo, kijoa@who.int
Tammy Steuerwald, tammy.steuerwald@roche.com

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# Reliance Playbook Case Study: QMS Evidence & Audit Reliance

# Speakers




**Melissa Torres**

Executive Vice President
Technology & Regulatory Affairs

AdvaMed
mtorres@advamed.org





**Thiago Cunha**

Health Regulation Specialist
International Affairs Office

ANVISA
Thiago.Cunha@anvisa.gov.br

# Learning Objectives

By the end of this session, participants will be able to:



Understand the importance of a Quality Management System (QMS).

Understand the various QMS auditing schemes.

Understand how to apply reliance principles for QMS auditing that are appropriate for your jurisdiction.

# Agenda

- Overview of a Quality Management System (QMS)
- Overview of common audit schemes
  - ISO 13485 Certificate
  - Medical Device Single Audit Program (MDSAP)
- Reliance applied to QMS audits
- Reliance in practice: Regulatory Authority examples
- Q&A

# QMS

# What is a QMS?

Medical device manufacturers are required to develop and implement an effective QMS. To do this, a manufacturer must:

- Determine needs and expectations of customers
- Establish quality policy and quality objectives
- Determine needed processes and responsibilities
- Provide resources to attain quality objectives
- Establish methods for process measurement
- Determine process efficiency and effectiveness
- Determine means to prevent nonconformities
- Apply process for improvement of the QMS
- Identify all applicable regulatory requirements



# Flexibility of a QMS

- QMS requirements are intended to be applicable to any medical device organization regardless of size and activity as a basis for demonstrating and supporting compliance with applicable regulatory requirements.

- A manufacturer's QMS depends on:
  - The activities performed by the organization
  - The size and structure of the organization
  - The risk and complexity of their products and/or services
  - The regulatory requirements for the countries in which they supply devices and/or services

# QMS Covers the Full Product Lifecycle

**Management**
Evaluates top management's responsibility, quality policy, planning, resource management, and organizational structures

**Design & Development**
Audits full product lifecycle, including planning, inputs, outputs, verification, validation, design transfer, & design changes

**Production & Service**
Covers environmental controls, infrastructure, equipment calibration, process validations, traceability & nonconforming materials handling

**Purchasing Controls**
Examines supplier evaluation, selection, performance monitoring, and purchasing controls

**Measurement, Analysis & Improvement Process**
Reviews mechanisms for customer feedback, internal audits, control of nonconforming product & CAPA

**Authorization & Registration**
Ensures devices & facility registrations are accurately authorized and documented according to local jurisdictional requirements

**Adverse Event Reporting**
Audits procedures & records for reporting AE & issuing field safety corrective actions/advisory notices to authorities

# A Robust QMS is a License to Operate

### Compliance

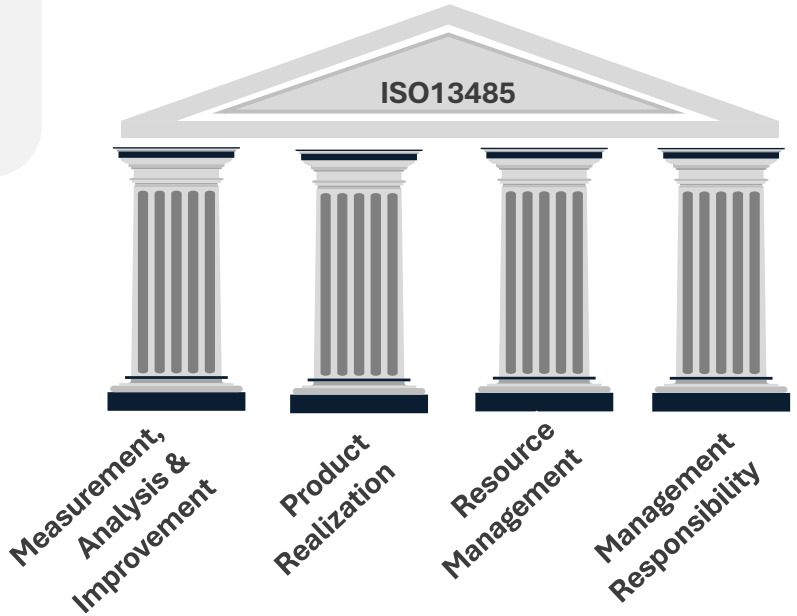
Laws, regulations & relevant essential principles of safety and performance is crucial

### Closed-loop QMS:

Ensuring continuous control & improvement (e.g., supplier release controls)

### International standards:

MDSAP & ISO 13485 serve as benchmarks for QMS in regulatory alignment




### Controlled development:

QMS confirms MD/IVDs are developed in controlled & safe environment

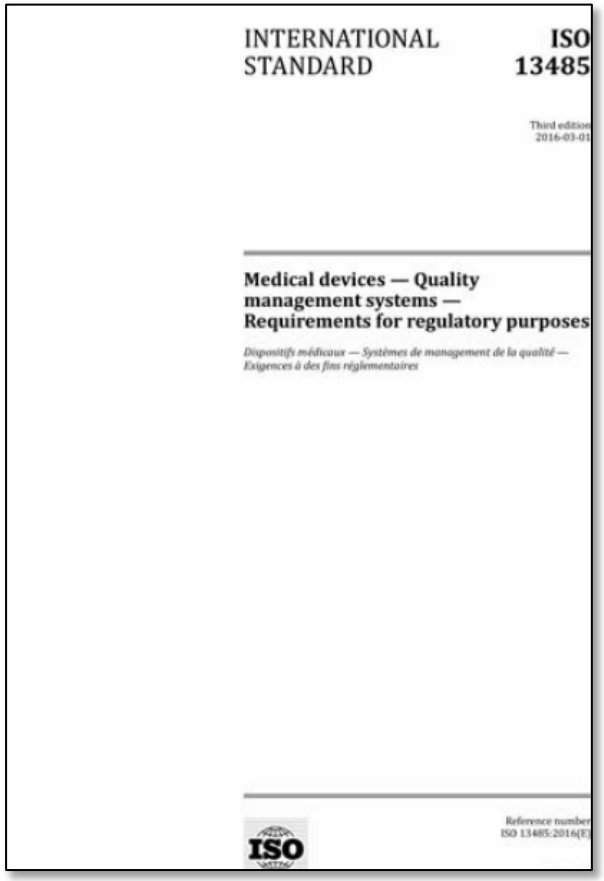
### Business operations

Supports robust business operations, integrating post-market surveillance for lifecycle management

# ISO 13485: 2016

*Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*

- Establishes requirements for a Quality Management System (QMS) that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including:
  - design and development
  - production
  - storage
  - distribution
  - installation
  - servicing and
  - final decommissioning/disposal of medical devices
- ISO 13485 employs a process-based approach



# ISO 13485:2016 — The Shared QMS Standard

Most medical device QMS regulatory requirements and audit pathways are built on the same core standard, ISO 13485:2016, which specifies QMS requirements for organizations across the medical device life cycle and underpins the EU conformity assessment, MDSAP, and many other Regulatory Authorities audit schemes.

- Process & risk-based approach to the full product life cycle
- Documented controls, records, and traceability
- Design, production, and service process controls
- Complaint handling, vigilance, and CAPA



## One standard, three audit lenses

**Notified bodies/Approved Bodies/Auditing Organizations** audit ISO 13485 for various jurisdiction certification schemes

**MDSAP Auditing Organizations** audit ISO 13485 requirements plus country specific requirements for the 5 MDSAP members

**Regulatory Authorities** audit based on regulatory requirements often aligned with ISO 13485

# Knowledge Check

Which statement best describes the role of ISO 13485:2016?

A. It is a market authorization.

B. Requirements for medical device quality management systems

C. Technical standard for product testing.



# Knowledge Check

Which statement best describes the role of ISO 13485:2016?

A. It is a market authorization.

**B. Requirements for medical device quality management systems**

C. Technical standard for product testing.



# QMS Audits

# Why QMS Audits are the Backbone of Market Access

A medical device quality audit is a systematic, independent, documented examination of objective evidence to judge how far a manufacturer's quality management system meets defined audit criteria. Across every major market, audits are the primary mechanism through which regulators and certification bodies verify safety, effectiveness, and ongoing compliance.



### Patient safety first

Audits confirm risk controls, design rigor, and production discipline that protect patients.



### Gateway to markets

Certificates and inspection outcomes determine where a device can legally be sold.



### Continuous oversight

Surveillance and re-inspection keep the QMS effective long after first marketing authorization.

# Three Pathways to Verify a QMS

## CERTIFICATION

### EU MDR QMS Certificate

Independent assessment against ISO 13485 and EU MDR / IVDR to grant and maintain CE certificates.

### ISO 13485 Certificate

Independent assessment against ISO 13485 to show compliance with the standard.

*Conducted by* **Notified Bodies (EU) Certification Bodies**

## SINGLE AUDIT

### Medical Device Single Audit Program (MDSAP)

One regulatory audit satisfying five authorities at once, built on ISO 13485 plus jurisdiction rules.

*Conducted by* **Recognized Auditing Organizations**

## INSPECTIONS/AUDITS

### Regulatory Authority Inspections/Audits

Government inspections verifying legal compliance with QMS requirements

Conducted by **Regulatory Authorities or Competent Authorities**

# MDSAP: One Audit, One Certificate, Five Markets

A single MDSAP audit is built on ISO 13485:2016 and layers each participating authority's specific regulatory requirements on top — so one evaluation satisfies them all.

MDSAP
Medical Device Single Audit Program



**ISO 13485:2016**

The common quality management foundation for every jurisdiction

*+ jurisdictional requirements*

| | |
|---|---|
| **United States** | Quality Management System Regulation — 21 CFR Part 820 (plus 803 & 806) |
| **Australia** | Therapeutic Goods (Medical Devices) Regulations, Schedule 3 |
| **Brazil** | Good Manufacturing Practices — RDC ANVISA 665/2022 |
| **Canada** | Medical Devices Regulations — Parts 1 and 1.1 |
| **Japan** | QMS Ordinance — MHLW Ministerial Ordinance 169 |

# Who Participates in MDSAP

## MEMBERS

**Australia** — TGA
**Brazil** — ANVISA
**Canada** — Health Canada
**Japan** — MHLW / PMDA
**United States** — FDA

Role: **Full decision-making authority**

## a OFFICIAL OBSERVERS

**World Health Organization**
**European Union**
**Singapore**
**United Kingdom**

Contribute to program development and monitor outcomes without decision-making authority.

Role: **Advisory, non-voting**

## AFFILIATE MEMBERS

**Argentina**
**Chinese Taipei**
**Israel**
**Kenya**
**Mexico**
**Malaysia**
**Republic of Korea**
**South Africa**

Recognition of MDSAP within their regulatory framework.

Role: **Adopting the program**

# Why MDSAP

- Provides for more effective, efficient and less burdensome regulatory oversight of the quality management systems of medical device manufacturers.
- Demonstrates feasibility of different forms of regulatory reliance.
- Promotes consistency, predictability, and transparency by:
  - standardizing the practices and procedures of participating regulators for the oversight of Auditing Organizations,
  - leveraging, where appropriate, existing requirements and procedures for conformity assessment, and
  - standardizing the practices and procedures of participating third-party Auditing Organizations.
- Increases efficiency and reduces duplication of regulatory audits.



# Notified Bodies: Roles and Responsibilities

A notified body is an organization designated by an EU Member State to assess the conformity of certain products before they reach the market. The notified body **conducts the QMS audits and issues EU MDR QMS Certificates.**

### Designated & monitored

Named by a Member State and audited by national authorities with EU expert oversight.

### Conformity assessment

Reviews technical documentation and **audits the QMS against ISO 13485 and MDR/IVDR**.

### Issues CE certificates

Grants the certificate that lets a device carry the CE mark within the EEA.

### Ongoing surveillance

Maintains oversight through **periodic and unannounced audits across the cycle.**

# EU: Audit Types Across the Certification Cycle

| STEP 1 | STEP 2 | STEP 3 | STEP 4 | STEP 5 |
|---|---|---|---|---|
| **Stage 1** | **Stage 2** | **Surveillance** | **Unannounced** | **Recertification** |
| *Readiness review* | *On-site QMS audit* | *Annual audits* | *Risk-driven* | *Cycle renewal* |
| Documentation and QMS design review to confirm the manufacturer is ready for full assessment. | Full on-site audit of QMS implementation and effectiveness against ISO 13485 and MDR/IVDR. | Periodic audits during the certificate's validity to confirm continued conformity. | Mandatory unannounced audits, sometimes at critical suppliers, to test real-world control. | Comprehensive reassessment before the certificate expires to renew the CE certificate. |

*Certificates typically run on a multi-year cycle with annual surveillance; nonconformities must be closed before certification is granted or maintained.*

# Regulatory Reliance for QMS Audits

# Why Reliance on QMS Audits Matters for Regulators

As device portfolios go global, repeating equivalent QMS audits in every jurisdiction strains finite regulatory resources. Reliance provides the ability to redirect the efforts of the Regulatory Authority towards the highest-risk work, while being able to rely on routine QMS audits conducted by other reliable sources.

### Efficient use of resources

Focus scarce review and audit capacity where it adds the most value.

### Less duplication

Avoid repeating equivalent audits already completed by a trusted authority.

### Greater predictability

More consistent, transparent process for auditing for manufacturers across various markets.

### Faster patient access

Speed the availability of safe, effective and high-quality devices.

### Stronger trust networks

Deepen trust and confidence among regulatory authorities.

### Global scalability

Reliance is a practical roadmap adaptable to authorities at different maturity levels.

# MDSAP: Three Types of Regulatory Reliance



## Work-sharing

Regulatory authorities collaborate to perform regulatory tasks jointly, sharing the workload and its outputs.

**EXAMPLE**
*The MDSAP members share resources to implement the program and accept the MDSAP certificates or reports in each of their jurisdictions.*



## Abridged pathway

A regulatory authority conducts a partial review that takes prior assessments by a trusted reference authority into account.

**EXAMPLE**
*A Regulatory Authority may take an MDSAP certificate or audit report into consideration to conduct a limited scope audit covering only country specific requirements.*



## Recognition

A regulatory authority accepts another authority's decision with minimal or no additional review.

**EXAMPLE**
*A Regulatory Authority may accept the MDSAP certificate or audit report to fully meet their QMS requirements without conducting additional audits or reviews.*

# Regulatory Reliance Example:

## Work-Sharing

- *The MDSAP members leverage each other's resources via work-sharing to:*
- *make decisions regarding the recognition of new Auditing Organizations*
- *conduct annual assessments of Auditing Organizations to ensure they continue to meet the criteria for MDSAP recognition*
- *create MDSAP policies and procedures; develop and improve program requirements; and*
- *conduct other operational activities that provide proper oversight of the program.*

IMDRF GRRP WG/N89: FINAL 2026 *Playbook for Medical Device Regulatory Reliance Programs*



# Work-Sharing: Reliance in Action

## What work-sharing means

Two or more authorities collaborate to carry out a regulatory task jointly — one piece of work is performed once and its output is shared across all participating authorities, each of which still makes its own decision.

The IMDRF Playbook's lead example: **MDSAP**

### One shared task
A single QMS audit is planned and executed once against an agreed common approach.

### Joint participation
Participating authorities set the requirements the shared audit must satisfy.

### Shared output
The resulting audit report and certificate are used by every participating authority.

### Independent decisions
Each authority still decides how to act on the shared result for its own market.

# Regulatory Reliance Example:

## Abridged Pathway

- *A Regulatory Authority (RA) reviewed their existing legal framework and identified they could recognize audit results (ISO 13485 certificates or MDSAP audit reports) from trusted authorities or institutions, but not decisions with respect to technical documentation review. Although they wish to implement a program allowing recognition of both areas from a reference RA, they proceeded with a phased approach:*
- *recognizing audit results in the short term*
- *abridging their review as a form of reliance for pre-market regulatory decisions, while working on legal changes to allow recognition of technical documentation review decisions in the future*
- *This example shows how you can start implementing reliance within current legal constraints while working toward your preferred approach.*

IMDRF GRRP WG/N89: FINAL 2026 *Playbook for Medical Device Regulatory Reliance Programs*

# Regulatory Reliance Example:

## Recognition

- *A Regulatory Authority decides to fully recognize MDSAP and ISO 13485 certificates to meet their jurisdiction's requirements for conducting QMS audits. They accept the certificates with no additional audits conducted to meet their requirements.*



# Key Takeaways

- A QMS documents the procedures and processes implemented throughout the lifecycle of a medical device and is essential for ensuring products are safe and effective for their intended use.
- ISO 13485:2016 facilitates global alignment of appropriate regulatory requirements for QMS applicable to organizations involved in one or more stages of the lifecycle of a medical device.
- Many Regulatory Authorities around the world utilize ISO 13485 as a part of their regulatory requirements for medical devices.
- Utilization of ISO 13485:2016 certificates or MDSAP certificates/reports are ways of ensuring that the design and manufacturing of a medical device is done in a way to ensure that the product meets specifications.
- MDSAP is a method of regulatory reliance and can be applied in different ways.

# Knowledge Check

Which type of reliance involves accepting another authority's decision with minimal or no additional review?

A. Work-sharing

B. Abridged pathway

C. Recognition



# Knowledge Check

Which type of reliance involves accepting another authority's decision with minimal or no additional review?

A. Work-sharing

B. Abridged pathway

**C. Recognition**



# Reliance Playbook Introduction

# Reliance Definition (Reliance Playbook – IMDRF)

"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**, while remaining responsible for its own decisions."



# Reliance Key Principles

- Leverage trusted regulatory work
- Avoid duplication of inspections and assessments
- Optimize regulatory resources
- Maintain regulatory sovereignty
- Improve efficiency without compromising oversight

Use trusted evidence ⟶ make independent national decisions

# Reliance and Inspection Activities

The Playbook explicitly recognizes that reliance can be applied to:

- Quality Management System (QMS) assessments
- GMP inspections
- Audit reports
- Manufacturing oversight activities
- MDSAP audits
- Post-market surveillance activities

# Important Consideration for Reliance

Not all ISO 13485 certificates provide the same level of confidence.

Important factors to consider:

- Who issued the certificate?
- Is the certification body recognized and credible?
- What confidence does the certificate provide?

**Reliance requires evaluation of the evidence source**

# Knowledge Check

What is one of the primary benefits of regulatory reliance?

A. Reduces duplication and optimizes resources

B. Removes all regulatory oversight

C. Eliminates national decision-making



# Knowledge Check

What is one of the primary benefits of regulatory reliance?

A. **Reduces duplication and optimizes resources**

B. Removes all regulatory oversight

C. Eliminates national decision-making



# MDSAP Overview

https://www.mdsap.global/

Regulatory Authorities

Auditing Organizations

Medical Devices Manufacturers



Assessment Program



Audit Program



Audit Reports

# MDSAP in Reliance Context

The Reliance Playbook identifies MDSAP as a major example of:

- Work-sharing;
- Regulatory cooperation;
- Reliance on trusted audits.

# MDSAP Audit Criteria

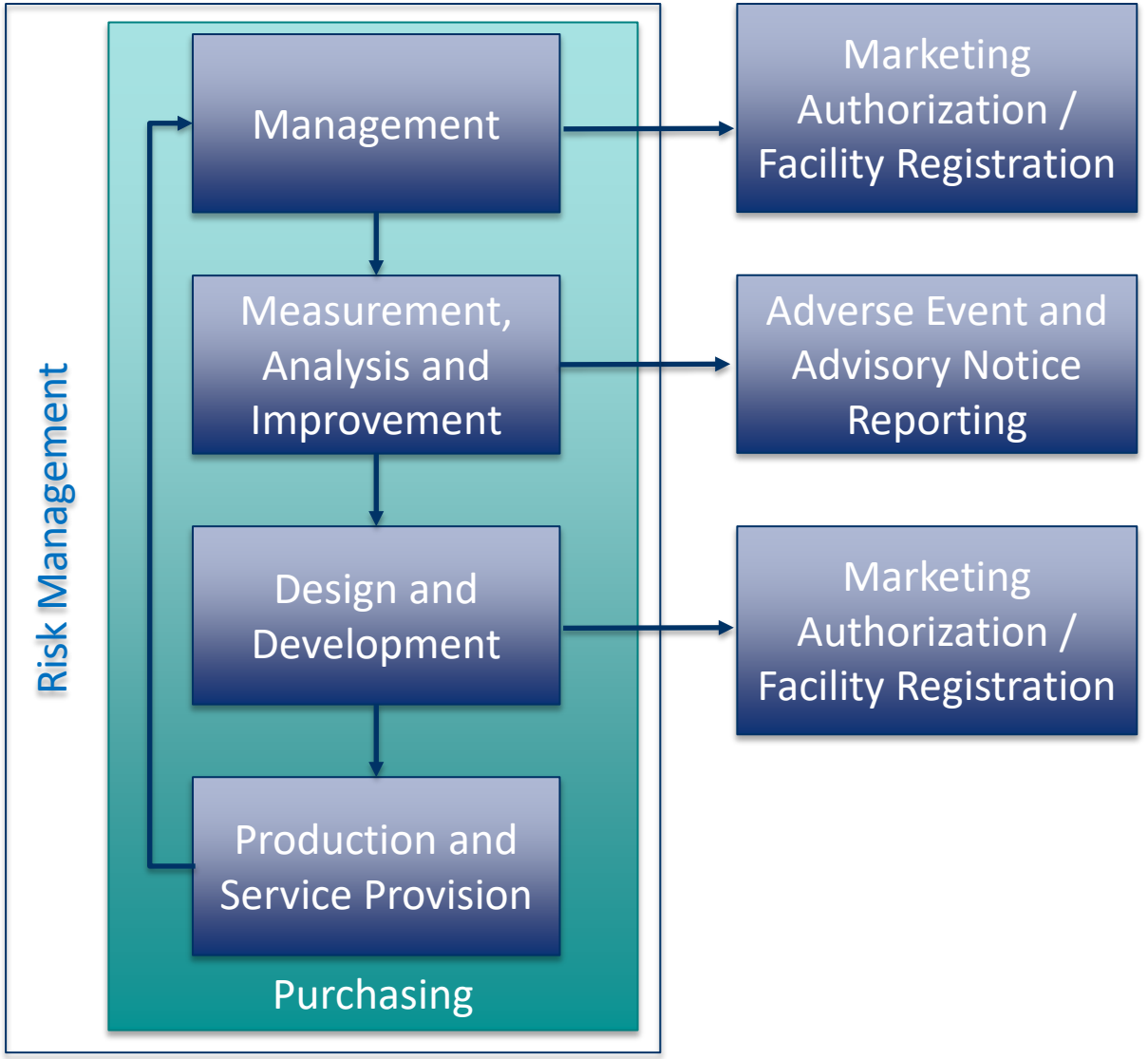
**ISO 13485**

**+**

**Specific Requirements:**



**MDSAP AUDIT APPROACH**



# MDSAP Assessment Criteria

**ISO 17021:2015**

**+**

**IMDRF/MDSAP/N3**

**+**

**IMDRF/MDSAP/N4**

**Assessment Activities**

- Management
- Use of external resources
- Measurement, Analysis & Improvement
- Competence Management
- Audit and certification decision
- Information Management

# MDSAP Reliable Outputs

MDSAP Certificates

- Must Allow authenticity check

MDSAP Reports

- Standard content (IMDRF/MDSAP WG/N24)
- ISO 13485 + Country Specific Requirements



# Knowledge Check

What gives regulators confidence in an MDSAP audit report?

A. The oversight, competence, and recognition of the AOs

B. The manufacturer's size

C. The country where the manufacturer is located



# Knowledge Check

What gives regulators confidence in an MDSAP audit report?

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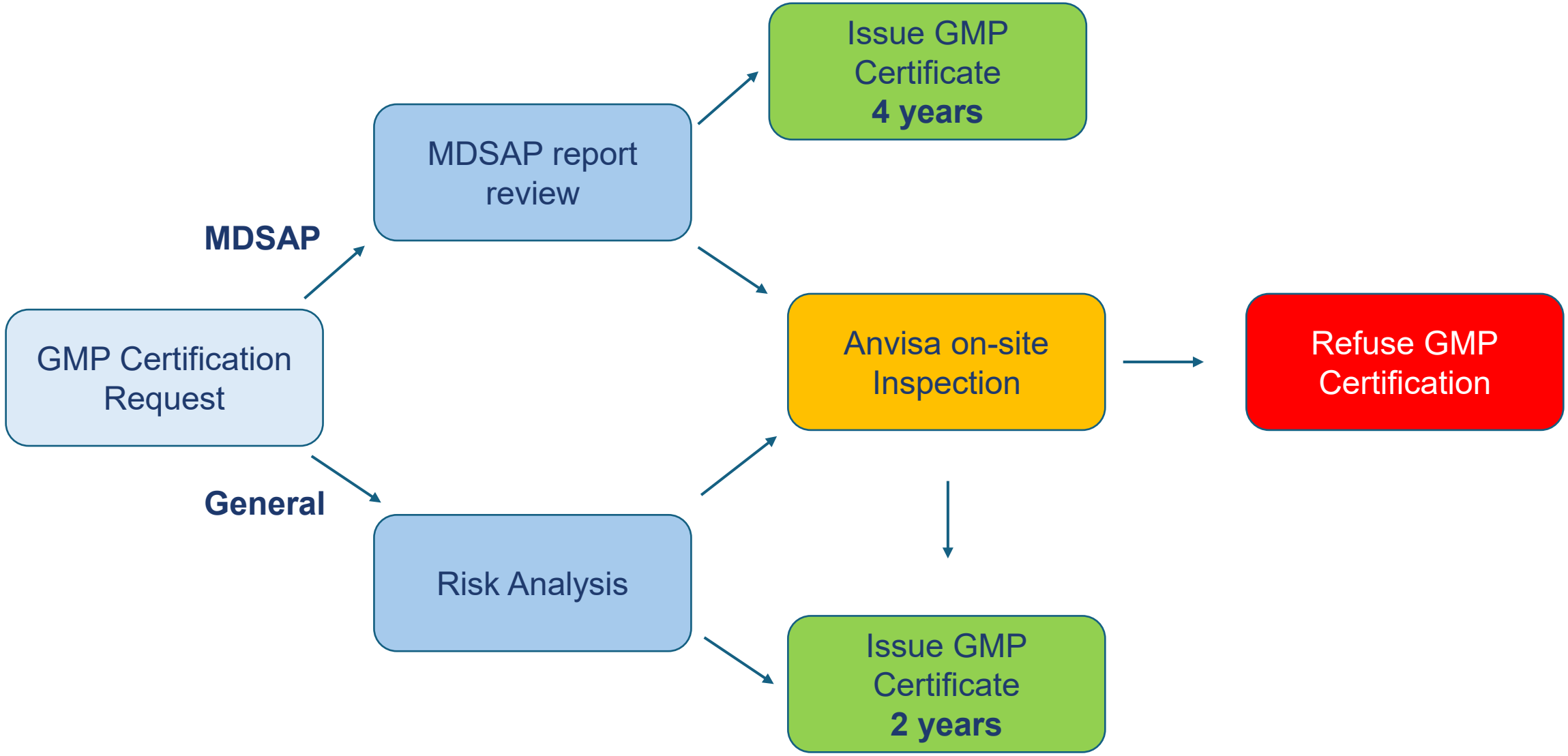


# ANVISA´s Experience

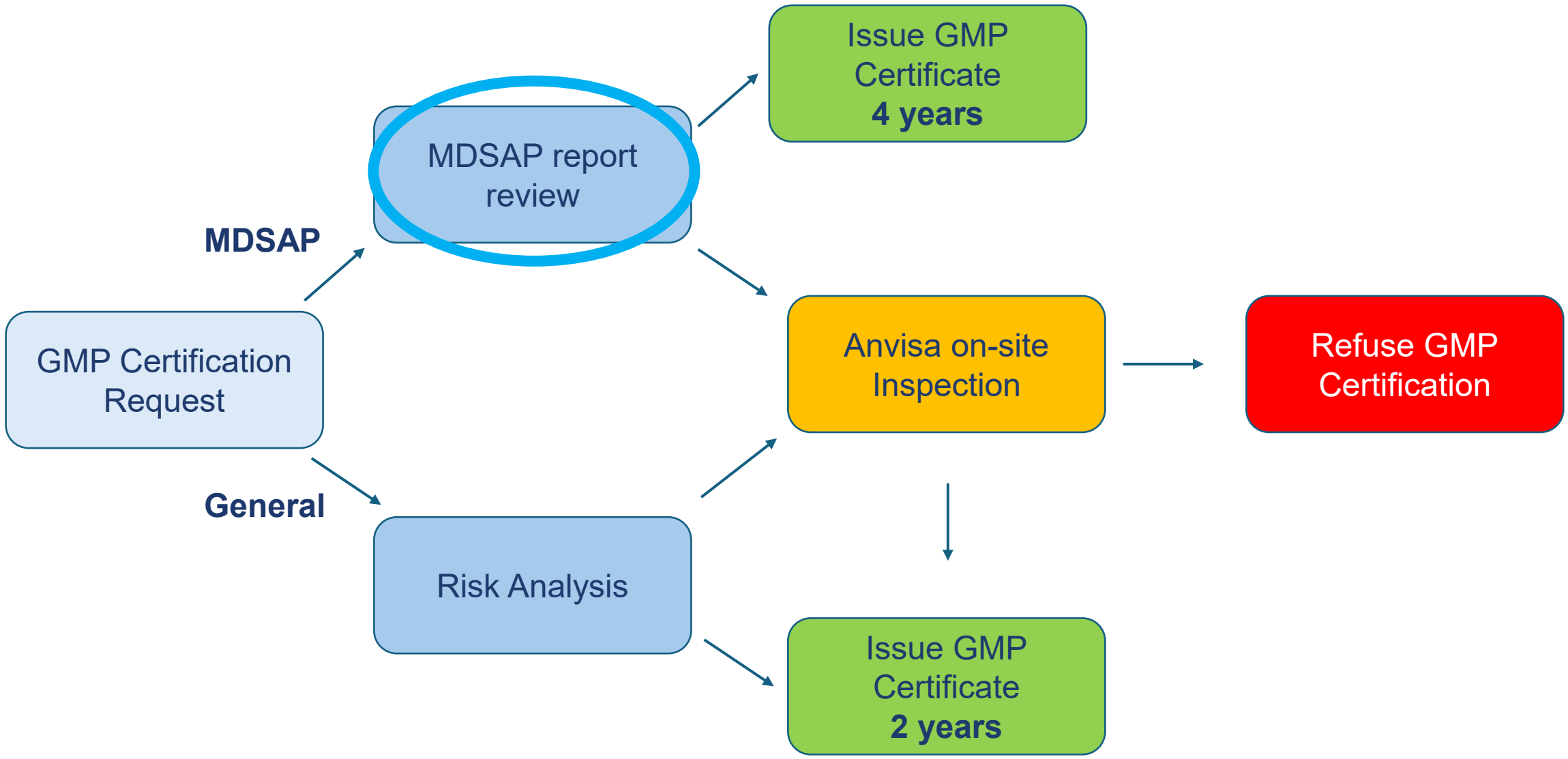
# Brazilian GMP Certificate

- Mandatory for market authorization of medical devices Risk Class III and IV (Resolution RDC n°687/2022)
- Valid for 2 years (general)
- Valid for 4 years (MDSAP)

# GMP Certification Flow



# GMP Certification Flow

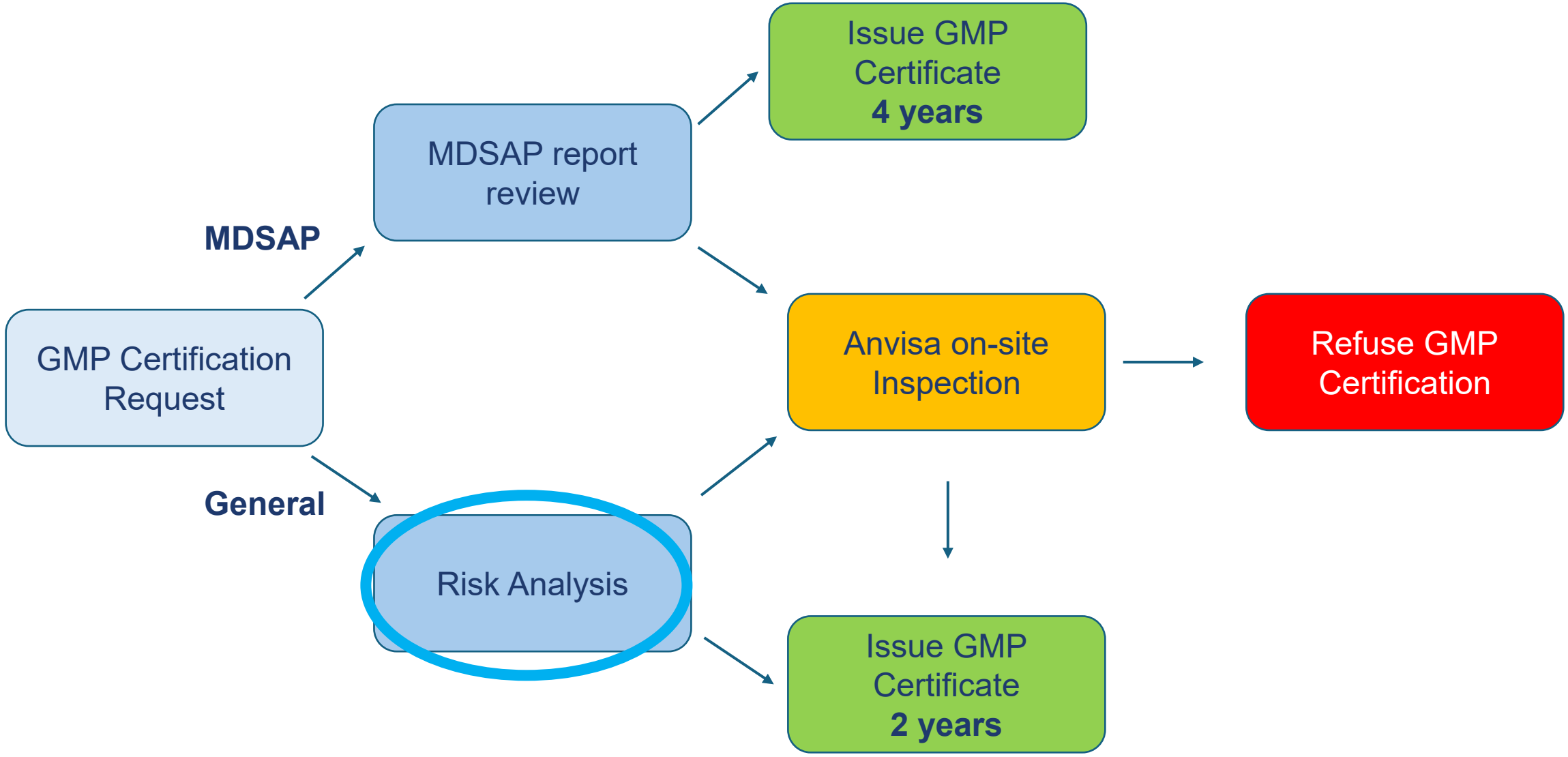


# Brazilian GMP Certification using MDSAP

- Must cover all requirements of RDC n°665/2022

- NGE Form reviewed (if applicable)
  - ✓ Approved corrective action plan
  - ✓ NCs grades 1 to 3 with satisfactory action plans
  - ✓ NCs grades 4 and 5 must be closed

# GMP Certification Flow

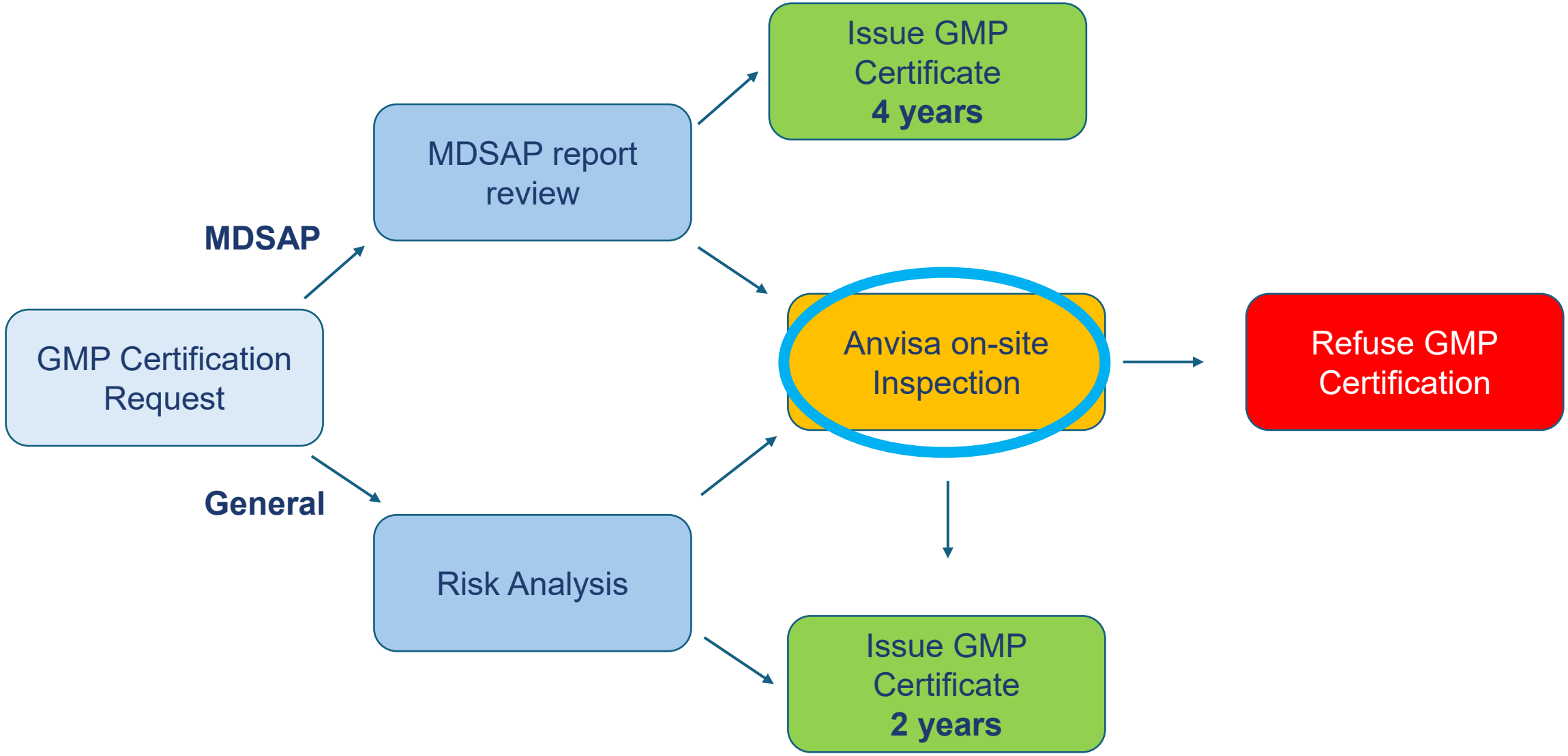


# Brazilian GMP Certification by Risk Analysis

Document review using the Risk Matrix

- Risk of the products
- Complexity of the facility and activities
- Compliance history with GMP standards
- Marketing complaints
- Major Changes (if applicable)
- Time since last Anvisa inspection

# GMP Certification Flow

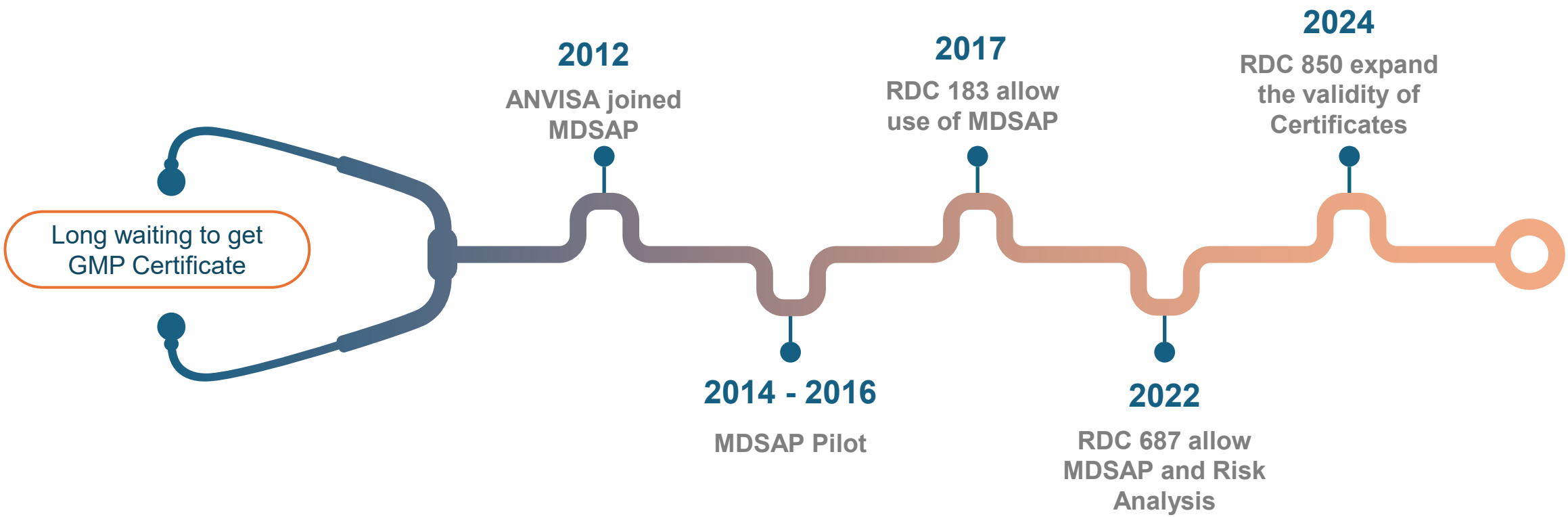


# Anvisa ´s GMP onsite inspection

- Normally 2 inspectors, 4 days
- Must cover all GMP Requirements (RDC 665/2022 )

- Inspection report describes company’s general information, inspected areas, non-conformities, legal basis and risk analysis.

# ANVISA´s Journey



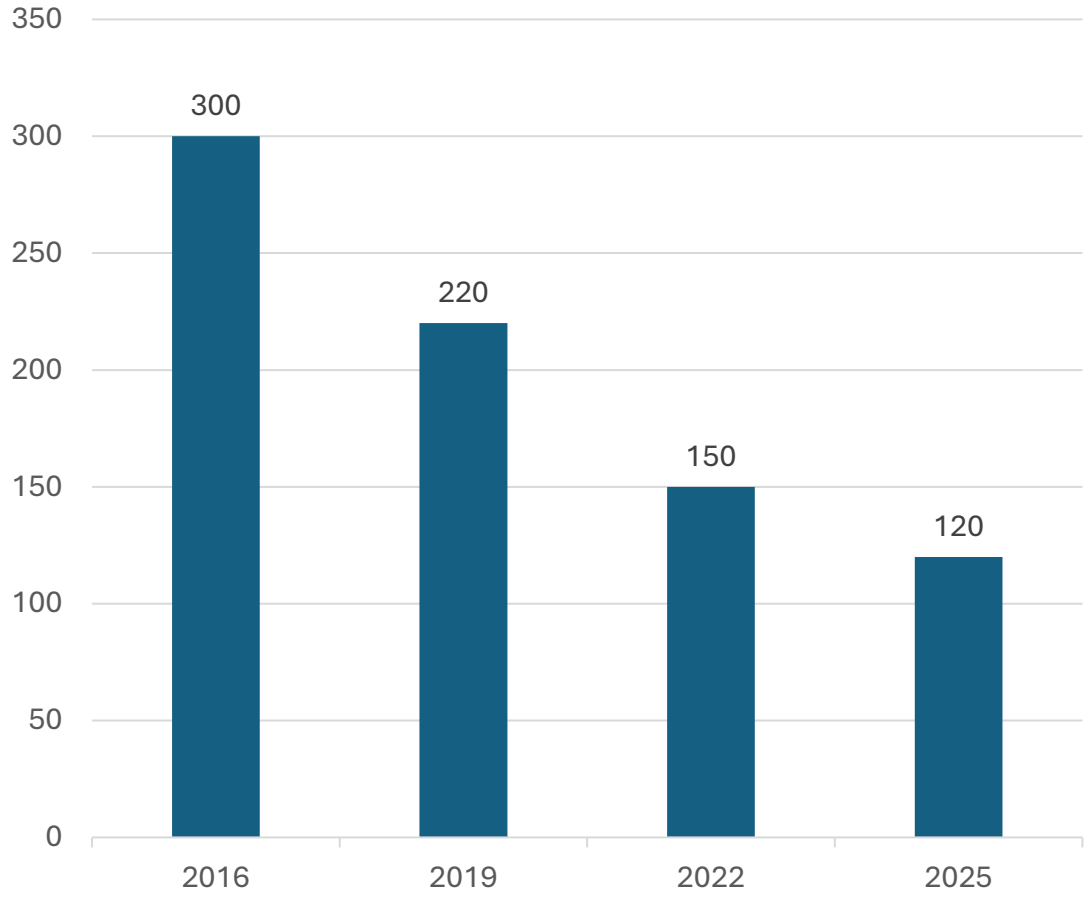
# Number of inspections performed by Anvisa per Year

**300** **Inspections performed in 2016**

**220** **Inspections performed in 2019**

**150** **Inspections performed in 2022**

**120** **Inspections performed in 2025**



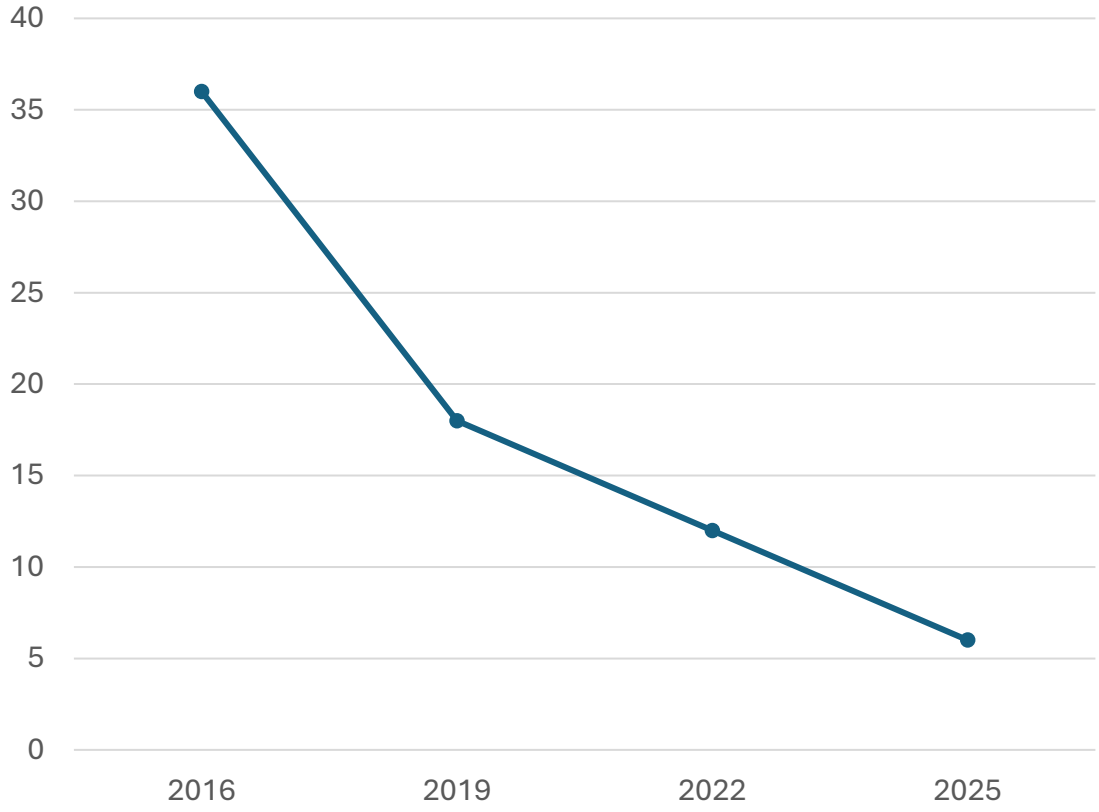
# Average waiting time to get the Brazilian GMP Certificate

**36** **Months to get Brazilian GMP Certificate in 2016**

**18** **Months to get Brazilian GMP Certificate in 2019**

**12** **Months to get Brazilian GMP Certificate in 2022**

**06** **Months to get Brazilian GMP Certificate in 2025**



# Implementation of Reliance Playbook

| IMDRF Reliance Principle | ANVISA´s Implementation |
|---|---|
| Use work from trusted authorities | Acceptance of foreign inspection reports as input for risk analysis certification |
| Use trusted audit programs | Recognition of MDSAP audit reports |
| Risk-based reliance | Risk analysis certification process |
| Resource optimization | Reduction of unnecessary duplicate inspections |
| Regulatory independence | ANVISA retains decision-making authority |
| Work-sharing and cooperation | Participate in an internationally recognized audit program |

# Thank you

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# Reliance Playbook Case Study

## Certificates, CFG/CFS, apostilles and practical verification

# Learning Objectives

By the end of this session, participants will be able to:



Identify and leverage available tools to confirm products identity and / or sameness

Understand how TGA approaches Reliance from a products' identity and / or sameness perspective

Understand pros and cons of the utilization of CFGs & CFSs and Apostille

# Reliance Playbook Case Study

## Certificates, CFG/CFS, apostilles and practical verification


- Speaker: John Jamieson
- Assistant Secretary
- Medical Devices and Product Quality Division
- Therapeutic Goods Administration (TGA)

# Agenda

- How certificates fit in a reliance framework
- What the TGA checks when using overseas regulatory evidence
- What do TGA certificates and registration records confirm
- Highlight how direct database verification is changing reliance practice

**15 minutes**

**Followed by Q&A**

# Reliance Playbook: practice lens



- Reliance means using another regulator’s work in a structured way
- The Playbook focuses on defining scope, processes, evidence and governance
- In practice, the key question is: does the evidence apply to this device, for this use, now?
- Certificates are one source of evidence — not the full reliance decision



# Australia’s framework: what the evidence is anchored to

## Australian Register of Therapeutic Goods (ARTG)

Medical devices generally need an ARTG inclusion before lawful supply in Australia, unless exempt or excluded

Public ARTG records support verification of status and scope

## Risk-based classes

Higher classification generally involves greater regulatory scrutiny

## Kind of medical device

An ARTG entry is for a “kind of medical device”

One entry may cover variants with defined shared characteristics

**For reliance, the point is to align the certificate or evidence to the application scope: Sponsor, manufacturer, class, Global Medical Device Nomenclature (GMDN) code, intended purpose and variants.**

# Comparable overseas regulators and regulatory evidence

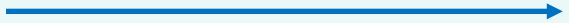
## The TGA allows applicants to use overseas assessments and approvals to support medical device applications in Australia.

Recognised evidence can support ARTG inclusion or abridged assessment.

Comparable regulators or assessment bodies include:
EU notified bodies, US FDA, Health Canada, MDSAP auditing organisations, Japan PMDA, Singapore HSA and UK approved bodies.

TGA reliance depends on the device type, the pathway and the application requirements — it is not automatic acceptance.

### Risk-based use of evidence



**Lower risk**
**Class I / IIa**

**Higher risk**
**Class III**

Evidence expectations increase with risk and assessment depth

Certificates alone may not establish scope, similarity or technical review

**The TGA looks at the source and scope of the overseas regulatory evidence relevant to the device class and application pathway**

# What the TGA checks in practice

### 1. Source

Is the evidence verifiable with the regulator or through an official database?

Are the certificate or document details consistent with the application?

### 2. Currency

Current, not expired, withdrawn, suspended or superseded

Dates and certificate scope are checked

### 3. Scope & ‘sameness’

Same manufacturer and device family

Same intended purpose and risk class

Models & variants are the same “kind of medical device”

**Practical test: does this evidence support this ARTG entry, for this device, at this time?**

# Australian CFS / Export Certificates: what they mean

## What they can confirm

The TGA can issue Certificates of Free Sale or Export Certificates for medical devices with a current ARTG inclusion

“Export Only” medical devices can be included in the ARTG as Class I medical devices
Note: if supplied in Australia they may be a higher risk class

## What still needs interpretation

The certificate and ARTG entry need to be read together:
Class, intended purpose & “kind of medical device” are important

Class I ARTG entries (including ‘export only”)
do not need TGA or third-party conformity assessment certification

**Key distinction: export documentation is administrative and**
**Not the same as ARTG inclusion or TGA conformity assessment certification.**

# Databases and the move to direct verification

## ARTG public search

Confirms ARTG status and public summary details

Useful for checking sponsor, product type and any special conditions

## TGA CA certificate search

TGA-issued Conformity Assessment certificates

Different from CFS or Export Certificates

## EUDAMED and other databases

Regulator databases are becoming more important for direct verification

EUDAMED is an example

**Reliance frameworks will evolve as authoritative databases become complete and searchable.**

# Key takeaways

Certificates help confirm regulatory status, but their meaning depends on wording and scope

TGA practice is to verify the source, currency, scope and product sameness of reliance evidence

ARTG records need to be interpreted through Australia's "kind of medical device" framework

TGA databases can provide direct verification

Reliance frameworks will evolve with Unique Device Identification (UDI) and improved regulator databases (eg EUDAMED)

# Reliance Playbook Case Study

## Certificates, CFG/CFS, apostilles and practical verification

## Industry Perspective


- Speaker: Sandra Ligia González,
- Executive  Secretary, Inter-American Coalition for Regulatory Convergence, Medical Technology Sector

# Agenda

- “Value” of CFGs & CFSs to confirm product identity and / or sameness
- How industry can facilitate the NRAs work

**5 minutes**

**Followed by Q&A**

# Background – CFG and CFS*



The **Certificate of Free Sale (CFS)**, the **Free Sale Certificate (FSC), the Certificate to Foreign Government (CFG), the Certificate of Free Trade (CFT) and the Declaration of Free Sale (DFS)** (hereafter referred to as "**CFS/CFG")** are different nomenclatures for the same document. Whichever term is used, these documents are meant to constitute one or all of the following: a) a document providing a level of attestation that a product does not suffer any commercialization restriction in the market in which it was manufactured or marketed; b) a document stating that a product complies and is in compliance with the regulations and technical norms of the country of origin and, thus, is able to enter the market of the **importing** country as condition of the importing country authorities; and c) it is a document able to make possible the registration of the product in the importing country, enabling the manufacturing company to participate in bids and other events in the importing country or to establish the conditions under which the CFS may be dispensed with for future exports.

- **Export-Only Certificates:** A Certificate of Exportability (COE) may be issued, upon request, for the export of MD/IVDs that may not be legally marketed in the origin country and that meet certain requirements for exportability.

*IACRC White Paper on CFG & CFS

# Background – Apostille*



- What is an Apostille
  - An Apostille is the Certificate issued under Article 3 of the Convention to certify the authenticity of the origin of a public document. Apostilles may be issued and presented in all Contracting Parties to the Convention.
- Certification of Origin and not content
  - The effect of an Apostille is limited, certifying only the authenticity of the origin of the underlying public document. It does so by certifying the authenticity of the signature on the document, the capacity in which the person signing the document acted and, where appropriate, the identity of the seal or stamp which the document bears.21
  - An Apostille does not relate in any way to the content of the underlying publicdocument.22 While the public nature of the document may imply that its content is true and correct, an Apostille does not enhance, or add any legal significance to, the legal effect that the signature / seal / stamp would produce without an Apostille. In this regard, the Special Commission recommends that Competent Authorities include a note on their Apostilles about this limited effect.

*Apostille Handbook. Practical Handbook on the Operation of the Apostille Convention

# Background



- CFGs and CFS
  - Time-limited validity
  - Market authorizations might be withdrawn throughout the validity period
- Apostille and eApostille
  - Simplified legalization process
  - Authenticity of the origin of the document – not the content

# Opportunities & Challenges in a Digital Era

- National Regulatory Authorities:
  - Direct access to product information through available data bases:
    - National Regulatory Authorities: Australia, Brazil, Canada, United States, Singapore, etc.
    - Medical Device Single Audit Program
    - Accredited Organizations – International Standards, i.e. ISO 13485
- Applicants
  - Provide accurate location of data (links, QR codes, etc.)

# Key Takeaways



- Opportunities to leverage the available digital tools:
  - Reliance - Facilitate the implementation
  - Reliance and Regular Pathways:
    - Certainty to the authorization processes
    - Efficiency in the regulatory processes
  - Continue evolution from paper-based documents: CFGs/CFSs & Apostille to electronic versions to complete obsolescence of the requirement
- Industry – co-responsibility to facilitate access to product information
- Continued capacity building to excel the utilization of data bases

# Thank you


- Sandra Ligia González
- **Email** sandra@interamericancoalitiion-medtech.org



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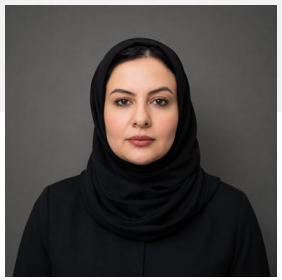
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# Opportunities for Reliance within the Elements of Conformity Assessment and Ensuring Sovereignty











- MHRA: Dr. Rob Reid (Rob.Reid@MHRA.gov.uk)

MHRA: Dr. Francisco Delgado (Francisco.Delgado@MHRA.gov.uk)

SwissMedic: Markus Wälti (Markus.Waelti@swissmedic.ch)

Saudi-FDA: Razan J. Asally (rjasally@sfda.gov.sa)

J&J: Sharad Shukla (sshukl10@ITS.JNJ.COM)

# Agenda:

- Introductory Presentation from our SFDA colleagues – 10 minutes
- Some explanation regarding today's activity – 2 minutes
- We'll jump into break-out groups – 10 minutes
  - For clarity groups will be only online or only in-person for ease
- We'll regroup and share our learnings -15 minutes

(timings are approximate)

# SFDA Medical Device Regulatory Reliance
# A Practical Case Study

From Primary Regulatory Pathway to Regulatory Maturity


- **Presenter:** Dr. Razan Asally
- Director of Clinical Trial and Biotechnology, Saudi Food and Drug Authority (SFDA)

# Objectives

This presentation will cover:

1

**Evolution of the SFDA Reliance Pathway**

Understand how the SFDA Medical Device Regulatory Reliance pathway has developed over time.

2

**Eligibility Criteria & Scope Exclusions**

Identify the eligibility and exclusion criteria governing use of the reliance pathway.

3

**Practical Case Study**

Demonstrate practical application of the reliance pathway through a real-world regulatory scenario.

# Evolution of the SFDA Reliance Pathway

**BEFORE 2021**

## Primary Regulatory Pathway

Regulatory decisions were largely based on marketing authorizations issued by Recognized Regulatory Authorities (RRAs), enabling timely patient access while building SFDA's regulatory expertise.

**AFTER 2021**

## Regulatory Maturity

Reliance evolved into a complementary tool. Scope and depth of SFDA assessment are now determined by product risk, available evidence, and Saudi national regulatory requirements.

RRA decisions continue to **support** — but do not replace — the SFDA's independent regulatory assessment.

# Recognized Regulatory Authorities (RRAs)

| | |
|---|---|
| **Australia**<br>TGA | **Canada**<br>Health Canada |
| **European Union**<br>EU MDR / Notified Bodies | **Japan**<br>PMDA |
| **United Kingdom**<br>MHRA | **United States**<br>FDA |

**Note:** The list of Recognized Regulatory Authorities  be expanded to include additional jurisdictions, including IMDRF Management Committee (MC) member jurisdictions, following periodic reviews by the SFDA.

# Eligibility Criteria & Scope Exclusions

## ✓ ELIGIBLE IF...

- Valid RRA marketing authorization
- Device identical to RRA-authorized version
- Compliant with Saudi national requirements

## ✗ NOT ELIGIBLE IF...

- Based on self-declaration only
- Relies on predicate equivalence
- Custom-made for individual patients
- Active Post-Market safety concerns or recalls

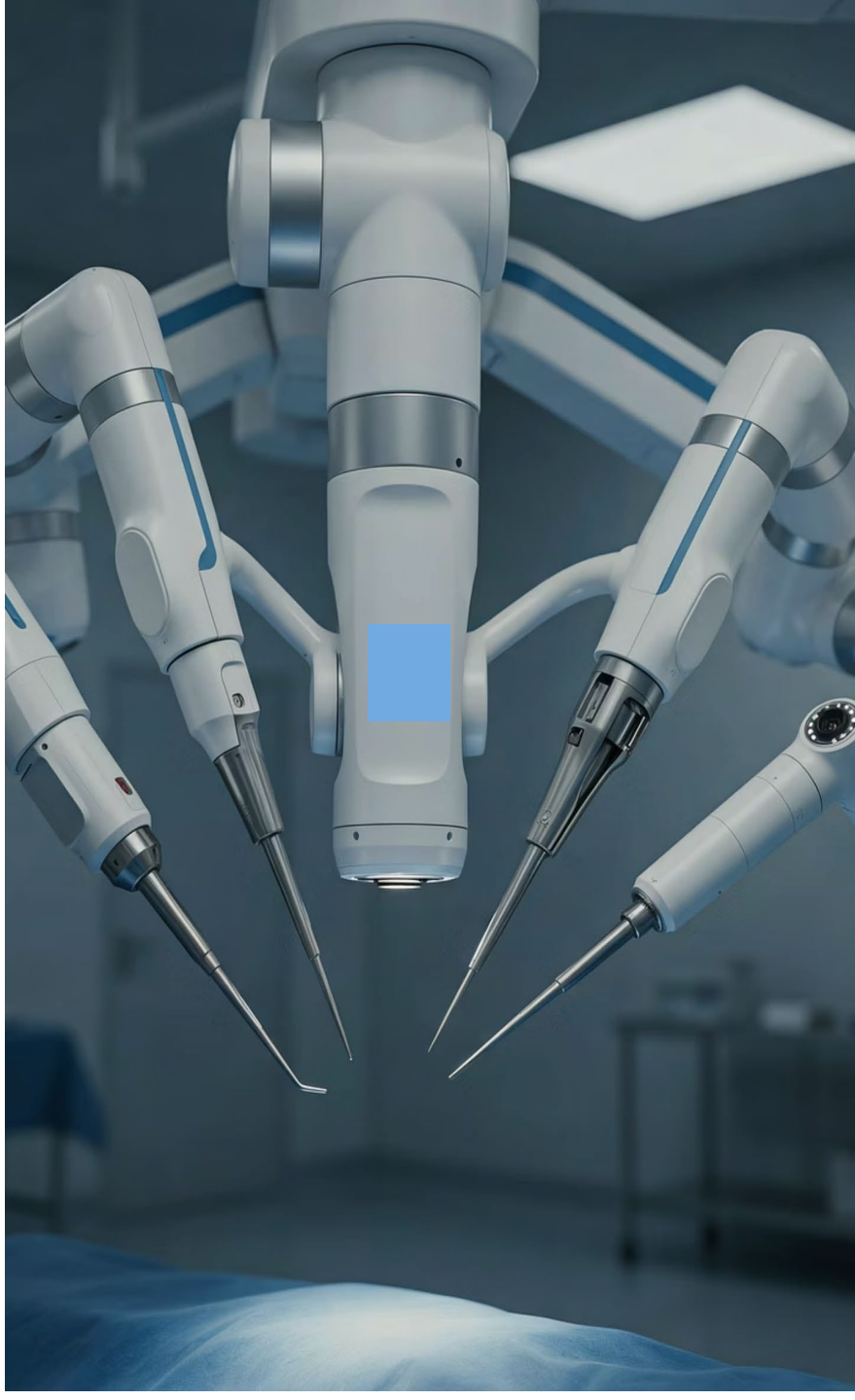
# Practical Case Study

SCENARIO

A manufacturer submits an application for a **surgical robot** through the SFDA Medical Device Reliance pathway. The application presents the following profile:

- Holds a **valid marketing authorization** issued by the US FDA and Health Canada.
- Device is **identical** to the US FDA authorized product in design, manufacturing, and intended use.
- **Complies** with Saudi national regulatory requirements.
- Includes **complete supporting documentation** as required by SFDA.

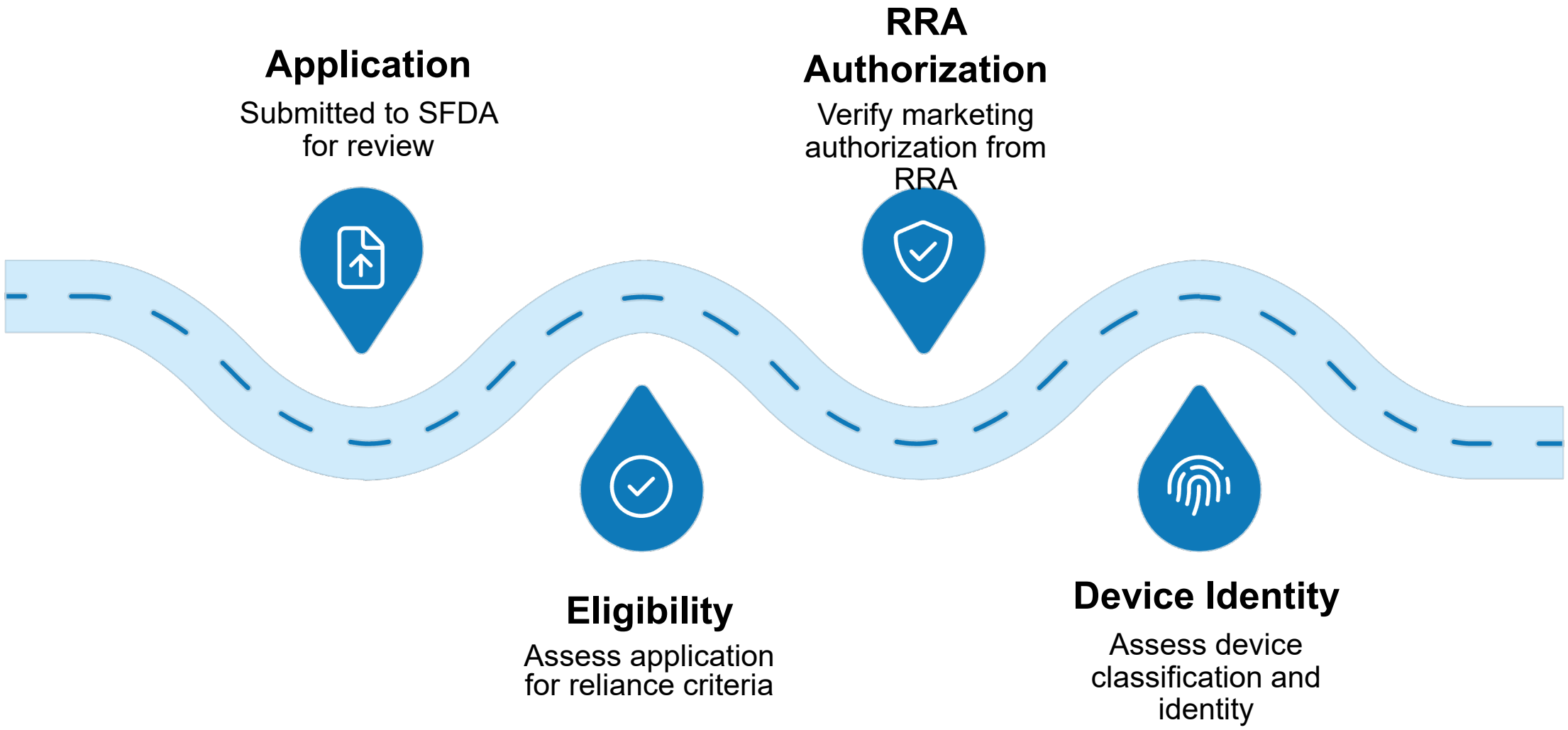
**Can this device qualify for the SFDA Medical Device Regulatory Reliance pathway?**



# Finlizing requirements before submission

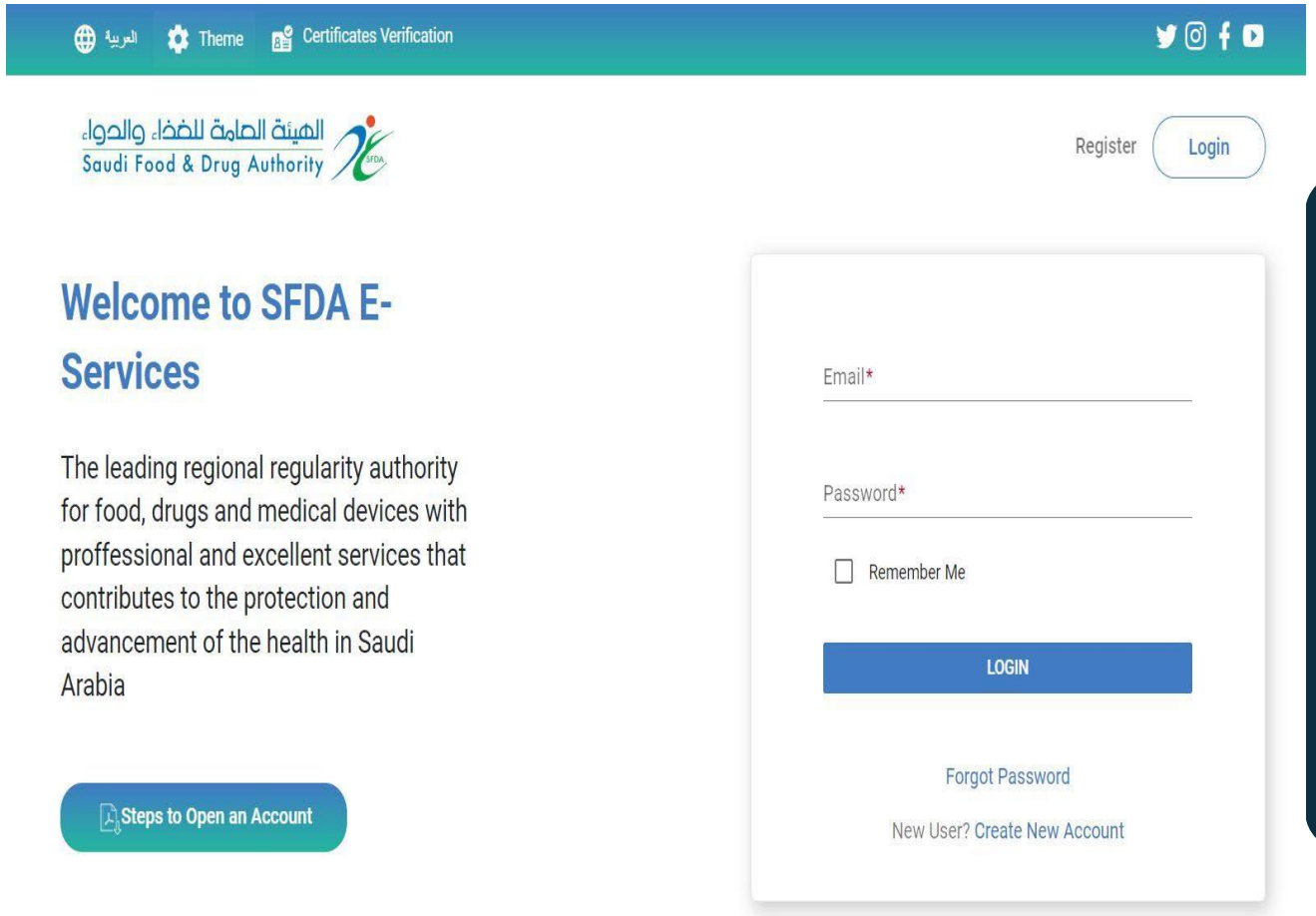


# Regulatory Assessment Process



# Application Through GHAD — Step 1

SUBMIT APPLICATION



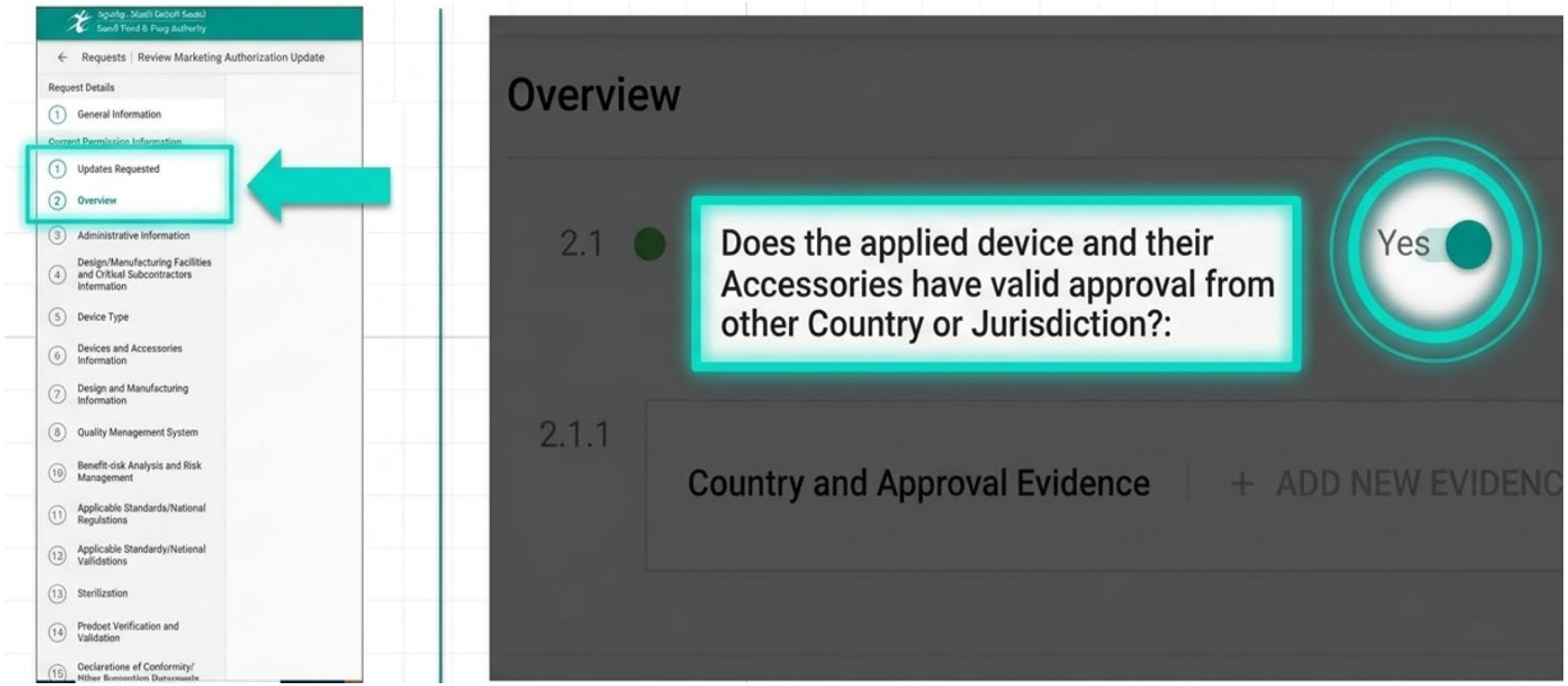

## MDMA Submission

The applicant initiates the Medical Device Marketing Authorization (MDMA) through the GHAD electronic portal, the SFDA submission platform for medical regulatory applications.

https://ghad.sfda.gov.sa/en/login

# Application Through GHAD — Step 2

ENABLE RELIANCE PATHWAY



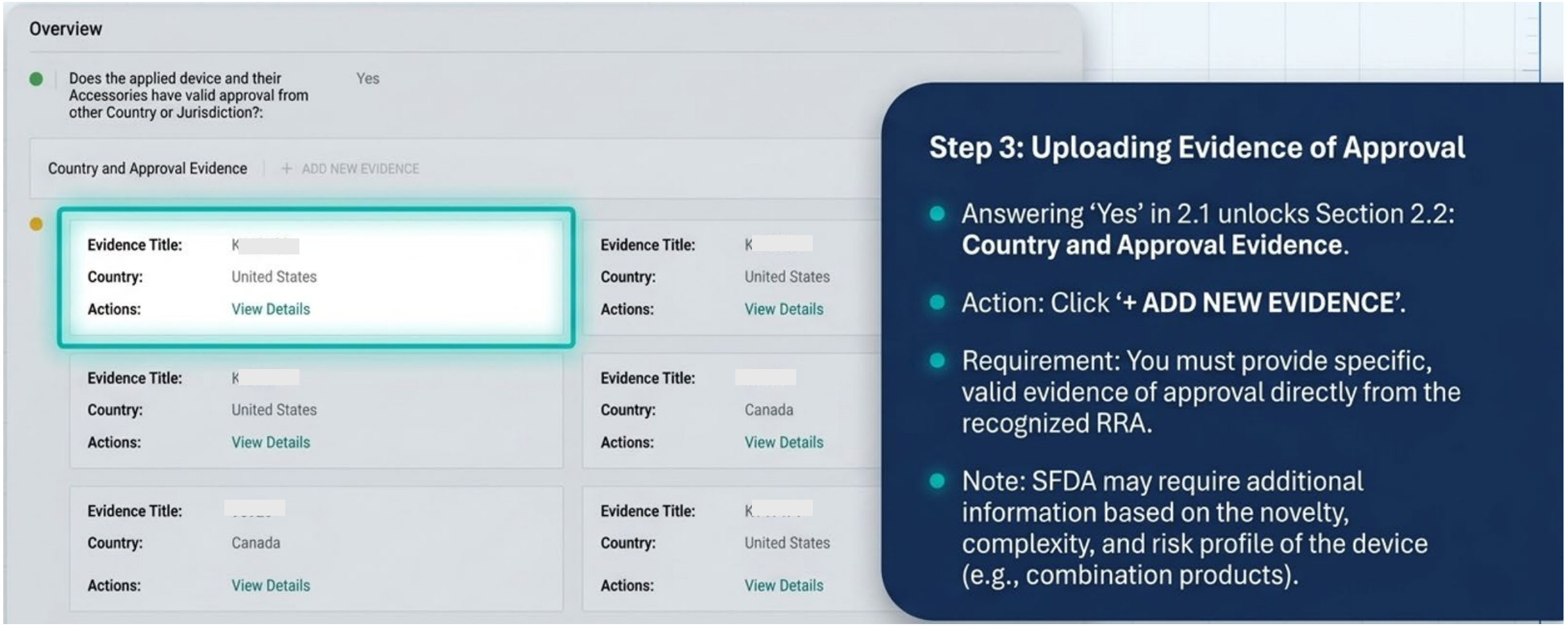

## Enable Reliance Pathway

This selection formally declares the applicant's intent to utilize an RRA marketing authorization as supporting evidence for the SFDA's regulatory assessment.

- Failing to select the reliance option will route the application through the standard pathway.

# Application Through GHAD — Step 3

RRA EVIDENCE UPLOAD



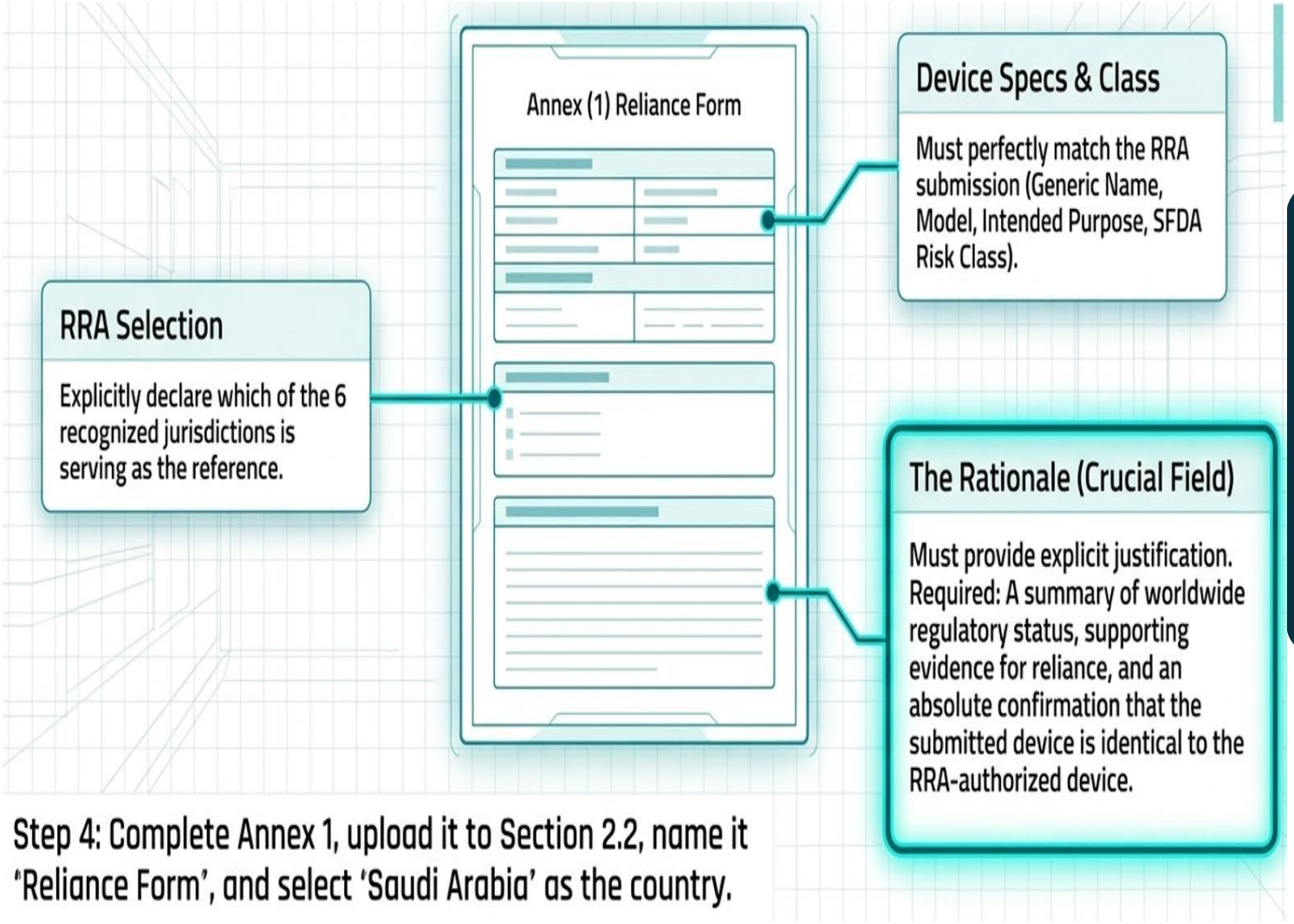

## Step 3: Uploading Evidence of Approval

- Answering 'Yes' in 2.1 unlocks Section 2.2: **Country and Approval Evidence.**
- Action: Click **'+ ADD NEW EVIDENCE'.**
- Requirement: You must provide specific, valid evidence of approval directly from the recognized RRA.
- Note: SFDA may require additional information based on the novelty, complexity, and risk profile of the device (e.g., combination products).

**Marketing Authorization Certificate** **Validity Confirmation** **Supporting Documentation**

# Application Through GHAD — Step 4

RELIANCE FORM SUBMISSION




**Annex 1 — Reliance Form**

The applicant uploads the completed Reliance Form (Annex 1), which provides a structured declaration confirming eligibility and summarizing the reliance basis for the SFDA's review.

# Accelerated review timeline

Standard Review: 35 – 60 Working Days

(Depending on product type and Class A-D risk profile)

The Reliance Pathway Advantage

**35 Working Days**

Across all risk classes (A, B, C, and D).

**Note:** This reduction relies on prior RRA approval instead of a full independent assessment and is strictly subject to complete eligibility and flawless documentation.

# Key Takeaways

### Efficiency Pathway

Regulatory reliance leverages decisions from Recognized Regulatory Authorities to streamline the SFDA review process.

### Independent Assessment

Reliance does not replace the SFDA's independent regulatory review — it informs and supports it.

### Full National Compliance

Authorization through reliance requires full compliance with Saudi national requirements, without exception.

### Risk-Based Approach

The SFDA applies a proportionate, risk-based framework while maintaining patient safety, product quality, and regulatory confidence.

# Opportunities for Reliance – Break-out Activity

# Our Exercise Today:

- We will provide information to the teams with salient points regarding international reliance and conformity assessment
- We will provide some rough definitions of Conformity Assessment and the 5 elements of there-of
- Each team will be come together to answer three questions regarding International Reliance and your jurisdictional approach
- We ask you:
  - Assign note taker
  - time-keeper, and
  - a representative

# Reliance and Sovereignty – Finding the Right Balance

- Reliance is not about giving up responsibility. Reliance is about using trusted information to make better use of limited regulatory resources while retaining full accountability for the final decision.

# Three Questions for the Breakout Groups

1. Where does reliance create the greatest value?
   - Which conformity assessment activities or which elements of conformity assessment could benefit most from leveraging work already performed elsewhere?
2. What are your jurisdiction's non-negotiables?
   - Which activities must remain under direct national oversight?
3. What creates trust?
   - What characteristics must another authority possess before you are willing to rely on its assessments?
   - Is it legal alignment? – Transparency? – Access to assessment reports? – Past experience? – Or something else?