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Playbook for Medical Device Regulatory Reliance Programs

AUTHORING GROUP

Good Regulatory Review Practices

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Preface

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1. Introduction

Medical devices¹ present great technological variation and diverse global regulatory frameworks, with rapid development and adoption timelines. As worldwide regulatory activities expand and health technologies grow more complex, resources for regulators, industry, and conformity assessment bodies become increasingly constrained.

Regulatory reliance is one approach that addresses these challenges by allowing regulators to leverage the work done by trusted partners to support regulatory decision-making processes – an approach promoted by the World Health Organization (WHO) in its *Good Reliance Practices in the regulation of medical products* (see [Section 7.1](#)).

Appropriately designed regulatory reliance programs benefit the entire medical device ecosystem, with the ultimate goal of improving patient access to safe and effective medical devices that meet the Essential Principles of Safety and Performance in IMDRF/GRRP WG/N47 - *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*.

What This Playbook Offers

The goal of this playbook is to promote efficient and aligned approaches to regulatory decision-making by providing examples and considerations to support the development and implementation of regulatory reliance programs. It builds on existing regulatory reliance approaches to provide high-level strategies, including specific considerations and suggested steps that:

- are sufficiently flexible to apply to various medical device technologies and throughout the product lifecycle
- are adaptable to suit regulator’s needs

This document aims to drive reliance program adoption. Following these considerations will advance reliance, convergence, and harmonization practices while strengthening communication and trust among regulatory jurisdictions. These achievements can be facilitated by continued development and adoption of globally aligned regulatory resources, such as IMDRF guidance and consensus standards.

This reliance playbook is written as guidance for regulatory authorities (RAs), both those embarking on their first reliance program and those aiming to enhance their existing program or create additional reliance frameworks. Although intended for regulators, this document is relevant to all medical device stakeholders.

¹ Unless otherwise specified, the use of the term “medical devices” in this document includes in vitro diagnostic (IVD) and non-IVD medical devices.

2. Scope

The information in this document applies to all medical devices, including IVD medical devices. Unless otherwise specified, the principles discussed can be applied to any phase of the product lifecycle (e.g., technical documentation² review, evaluation of quality management systems, post-market activities, device changes requiring regulatory review) and are meant to work with a variety of reliance mechanisms (e.g., harmonized decisions, unilateral or multilateral/mutual recognition, work-sharing). Reliance can also be deployed as a strategic tool during public health emergency contexts, such as pandemics or natural disasters.

As a regulator looking to set up a reliance program, you should note:

- There is information in this document about factors that are beyond your direct control, but is included to give you a broader understanding of factors impacting the design and implementation of a reliance program
- It is not intended to provide an IMDRF-endorsed reliance framework, nor promote one specific reliance framework
- The extent to which an RA relies on a trusted partner's work can vary. You have flexibility in determining your reliance extent
- You maintain flexibility in how you conduct activities within the reliance scope, including the use of third parties

This document provides advice and information to help you establish a program that best meets your and your jurisdiction's needs.

² GHTF/SG1/N78:2012- *Principles of Conformity Assessment for Medical Devices* includes a definition and additional discussion of "technical documentation" as used in this document.

3. Definitions

- 3.1.** *Abridged Regulatory Pathway:* Regulatory procedures facilitated by reliance, whereby a regulatory decision is solely or partially based on application of reliance. This usually involves some work by the regulatory authority that is practicing reliance.

(Modified from WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report, Annex 10)

- 3.2.** *Convergence:* A voluntary process whereby the regulatory requirements in different countries or regions become more similar or “aligned” over time. Convergence results from gradual adoption of internationally recognized technical guideline documents, standards, scientific principles, common or similar practices and procedures, or the establishment of appropriate domestic regulatory mechanisms that align with shared principles to achieve a common public health goal.

(WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report, Annex 11)

- 3.3.** *Harmonization:* A process whereby the technical guidelines of participating authorities in several countries are made uniform.

(WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report, Annex 11)

- 3.4.** *Medical Device:* Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- investigation, replacement, modification, or support of the anatomy, or of a physiological process,
- supporting or sustaining life,
- control of conception,
- cleaning, disinfection or sterilization of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

NOTE 1: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,

- devices for in-vitro fertilization or assisted reproduction technologies.

NOTE 2: For clarification purposes, in certain regulatory jurisdictions, devices for cosmetic/aesthetic purposes are also considered medical devices.

NOTE 3: For clarification purposes, in certain regulatory jurisdictions, the commerce of devices incorporating human tissues is not allowed.

(IMDRF/GRRP WG/N47)

- 3.5.** *Recognition:* Acceptance of the regulatory decision of another regulator or trusted institution. Recognition should be based on evidence that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority.

(Modified from WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report, Annex 10)

- 3.6.** *Reference Regulatory Authority:* A national or regional authority or a trusted institution, which can include the WHO prequalification program or a conformity assessment body, whose regulatory decisions and/or regulatory work products are relied upon by another regulatory authority to inform its own regulatory decisions.

(Modified from WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report, Annex 10)

- 3.7.** *Regulatory Submission:* A regulatory submission can be any type of information related to a medical device regulatory process. This includes but is not limited to a request for approval/authorization to market a device, any communications relating to the original submission, and any request for modification to an existing approval. A regulatory submission includes the technical documentation and an explanation of how the technical documentation demonstrates that the medical device conforms with essential principles of safety and performance and other relevant regulatory requirements and guidelines. Guidance on contents for a regulatory submission is provided in IMDRF/RPS WG/N9 and IMDRF/RPS WG/N13.

(IMDRF/GRRP WG/N59)

- 3.8.** *Reliance:* The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

(WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report, Annex 10)

- 3.9.** *Work-Sharing:* A process by which regulatory authorities of two or more jurisdictions share activities to accomplish a specific regulatory task.

(Modified from WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report, Annex 10)

4. Overview of Medical Device Regulatory Reliance Programs

4.1. Role of regulatory reliance

Reliance programs streamline and expedite regulatory processes by allowing regulators to leverage assessments performed by trusted partners. Adopting appropriate reliance approaches helps improve:

- *Efficiency*: reducing duplicative work while maintaining rigorous oversight
- *Resource optimization*: freeing up your resources for priority areas or emergency responses like pandemics
- *Industry support*: minimizing regulatory burdens, including those on small and medium-sized enterprises

Your reliance program should offer concrete participation incentives, such as shorter review timeframes. Reliance programs that are voluntary in nature and not the only possible pathway for a given regulatory process are more likely to demonstrate benefit.

Understanding Key Concepts

Reliance, convergence, and harmonization are distinct but interconnected concepts, as shown in Table 1:

- **Reliance** is where an RA leverages another reference RA's assessment or decision to reach their own decision
- **Convergence** refers to efforts to align regulatory practices and requirements among different RAs. It does not mean decisions made by other organizations are always accepted or recognized
- **Harmonization** aims for a higher level of uniformity by creating consistent standards and requirements across jurisdictions, striving for global regulatory consistency

While reliance focuses on using existing approvals or decisions, convergence and harmonization aim to achieve broader alignment across different regulatory systems. Each plays a different role in regulatory practice. Convergence and harmonization can facilitate reliance, but you can implement reliance programs without them. Understanding these concepts and using reliance with your other regulatory programs will improve efficiency and cooperation in medical device regulation.

Table 1. Comparing Reliance, Convergence, and Harmonization

Concept	Definition	Example
Reliance	RA considers the assessments made by a reference RA when making its own decisions	See Section 4.2 for several examples
Convergence	Voluntary, gradual alignment of regulatory frameworks through shared guidance and principles	Common use of IMDRF guidance or ISO standards
Harmonization	Formal unification of technical requirements among multiple RAs	CE-marking system within the European Union

4.2. Types of regulatory reliance

This section explores some reliance types you can use to develop a reliance program for your specific needs. Each reliance type is summarized in Table 2 and defined in [Section 3](#). To help you understand how these work in practice, we have included real-world examples, along with discussion of why regulators choose each type. Keep in mind that this is not an exhaustive list, and you can create your own variations or combine different elements from these approaches.

Table 2. Comparison of Regulatory Reliance Types

Type of Reliance	Definition	Example
Work-Sharing	Collaboration among authorities to jointly perform regulatory tasks or evaluations	MDSAP: Single audit for multiple jurisdictions
Abridged Regulatory Pathway	Partial review relying on prior assessments from a trusted authority	ANVISA (Brazil) abridged marketing pathway
Recognition	Direct acceptance of another authority's decision with minimal or no review	TGA (Australia) and MHRA (UK) mutual recognition

4.2.1. Work-sharing

[Work-sharing](#) occurs when multiple RAs work together to complete a regulatory task. Shared activities optimize resource use and build on specialized knowledge and expertise for tasks, including:

- joint application assessments
- coordinated inspections
- joint development of documents like technical guidelines and regulatory standards

Work-sharing typically requires you to establish how shared activities are distributed, and creation of agreements among participating authorities for information exchange, when necessary.

Example: The Medical Device Single Audit Program (MDSAP) originated from the IMDRF members' desire to develop a global approach to auditing and monitoring the manufacturing of medical devices as a way to improve oversight and efficiency on an international scale. This program allows MDSAP-recognized Auditing Organizations to conduct a single audit of a medical device manufacturer to satisfy the relevant requirements of participating RAs. MDSAP consortium 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.

MDSAP incorporates other aspects of reliance in addition to work-sharing. For example, regulatory authorities, including Affiliate Members who do not participate in MDSAP work-sharing activities, can rely to different extents on the MDSAP reports and/or certificates to fulfill their regulatory requirements, instead of conducting their own inspections.

4.2.2. Abridged regulatory pathway

[Abridged regulatory pathways](#) streamline reviews by relying on comprehensive assessments from a reference RA. Rather than conducting a full review, you may focus on key considerations such as:

- additional requirements or aspects unique to your market
- areas where specific confirmation is warranted

This approach is useful when manufacturers seek approval in your jurisdiction after obtaining approval elsewhere, especially when both jurisdictions have similar regulatory requirements.

Example 1: The Health Sciences Authority (HSA) of Singapore offers an abridged regulatory pathway for registration of medical devices. This pathway is designed for devices that have previously undergone review and approval by one of HSA's recognized reference RAs. To be eligible, devices must meet specific criteria, including having no essential differences in intended use between the device to be marketed in Singapore and the version approved by the recognized authorities. As part of this abridged regulatory pathway, supporting documents including proof of approval from the reference RAs and summarized technical documents must be provided. This process allows HSA to abridge its assessment, taking into account the review conducted by the relevant reference RA, while retaining the ability to request additional information as needed to ensure the device meets the required safety, quality, and performance standards for use in Singapore. The final decision-making authority for registration remains with HSA. This reliance-based pathway was developed with the intention to conserve resources and time and facilitate faster market access as compared to standard pathways, while maintaining rigorous regulatory oversight.

Example 2: The Brazilian Health Regulatory Agency (ANVISA) allows a regulatory pathway called "optimized review", which is consistent with the concept of an abridged regulatory pathway. Through this pathway, applicants may submit technical reports or regulatory documents issued by an AREE (Autoridade Reguladora Estrangeira Equivalente – Equivalent Foreign Regulatory Authority), defined as a reference authority or international entity whose regulatory practices are aligned with those adopted by ANVISA. To request an optimized review, applicants must provide a declaration of eligibility demonstrating that the criteria established by ANVISA have been met, as well as the approval document issued by the AREE, which explicitly identifies the medical device, its intended use, its manufacturer, and the instructions for use authorized by the AREE. The medical device submitted in Brazil must be essentially identical to the device approved by the AREE (see [Section 6.3](#) for further discussion of this concept). ANVISA retains full decision-making authority regarding the granting of marketing authorization and may request additional information or data during the review process, in accordance with Brazilian regulations and guidelines.

4.2.3. Recognition

[Recognition](#) occurs when you accept a regulatory decision made by a reference RA. Generally, this involves the reference RA using standards and requirements that satisfy requirements in your jurisdiction.

Recognition-based reliance includes unilateral or bi/multilateral (mutual) recognition. For mutual recognition, a formal agreement among involved parties is not always required but may be necessary in certain circumstances.

Example 1: The Therapeutic Goods Administration (TGA) in Australia has implemented two recognition-based reliance frameworks. One framework involves recognizing decisions made by a list of reference RAs identified in Australian law, taking into consideration the comparability of the regulatory framework, life cycle approach and post-market vigilance, expertise, cooperation, and membership in IMDRF. It allows TGA to use marketing authorization evidence from these authorities in support of applications for inclusion of medical devices in the Australian Register of Therapeutic Goods before supplying them in Australia. Some aspects of the recognition process, including the required approval evidence and documentation issued by the reference authority and the need for TGA to audit specific applications, depend on factors such as the category, classification, and technological aspects of the medical device or their post-market surveillance data in other countries. However, all medical devices going through this process are still required to meet TGA's existing regulatory requirements for safety, quality, and performance regardless of the overseas evidence provided.

In addition, Australia and the United Kingdom (UK) have a Mutual Recognition Agreement that provides conformity assessment services between the Governments of the UK and Australia. This agreement allows the UK to recognize some Certificates of Conformity issued by TGA to Australian manufacturers under the UK Medical Devices Regulations 2002 without further review. The agreement also allows TGA to recognize some certificates issued by a UK Market Conformity Assessment Body (UKMCAB).

Example 2: Europe has established a legal framework for a single market for goods including medical devices, where the Member States' EU authorities mutually rely on the activities of the other Member States' authorities and of notified bodies designated by Member States following joint assessments. Medical devices bearing the CE marking can be lawfully placed on the market in any of the 27 EU Member States, additional countries of the European Economic Area, and other countries with which there are valid agreements (e.g., Mutual Recognition Agreements or Customs Union Agreements).

5. Considerations Prior to Developing a Reliance Program

5.1. Introduction

You can decide to develop a reliance program at any stage of your organization's development.

Before starting to develop a reliance program, you should assess:

- your specific needs
- if your environment is ready to support it
- your operating circumstances, including aspects beyond your control such as other laws in your jurisdiction

This assessment helps you understand:

- the possibilities and limitations of your reliance program
- where to focus your efforts

While some factors may be beyond your direct responsibility, you can still advance reliance by working with key governmental partners where necessary.

This section outlines considerations you should typically explore. Keep your program goals in mind as you work through these considerations. They apply to any type of reliance program, although there may be additional considerations for your specific situation.

You may also benefit from revisiting these considerations as you develop your program, to determine whether your environment for reliance has changed in ways that warrant adjustments to your strategy or scope.

5.2. Researching existing and planned reliance programs

Before developing your program, consider reviewing how other RAs approached reliance, particularly if they:

- are geographically close to you, or
- have similar regulatory frameworks

Other RAs have likely faced similar challenges. Discussing challenges and solutions with others might:

- help align regulatory approaches
- provide mutual learning from each other's experiences

However, the absence of a reliance program among similar RAs should not prevent you from developing your own program.

5.3. Understanding the legal framework for reliance

Understanding your existing legal framework is an important first step because you often cannot easily or quickly influence changes to existing laws. Review your jurisdiction's existing legal framework, including statute and common law, to determine:

- the extent to which reliance may be implemented through interpreting existing regulations
- if changes to legislation/regulations are required
- how to implement any necessary changes

The approach discussed in WHO's Good Reliance Practices document may help when determining whether reliance is possible:

“When regulations do not make explicit provision for the application of reliance, it may be adopted through interpretation of existing regulations, if the legal framework does not explicitly preclude application of reliance approaches by the NRA [National Regulatory Authority]. Reliance can be implemented through policy change, as long as it is broadly consistent with national legislation. If application of reliance is prohibited, revision of the legislation should be considered within a reasonable timeframe.”

Ideally, reliance should be based on a legal framework for medical devices, not for other regulated products such as pharmaceuticals. Legal language varies between jurisdictions, which can make it difficult to identify language that allows (or prevents) regulatory reliance in all situations. If you have laws that allow you to collaborate with other institutions (such as other RAs), they will potentially support reliance.

Mapping Your Options

Your review may identify limitations for various reliance aspects, including different:

- types of reliance programs (see [Section 4.2](#))
- product types
- regulatory decisions

Consider mapping the benefits and limits for each reliance approach. It helps to identify areas in your existing laws, programs, and higher-level strategic priorities that will work with the reliance program you are trying to develop, enabling a straightforward, efficient, and effective implementation strategy.

Your preferred path may present more limitations or require more implementation time. Look for opportunities offering early wins with less initial resource investment, legal framework revision, and organizational change. These successes may provide supporting evidence for long-term changes.

Example: An RA reviewed their existing legal framework and identified they could recognize audit results (ISO 13485 certificates or MDSAP audit reports) from other RAs, 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.

5.4. Identifying potential reference regulatory authorities

To establish a reliance program, you will need to start researching to find suitable reference RAs. These will typically be RAs in other jurisdictions, or third-party organizations that perform regulatory activities in these jurisdictions³. You may also want to consider jurisdictions commonly included in industry marketing strategies alongside your jurisdiction, or other factors that may improve market access for medical devices.

Once you have identified potential reference RAs, conducting an analysis of their regulatory framework will help you understand:

- how their framework compares to and differs from your current or planned framework
- the significance of any differences

You can gather this information by:

- reviewing their guidance, policy, and legal documents
- reaching out to them directly

Where necessary, and subject to the reference RA's capacity and openness to collaboration, you could consider more intensive approaches such as participating in their regulatory activities either:

- *passively*: observing what they do (e.g., shadowing)
- *actively*: participating in their work (e.g., joint assessments)

These collaborative approaches can help you build knowledge and trust, potentially leading to the establishment of bilateral reliance processes such as mutual recognition.

The [Annex](#) to this document includes a list of questions that may be useful in determining whether potential reference RAs are suitable to rely on. In addition to the resources mentioned in the Annex, IMDRF regularly publishes the IMDRF Document Implementation Reports on their website showing how members have adopted IMDRF guidance documents, which may be useful if you're considering reliance on an IMDRF member's decisions.

³ While many of the reliance activities discussed in this document are written such that they involve one RA relying on the decisions of one or more other RAs, they may also apply to an RA relying on decisions from conformity assessment bodies or other organizations where appropriate.

Differences between your and your potential reference RA's frameworks should not preclude your reliance on them, although these differences might impact how, and how extensively, you implement reliance if not addressed. Depending on the differences, a mapping exercise comparing frameworks will help you evaluate and support your desired reliance program. In some cases, changes to your legal framework or policy approaches may be necessary to support future alignment.

Example: Regulator A is considering recognizing the regulatory decisions of Regulator B. However, the two regulators have different classification systems for medical devices. Regulator A uses a four-tier system and Regulator B uses a three-tier system. Regulator A conducts a mapping exercise, with the help of Regulator B when needed, to determine how devices across Regulator A's four-tier system equate in Regulator B's three-tier system. The results are paired with an understanding of the regulatory requirements across device classification systems. Upon analyzing, Regulator A understood that Regulator B exempts low-risk devices from registration. Despite classification differences, Regulator A chose to only rely on Regulator B's decision for moderate to high-risk devices where assessment is performed, while excluding low-risk devices from the reliance program.

5.5. Assessing agreements between interested parties

Once you understand another regulator's framework and decide on a reliance mechanism (e.g., work-sharing, unilateral reliance), you can assess whether agreements are needed and what agreement type would be appropriate. These agreements typically address information-sharing requirements for relying on another regulator's assessments, data handling procedures, or any work-sharing or recognition arrangements (see [Section 4.2](#)).

When considering *what* information is needed to support a reliance-based decision, you should also consider *how* the information will be obtained.

Prioritize public information

You should first determine if publicly available information is sufficient to support your decision-making needs. Many regulators publish regulatory decisions and decision-making processes on their websites. You may also require manufacturers to notify you of changes or actions by other regulators involving their product. However, information from sources other than the RA may not always be sufficient.

If public information is inadequate and you anticipate needing access to information that is non-public or that the manufacturer cannot provide (e.g., audit reports from conformity assessment bodies), you could consider whether it's feasible to engage with the reference RA to explore an external agreement between the two regulators. Such agreements can facilitate sharing of specific non-public information between parties (e.g., specific regulators or trusted institutions) and provide opportunities to discuss decision-making aspects that would otherwise be unavailable to you as a relying RA. This would require significant discussion and alignment with the reference RA.

Consider effort and sensitivity

You should assess the sensitivity of required information (e.g., trade secret, company confidential information from manufacturers such as test protocols or data, pre-decisional or deliberative information from the RA) and the extent to which the agreement would need to cover this. Assess information-sharing necessity and scope carefully, considering sensitivity of required data. Also consider what information you would be expected to share with your counterparts under such an agreement, as well as the internal resources required to meet these expectations and make this information available. Depending on the sensitivity and type of information about a medical device to be shared, you may need to notify or request permission from the manufacturer.

To minimize workload on participating organizations and limit exposure of sensitive information, share only information necessary for you to make a decision.

Consider legal requirements

Review should also consider both parties' legal frameworks to determine what external agreements are permitted (e.g., what type of information may be shared and with whom). This review should assess factors for protecting shared information, including disclosure requirements in each jurisdiction and measures to mitigate information security risks as needed. Any plan for developing a reliance program should also consider the timelines associated with establishing and/or modifying external agreements.

Assessing agreement necessity

External agreements can be valuable, but you do not always need them for reliance, especially for unilateral reliance and when you establish sufficient trust and understanding of the reference RAs framework. It is important to recognize that agreements can take significant time to develop, and in some cases reference RAs may not be in a position to establish an agreement.

In many cases, reliance can be implemented unilaterally without the active participation of the reference RA. Publicly available information and regional requirements placed on manufacturers for reporting provide sufficient support for your decision-making. As such, you are encouraged to assess your threshold for evidence for reliance-based regulatory decision-making with a focus on the availability, sufficiency, and usability of public information, along with your existing external agreements and whether any modifications are needed to support the reliance approach. Before pursuing external agreements, you should carefully assess whether your reliance objectives can be achieved through these simpler approaches.

Example: Regulator A seeks to rely on Regulator B's post-market decisions, including any restrictions or conditions for the same device(s) marketed in their jurisdiction. They also wish to have the ability to discuss confidential information with Regulator B regarding these decisions. Neither regulator currently has an agreement to share confidential information with the other. Regulator A and Regulator B discuss options for sharing confidential information with one another.

5.6. Engaging stakeholders

Medical device regulation involves different stakeholders who may be affected differently by your reliance program, including:

- internal stakeholders within your own organization
- external stakeholders (e.g., medical device industry members, patients, health care providers and other government areas and levels)

Sharing information and collecting stakeholder feedback supports program transparency, as discussed in WHO's Good Regulatory Practices (see [Section 7](#)).

Before developing your reliance program, engage each stakeholder group to:

- understand their perspectives
- gain their support and feedback
- inform them of progress towards your end goal

Use two-way communication when appropriate so your program design and implementation can benefit from various insights and experiences, while understanding that you may not be able to accommodate every stakeholder's preference. Stakeholder participation and support are crucial for success; stakeholders are more likely to support and correctly implement a program they helped develop. Specific considerations for different stakeholders are provided below.

Internal stakeholders

Transparent and well-timed communication is critical to successful implementation. You should clearly explain the intent, timeline, scope, and anticipated impact of your planned changes. Any concerns expressed within the RA should be understood and addressed to support eventual adoption of the reliance program.

Example: Those within the RA responsible for development of a reliance program conduct a number of outreach opportunities within their organization (e.g., town halls, newsletters, attendance at other meetings, establishment of a specific internal website) in order to provide initial and evolving information about progress towards implementation of a reliance program. Internal stakeholders are asked for their opinions and perspective on different policy decisions. Concerns are addressed in an open and transparent manner.

External stakeholders

Seek to understand external stakeholders' needs and interests. Your outreach should address each stakeholder group to:

- inform them of potential benefits (e.g., continued or improved RA performance in non-reliance areas without loss of device quality, and the reliance program's ability to facilitate access to other markets)
- learn about their interests and concerns associated with reliance

Your local medical device industry may be particularly sensitive to reliance program development and its potential domestic market impact. Target your outreach appropriately to include both large and small/medium-sized enterprises. During outreach, consider discussing:

- the expected impact on resources available for other regulatory activities
- any resulting changes in timelines for these activities
- any different opportunities outside the local market that the reliance program could introduce

Example: The RA considering a reliance program solicits feedback from external stakeholders regarding planned changes to the regulatory framework. The consultation includes specific questions and is publicized via a variety of channels (e.g., press announcements, presentations at external conferences) in order to reach as many stakeholders as possible. After considering stakeholder responses, the RA provides updates at regular intervals in a variety of formats (e.g., meetings, conferences, workshops, websites) regarding progress towards the implementation of the reliance program.

5.7. Conducting a regulatory analysis

Using information discussed throughout this playbook, you will be able to conduct a regulatory analysis to make informed decisions regarding the best approach to a reliance program with insights gained from:

- information gathering (e.g., regulatory data, operational metrics, cost estimates)
- internal assessments
- stakeholder engagement

This analysis allows you to:

- assess costs and benefits of potential changes and identify alternative policy options
- evaluate resource investment needs, including training, necessary to support long-term program success
- address stakeholder questions and support any change associated with implementing your desired program

Based on this analysis and other factors, you may decide to develop a regulatory reliance program. Your next phase will include taking actionable steps to:

- establish the program
- determine implementation details
- maximize its likelihood of success

These steps are discussed in the next section.

6. Steps to Develop and Implement a Reliance Program

6.1. Introduction

Once you clearly understand the operating landscape for your future reliance program, you can begin developing it and taking concrete steps toward implementation. Many actions will be guided by learning from activities discussed in the previous sections. Developing your program may become iterative, requiring changes in previously settled areas as you gain experience and new information becomes available. You may also pursue phased implementation, such as gaining experience with reliance in well-understood regulatory activities before expanding further.

The following sections include specific steps for establishing a robust reliance program. You do not have to do them in the order listed, although some actions will naturally occur after others (e.g., external outreach regarding your reliance program's details can only happen once these details are established). Like the considerations in the previous section, you may need additional steps beyond those listed to fully implement your program. Unless otherwise specified, these steps apply to any reliance program regardless of regulatory activities or partners involved.

Retaining Independence

It is important to remember that a reliance program should not be imposed on any RA 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. When developing your reliance program, it is important to retain the ability to make future program changes, including terminating it if desired.

6.2. Establish the scope of reliance

Early in your reliance program development process, you should establish the scope of your desired reliance-based activities. These boundaries significantly impact implementation, so you should establish the scope before developing any detailed processes. What you learned from activities discussed in [Section 5](#) will influence your desired program scope, along with internal considerations such as available resources, existing initiatives, memoranda of understanding, and partnerships.

Key Elements for Scope Setting

Consider the following elements when setting your reliance program's scope. These elements are interdependent and can be challenging to separate.

For example, the type of reliance and extent to which a reference RA's assessment impacts your decision-making may vary by RA, depending on factors such as:

- similarities between regulatory frameworks
- device risk classifications
- decision-making approaches
- availability of information supporting regulatory decisions

Other considerations beyond those listed may also be important.

6.2.1. Identifying Specific Regulatory Activities

You should identify the specific regulatory activities to be included in your program (e.g., inspections, audits, emergency use authorization, market surveillance, enforcement actions such as recalls). Reliance could also involve a subset of activities (e.g., pre-market regulatory decisions only for certain device types, routine but not for-cause inspection results). Your desired reliance-based regulatory activities' scope should be consistent with your regulatory system's legal framework (see [Section 5.3](#)).

When determining specific activities to include, consider the benefits and challenges of different approaches. Some strategic approaches are:

- **Resource-based approach.** Review your current resources and expertise alongside your envisioned future role. You may continue performing activities where you have expertise and adopt reliance where you have limited resources. Alternatively, you may develop expertise in new areas and gradually adopt reliance in familiar areas based on your comfort level.
- **Feasibility-based approach.** Consider activities where adopting reliance would be easiest from legal and organizational perspectives. These activities may include those for which sufficient expertise exists to evaluate potential reliance paths' suitability, and different levels of reliance for activities you are newly undertaking.

Example: Regulator A has limited resources for post-market activities and identifies these as a potential area for reliance. A review on their legal framework confirms no restrictions exist that would prevent reliance-based approaches. Through an agreement, Regulator B shares regulatory decisions on market withdrawals due to safety reasons involving devices also marketed in Regulator A's jurisdiction. Regulator A reviews these decisions, considers local context, and determines whether similar action is needed in their jurisdiction. This enables timely identification of safety issues while maintaining regulatory independence.

6.2.2. Selecting Reference Regulatory Authorities

You should identify the reference RA(s) you plan to rely on based on:

- comparison of key factors with potential RAs (outlined in [Section 5.4](#))
- any existing or planned agreements that may impact your choice (see [Section 5.5](#))

Selecting reference RAs is interdependent with choosing specific regulatory activities to include in your reliance program. Different RAs have different approaches to different regulatory activities. You may choose to:

- work with one RA for one activity and a different RA for another activity; or
- implement different reliance types for the same regulatory activity

Example: Regulator A incorporates different forms of reliance based on decisions from three different reference RAs. They recognize (per [Section 4.2](#)) pre-market regulatory decisions of Regulator B given their similarities in device classification and regulatory controls. They also establish an abridged regulatory review pathway that uses pre-market regulatory decisions from Regulator C, due to some differences in regulatory controls. They accept the results of routine inspections conducted by Regulator D, due to similarities in inspections requirements.

You are encouraged to engage with potential reference RAs:

- when questions arise about differences in approach, particularly when those differences would result in a more complicated or challenging reliance program. Benefits are best realized when the reliance approach is straightforward and easy for all stakeholders to understand
- to determine if new or modified agreements should be established

to promote awareness of your reliance program to learn about regulatory changes that could impact your program. Given the importance of trust in a reliance program, you may wish to select reference RA(s) with whom you already work closely or have existing partnerships at other government levels. You may also consider how frequently other RAs rely on them (e.g., choosing a reference RA that is relied upon by a large number of other regulators whose decisions you trust).

6.2.3. Determining the Type of Reliance

You should determine how you use reliance in your own decision-making process. Different types of reliance (see [Section 4](#)) vary in their impact on your decision-making, depending on:

- activity scope (see [Section 6.2.1](#))
- selected reference RA (see [Section 6.2.2](#))
- legal framework

Your legal framework may restrict using information beyond what you receive and review yourself, and/or require that you make final decisions. If legal framework changes would be necessary to accommodate your desired extent of reliance, you should pursue these changes before developing your program or consider different implementation approaches that fit within existing legal frameworks until or unless other legal changes are enacted.

Example: Regulator A wishes to develop a recognition-based reliance program so that it can completely accept pre-market regulatory decision granted by Regulator B without any need for further review. After conducting the assessment discussed in [Section 5.3](#), Regulator A determines that the current legal framework for their regulatory system requires that they (Regulator A) issue the final decision. With this requirement in mind, they begin to develop a reliance process that heavily incorporates the pre-market regulatory decisions made by Regulator B as part of their own decision-making, but with Regulator A issuing the final decision. Regulatory efficiency is still gained from this process while legal requirements are met.

As part of this process, you should also consider your approach for managing device lifecycles in your reliance program, including change management and regulatory status changes (including market withdrawals). Different authorities may have varying procedures for manufacturer obligations to inform them of changes that impact device safety and effectiveness, and different change assessment processes. Additionally, if a device is removed from the market in the reference RA's jurisdiction, you must decide whether it remains eligible for the reliance program. The significance of these factors in the planned reliance program and the availability of this information for other regulatory jurisdictions are therefore important considerations when deciding which regulatory activities and reference RA to include.

Managing changes in reliance scope

After establishing your desired scope and implemented the reliance processes, you may later decide that scope changes are required. You should allow for such changes to ensure appropriate reliance options remain available, accompanied by reviews of current processes to determine if process changes are also needed (see [Section 6.7](#)).

6.3. Establish reliance processes and procedures

After establishing your program scope, you should develop implementation details for your agency and jurisdiction. This process will likely involve developing or modifying internal resources such as standard operating procedures, work aids, templates, memoranda of understanding, and externally-facing publications.

Because these steps are highly specific to your circumstances and your chosen program, a detailed listing of which steps to take is difficult to provide. However, you should ensure your reliance processes and procedures clearly describe the following elements to avoid misinterpretation:

Eligibility

Define eligibility criteria for your reliance program, including:

- medical device types, including risk classification and category/nomenclature
- whether the reliance process could be applied to groups of similar devices in addition to individual devices, and under what conditions this would be permissible
- regulatory activities (e.g., marketing registration/placement, post-market surveillance)

- whether eligibility is affected by the marketing status in the reference RA jurisdiction (e.g., whether medical devices would be eligible if they are or have been withdrawn from the market in these jurisdictions, and if so, whether the reason for withdrawal would impact eligibility)
- any eligibility conditions related to the specific regulatory decision being relied upon (e.g., if the original decision can be made via abridged or recognized review or if the decision must have been made via full review)
- any exclusions, as well as a process for confirming eligibility

Process Steps

Establish steps for your reliance-based regulatory process, including:

- how information regarding the reference RA's decision will be obtained (e.g., information-sharing agreements with other RA, public information, documentation from the manufacturer), including any future updates related to that decision (e.g., subsequent recalls, market withdrawal, device changes)
- process for confirming that the medical device under review and its intended use can be considered identical to the version on which the reference RA's decisions were based, including any necessary evidence and justification for any differences. This concept of establishing "sameness" of the device is important in instilling confidence in your reliance program. The definition of *essentially identical medical device*⁴ developed by the Brazilian Health Regulatory Agency (ANVISA) may be helpful in developing criteria for this process
- to what extent you will conduct the review, which will depend in part on the reliance type (see [Section 4](#)) and approach, including any role of third parties in relation to the reliance program
- any timelines, if applicable, associated with any of the above steps

Documentation

Types of documents needed, including:

- evidence to support your review, from the reference RA or manufacturer
- documentation of your final regulatory decision

When determining document needs and where they come from, you should:

- ensure the requirements do not go beyond what is necessary for you to make a sufficiently informed reliance-based decision
- consider any additional burden on manufacturers and reference RAs as part of this process
- prioritize publicly available information such as online databases where possible. Supporting documentation issued by the reference RA (e.g., free sale certificates, certificates to foreign government) can serve as secondary evidence to support your reliance decisions. It is important to avoid unnecessary restrictions on when this documentation can be accepted (such as only accepting this evidence if the device is manufactured in the reference RA jurisdiction, rather than focusing on whether the device has been authorized by a reference RA)

⁴ *Essentially identical medical device*: Device with essential characteristics identical to the one approved by the reference regulatory authority, including those related to the quality of the product and its components, such as technical specifications (same qualitative and quantitative composition, physical, chemical, mechanical, electrical and biological properties), indications and intended use, manufacturer, manufacturing process, results of safety and performance studies. (ANVISA Normative Instruction No. 290, April 4, 2024)

Communication Plan

Processes for disclosing information on your reliance program to the public, including:

- details of reliance-based regulatory processes, such as eligibility criteria
- processes that manufacturers/local representatives would need to follow to use the program
- regulatory decisions resulting from your reliance program and the level of transparency of this information (e.g., whether to disclose that the decision was reliance-based)

While not all the details of reliance programs need to be shared publicly, you should provide sufficient transparency so that the public understands the purpose, benefits, and outcomes of your program to minimize the risk of losing public trust.

Staff Training

Ensure all staff and management involved in carrying out reliance functions received relevant process training. Training should:

- cover procedural steps for reliance activities
- communicate the benefits of adopting the reliance program for your regulatory jurisdiction
- gather feedback on your proposed program

The contents of IMDRF/GRRP WG/N40 - *Competence, Training, and Conduct Requirements for Regulatory Reviewers* may be a useful resource in developing these training needs. While this document is intended for those performing regulatory reviews and/or making decisions related to the device, many of the concepts and approaches can be adapted to other regulatory activities.

Example: After developing its reliance program, the RA has prepared various materials. The materials intended for internal use include detailed standard operating procedures for conducting all aspects of the reliance-based regulatory activities, along with training materials to educate management and staff on these processes and promote understanding of the purpose of the program. Externally focused materials (as discussed further in [Section 6.6](#)) include an announcement of the initiation of the reliance program, a guide for industry on how the reliance program is expected to impact them, and information on the RA's website for communicating the outcomes of reliance-based regulatory work.

6.4. Define roles of supporting documents and resources

A key part of developing implementation processes is identifying what information and approaches you'll use to support your decision-making. The supporting documents you need will depend on:

- your selected regulatory activities
- your reference RA
- how reliance affects your decision-making

For example, you may require more documentation from the manufacturers when choosing reference RAs that use different regulatory controls to ensure your own requirements are met.

Maximizing Benefits Through Existing Approaches

While you can develop new evaluation criteria or processes for reliance purposes or apply your existing jurisdiction-specific approaches, you can maximize your reliance program's benefits by leveraging existing approaches developed using consensus-based processes involving multiple regulatory jurisdictions (ideally involving both you and your reference RA). This approach:

- reduces ambiguity and differences across jurisdictions
- builds on confidence already established in these resources
- increases reliance-related efficiencies

Examples include using globally-adopted consensus standards for medical devices or relevant IMDRF guidance for your reliance-based activity. Ensuring that your reliance program requirements align with established regulatory practices helps support regulatory convergence.

Below are examples of supporting information types for certain reliance activities, along with approaches you may consider in optimizing available and aligned regulatory resources:

- For regulatory submission-related processes, the criteria used to place the device on the market
 - IMDRF Good Regulatory Review Practices Working Group (GRRP WG) documents
 - IMDRF Regulated Product Submission Working Group (RPS WG) documents
 - Consensus standards for medical devices that facilitate the use of a common set of safety and performance evaluation criteria
- For medical device quality management systems (QMS), the QMS requirements the manufacturer needs to meet and the audit process
 - ISO 13485 Medical devices – *Quality management systems – Requirements for regulatory purposes*
 - Regulatory participation in MDSAP, as mentioned in [Section 4.2](#) as an example of work-sharing

- For post-market surveillance of adverse events, the classification and definition of adverse events and the reporting requirements
 - IMDRF Adverse Event Terminology Working Group (AET WG) documents
 - GHTF/SG2/N54R8 - *Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices*
- For recalls and other enforcement activities, the classifications and consequences for these actions

Example: Regulator A and Regulator B develop a reliance program using a work-sharing model. Based on the assessment of each RA's regulatory system, they conclude that the scientific evidence needed to support pre-market regulatory decisions in each regulatory jurisdiction is consistent with the expectations described in IMDRF/GRRP WG/N47 - *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices* and IMDRF/GRRP WG/N52 - *Principles of Labeling for Medical Devices and IVD Medical Devices*. Therefore, they decide that the eligibility criteria for this program should include the requirement that the manufacturer demonstrate that the relevant Essential Principles in the IMDRF documents have been met for the candidate medical device.

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

In addition, you may wish to actively contribute to the development of resources like those listed above. This would allow you to apply experience gained from implementing your reliance programs and develop work products that could assist your ongoing reliance work.

6.5. Formalize any necessary agreements

As part of identifying your reference RAs and establishing work processes, you may need to create or revise agreements with your reference RAs to implement your reliance program, as discussed in [Section 5.5](#).

A key consideration in these agreements is how you will handle information-sharing. Keeping in mind that efficiency is one of the main benefits of reliance, you should minimize additional information requirements beyond what has already been submitted to and assessed by the other regulator, where possible. A risk-based approach to additional information requirements and review allows you to appropriately set regulatory requirements under a reliance program and maximize its benefits.

Example: Regulator A would like to recognize the regulatory decisions of Regulator B and is considering whether an information-sharing agreement is needed. Regulator A conducted an analysis of Regulator B's regulatory controls and determined that they are sufficiently similar to those of Regulator A with the exception of post-market reporting requirements. While both Regulator A and Regulator B require manufacturers to establish a quality system, Regulator A requires manufacturers to report specific trend data on an annual basis and Regulator B only requires submission of trend data if an issue is identified. Based on the similarities between the two regulatory systems, Regulator A decides that it will recognize decisions of Regulator B with the condition that manufacturers must submit proof of marketing registration/placement by Regulator B and also annual trend data in order to meet the requirement of Regulator A that is not part of Regulator B's requirements. As a result, Regulator A determines that an information-sharing agreement with Regulator B is not needed in order to implement this reliance program.

These agreements can also serve as a mechanism for achieving the following goals, if desired:

- Aligning regulatory approaches, such as by agreeing to the use of common evaluation criteria or definitions as discussed in [Section 6.4](#)
- Establishing the details of a mutual recognition or work-sharing reliance program
- Clarifying how to communicate regarding any changes in either regulatory jurisdiction that could impact the reliance program
- Facilitating the exchange of information related to post-market regulatory decisions, such as market withdrawals
- Creating a method for communicating to the public on reliance-based regulatory decisions

It is also important to recognize that establishing an agreement may not always be necessary or feasible, as discussed in [Section 5.5](#).

6.6. Continue stakeholder engagement

You should have a comprehensive plan for engaging with internal and external stakeholders throughout your reliance program's lifecycle, including during:

- development
- implementation, and
- post-implementation

These interactions should build on the initial engagement activities discussed in [Section 5.6](#) and focus on maintaining your program's quality and utility.

The following are suggested elements you could incorporate in your stakeholder engagement plan, during and after reliance program development:

- **Conduct training** for both internal and external audiences, with potential differences in content for each. For example, internal training will likely focus on relevant regulatory review processes and building required competencies, while external training focuses on industry-related aspects such as participation pathways for manufacturers and the impact on regulatory requirements

- **Publicize your program** to ensure the medical device industry, both domestic and global, understands the potential benefits. Extend similar outreach to relevant public sectors such as patient advocacy groups, including discussion of any expected impact on patient safety and medical device access
- **Allow for ongoing feedback** throughout your program's lifecycle, and use it to inform potential changes through your management system as discussed in [Section 6.7](#)
- **Keep reference RAs informed** of changes in your regulatory system. This communication may be part of agreements you establish (see [Section 6.5](#)). Even without formal agreements, discussing your respective regulatory systems' status and planned changes can establish trust and potentially create more collaboration opportunities
- **Engage in appropriate forums** such as IMDRF and other knowledge-sharing and mutual learning initiatives (e.g. [WHO Collaborative Registration Procedure](#)), to share successes and lessons learned, and learn from others with similar experiences. Such discussions can help improve your reliance program or lead to expanded activities
- **Conduct a pilot** to evaluate your reliance program and collect feedback from internal and external participants

Example: After MDSAP's foundational documents were established, a pilot program was conducted from 2014 - 2016 with the goal of gathering objective data to establish the "proof-of-concept" that a regulatory audit of a medical device manufacturer conducted by an MDSAP-recognized Auditing Organization could fulfil the needs of multiple regulatory jurisdictions. The pilot also helped refine the infrastructure, policies, and procedures of the operational program. In 2017, a final pilot report was published, determining that the MDSAP pilot had satisfactorily demonstrated the viability of MDSAP. Results of the report were used to support final approval of the program, as well as identify potential weaknesses and changes to the program.

6.7. Establish a management system for the reliance program

Establishing a management system ensures your reliance program meets:

- its intended goals
- your stakeholder needs

Management systems are valuable for any regulatory process but are especially important for reliance programs due to their broader impact and potential for substantial change. Starting your reliance program with a management system in place provides the best conditions for long-term success.

At a minimum, your management system should allow for:

- **Process monitoring** to determine if processes meet program needs, whether any training is required, and whether any corrective or preventive actions are warranted
- **Performance measurement.** Establish and monitor key performance indicators that align with your reliance program's specific aims and expected benefits

- **Feedback collection** from both internal and external stakeholders on your reliance program's performance
- **Change management.** Establish processes for making changes to your reliance program when needed
- **Assessment of decision-making differences** between you and your reference RAs, along with the reasons for these differences
- **Ensuring continued suitability** of your reference RAs, including maintaining awareness of relevant changes in their regulatory systems (see [Section 6.5](#) for how this could be achieved via external agreements)

Example: Regulator A has established a reliance program for emergency use authorizations by which they can rely on emergency use decisions from Regulator B in case of device shortages. Because Regulator A requires information on the manufacturing of the device for any emergency use authorization and Regulator B does not, as part of this reliance program manufacturers are required to submit this manufacturing information to Regulator A so that this information can be considered together with Regulator B's decision. The management system that was established for this reliance program includes a mechanism for both regulators to share information regarding changes to their emergency use authorization process.

Two years after implementation of this reliance program, Regulator B changes their emergency use authorization process so that manufacturers are now required to submit additional manufacturing information. Regulator A is informed of this change through their management system, conducts a new assessment of the emergency use authorization requirements for Regulators A and B, and concludes that their requirements for manufacturing information are now sufficiently similar. As a result, Regulator A modifies their reliance program per their management system so that submission of additional manufacturing information is no longer required.

7. References

7.1. Referenced in text

The following resources were used in the development of this playbook and are referenced in the text:

- ANVISA Normative Instruction No. 290, April 4, 2024
- GHTF/SG1/N77 – *Principles of Medical Devices Classification*
- GHTF/SG2/N54R8 - *Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices*
- IMDRF/AE WG/N43 - *Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes*
- IMDRF/GRRP WG/N40 - *Competence, Training, and Conduct Requirements for Regulatory Reviewers*
- IMDRF/GRRP WG/N47 - *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*
- IMDRF/GRRP WG/N52 - *Principles of Labeling for Medical Devices and IVD Medical Devices*
- IMDRF/GRRP WG/N59 - *Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews*
- IMDRF/IVD WG/N64 - *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification*
- IMDRF/GRRP WG/N71 - *Medical Device Regulatory Review Report: Guidance Regarding Information to be Included*
- IMDRF/RPS WG/N9 - *Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)*
- IMDRF/RPS WG/N13 - *In Vitro Diagnostic Medical Device Regulatory Submission Table of Contents (IVD ToC)*
- IMDRF/Standards WG/N51 – *Optimizing Standards for Regulatory Use*
- ISO 9001 - *Quality management systems — Requirements*
- ISO 13485 - *Medical devices — Quality management systems — Requirements for regulatory purposes*
- WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report (TRS 1033) , Annex 10: *Good Reliance Practices in the regulation of medical products: high level principles and considerations*
- WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report (TRS 1033), Annex 11: *Good Regulatory Practices in the regulation of medical products*
- WHO Expert Committee on Biological Standardization, Seventy-sixth Report (TRS 1045), Annex 3: *WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices*

7.2. Additional resources

The following resources may be informative to the development or implementation of specific reliance programs by a given RA:

- IMDRF/MDSAP WG/N3 - Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition
- IMDRF/NCAR WG/N14 - Medical Devices: Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form
- ANMAT 1000-MAN08 - Good Reliance Practices (GRelP) Manual
- CECMED – 78/2023 – Regulatory Reliance Practice for all regulatory functions
- PAHO – Regulatory Reliance Principles: Concept Note and Recommendations
- PAHO – Reliance for Emergency Use Authorization of Medicines and Other Health Technologies in a Pandemic (e.g. COVID-19)

Annex: Evaluation Questions for Potential Reference Regulatory Authorities

The following questions can help you decide whether a potential reference RA is suitable to rely on. These questions include specific considerations and resources to help you compare similarities across jurisdictions or to norms established by IMDRF or other organizations.

It is important to note that this is not an exhaustive list, and you may want to explore other questions and aspects relevant to regulatory activities where you are considering reliance. The criteria and approaches described in these resources do not necessarily serve as benchmarks that each RA must meet or implement.

1. How does the RA define and classify medical devices?

- Definition of “medical device” and related terms
 - IMDRF/GRRP WG/N47 - *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*
- Medical device classification systems
 - GHTF/SG1/N77 – *Principles of Medical Devices Classification*
 - IMDRF/IVD WG/N64 - *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification*
- Regulation of medical device accessories, including definition, classification, and any special considerations

2. How does the RA approach different levels of regulatory control and enforcement?

- General regulatory system considerations and types of controls
 - *WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices (GMRF)*
- Post-market surveillance adverse event terminology and categorization
 - IMDRF/AET WG/N43 - *Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes*
 - GHTF/SG2/N54R8 - *Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices*

- Management system for the RA
 - ISO 9001 - *Quality management systems — Requirements*
- Quality management system (QMS) requirements and audit processes for medical devices and their manufacturers
 - ISO 13485 - *Medical devices — Quality management systems — Requirements for regulatory purposes*
 - RA participation in MDSAP

3. For regulatory submissions (see the definition in [Section 3](#)), what information is included, and how and by whom is the information assessed?

- Required contents of regulatory submissions
 - IMDRF/RPS WG/N9 - *Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)*
 - IMDRF/RPS WG/N13 - *In Vitro Diagnostic Medical Device Regulatory Submission Table of Contents (IVD ToC)*
 - IMDRF/GRRP WG/N47 - *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices*
 - IMDRF/GRRP WG/N52 - *Principles of Labeling for Medical Devices and IVD Medical Devices*
- Regulatory review process
 - IMDRF/GRRP WG/N40 - *Competence, Training, and Conduct Requirements for Regulatory Reviewers*
 - IMDRF/GRRP WG/N71 - *Medical Device Regulatory Review Report: Guidance Regarding Information to be Included*
- Any specific requirements for testing (e.g., from accredited centers)

4. How does the RA communicate its decisions (e.g., at what frequency and to what level of detail, is information publicly available)?

Many RAs post information about their decisions on publicly accessible websites. Depending on the current level of transparency and the amount of detailed information you need, the two jurisdictions may wish to consider agreements to allow for confidential exchange of information on certain topics (see [Section 5.5](#)).

5. Are there any other factors that could impact the success of your reliance program?

- Legal and regulatory responsibilities of medical device manufacturers
- Relevant laws involving product liability and consumer protection
- Impact of any differences in population characteristics or other societal factors (e.g. clinical practice or device use environment)

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