IMDRF International Medical Device Regulators Forum

Draft

IMDRF/GRRP WG/N89 DRAFT:2025

Playbook for Medical Device Regulatory Reliance Programs

AUTHORING GROUP

Good Regulatory Review Practices

25 March 2025

Preface

Naoyuki Yasuda, IMDRF Chair

Contents

1. Introduction

The efficiency of regulatory practices and decision-making processes for medical devices, including IVD medical devices[1], can be enhanced by the development and implementation of robust schemes that allow regulators to leverage the work done by trusted partners. One such approach is regulatory reliance, which the World Health Organization (WHO) defines as the process in which a "*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.*" Reliance principles can be applied to any and all stages of the medical device product lifecycle, and the extent to which a given regulatory authority (or jurisdiction) relies on the work of another body can vary under such a scheme.

Appropriately designed regulatory reliance programs for medical devices can benefit the medical device ecosystem as a whole. Compared to drug products, medical devices offer greater variation in technology and global regulatory evaluation frameworks, and any opportunity to align regulatory thought processes can be valuable. As worldwide regulatory activities increase and health technologies become more complex, industry, regulator, and conformity assessment body resources are becoming increasingly constrained and often tasked with understanding and adapting to regulatory differences across jurisdictions. By developing and promoting regulatory reliance paradigms, all stakeholders can use their resources more efficiently to focus on higher-priority issues with greater clarity and predictability. The ultimate goal of fostering the development of transparent and rigorous reliance programs is to improve patient access to medical devices that meet the Essential Principles of Safety and Performance in IMDRF/GRRP WG/N47.

There have been several proposed approaches to regulatory reliance, including Good Reliance Practices for medical products proposed by the WHO (see Section 3.1) and various reliance programs for medical devices established by regional regulatory authorities. This document is intended to build on these existing resources and serve as a "playbook" for regulatory reliance programs specific to medical devices, which can be adapted to suit the particular needs of a given regulatory jurisdiction. This playbook provides high-level strategies for developing a medical device regulatory reliance program, along with more granular and actionable considerations regarding the actual implementation of these strategies, depending on the desired goals of the program.

The goal of this playbook is to promote efficient and aligned approaches to regulatory decision-making by providing examples and practices to follow when establishing reliance programs in their jurisdiction. This approach is intended to be flexible, such that it can be applied to multiple types of medical device technologies and throughout the product life cycle, without intention of promoting one regulatory reliance model over another or establishing any type of criteria for acceptance of a specific reliance model over another. It is hoped that the adoption of reliance programs following the considerations provided in this document will drive additional advances in regulatory reliance, convergence, and harmonization practices, as well as communication and trust across regulatory jurisdictions. Such achievements can be further facilitated by continued development and adoption of globally aligned regulatory resources, such as IMDRF guidance and consensus standards, across multiple regulatory jurisdictions.

[1] Unless otherwise specified, the use of the term "medical devices" in this document includes IVD and non-IVD medical devices.

2. Scope

This document provides high-level strategies for developing regulatory reliance programs for medical devices, along with specific considerations and steps related to actual program implementation. It is intended to be equally applicable to all medical devices. Unless otherwise specified, the reliance principles discussed in the document are intended to apply to any phase of the product lifecycle (e.g., technical documentation review, evaluation of quality management systems) and are meant to encompass a variety of different reliance mechanisms (e.g., harmonized decisions, unilateral or multilateral/mutual recognition, work-sharing). Some of the considerations may not be applicable to a particular reliance program due to factors such as the specifics of the regulatory system or the enabling legislative framework.

This document is not intended to be applicable to aspects of regulatory reliance that typically lie outside the direct control of regulatory authorities, such as legislative issues enabling or preventing the development of reliance programs. However, some of the contents of this playbook may be informative in these areas.

This document is not intended to provide the basis of a reliance framework under the official auspices of IMDRF, nor promote one specific reliance framework to be used in all regulatory jurisdictions. Regulatory authorities should establish reliance programs using a framework that can best meet their needs and the needs of their constituency.

3. References

3.1. 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 Device 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/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*
- ISO 17065 - *Conformity assessment — Requirements for bodies certifying products, processes and services*
- WHO Expert Committee on Specifications for Pharmaceutical Preparations, Fifty-fifth Report, 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, Annex 11: *Good Regulatory Practices in the regulation of medical products*
- WHO Expert Committee on Biological Standardization, Seventy-sixth Report, Annex 3: *WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices*

3.2. Additional resources

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

- 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)*

4. Definitions

4.1. *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)

4.2. *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)

4.3. *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)

4.4. *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)

4.5. *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)

5. Overview of Medical Device Regulatory Reliance Programs

5.1. Role of regulatory reliance

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

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

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

5.2. Types of regulatory reliance

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

5.2.1. Work-sharing

Work-sharing is a process where multiple regulatory authorities collaborate to complete a regulatory task. It is intended to optimize resource use and leverage the specialized knowledge and expertise of different regulatory authorities. This cooperation creates opportunities for shared activities such as joint assessment of applications or inspections, and joint development of technical guidelines or regulatory standards.

> **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 regulatory authorities. 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, all regulatory authorities participating in MDSAP, including Affiliate Members who do not participate in MDSAP work-sharing activities, can rely to dfferent extents on the reports and/or certificates generated from the Auditing Organizations' audits of manufacturers.

5.2.2. Abridged review

Abridged review is a process that involves streamlining a review by relying to some extent on the comprehensive assessment previously performed by another trusted regulatory authority. This process typically involves a review of a subset of the documentation, focusing on aspects that may be unique or additional to the new market or where some specific confirmation is warranted. It is particularly useful for devices that have obtained approval in one jurisdiction and the manufacturer is seeking approval in another jurisdiction with similar regulatory requirements.

> **Example**: The Health Sciences Authority (HSA) of Singapore offers an abridged review 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 overseas regulatory authorities. To be eligible, devices must meet specific criteria, including having no safety issues reported and no 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 review pathway, supporting documents including proof of approval from the overseas regulatory authorities and summarized technical documents must be provided. This process allows HSA to abridge its assessment, taking into account the review conducted by the overseas regulatory authorities, 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.

5.2.3. Recognition

Recognition is the process of accepting a regulatory decision made by another authority or a trusted institution. It involves accepting that the standards and requirements of the reference authority are adequate to satisfy the requirements of the relying authority.

Recognition-based reliance can be in the form of unilateral or bi/multilateral recognition. In the specific case of bi/multilateral recognition, a formal agreement among the involved parties may be required.

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 overseas regulators 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 overseas regulators or assessment bodies 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 overseas regulator or assessment body 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 safety signals 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 Device Regulation of 2002 without further review. The agreement also allows TGA to recognize some certificates issued by a UK Market Conformity Assessment Body (UKMCAB), although as of January 2025 this aspect of the program is not yet operational.

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).

6. Considerations Prior to Developing a Reliance Program

6.1. Introduction

Prior to starting the process of developing any reliance program, it is important for the regulatory authority to evaluate whether a suitably favorable environment exists to support the program and use this information to inform the design of the program and determine whether any changes are necessary before implementation. Many of the factors to evaluate as part of this process, such as the legal framework for reliance, lie outside the direct influence of the regulatory authority, and having a full understanding of these conditions is helpful in forming an initial understanding of the possibilities and limits of a given reliance program as well as where to target future actions.

This section includes some of the considerations that a regulatory authority should typically explore in this context. These considerations would likely be applicable to any type of reliance program, although additional considerations will often be warranted. This evaluation should be performed with the desired purpose and goals for the planned reliance program in mind. The regulatory authority may also benefit from revisiting some or all of these considerations as the reliance program is being developed, to determine whether the environment for reliance has changed in a way that warrants adjustments in regulatory strategy or scope.

6.2. Researching existing and planned reliance programs

Regulatory authorities are likely to face similar challenges in developing a reliance program. Regulators in close geographic proximity or with similar regulatory frameworks may be in particularly similar situations. Prior to developing a reliance program, a regulatory authority should review how other, like-minded regulatory authorities have incorporated or plan to incorporate reliance into their frameworks. As part of this approach, the regulatory authority may want to discuss implementation challenges and solutions with other regulatory authorities to potentially align regulatory approaches and benefit from each other’s experiences.

6.3. Understanding the legal framework for reliance

Prior to developing a reliance program, a regulatory authority should review and evaluate their jurisdiction's existing legal framework, including statute and common law, to identify any limits to implementing a reliance approach. A clear understanding of the existing legal framework is necessary to identify the extent to which reliance may be implemented through interpretation of existing regulations, whether changes to legislation/regulations are required, and how any necessary changes would be implemented. Having an informed understanding of the existing framework is a critical first step in considering regulatory reliance because a regulatory authority is often not able to easily or quickly influence changes in the law.

The approach discussed in WHO's Good Reliance Practices document may be helpful when determining whether reliance is possible within a regulatory jurisdiction:

> "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."

Legal language will be structured differently in different jurisdictions. While it is difficult to identify language in the legal framework that would definitively allow (or preclude) the use of regulatory reliance in all situations, reliance should ideally be based on a legal framework for medical devices specifically and not for other regulated products such as pharmaceuticals. Laws that provide a regulatory authority with the ability to collaborate with other institutions, such as regulatory authorities, can also potentially support reliance.

The review of the existing legal framework may identify different limits for different types of reliance programs (see Section 5.2), for different product types, for different regulatory decisions, or other factors. A regulatory authority may wish to map out different approaches to reliance with the benefits and limits that apply to each scenario. Identifying synergies between a planned reliance program and existing laws, programs, and higher-level strategic priorities will help a regulatory authority develop a strategy for implementing reliance in a straightforward, efficient, and effective manner. The path that a regulatory authority would most prefer may end up presenting more limitations or requiring more time for implementation. However, there may be opportunities for early positive outcomes requiring less initial resource investment, revision to the legal framework, and culture change. Early positive outcomes may provide supporting evidence for long-term changes.

Example: A regulatory authority wishes to recognize the marketing authorizations of another regulatory authority. They conduct a review of their existing legal framework and identify the ability to recognize inspection results of other regulatory authorities, but not the decisions with respect to marketing authorization. Although the regulatory authority wishes to implement a program allowing for full recognition that includes both areas, they may consider recognizing inspection results in the short term while working on changes to the legal framework that would allow recognition of marketing authorizations in the future. They may also wish to consider abridged reviews as a type of reliance while they seek to change their existing legal framework to support recognition of marketing authorizations from other regulatory authorities.

6.4. Targeting potential regulatory partners

Subsequent to or concurrent with assessing their legal framework, a regulatory authority should gather regulatory intelligence to identify suitable partners upon which to rely. Such partners will typically be regulatory authorities in other jurisdictions, or third-party bodies that perform regulatory activities in these jurisdictions[2]. Once potential partners have been identified, a thorough analytical understanding of a potential partner's regulatory framework, how it compares to one's own, and the significance of any differences will inform the steps needed to implement a reliance program.

This information can be collected by reviewing relevant guidance, policy, and legal documents from potential partners, and by engaging in direct dialogue with them. Where necessary, more intensive methods such as participating in regulatory activities conducted by these partners, either passively (e.g.,"shadowing") or actively (e.g.,joint assessments) may also be practical ways to better understand another partner's framework and to build trust. These collaborative approaches can be especially valuable in establishing bilateral reliance processes such as mutual recognition.

Answering the following questions for potential partners may be useful in determining whether they are a suitable regulatory partner to rely on. It is important to note that this is not an exhaustive list of considerations and that the regulatory authority may want to explore other questions and aspects that are relevant to the regulatory activities where reliance is being considered. Some specific points of consideration are also listed for these questions, along with resources that may facilitate comparing and assessing the similarity of relevant regulatory activities across jurisdictions or to norms established by IMDRF or other organizations. The criteria and approaches described in these resources do not necessarily need to serve as benchmarks that each regulatory authority needs to meet or implement.

- How does the regulatory authority 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 Device Classification*
    - Regulation of medical device accessories, including definition, classification, and any special considerations
- How does the regulatory authority 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/AE WG/N43 - *Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology and codes*

[2] While many of the reliance activities discussed in this document are written such that they involve one regulatory authority relying on the decisions of one or more other regulatory authorities, they may also apply to a regulatory authority relying on decisions from third-party bodies where appropriate.

        - GHTF/SG2/N54R8 - *Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices*
    - Management system for the regulatory authority
        - 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*
        - Regulatory authority participation in MDSAP

- For regulatory submissions (see the definition in Section 4), what information is included and how and by whom is the information assessed?
    - Required contents of regulatory submissions for marketing[3]
        - 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)*
    - Medical device requirements for marketing
        - 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 for marketing
        - 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*
- How does the regulatory authority communicate its decisions (e.g., at what frequency and to what level of detail, is information publicly available)?
    - Many regulators post information about their decisions on publicly accessible websites. Depending on the current level of transparency and the amount of detailed information needed by the regulatory authority considering a reliance program, the two jurisdictions may wish to consider agreements to allow for confidential exchange of information on certain topics (see Section 6.5).
- Are there any other factors that could impact the success of a 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

[3] "Marketing" as used in this document refers to placement on the market.

In addition to the resources listed above, IMDRF regularly publishes the IMDRF members' implementation status of IMDRF guidance documents. These implementation reports are available on the IMDRF web site and may be another useful reference for regulatory authorities considering a reliance program based on decisions from an IMDRF member.

Differences between one's own regulatory framework and that of another jurisdiction does not preclude reliance on that regulator. However, differences are likely to impact the extent to which and how reliance is implemented. Depending on the difference itself, a mapping exercise to clarify how the two frameworks compare to one another may be sufficient to evaluate and ultimately support the desired reliance program. In some instances, changes to the legal framework or policy approaches may be needed to support future alignment.

> **Example**: Regulator A is considering recognizing the marketing authorization 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 if needed, to determine how devices across Regulator A's four-tier system are classified in Regulator B's three-tier system. The results are paired with an understanding of the regulatory requirements across device classification systems. Regulator A can then determine whether to recognize Regulator B's assessments of marketing authorizations for all, some, or no medical devices.

6.5. Assessing agreements between interested parties

Once a regulatory authority sufficiently understands another regulator's framework, it will be able to consider what agreements with that regulator may be necessary and relevant. These agreements often involve, but may not be limited to, provisions to share information needed when relying on assessments performed by the other regulator and how to share and handle that information, or any work-sharing or recognition considerations (see Section 5.2). The particular considerations to include in an agreement, as well as the need for any agreement at all, will depend on the specific situation and the needs of the regulatory authorities involved.

When considering *what* information is needed to support a reliance-based decision, a regulatory authority should also consider *how* the information will be obtained. Many regulatory authorities provide information regarding their decisions and decision-making processes to the public, such as via their website. In addition, regulatory authorities may choose to require manufacturers to inform them of specific changes or actions by other regulatory authorities that involve their product. However, information obtained from non-regulator sources may not always be sufficient.

If a relying regulatory authority anticipates needing access to information from another regulatory authority that would not be available publicly or that the manufacturer may be unable or unwilling to provide, an external agreement between the two regulators may be helpful. External agreements can facilitate the sharing of specific non-public information between parties (e.g., specific regulators or trusted institutions) and provide an opportunity for entities to discuss aspects of decision-making that may not otherwise be available to a relying regulatory authority.

External agreements may not be required for reliance when sufficient trust and understanding can be established between regulatory authorities, although having such an agreement in place can be valuable for *ad hoc* discussions when issues arise or in cases where the disclosing regulatory authority is willing to provide information regarding regulatory decisions. In many cases, access to publicly available information and regional regulatory requirements placed on manufacturers for reporting provide sufficient information to support a relying regulatory authority's decision-making. That being said, prior to developing a reliance program, a regulatory authority is encouraged to consider the threshold for evidence for reliance-based regulatory decision-making with a focus on publicly available information, along with its existing external agreements and whether any modifications are needed to support the new reliance approach.

As part of assessing any existing agreements and the need for new or modified agreements, the regulatory authority should consider which specific types of information would be needed as part of the desired reliance program (e.g.,trade secret or company confidential information from manufacturers, pre-decisional or deliberative information from the regulatory authority) and the extent to which any agreement would need to cover this information. The regulatory authority should also consider what types of information they would be expected to share with their counterparts as part of such an agreement, as well as the internal resources that would be required to fulfill these expectations and make this information available. Agreements can also specify any situations in which the regulatory authority would notify or request permission from a manufacturer when information involving their medical device is shared.

A review of external agreements should be informed by the regulator's own legal framework as well as that of the potential trusted regulatory partner. That is, both organizations will need to consider what external agreements are permitted (e.g., what type of information may be shared) and with whom. This review should include an assessment of factors related to protecting information being shared by either party, including any relevant disclosure requirements in each jurisdiction and measures to mitigate IT security risks where needed. Any plan for developing a reliance program should also factor in the timelines associated with establishing and/or modifying external agreements.

> **Example**: Regulator A would like to recognize marketing authorizations and recall decisions of Regulator B. Regulator A is considering requiring manufacturers to provide evidence of marketing authorization by Regulator B and to commit to conducting recalls in Regulator A's jurisdiction if a recall is conducted in Regulator B's jurisdiction. In addition, Regulator A would like to have the ability to discuss confidential information with Regulator B related to its decisions in the event of a non-compliant manufacturer. 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.

6.6. Engaging stakeholders

There are many different stakeholders in medical device regulation, all of whom may be impacted differently by a reliance program. These stakeholders can be internal (i.e., within the regulatory authority developing the reliance program) or external (including medical device industry members, patient groups, and other areas of government). Sharing information and collecting stakeholder feedback on the reliance program supports the transparency of the program, as discussed in WHO's Good Regulatory Practices (see Section 3 for reference).

Prior to developing a reliance program, a regulatory authority should engage with each stakeholder group to understand their perspectives, solicit support and feedback, and inform of progress towards the end goal. Communication should be two-way where appropriate such that the design and implementation of the program may be informed by and benefit from the insights and experiences of a variety of sources, with the understanding that it may not be possible to accommodate every stakeholder's preference. Participation and support of all stakeholders is crucial to the success of the program; stakeholders are more likely to positively support and correctly implement a well-designed and executed program if they were engaged in the development process, and this input can help address their needs. Specific considerations for different stakeholder types are provided below.

- **Internal stakeholders**. Those responsible for development of a reliance program should clearly articulate the intent, timeline, and scope of the planned changes. Transparent and well-timed communication is critical to successful implementation. Any concerns expressed within the regulatory authority should be understood and addressed to support eventual adoption of the reliance program.

> **Example**: Those 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, transparent manner.

- **External stakeholders**. Those responsible for development of a reliance program should seek to understand the needs and interests of external stakeholders. Outreach should address each of these stakeholder groups, informing them of the potential benefits such as continued/improved regulatory authority performance in non-reliance areas without loss of device quality and the ability of reliance to facilitate access to other markets, and learning of any interests and concerns associated with reliance.

  The local medical device industry in the regulatory authority's jurisdiction may be particularly sensitive to the development of a reliance program and its potential impact on their domestic market. Therefore, outreach to this group should be targeted appropriately and include both large and small/medium-sized enterprises. For example, the regulatory authority may want to include in their dialogue with local industry the expected impact of implementing the reliance program on the resources that would be available for other regulatory activities, any resulting changes in timelines for these activities, and any different opportunities outside the local market that the reliance program would introduce.

> **Example**: The regulatory authority 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 regulatory authority provides updates at regular intervals in a variety of formats (e.g., meetings, conferences, websites) regarding progress towards the implementation of the reliance program.

6.7. Conducting a regulatory analysis

Using the information discussed in Sections 6.2 to 6.6 or gathered in additional areas, a regulatory authority considering a reliance program should conduct a regulatory analysis. This regulatory analysis uses empirical information to assess the costs and benefits of potential programmatic changes and identifies alternative policy options. The regulatory analysis provides an opportunity to bring together the insights gained from regulatory intelligence gathering, internal assessments, and stakeholder engagements so that the regulatory authority may make an informed decision on how to approach a potential reliance program. The analysis may also serve to address questions from stakeholders and support any culture change associated with implementation of the desired program.

Based on this analysis and other factors, the regulatory authority may decide to move forward with developing a regulatory reliance program in some form. If so, this next phase will include taking more actionable steps to establish the program, fill in the details of actual implementation, and maximize its likelihood of success. These steps are discussed in the next section.

7. Steps to Develop and Implement a Reliance Program

7.1. Introduction

Once a regulatory authority has a sufficiently clear understanding of the landscape under which the future reliance program would be operating, it can begin to develop the actual program and take concrete steps towards implementation. Many of these actions will be informed by what was learned through the activities discussed in the previous section, and developing the program may become an iterative process whereby changes need to be made in areas that were previously settled as new information becomes available and experience is gained.

The following sections include specific steps that a regulatory authority should take in order to establish a sufficiently robust reliance program. These steps do not need to be taken in the order listed, although some actions will naturally need to take place after others (for example, external outreach regarding the details of the reliance program can also be performed once these details have been established). As with the considerations in the previous section, it may be necessary to take additional steps beyond those listed in order to fully implement the program. Unless otherwise specified, these steps apply to any type of reliance program regardless of the exact regulatory activities or partners involved.

Throughout this process, it is important to remember that the reliance program should not be imposed on the regulatory authority by another regulatory authority or other institution. The regulatory authority should retain its independence in choosing to adopt a reliance-based model and make changes to its regulatory reliance-based processes when warranted, in order to best meet its needs as well as the needs of the population it represents. When developing the reliance program, the regulatory authority should ensure that it retains the future ability to make changes to the program, up to and including terminating the program if desired.

7.2. Establish the scope of reliance

Early in the reliance program development process, the regulatory authority should establish the scope of the desired reliance-based activities. These boundaries have a significant impact on how the reliance program will be implemented, and so the scope should be established prior to developing any detailed reliance-based processes. The intelligence gathered via the activities discussed in Section 6 will influence the desired scope of the reliance program, as will internal considerations such as available regulatory authority resources and existing initiatives and partnerships.

The following are elements that the regulatory authority should consider when setting the scope of their reliance program. These elements are interdependent and can be challenging to separate. For example, the type of reliance and extent to which another regulator's assessment impacts the relying regulator's own decision-making may vary by regulatory authority, depending on factors such as the similarities between the two regulators' frameworks, approach to decision-making, and the availability of information supporting regulatory decisions. Other considerations beyond those listed may also be important:

- The regulatory authority should identify the specific regulatory activities included in the program (e.g., marketing authorization, emergency use authorization, post-market surveillance, enforcement actions such as recalls). It is possible that reliance may only involve a subset of a given activity (e.g., marketing authorization only of certain types of medical devices). The scope of desired reliance-based regulatory activities should be consistent with the legal framework for the regulatory system (Section 6.3).

  In determining the specific activities to include in the program, the regulatory authority should consider the benefits and challenges of different approaches. One approach may be to review the regulatory authority's current resources and expertise as well as how it envisions its role in the future. A regulatory authority may elect to continue performing the activities it already has expertise in and to adopt reliance for those activities for which it has limited resources. Alternatively, the regulatory authority may choose to develop expertise in a new area and, with its current knowledge of the activities it performs, gradually adopt reliance given its comfort level with the subject matter.

  Another approach may be to consider the activities for which adoption of reliance is expected to be easiest from a legal and/or cultural perspective. These activities may include those for which there exists sufficient expertise to evaluate the suitability of potential reliance paths, and different levels of reliance for activities that are newly being undertaken by the regulatory authority.

  Example: A regulatory authority is interested in incorporating reliance into its framework. The regulatory authority's resources for post-market surveillance activities are particularly limited, and therefore it would like to target this activity for reliance. The regulatory authority reviews its existing legal framework; the legal framework does not include any restrictions on who can perform post-market activities, meaning that implementing a reliance-based approach for these activities should not require legal changes.

  Next, the regulatory authority considers the culture within its organization as well as perspectives of regulated industry and the public. These groups are not familiar with reliance and have some reservations about its benefits and risks. The regulatory authority adopts a risk-based approach, in which it focuses its own resources on post-market surveillance activities for highest risk devices and incorporates reliance into post-market surveillance activities for lower risk devices (such as via information-sharing agreements with other regulatory authorities). As the regulatory authority gains experience with reliance, it may elect to expand the scope of reliance to include other activities or other types of devices.

- The regulatory authority should identify the regulatory partner(s) on whose decisions it plans to rely. This decision should be informed by the comparison of key factors with potential regulatory partners outlined in Section 6.4, and may be impacted by existing or planned agreements with these partners (Section 6.5).

Selecting a regulatory authority upon which to rely is interdependent with the decision regarding the specific regulatory activities to include in the reliance program. Different regulatory authorities have different approaches to different regulatory activities. A regulatory authority may choose to rely on one regulatory authority for one activity and a different regulatory authority for another activity, or implement different forms of reliance for the same activity.

Example: Regulator A incorporates different forms of reliance based on decisions from three different regulatory authorities. They recognize (per Section 5.2) marketing decisions of Regulator B given their similarities in device classification and regulatory controls. They also conduct abridged review based on marketing decisions from Regulator C, due to some differences in regulatory controls. They accept the results of inspections conducted by Regulator D for routine inspections, but not for-cause inspections due to the greater significance of those findings.

A regulatory authority is encouraged to conduct outreach with prospective partners as questions arise about differences in approach, particularly when those differences would result in more complicated and challenging reliance programs to implement. The benefits of a reliance program are best realized when the approach is straightforward and easy for all stakeholders to understand. Outreach is also recommended with potential partners to determine if new or modified agreements should be established. Establishing a dialogue with partner regulatory authorities can also promote awareness of the reliance program and allow for advanced notice of any regulatory changes that could impact it.

Given the importance of trust in a reliance program, a regulatory authority may wish to rely on other regulatory authorities from jurisdictions with which the regulator already works closely or where partnerships already exist in other levels of the government. The regulatory authority may also wish to consider how frequently that regulator is relied upon by other regulatory authorities. For example, it may decide to rely on a regulator that is relied upon by a large number of other regulators whose decisions it trusts.

- The regulatory authority should determine how it will use reliance in its own decision-making. Section 5 describes several different types of reliance. Each varies in the impact of reliance on the relying regulatory authority's own decision-making process. The impact on decision-making depends on the scope of regulatory activities and the regulatory partners selected, as discussed earlier in this section. The regulator's legal framework as discussed in Section 6.3 is also an important factor. The legal requirements for the regulatory authority could include restrictions on its use of any information beyond that which it receives and reviews itself in making regulatory decisions, or on any institution but the regulatory authority itself making the final determination for a given regulatory process.

If changes in the legal framework would be necessary to better accommodate the desired extent of reliance, these changes should be pursued and implemented prior to developing the reliance program, or the regulatory authority should consider a different implementation of reliance that fits within the existing legal framework until and unless other legal changes are enacted.

> **Example**: Regulator A wishes to develop a recognition-based reliance program for marketing authorization, so that it can completely accept marketing authorizations granted by Regulator B without any need for further review. After conducting the assessment discussed in Section 6.3, Regulator A realizes that the current legal framework for their regulatory system requires that they (Regulator A) issue the final decision for all marketing authorizations. With this requirement in mind, they begin to develop a reliance process that heavily incorporates the marketing authorization decisions made by Regulator B as part of their own decision-making, but with Regulator A issuing the final authorization. Regulatory efficiency is still gained from this process by requiring only minimal Regulator A re-review of Regulator B's decision prior to issuing their authorization.

As part of this process, the regulatory authority should consider its approach for managing the life cycle of devices included in the reliance program, including change management and regulatory status (including market withdrawal). Different regulatory authorities may have different procedures in place related to manufacturer obligations to inform them of any changes that impact the safety and effectiveness of the device, as well as differences in change assessment processes. Additionally, if a device included in the reliance program is removed from the market in the relied-upon jurisdiction, the relying authority must decide whether that device would remain eligible for the reliance program in their jurisdiction. 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 on which regulatory activities and partners to include.

After establishing the desired scope and proceeding with developing and implementing reliance processes as discussed later in this section, the regulatory authority may decide that a change in scope would be warranted. The regulatory authority should allow for this type of change in order to ensure that the most appropriate options for reliance are available, and any change in scope after development of the reliance program is accompanied by a review of the current reliance processes to determine whether any process changes are also needed.

7.3. Establish reliance processes and procedures

After the overall scope of the reliance program is established, the regulatory authority should develop the details of how the reliance program will actually be implemented within their agency and across their jurisdiction as a whole. This process will likely involve development or modification of internal resources such as standard operating procedures, work aids, templates, internal memoranda of understanding, and externally facing publications.

Because many of these steps will be highly specific to each regulatory authority and their chosen reliance program, a detailed listing of which steps to take is difficult to provide. However, the regulatory authority should ensure that their reliance processes and procedures sufficiently describe the following elements in as concrete and clear a manner as possible to avoid the risk of misinterpretation:

- the specific criteria for eligibility for the 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 regulatory jurisdictions to be relied upon (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)

plus any exclusions, as well as a process for confirming eligibility

- the steps in the reliance-based regulatory process, including:
  - how information regarding the other regulatory authority's decision will be obtained (e.g.,information-sharing agreements with other regulatory authorities, public information, documentation from the manufacturer), including any future updates related to that decision (e.g.,subsequent recalls, market withdrawal, device changes)
  - the process for confirming that the medical device under review and its intended use are identical to the version on which the partner regulatory authority's decisions were based, including any necessary evidence. This concept of establishing "sameness" of the device is important in instilling confidence in the 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 the relying regulatory authority will conduct its own review, which will depend in part on the type of reliance desired (Section 5)
  - processes for issuing final decisions
- the types of documents needed for these activities, including:
  - evidence to be provided to support the review, including information from the relied-upon regulatory authority or the manufacturer. The evidentiary requirements should not go beyond what is necessary to make a sufficiently informed reliance-based decision and should consider the burden added to manufacturers or regulatory authorities as part of this process. For example, documentation issued by relied-upon regulatory authorities such as Free Sale Certificates or Certificates of Foreign Government can be used for this purpose, but it is important not to add unnecessary restrictions on when this documentation can be accepted (such as only accepting this evidence if the device is manufactured in the relied-upon jurisdiction). The regulatory authority should consider opportunities to use publicly available information such as databases maintained by regulatory authorities for these purposes wherever possible and appropriate
  - documentation of the regulatory authority's decision

[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)

- the processes for disclosing information on the reliance program to the public, including:
    - relevant details of the reliance-based regulatory processes such as eligibility criteria
    - any processes that manufacturers would need to follow in order to use this program
    - the regulatory decisions resulting from the reliance program and the level of transparency of this information (e.g.,whether to disclose that the decision was based on a reliance program)

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

After establishing these processes, the regulatory authority should ensure that all staff and management who will be involved in carrying out reliance functions are trained in the processes relevant to their work. In addition to covering the procedural steps involved in reliance activities, the training should also communicate the benefits to the regulatory jurisdiction of adopting the reliance program and solicit feedback on the proposed program.

> **Example**: After developing its reliance program, the regulatory authority 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 7.7) 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 a new section of the authority's web site for communicating the outcomes of reliance-based regulatory work.

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 related to device marketing, many of the concepts and approaches can be adapted to other regulatory activities.

7.4. Define roles of supporting documents and resources

An essential part of developing the exact processes for implementation within the desired scope is identifying the types of information and approaches that will be used by the relying regulatory authority to support its own decision-making. The role of supporting documents will depend on the regulatory activity, the regulatory partner, and the impact of reliance on the regulatory authority's own decision-making. For example, a regulatory authority may require more supporting documentation for regulators that use dissimilar regulatory controls in order to ensure their own requirements are met.

While regulatory authorities can develop new evaluation criteria or processes for reliance purposes or apply their own previously developed jurisdiction-specific approaches, the benefits of implementing a reliance program can be maximized by leveraging existing approaches that have been developed using consensus-based processes involving multiple regulatory jurisdictions (ideally involving both the relying and partner regulatory authority). This type of approach can minimize ambiguity and differences across jurisdictions, gain support from the confidence that has already been placed in these resources, and increase reliance-related efficiencies. One example of such an approach is the use of globally developed and adopted consensus standards for medical devices, or of IMDRF guidance appropriate for the reliance-based activity.

Some examples of these types of information for certain reliance activities are listed below. This list also includes some approaches that a regulatory authority may want to consider as a way to optimize the use of 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
    - 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. The approaches discussed in IMDRF/Standards WG/N51 - *Optimizing Standards for Regulatory Use* may be helpful in adopting a reliance program that leverages standards, as well as for developing new standards that would be most suitable for such a program
- 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 5 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 (AE WG) documents and 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 for marketing authorization using a work-sharing model. Based on the assessment of each regulatory authority's regulatory system for marketing authorization, they conclude that the scientific evidence needed to support marketing 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 have been met for the candidate medical device.

In addition, the regulatory authority may wish to actively contribute to the development of resources like those listed above. This would allow them to apply the experiences gained from implementing their own reliance programs and develop work products that could assist in their ongoing reliance work.

7.5. Formalize any necessary agreements

As part of identifying the partner regulatory authority(ies) and establishing the work processes of the reliance program, the regulatory authority may need to create or revise agreements with their partner(s) if necessary, in order to implement the reliance program in its desired form, as discussed in Section 6.5. One key consideration with these agreements is how information-sharing will be handled. Keeping in mind that one of the benefits of reliance is efficiency, a relying regulatory authority should seek, where possible, to minimize the information it requires for submission and review above and beyond that which has already been submitted to and assessed by the other regulator. A risk-based approach to additional information requirements and review allows the relying regulatory authority to appropriately set its own regulatory requirements under a reliance program and maximize its benefits.

> **Example**: Regulator A would like to recognize the marketing authorizations 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 identical 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 should an issue be identified. Based on the similarities between the two regulatory systems, Regulator A decides that it will recognize decisions of Regulator B with the caveat that manufacturers not only submit proof of marketing authorization by Regulator B, but 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 7.4
- 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

7.6. Establish a management system for the reliance program

In order to ensure that the reliance program is meeting the needs of its stakeholders, the regulatory authority should establish a management system to ensure that the reliance program is meeting, and continues to meet, its intended goals. While a management system is valuable for any regulatory process, it can be especially important for reliance programs due to their broader impact and the potential for significant changes, and starting the reliance program with a management system already in place will provide the best conditions for long-term success.

At a minimum, the management system should allow for the following:

- Monitoring the processes involved in the reliance program to determine if they are meeting the needs of the program, whether any training is needed, and whether any corrective or preventive actions are warranted
- Collection of feedback, both internal and external to the regulatory authority, on the performance of the reliance program
- Processes for making changes to the reliance program at any time, when needed
- Ensuring the continued suitability of any regulatory partners, including the ability to maintain awareness of any changes in their regulatory system (see Section 7.5 for a discussion of how this could be achieved via external agreements)
- Assessment of any differences in relevant decision-making between the relying regulatory authority and their regulatory partners, along with the reasons for these differences

> **Example**: Regulator A has established a reliance program for emergency use authorizations in 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 specifically 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 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.

One potential approach to establishing a management system for the reliance program is described in Section 8 of ISO 17065 - *Conformity assessment — Requirements for bodies certifying products, processes and services*. As mentioned in the standard, such an approach can include (but does not require) the adoption of ISO 9001 - *Quality management systems — Requirements*.

7.7. Continue stakeholder engagement

Throughout the life cycle of the reliance program, including development, implementation, and post-implementation, the regulatory authority should have a comprehensive plan for engaging with internal and external stakeholders regarding the reliance program. These interactions should build on the initial engagement activities discussed in Section 6.6, and focus on maintaining the quality and utility of the reliance program.

The following are some suggested elements to incorporate in a stakeholder engagement plan for the reliance program during and after development:

- Conduct training on the reliance program. This training can involve both internal and external components, although the contents of each component will likely be different. For example, internal training will likely focus on the relevant regulatory review processes and on building the competencies required for those processes, while external training will focus on industry-related aspects such as pathways for manufacturers to participate and the impact of the reliance program on their regulatory requirements
- Publicize the reliance program to ensure that the medical device industry, both domestic and global, understand the proposed benefits of the program. Similar outreach should also be extended to relevant sectors of the public such as patient advocacy groups, and should include a discussion of any expected impact of the reliance program on patient safety and medical device access
- Allow for feedback on the reliance program, with the goal of using this feedback to inform potential changes to the program through its management system as discussed in Section 7.6
- Keep the regulatory partners that are being relied upon informed of any changes in the relying regulatory authority's regulatory system. Communication on this topic may be a part of agreements between the regulator (see Section 7.5). Even in the absence of a formal agreement, discussing the status of their respective regulatory systems and any planned changes can further establish trust among the regulatory authorities and potentially lead to more opportunities for collaboration
- Engage in appropriate forums, such as IMDRF, to share successes and lessons learned through reliance and learn from others who may have had a similar journey. Such discussions can help to improve the reliance program or lead to expanded reliance activities
- Conduct a pilot to evaluate the reliance program and collect feedback from both 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 fulfill 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.

1138

Please visit our website for more details.

www.imdrf.org