IMDRF International Medical Device Regulators Forum

Standards Implementation: A Strong Foundation for Standards Success

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Why does this discussion matter?

Audience question: At the end of the day, why are we here in this room or virtually trying to learn from each other?

Key message: **There is always a patient waiting**. It could be one of us, or a family member or friend.

Objective:

- What we learn here together today can help improve the healthcare experience and **positively affect health outcomes**.
- Getting to efficient sustainable regulation can make all the difference in the **world…for you…for me…for our family and friends**.

Recipe for Successes

WTO+GRP = Standards and Regulatory Success = Better health outcomes

Following WTO obligations

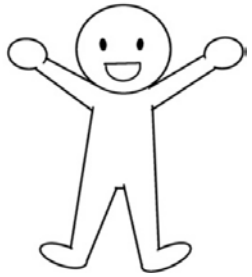
Guided by Good Regulatory Practices

Will lead to:

- ✓ Recognition of international standards
- ✓ Increased global collaboration and convergence
- ✓ Implementation of reliance
- ✓ Alignment to WHA Resolutions
- ✓ GBT+ (regulatory maturity) success

Results in:

- ✓ More effective regulation
- ✓ Faster access to safe and effective MD/IVDs
- ✓ Faster diagnosis and treatment
- ✓ **Improved health outcomes**
- ✓ Containment of healthcare cost pressures



Which gets us to our main goal…the patient.

World Health Assembly (WHA) Recommendations

WHA 67.20 (2014)

- Recognized the importance of robust regulatory systems.
- Effective regulatory systems are an essential component of health system strengthening.
- Inefficient regulatory systems can be a barrier to access to safe, effective, and quality medical products.

WHA 76.5 (2023): Strengthening Global Diagnostics Capacities

- Approximately 70% of healthcare decisions are made based on diagnostic test results.
- WHO urged Member States to leverage international/regional collaboration to harmonize and promote reliance mechanisms for the regulation, manufacturing, and supply of diagnostics.

WHO Resolution 67.20 Regulatory System Strengthening for medical products
WHO Strengthening Diagnostics Capacity, May 2023

World Trade Organization Obligations

Another critical element to standards success are the WTO obligations which:

- Seek to achieve a **balance** between Members protecting their legitimate interests

- and -

- Ensuring technical regulations, **standards and conformity assessment procedures do not become unnecessary obstacles to international trade**.

The WTO Agreements Series, Technical Barriers to trade Agreements, Series , page 5

WTO and Economic Growth & Maturity Level

- The WTO obligations and **commitments support import and export** - thus fostering local economic growth and supply chain resiliency essential for global public health system strengthening and health emergency preparedness.
- Lastly, following WTO obligations helps secure a **reference agency designation** and an strong **WHO GBT+ regulatory maturity rating**.

As if regulators didn't have enough on their plate, they also need to be mindful to follow WTO obligations and pursue the WHA Resolutions.

Question: So what tools are accessible to regulators to help tackle all of these challenges?

Answer: One available tool is the GRP (Good Regulatory Practices)

Annex 11

Good regulatory practices in the regulation of medical products

Background

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

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

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

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- GRP includes a set of principles and practices that can be applied to the development, implementation and review of regulatory instruments – laws, regulations and guidelines – to achieve public health policy objectives in the most efficient way.

Inefficient regulatory systems impacts the health system, with potentially significant implications for morbidity and mortality, health care costs and the economy.

TRS 1033 - Annex 11: Good regulatory practices in the regulation of medical products, WHO Technical Report Series, No.1033, 2021, 9 October 2021

Good Regulatory Practices: Foundational Elements

Elements of Good Regulatory Practices per the WHO:

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

GRP in action:

- Provide opportunity for **Public Comment – 60 days**
- Take into consideration and respond to stakeholder input
- Conduct **Regulatory Impact Assessments** to measure the potential impact (financial and patient impact)
- Use **International Standards** as a basis for National Regulations

Careful Considerations for Standards Success

We have considered WTO obligations and commitments which require implementation of regulation and standards in the least restrictive manner & the use of international standards as the basis of local technical standards

We have also learned about the WHA Resolutions which recommends global collaboration, adoption of international best practices, international standards and use of regulatory reliance

With these guide posts in place, let's explore some fundamental considerations implementing standards to ensure standards success!!

One foundational decision to make when implementing standards is whether they should be mandatory or voluntary.

- **Mandatory** standards are ones that are specifically written into law or regulation. This can include both international standards or local standards.
- **Voluntary** standards maintain a high bar while allowing the flexibility necessary to demonstrate conformity.

Kenneth J. Cavanaugh Jr.
Associate Director for
International Policy and
Strategy, FDA

- International Standards should be applied with **adequate flexibility** to allow appropriate alternative methods to prove conformity.
- Standards **should not be mandatory** and it should be recognized that it is **normal for only part of a standard to be used**.
- It is even **acceptable for the manufacturer to submit their own protocol** used to test the product.

In sum, **use common sense and scientific judgment** for how the EPs are met – it could be the standard or a protocol from the manufacturer. There are multiple ways you can meet conformity – or, the EP may not apply at all.

Audience Question: When might a mandatory standard be appropriate?

A mandatory standard may be appropriate when the use of the standards provides an **overwhelmingly, strong justification and support of meeting an agencies statutory obligations** and promotes the **highest direction towards public health and patient safety**.

However in general, standards should be considered voluntary. Technologies continuously evolve. Voluntary, but encouraged use, of standards with the ability to justify appropriate deviations via the risk management process is recommended.

Extra Credit: Who do you think provided the answer? Hint: His initials are S.C., he spent 27 years serving in the US Army and US Public Health Service Commissioned as a nurse, and he helped provide standards training in September 2024 at IMDRF.

Scott Colburn

Scott Colburn, the Director of the Office of Readiness and Response (ORR) at the Food and Drug Administration's Center for Devices and Radiological Health.

Thank you Scott and Ken for all of your support!!

I would also like to thank Melissa Torres and her team for their continued support and engagement in IMDRF and global initiatives. The FDAs participation in Standards Developing Organizations, IMDRF, and other global initiatives is necessary for global health and economic success. We look forward to seeing you in Japan in September!!

A second foundational decision to make when implementing standards is the degree that international standards are recognized.

As a manufacturer, we see many variations to standards adoption. We see **full adoption, partial adoption and no adoption**.

This **creates enormous complexity** when designing, manufacturing and testing MDs and IVDs. Let's take a look at a few examples.

Example 1: A jurisdiction does not recognize the international standard and instead creates a local standard that departs from the international standard.

- A jurisdiction specific standard that departs from the international standard **creates an entirely new set of requirements** the manufacturer must meet to bring the product to that market. This might be cost prohibitive, especially if the product is already in multiple jurisdictions. **At best, patient access is delayed but in this case, patients may not get access at all**.
- In addition, departure from an international standard without appropriate justification **may be a WTO violation**.
- Designing products to a standard that differs from the international standard **can impact the ability to export** which impacts economic growth.

Example 2: Jurisdiction puts in place a local standard that varies from the international standard.

- Even though the jurisdiction partially recognizes international standards, **deviations still create complexities** for the manufacturer that they may be unwilling/unable to overcome. Again, at best, **this delays access – but worse case scenario is no access at all**.
- WTO and **export challenges** still apply to this example.

Where possible the **international standard should remain unchanged** unless there is a unique characteristics that demands adaptions to prove conformity.

If adaptions are necessary, they should be based on a **publically available scientific rational**.

Example 3: The jurisdiction recognizes the international standard but copy and pastes the entire standard into regulation.

- While it is commendable that the jurisdiction has chosen to adopt the entire standard, **copying and pasting** the entire international standard (e.g., Essential Principles) into regulation **takes considerable time a resources** especially when translation is needed.
- It can also be **quite challenging to update** the standard when it is in the regulation word for word.
- If the entire standard is copied and pasted into law or regulation, there is **no flexibility i**n how the regulation can be met.

Example 4: Create regulation that requires the agency to recognize and accept conformity assessments performed against the international standard(s) – This is ideal!!

"[T]he Secretary **shall**…recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement…"

"[The Secretary] **shall** review and update, if necessary, previously published guidance…taking into account the experience with and reliance on a standard by foreign regulatory authorities and the device industry, and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices"

This approach:

- Saves considerable time
- Allows reliance to be implemented
- Meets the WTO obligations
- Leaves room for scientifically justified needs to be fulfilled

Solution: Benefits of the example text – harmonization, reliance, efficiency & meets WTO obligations

- That is **not to say** every standard should be incorporated by name.
- **Rather** the regulation should state - **the agency shall use of all or part of an internationally recognized standard to demonstrate safety and effectiveness**.
- This approach does not make the standard itself mandatory – rather **this approach makes it mandatory for the agency to recognize and accept conformity assessments performed against the international standard(s)**.

The language in 514(c) is the US FDA's recognition program because the approach requires FDA to recognize all or part of the international standard(s) used in the design, development and manufacturing of a MD or IVD. This promotes **global harmonization**, **expedites review** and **trusts** the quality, completeness, thought, and consideration that went into bringing an international standard into existence.

Consider another example

FDA Symbols Rule: Updates 21CFR part 801-Labeling:

- Symbols established in a standard developed by a standards development organization (SDO) may be used…without adjacent explanatory text.
- **Does not call out a specific standard**, but **rather that the symbol be from any standard by a national/international standards organization**

A third foundational decision to make when implementing standards is whether standards should be general or specific

Standards – Group Discussion

- Why should most standards be general?
- When are specific standards acceptable?
- What happens if the majority of standards are super specific and jurisdictionally unique?

A fourth decision to make when implementing standards is the transition time for new or changed standards

- What might be a reasonable transition period?
- Might the transition period need to change depending on the significance of the standards revision? Or even a brand new standard?
- What happens if all the sudden the standards target moves?
- What might mean for the manufacturer?

Transition Time for New or Changed Standards: Manufacturer and Lab Considerations

Manufactures must:

- Control all aspects of product design, development, testing, packaging, labeling, and post-market surveillance
- Adapt Quality Management Systems (QMS) and risk management files to new standards.
- Implement changes while ensuring ongoing compliance with existing regulations.
- Testing labs also need time to get accredited to new standards as they are updated, this may take several months to a few years. And for complex testing, such as ISO 10993 series, IEC 60601 family, etc…), accredited conditions help to ensure consistency and quality.

Regulatory flexibility is critical.

- Therefore, the transition period should allow continued use of the previous standard while manufacturers update their systems.

What is best practice?

- A reasonable time to transition to a new standard is **3 years**.
- **Complex standards might require more** transition time.
  - US FDA typically allows 3 years for new standards unless there is a public health need. See Section V Managing Product Development When Standards Change: Transition Periods in Appropriate Use of Voluntary Consensus Standards.
- AAMI, ISO, IEC review and evaluate **standards every 5 years** to ensure they remain relevant and practical.

Should the conformity assessment testing be required in each jurisdiction?

- **It is best practice to perform conformity assessment testing once to the international standard(s)**.
- That is the beauty of international standards and the vigor they are subjected to during development.
- Once the conformity assessment testing has been done in an accredited lab to the international standard(s) and accepted by a trusted regulator, re-testing is not necessary. This is reliance and can save the regulator considerable time without lowering the regulatory bar.

One Test, One Approval – Accepted Everywhere

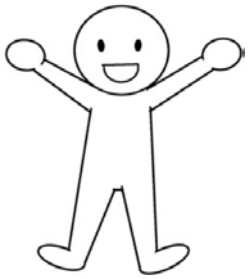
- **Which gets us to our ultimate objective - to facilitate global product acceptance by means of one test, one certification*.**
- It is best practice for jurisdictions with a participating CAB (Conformity Assessment Body) accept each others conformity assessment results because they know they would get the same results themselves.
- This is because they recognize international standards and would test the product against the same standards.

…And that is why its important to participate in the standard development process – to help define the substance and language needed for regulatory ready standards. This help set us up for global standards success!! Which gets us back to the slide we started with….

*Understanding conformity assessment

Recipe for Successes

The Patient!!



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Thank you/Questions

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World Trade Organization Obligations: For your later review

These principles have been captured in document "G/TBT/ 1/REV. 8. Section IX" titled **Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement.**

- "**Article 2.2** Members **shall** ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, **technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective**…"
- "**Article 2.3 Technical regulations shall not be maintained if** the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives **can be addressed in a less trade-restrictive manner**."
- "**Article 2.4** Where technical regulations are required and relevant **international standards exist** or their completion is imminent, **Members shall use them**, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems."

The WTO Agreements Series, Technical Barriers to trade Agreements, Series , page 5