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Optimizing regulatory use of standards

Fatemeh Razjouyan
Sr Director of Regulatory Policy, International and Harmonization
Medtronic

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Essential Principles (EPs) are blueprint for safe & effective medical device

Imagine using these LEGO bricks …

to build this complex skyscraper …

- Like blueprints guide complex construction, **EPs provide a regulatory framework** to ensure medical devices are safe, effective, and meet regulatory requirements that are based on EPs
- **Standards offer technical direction** on how to achieve this vision by providing technical details, and measurable and verifiable requirements for demonstrating conformity
- Regulatory authorities can offer **flexibility** to manufacturers, allowing alternative methods for demonstrating conformity without compromising safety and performance

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The great Baltimore fire & importance of standards

- **Firefighters were ready, but powerless**
  - **1904:** 1,231 firefighters from neighboring cities rushed to help
  - Their **hoses didn't fit Baltimore's hydrants**
- **The problem: No standard coupling**
  - **600+ variations** in fire hose connections across the U.S.
  - Cities used different diameters & threads, blocking mutual aid
- **The Push for standards**
  - **1905:** Establishment of national standards for firefighting equipment

Without standards, critical systems fail, putting lives & property at risk.

At which levels does standards development take place?

1. International
2. Regional
3. National
4. All of the above

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Regulator participation in standards development at all levels is crucial

Patient minded engagement

International level

- Participation **by country delegation only**
- Common global SDOs: ISO, IEC, ITU

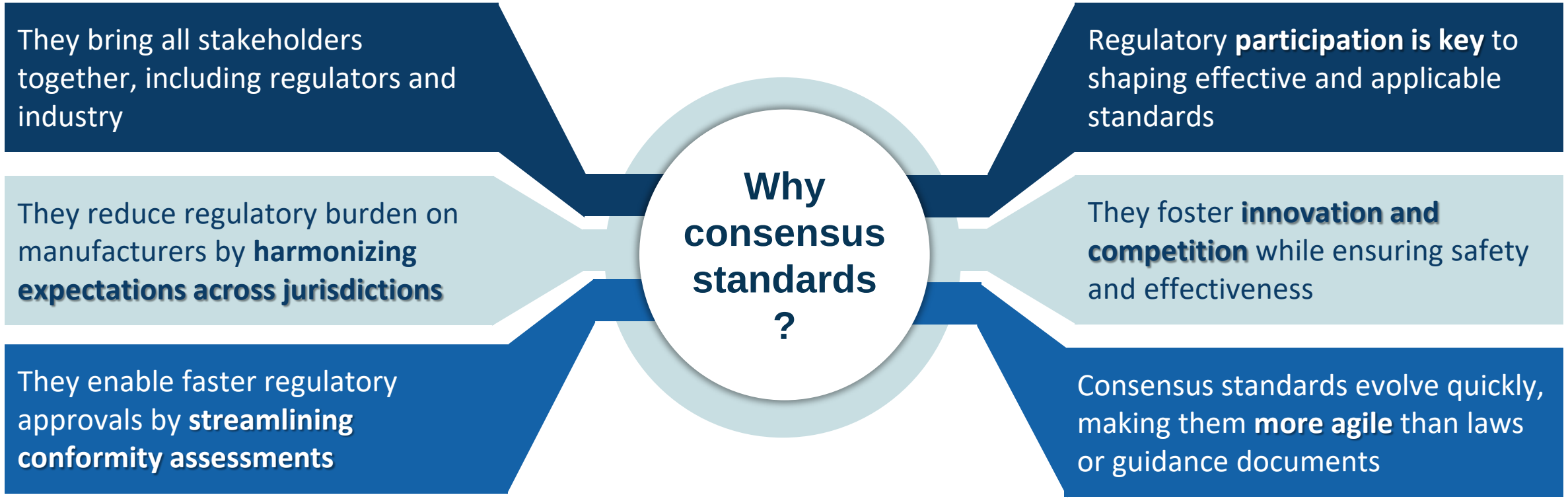
National level

Each country has a **National Body** that oversees standards activities and participation

Regional level

Regional groups work to harmonize standards across multiple countries

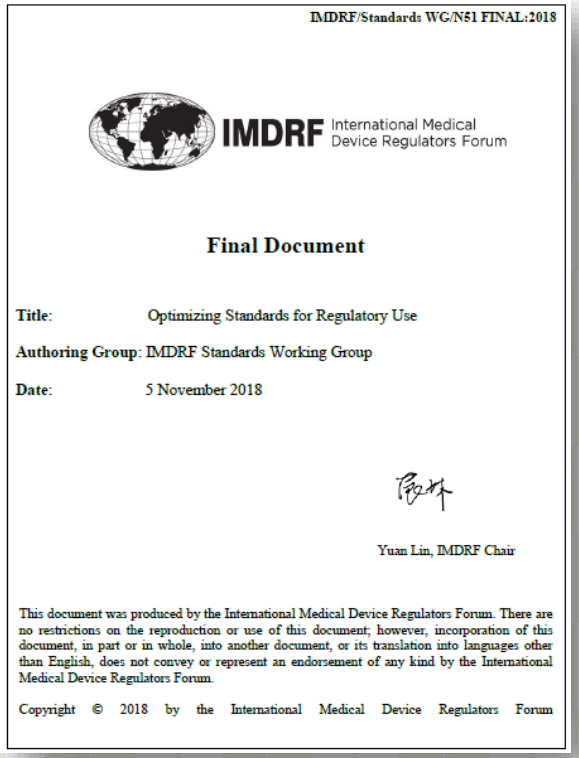
IMDRF Standards WG/N51 FINAL: 2018


Why consensus standards ?
They bring all stakeholders together, including regulators and industry
They reduce regulatory burden on manufacturers by **harmonizing expectations across jurisdictions**
They enable faster regulatory approvals by **streamlining conformity assessments**
Regulatory **participation is key** to shaping effective and applicable standards
They foster **innovation and competition** while ensuring safety and effectiveness
Consensus standards evolve quickly, making them **more agile** than laws or guidance documents

Which stakeholders should be actively involved in developing and using medical device standards? (select all that apply)

1. Regulators
2. Manufacturers
3. Clinicians and healthcare organizations
4. Patients and device users
5. Testing laboratories
6. Health authorities

Overview of IMDRF N51: Optimizing Standards for Regulatory Use



IMDRF/Standards WG/N51 FINAL:2018

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Final Document

Title: Optimizing Standards for Regulatory Use

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➢ Why Was IMDRF N51 Developed?

- To improve how standards are used in regulation
- To enhance participation in standards development
- To prioritize use of international consensus standards over regional/national standards, reducing the burden of multiple/repeat testing for the same performance requirements
- To recognize that industry relies on multiple international standards beyond ISO/IEC (e.g., ASTM, UL) to gain market access across various regions

➢ Key Takeaways from N51:

- Standards streamline regulatory processes
- Greater participation by regulators ensures relevant and effective standards
- Aligning standards with IMDRF Essential Principles improves clarity and consistency

➢ Challenges in Standards Development:

- Standards don’t always reflect regulatory needs
- Limited regulator involvement leads to gaps
- Some standards lack clarity on conformity assessment

➢ Recommendations for Improvement:

- Align standards with IMDRF Essential Principles
- Increase regulatory participation in standards development
- Ensure standards are **clear, practical, and aligned with regulatory needs**

Myth or Fact – Regulators have little influence over standards development, so participation is not necessary.

1. Myth
2. Fact

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Regulatory Authorities (RAs) should **actively engage** in standards development at national and international levels.

RAs should join relevant committees and contribute to the **drafting and commenting** stages. See annex B of IMDRF N51 for participating with your national bodies/committees for ISO and IEC and to contact other SDOs directly to join as an expert.

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Why should regulators and industry participate in standards development?

- If you don't participate, you may not have the opportunity to influence the outcome
- **Early involvement is critical**; it's easier to shape standards during development than to modify them later

Regulators

- Ensures regulatory needs are addressed early in standards development process & substance & language useful for regulatory purposes gets included
- Supports smoother implementation of standards across jurisdictions
- Maintains oversight while leveraging industry expertise
- Improves understanding of technical feasibility for enforcement
- Helps avoid developing standards that don't align with international best practices

Industry

- Helps shape practical & achievable standards
- Promotes global alignment, reducing unnecessary duplications across jurisdictions
- Facilitates appropriate industry buy-in of the final standard
- Supports **timely patient access** to safe, effective, and quality-assured medical devices and IVD

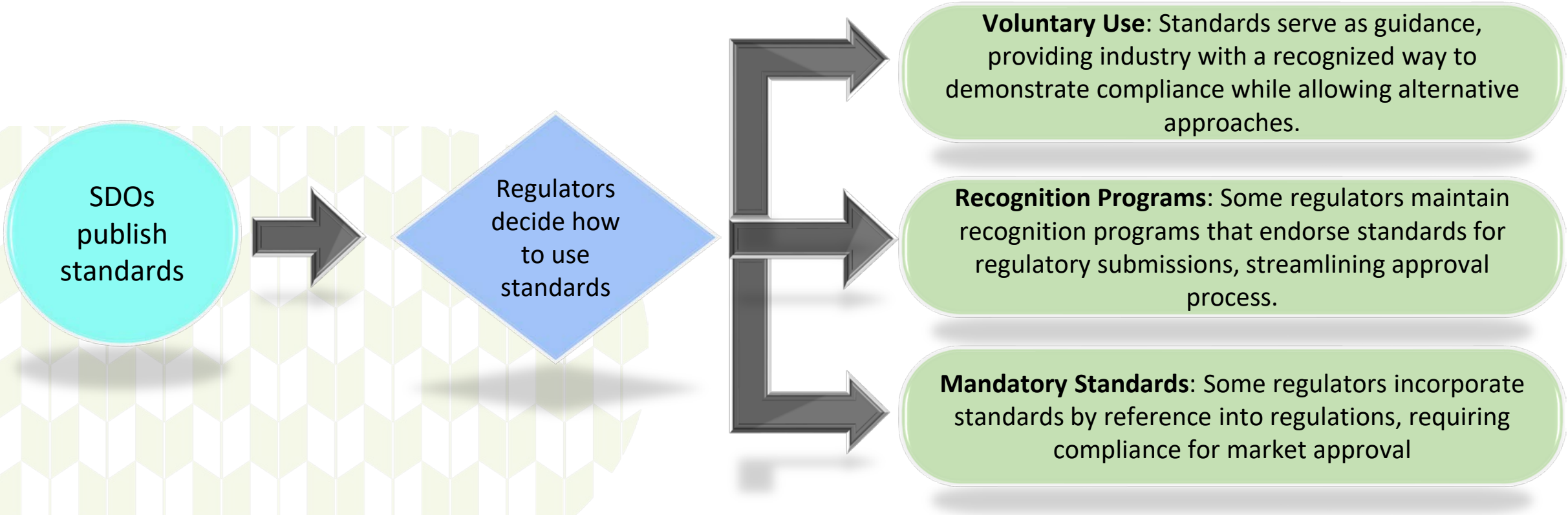
How to maximize impact

- With digital access and virtual meetings, global participation is now easier than ever
- Read and review drafts; many participants don’t engage deeply, so thoughtful feedback has a significant influence
- Ensure your region’s regulatory needs are considered. This strengthens global harmonization
- Regulatory participation benefits everyone by ensuring standards are inclusive and applicable across different markets

Which of the following ways do you use consensus standards in your jurisdiction?

1. As legally required, mandatory regulations
2. As voluntary guidance for demonstrating compliance
3. Through recognition programs that allow their use in submissions
4. All of the above

How regulators use consensus standards



A **flexible** approach to standards promotes **innovation and efficiency** while maintaining safety and effectiveness

Flexibility in voluntary standards drives innovation

Standards should not be mandatory or modified

Applying standards should be adaptable, enabling manufacturers to use alternative methods to demonstrate conformity, when necessary, along with **a clear rationale**.

Standards should be applied with flexibility

Only parts of a standard may be relevant to a specific product or process. Manufacturers should be allowed to determine applicable portions using **a clear rationale**.

Adaptation to evolving technologies

As new technologies emerge, manufacturers need the flexibility to conform to EPs using different methods, scientific judgment, and common sense.

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Managing deviation from standards

Lack of participation in standards development

- Regulators who do not engage in global discussions may develop misaligned national standards, leading to:
  - Inconsistent requirements
  - Regulatory trade barriers
  - Delays in product approvals

Jurisdiction-specific requirements

- IMDRF N51 cautions regulators about introducing country-specific requirements unless absolutely necessary and accompanied with strong scientific and regulatory rationale
- Example: The US National Committee created a US deviation under ANSI/USNC to meet the US Electrical Code requirements which permitted FDA to recognize that version as a complete standard

Minimizing unnecessary deviation

- Ensure deviations are scientifically justified & address essential public health concerns
- Align with internationally recognized standards where possible to maintain regulatory consistency
- Foster mutual recognition and reliance to avoid redundant testing and delayed patient access

Optimizing standards content

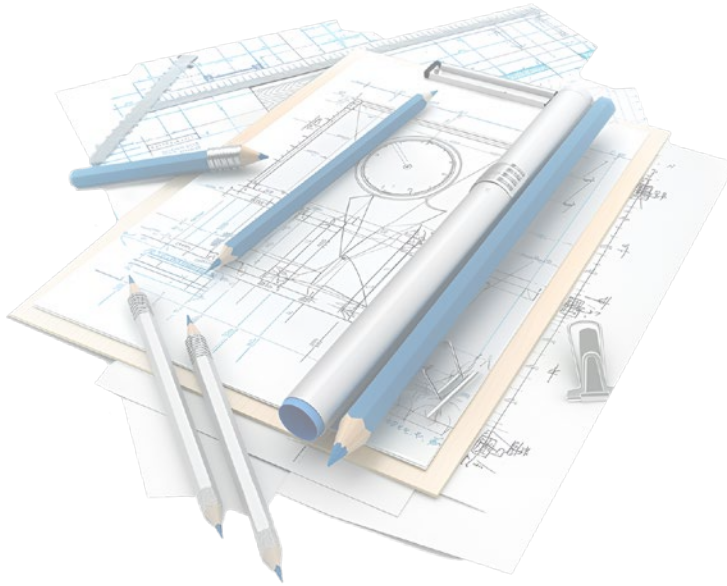
- **Clearly specify** which IMDRF Essential Principles (EPs) a standard addresses to improve usability in regulatory decision-making
- **Strong rationale** explaining the general requirements, test methods, and/or other means of demonstrating compliance
- **Identification of foreseeable risk** and outline of risk mitigation strategies to enhance regulatory confidence
- **Clear scope** to stablish clear boundaries for applicability

Enhancing standards development: a collaborative approach

- Develop standards **collaboratively** using consensus principles to ensure broad acceptance
- Integrate **regulatory needs early** in the process to ensure standards **facilitate timely patient access** while maintaining compliance pathways
- **Encourage diverse participation** to improve fairness and ensure standards reflect real-world needs and applications
- Active regulatory participation ensures that emerging standards **align with policy objectives** and do not require future modification

Use of standards in meeting IMDRF EPs

- **Clear, objective, and measurable criteria** that support efficient conformity assessment, reducing ambiguity in regulatory enforcement
- Explanation of how conformance can be met if no acceptance criteria are included
- If acceptance criteria are not present, a justification to support why the acceptance criteria used demonstrates conformance to the standard and supports safety and/or performance
- Well-accepted and verified test methods (including for new or unfamiliar methods)



- **Mapping standards to EPs:** It's best practice for SDOs to work with all stakeholders, including an international regulatory organization (e.g. IMDRF) to achieve this with support from industry. This collaborative approach ensures standards align with regulatory expectations, promote harmonization, and facilitate compliance at a global level.

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Key takeaways for effective standards use & development

Join national and international standard development bodies

- Get involved early at NWIP stage and provide **early feedback** during drafting
- Consider leadership role
- Contribute regulatory perspective

Recognize & adopt internationally accepted standards for conformity assessment

- Use international standards dynamically instead of codifying them into law
- Allow manufacturers to use alternative methods to demonstrate conformity, when necessary, along with **a clear rationale**

Avoid unnecessary deviations. If necessary, provide **clear justifications** and ensure changes are **scientifically and technically sound** to maintain alignment with international best practices

Adopt "one test, one approval" principle: Reduce redundant testing by accepting conformity assessments conducted in trusted jurisdictions, expediting market access while maintaining safety and quality

Resources

1. IMDRF Optimizing Standards for Regulatory Use (IMDRF/Standards WG/N51 FINAL:2018)
2. IMDRF Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47 FINAL:2018)

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Thank you/Questions