IMDRF International Medical Device Regulators Forum

IMDRF Standards Document: How the Guidance Supports the Goals of Regulatory Harmonization

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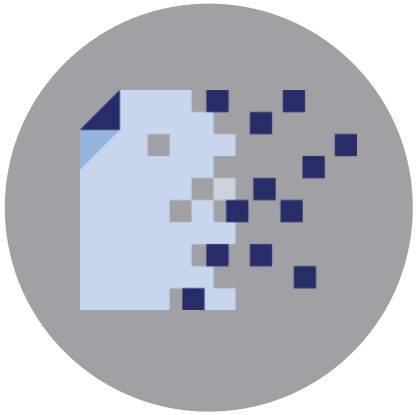
Why are Standards Important?



Consistency + Predictability + Credibility

= Science Based Decisions

Advantages of Using Standards for Regulatory Purposes

- Standards play a significant role in the design, production, post-production and regulation of medical devices throughout their lifecycle.
- Use of standards by Regulatory Authorities (RAs) can:
  - Reduce burdens on the medical device industry by harmonizing expectations across international jurisdictions
  - Increase efficiencies for RAs and improve the effectiveness and efficiency of the pre-market review processes by encouraging the use of standardized conformance assessments and test reporting
  - Promote regulatory science at an international level

Examples of Current Challenges

- *Poor participation by RAs* → can lead to the development of standards that do not include substance and language that are useful for regulatory purposes
- *Unbalanced representation* → can result in some groups' disproportionate voice in and impact on standards development
- *Content of standards can be too flexible* → can render standards less useful as they may not adequately identify minimum requirements for quality, safety and/or effectiveness/performance.

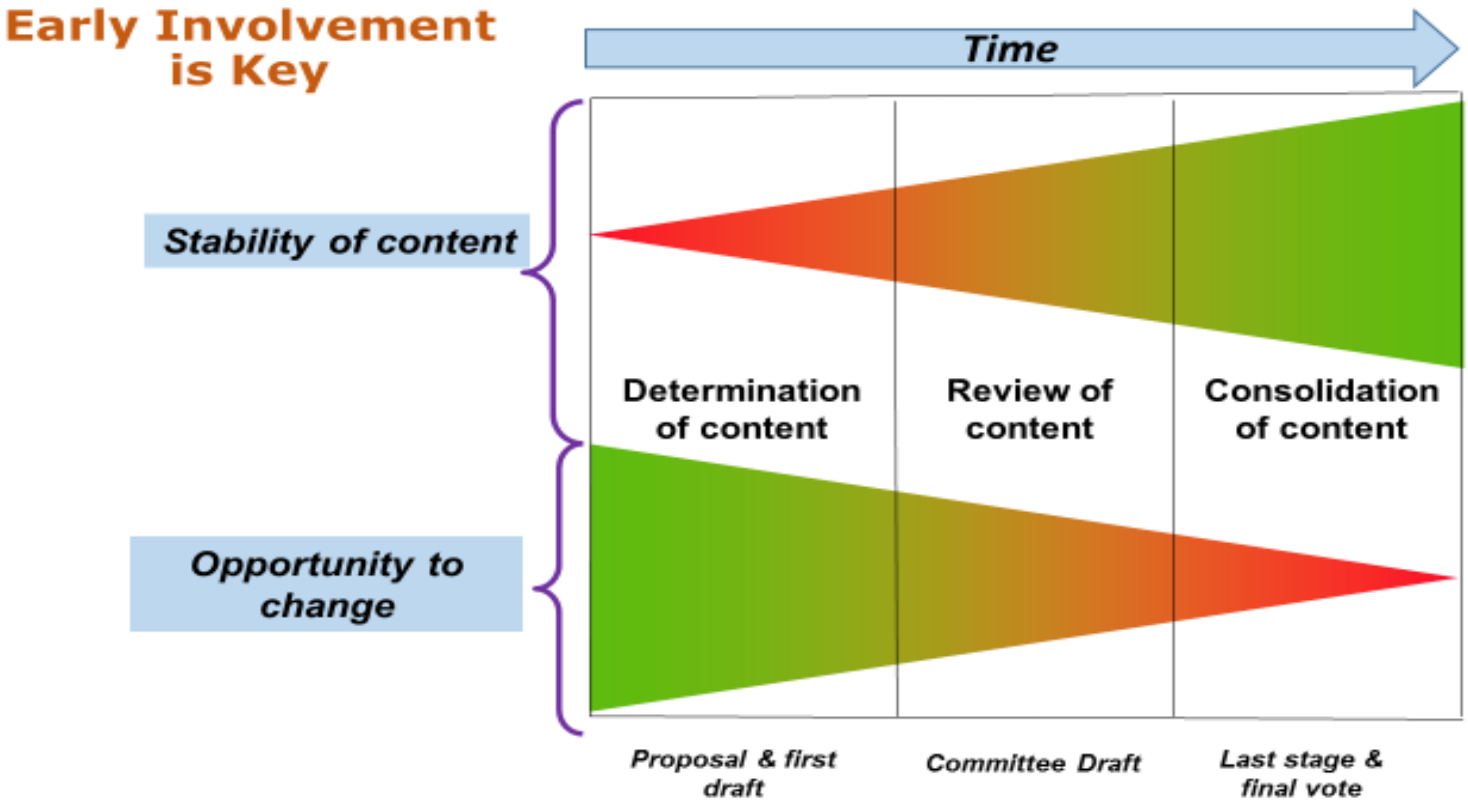
WHY DEVELOP THIS IMDRF DOCUMENT?

- The goals for developing the IMDRF/SWG/N51 *Optimizing Standards for Regulatory Use* were to:
  - Enhance the use of standards to harmonize regional and national regulatory approaches
  - Increase confidence in standards and how they can be better used for regulatory purposes
  - Increase participation by Regulatory Authorities in the standards development process
  - Discuss ways in which international standards can be improved
  - Increase cooperation and coordination with Standards Developing Organizations (SDOs)

Key Items in IMDRF Document: Recommendations for Standards Development

- Ensuring that standards content is optimized by providing goals for standards developers to ensure regulatory needs can be met. For example:
  - Alignment of definitions and terminology
  - Clear acceptance criteria
  - Detailed test methods
  - Rationale for the requirements
  - Highlight of any changes from previous versions
- Providing best practices for standards development procedures

KEY ITEMS IN IMDRF DOCUMENT: ENHANCING STAKEHOLDER PARTICIPATION



KEY ITEMS IN IMDRF DOCUMENT: IMDRF AND STANDARDS DEVELOPMENT

- Establish relationships between SDOs and IMDRF to ensure regulators have a voice in the standards development process.
- Formalize relationships with SDOs
  - Liaison status and MOUs with ISO and IEC
- Engagement in the standards development process

CONCLUSION

- Standards are key to ensuring regulatory harmonization across jurisdictions
- Implementation of the best practices in the IMDRF guidance can lead to standards that are developed with regulatory purposes in mind
- Engaging early and often in the standards development process can help ensure that the regulator's voice is heard

THANK YOU