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

Early Involvement is Key

Stability of content

Opportunity to change

Time

Determination of content

Review of content

Consolidation of content

Proposal & first draft

Committee Draft

Last stage & final vote
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