



IMDRF

International Medical
Device Regulators Forum

Standards Working Group

Management Committee Update
September, 2019

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Topics

- Achievements against objectives to date
- Final report: *Analysis of Standards' Recognition and Use*
- Interim Report: draft *Standards Liaison Program Framework*



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SWG Goal

Enhance the use of standards to
harmonize regional and national
regulatory approaches



SWG Objectives





Achievements Against Objectives

Objective 1: Regulatory-Ready Standards

- 2017 Report: *Improving the Quality of International Medical Device Standards for Regulatory Use* analyzes:
 - Regulatory readiness of standards
 - Participation in Standards Developing Organizations (SDOs)
- 2018 Guidance: *Optimizing Standards for Regulatory Use*
 - How to improve standards and standards developing processes for use in device review
 - Encourage regulator participation in standards development
- IMDRF Standards Workshop, spring 2019



Achievements Against Objectives

Objective 2: Regulatory Authority (RA) participation in standards development

- Measured jurisdictional participation in standards developing organizations
 - 2017 *Improving the Quality of International Medical Device Standards for Regulatory Use* Report to Management Committee)
- Developed in-depth recommendations for effective regulator participation (see 2018 guidance *Optimizing Standards for Regulatory Use*)
 - The SWG wrote clear instructions for how regulators around the globe can engage productively with their National Bodies and standards developing organizations.



Achievements Against Objectives

Objective 3: Advance relationships with ISO and IEC

- Achieved Category A Liaison status with ISO and IEC
- *Liaison Program Framework*
 - Interim report outlining the draft Policies and procedures to guide the liaison participation.
- Participation in key TC62 and TC210 meetings in October 2019
 - Plan for IMDRF liaison contributions to these two key meetings will establish our position with ISO and IEC while at the same time yielding valuable information for finalizing the *Liaison Program Framework*.
- IEC-IMDRF Standards Symposium, 19 October 2019
 - As stipulated in the IMDRF-IEC MoU, IEC and IMDRF will jointly sponsor a half-day symposium during the IEC General Meeting.



Achievements Against Objectives

Objective 4: Analyze RAs' approaches to use of standards

- The SWG surveyed IMDRF members to learn how each jurisdiction evaluate and use standards.
 - Policies and processes for evaluating standards for inclusion in their standards programs and 'recognition' practices
 - Update list of commonly recognized standards
- *Analysis of Standards' Recognition and Use*, report submitted to Management Committee 2019



Achievements Against Objectives

Objective 5: Harmonize approaches to the use of standards

- SWG to update strategy: this objective to become our new Goal
 - Objectives may include:
 - Consensus on an approach/elements for convergence
 - Guidance
 - RA commitment to convergence



Report: *Analysis of Standards' Recognition and Use*

- Two elements
 - Survey: analyze RAs' policies and processes
 - Checklist: capture commonly 'recognized' standards
- Conclusions: agreement on
 - Principles
 - Value of standards to contribute to efficiencies in regulatory review
 - Commitment to consensus standards
 - Criteria for evaluation (ease of determining conformity assessment and alignment with IMDRF's *Essential Principles*)
 - 'Recognition' not as meaningful as 'allowed to use'
 - Momentum toward more and more acceptance
 - Resources are limited to support standards' work within RAs and SDOs; IMDRF work is essential



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Interim Report: Draft *Standards Liaison Program Framework*

- Blueprint for IMDRF to meet obligations of Category A Liaison role
 - Structure
 - Roles, qualifications and responsibilities
 - Policies and processes
- Participation in upcoming ISO/IEC TC meetings