Standards Working Group

Management Committee Update
September, 2019

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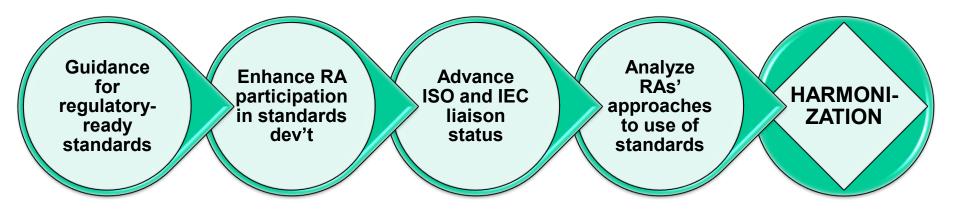
Chair, IMDRF Standards Working Group

Topics

- Achievements against objectives to date

- Final report: *Analysis of Standards' Recognition and Use*

- Interim Report: draft *Standards Liaison Program Framework*

SWG Goal

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

SWG Objectives

Guidance for regulatory-ready standards → Enhance RA participation in standards dev't → Advance ISO and IEC liaison status → Analyze RAs' approaches to use of standards → HARMONI-ZATION

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

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