Standards Working Group

Management Committee Update
September, 2019

CAPT Scott Colburn, USPHS
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**

**HARMONIZATION**
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