Standards Working Group

Scott Colburn, Chair
US Food and Drug Administration
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<th>Standards Working Group (SWG) Members</th>
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<td>Australia</td>
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Goal: Enhance the use of standards to harmonize regional and national regulatory approaches

Objectives

1. Publish recommendations for developing ‘regulatory-ready’ standards (guidance)
2. Enhance Regulatory Authority (RA) participation in standards development processes
3. Advance IMDRF relationships with ISO and IEC as Category A Liaisons
4. Analyze RAs’ approaches to the use of standards in regulatory review
5. Harmonize our approaches to the use of standards
Current Plan

- Guidance for regulatory-ready standards
- Enhance RA participation in standards dev’t
- Advance ISO and IEC liaison status
- Comparative recognition policy analysis
- HARMONIZATION
Groundwork

• Built
  - Relationships: with each other, standards users and Standards Developing Organizations (SDOs)

• Analyzed
  - How Regulatory Authorities (RAs) participate in standards development
  - Current state of standards for regulatory use

• Published and promoted
  - 2017 Report: *Improving the Quality of International Medical Device Standards for Regulatory Use*
    - 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
Current Work Item

• Standards Recognition and Use
  - Goal: advance harmonized use of standards
  - Two objectives
    - Compare RAs’ recognition and utilization policies (survey)
    - Update list of commonly recognized standards (checklist)
  - Preliminary analysis shows broad commitment to use of standards but differing policies and programs: mostly in how formal RAs’ approaches are
  - Proceeding on schedule
    - Preliminary results shared at Monday’s Standards Workshop
    - Report to MC in September 2019
Proposed New Work Item

• SDO Liaison Program
  - Establish program parameters for serving as Liaison to IEC and ISO
    - Represent IMDRF effectively in liaised SDO committees and working groups
    - Lead multilateral communications between IMDRF MC, members, liaisons and SDOs
    - Foster and convey consensus among IMDRF members to establish positions of regulatory importance to share with SDOs
The Future

- NWIP under consideration
  - Guidance: offer best practices and policies for the use and recognition of standards
  - Commitment to real harmonization of practices
Thank you