IMDRF International Medical Device Regulators Forum

Standards Working Group

Scott Colburn, Chair

US Food and Drug Administration

Standards Working Group (SWG) Members

Australia

Brazil

Canada

China

European Union

Japan

Korea

Russia

Singapore

USA

DITTA

GMTA

SWG Goal and Objectives

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

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

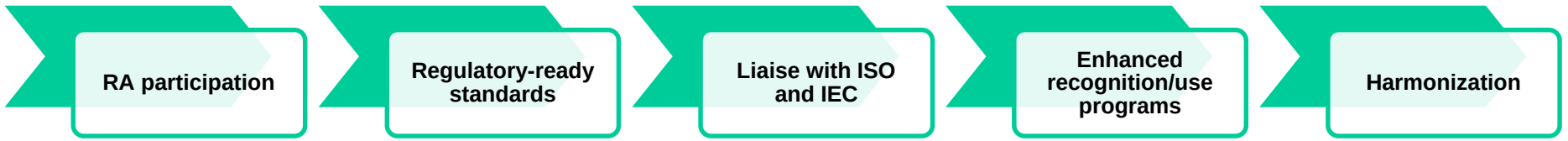
- Standards Recognition and Use
  - Goal: advance harmonized use of standards
  - Two objectives
    - Compare RAs' recognition and utilization policies (survey)
    - Update list of commonly recognized standards (checklist)
  - Preliminary analysis shows broad commitment to use of standards but differing 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