IMDRF International Medical Device Regulators Forum

Standards Working Group Update

Hospitalar

São Paulo, 22 de maio de 2019

Adaptado da apresentação de Scott Colburn – 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

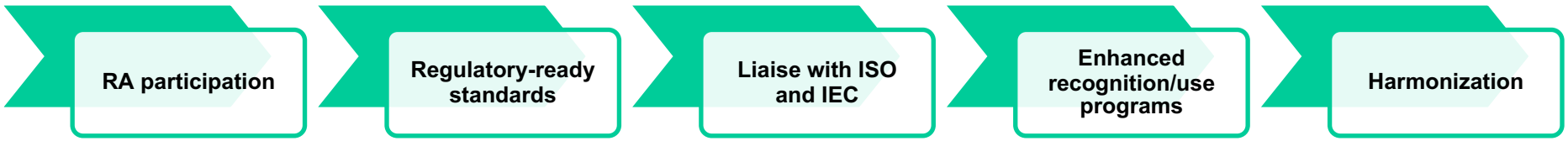
- Standards Recognition and Use
  - Goal: advance harmonized use of standards
  - Two objectives
    - Compare RAs' recognition and utilization policies (survey)
    - Update list of commonly recognized standards (checklist)
  - Preliminary analysis shows broad commitment to use of standards but differing policies and programs: mostly in how formal RAs' approaches are
  - Proceeding on schedule
    - Preliminary results shared
    - 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