IMDRF International Medical Device Regulators Forum

IMDRF Standards Working Group (SWG)

Working Group Chair: Scott Colburn
US Food and Drug Administration

STANDARDS WORKING GROUP MEMBERSHIP

- Scott Colburn/FDA/USA, Chair
- Ying Huang/TGA/Australia
- Fabio Quintino/ANVISA/Brazil
- Kevin Day/Health Canada
- Jia Zheng/SDA/China
- Maurizio Andreano/DITTA/Siemens
- Peter Linders/DITTA/Philips
- Naoki Marooka/DITTA/Shimadzu
- Erik Hansson/European Commission
- Matthias Neumann/European Union
- Jeff Eggleston/GMTA/Medtronic
- Hideki Asai/GMTA/Hitachi
- Hiroshi Ishikawa/PMDA/Japan
- Madoka Murakami/PMDA/Japan
- Vladimir Antonov/Roszdravnadzor/Russia
- Christopher Lam/HSA/Singapore
- Kookhan Kim/MFDS/Korea
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- Kyunghyun Kim/MFDS/Korea
- Gail Rodriguez/FDA/USA

STANDARDS WORKING GROUP

- **Goal**
  - Enhance the use of standards to harmonize regional and national regulatory approaches
- **Objectives**
  1. Publish recommendations for developing 'regulatory-ready' standards
  2. Enhance Regulatory Authority (RA) participation in standards development processes
  3. Advance IMDRF relationships with ISO and IEC
  4. Analyze RAs' approaches to the use of standards in regulatory review

OBJECTIVE ONE

Publish recommendations for developing 'regulatory-ready' standards

- 2017 report to Management Committee
  - *Improving the Quality of International Medical Device Standards for Regulatory Use*
- 2018 guidance
  - *Optimizing Standards for Regulatory Use*
    - How to improve standards and standards developing processes for use in device review
    - Sent to MC for consideration as final document
  - *Implementation Plan* underway to promote its use and adoption

Objective Two

Enhance Regulatory Authority (RA) participation in standards development processes

- Workshop with IEC and ISO leadership in 2017
- *Optimizing Standards for Regulatory Use* guidance
  - How to join and contribute to standards development efforts
  - How to effectively communicate RA needs and positions into standards content

Objective Three

Strong Relationships with IEC and ISO

- IEC
  - MoU executed
  - Category A Liaison status with TC62
  - Joint meeting in spring 2018
  - Contributing to Architectural Working Group for future 60601 standards family
- ISO
  - Category A Liaison status with ISO TC210
  - Plenary agenda slot for 2018 meeting

OBJECTIVE FOUR

Analyze RAs' approaches to the use of standards in regulatory review ('recognition')

- NWIP approved March 2018
- Survey to investigate RAs':
  - Policy approaches to standards recognition programs
  - Technical differences in recognitions:
    - Mandatory versus voluntary
    - Partial versus complete recognition
    - Modifications
    - Rationales for non-recognition
  - Identify commonly recognized/used standards
  - Report to Management Committee
  - Groundwork for future 'best practices' guidance

NWIP Progress

- Policy differences
  - Survey instrument complete
  - Respondents database constructed
- Technical differences
  - Checklist prepared to elicit non-recognition rationales
- Update the list of commonly used/recognized standards
  - Master checklist complete
- Launch to participants by the end of September

Next Steps

- Short term
  - Launch guidance *Implementation Plan*
  - Advance and operationalize SDO relationships/agreements
  - NWIP research
- Longer term – sustainability
  - Lead productive participation in standards development ('voice of regulators')
  - Ensure that regulatory readiness and quality are built into standards so that they demonstrate their utility for regulatory purposes and meet *Essential Principles*
  - Drive application of these optimized standards to regulatory convergence – *How can we put standards to work on behalf of harmonization?*
  - Future NWIP under consideration to advance the goal of encouraging the use of standards (new guidance on effective recognition program practices for RAs)

THANK YOU