STANDARDS WORKING GROUP UPDATE

Working Group Chair: Scott Colburn
US Food and Drug Administration
STANDARDS WORKING GROUP (SWG)

• NWIP Goal
  – Improve the utility of standards for regulatory use in order to streamline review processes and harmonize regional and national regulatory approaches

• Objectives
  1. Background research:
     • Identify problems in standards development that diminish their regulatory utility
     • Analyze IMDRF member engagement with Standards Developing Organizations (SDOs)
  2. Draft recommendations for developing ‘regulatory-ready’ standards
  3. Enhance IMDRF relationships with ISO and IEC
NWIP Outcomes

• 2017 report to Management Committee
  – Improving the Quality of International Medical Device Standards for Regulatory Use

• 2018 draft guidance for public consultation
  – Optimizing Standards for Regulatory Use

• Strong and growing relationships with ISO and IEC
  – Agreement with IEC
  – Liaison A status with ISO TC210 pending ISO resolution
NWIP Outcomes

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  – *Improving the Quality of International Medical Device Standards for Regulatory Use*

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Outcome: MC Report

- **Audience**
  - Management Committee members
  - IMDRF members

- **Background research**
  - Many standards not useful for regulators
  - Regulatory Authorities’ (RAs’) participation in ISO and IEC is inconsistent, at both national and international levels
  - Standards created with regulatory purposes in mind can streamline and harmonize regulatory processes

- **Proceedings from ISO/IEC/IMDRG SWG workshop**
  - SDOs welcome greater regulator and IMDRF engagement
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OUTCOME: DRAFT GUIDANCE

• **Audience**
  – Regulatory Authorities
  – SDOs
  – Stakeholders interested in standards’ improvement for regulatory purposes

• **Recommendations**
  – For standards development
  – For participation in ISO and IEC
  – For future IMDRF engagement
GUIDANCE: STANDARDS DEVELOPMENT

• Optimizing standards’ content, e.g.,
  – Elements for inclusion
  – Attention to appropriate rationale
  – Straightforward and clear conformance acceptance criteria

• Best practices for standards procedures, e.g.,
  – Applying consensus principles
  – Emphasis on RAs’ contributions
  – Transparency on authorship of standard and comments
GUIDANCE: RA PARTICIPATION

- Engagement: why and how to work with
  - National Bodies and mirror committees
  - SDOs at the international level

- Effective commenting: quality and timing
**GUIDANCE: IMDRF ENGAGEMENT**

- IMDRF enjoys a unique position of authority in device regulation harmonization
- IMDRF standards group offers opportunity for RAs to speak with one voice to SDOs
- IMDRF can
  - Act as a resource and communications hub to both members and SDOs
  - Advance regulatory science
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**Outcome: SDO Relationships**

**ISO**
- TC210 exploring Category A liaison status
- Resolution at Technical Committee level is required; Chair is SWG member
- Joint IMDRF/ISO meeting planned for May 2018

**IEC**
- Memo of Understanding under review
- Possible execution at joint IEC TC62B meeting April 2018
**NEXT STEPS**

- **Short term**
  - Gain MC’s approval for public consultation of the IMDRF draft guidance *Optimizing Standards for Regulatory Use*
  - Standards working group meeting in June 2018
  - Finalize guidance by Sept 2018, then promote and educate

- **Medium term**
  - Advance SDO relationships/agreements
  - Discern how to effectively represent IMDRF members in standards development priorities
  - Operationalize liaison status and MoU/agreements with SDOs
**Next Steps (cont’d)**

- **Longer term – consider sustainability**
  - Analyze further how standards’ can contribute to IMDRF strategic goal to ‘...accelerate international medical device regulatory convergence...’
  - Determine appropriate future role for standards in IMDRF
    - Liaise with SDOs
    - Lead productive participation in standards development (‘voice of regulators’)
    - *Drive application of standards to regulatory convergence – how can we put standards to work on behalf of harmonization?*
THANK YOU