IMDRF International Medical Device Regulators Forum

STANDARDS WORKING GROUP UPDATE

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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- 2018 draft guidance for public consultation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

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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OUTCOME: DRAFT GUIDANCE

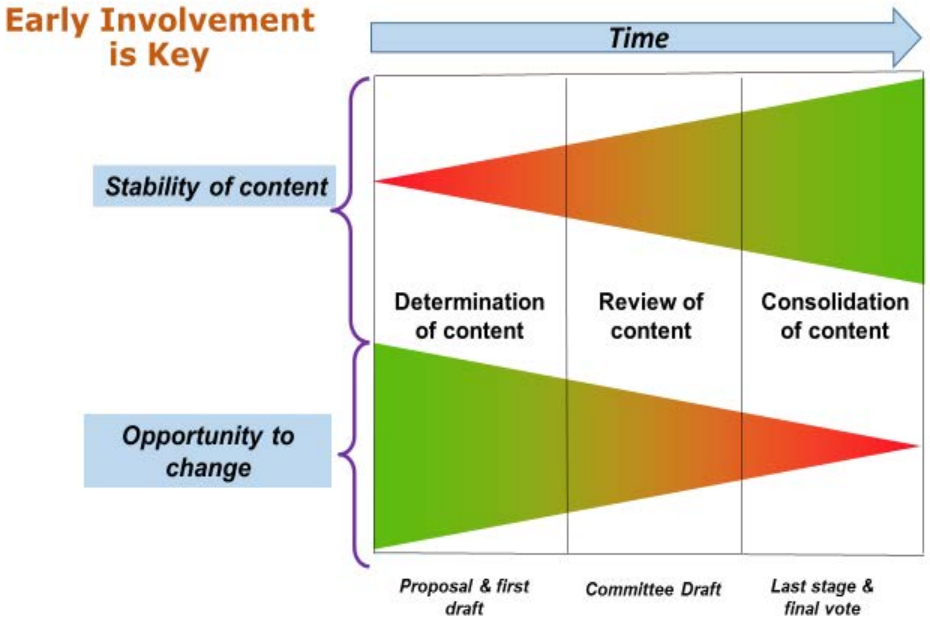
- **Audience**
  - Regulatory Authorities
  - SDOs
  - Stakeholders interested in standards' improvement for regulatory purposes
- **Recommendations**
  - For standards development
  - For participation in ISO and IEC
  - For future IMDRF engagement

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