Welcome to the SES March 2018 Webinar
“The Regulators Role in Improving Standards to Support International Harmonization – International Medical Devices Regulators Forum [IMDRF] Standards Working”

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INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF)

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AGENDA

• Overview of IMDRF
  • Mission
  • Background and history

• Current IMDRF programs
• Standards Working Group
Forum established in 2011 to accelerate international medical device regulatory harmonization and convergence building on the work of the Global Harmonization Task Force (GHTF)

- Address common public health regulatory challenges to convergence due to the globalization of medical device production and the emergence of new technologies

- Accelerate innovation by clear and practical regulatory expectations
IMDRF Mission

To strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.
IMDRF

• Background
  – Successor to Global Harmonization Task Force
  – Launched 2011
    • 7 countries/WHO
  – Present:
    • 10 countries/WHO/PAHO/APEC/AHWP(industry associations)
  – Working Group framework
  – Rotating leadership among member countries
IMDRF Working Groups

• Adverse Event Terminology
• Good Regulatory Review Practices
• Patient Registries
• Regulated Product Submission (RPS)
• Unique Device Identification (UDI)*
• Patient Specific Devices*
• National Competent Authority Report (NCAR)
• Software as a Medical Device (SaMD)
• Medical Device Single Audit Program (MDSAP)
• Standards
WORKING GROUP GOALS

Adverse Event Terminology WG
Develop harmonized terminology and systems being used to code information relating to medical device adverse events in order to improve the efficiency of adverse event management systems for faster response by both industry and regulatory agencies, with the use of a single harmonized adverse event terminology and coding system.

Good Regulatory Review Practices WG
Develop harmonized requirements for assessing conformity to safety and performance regulatory requirements for new medical devices.
WORKING GROUP GOALS

Patient Registries Working Group
Develop shared essential principles of informatics infrastructure and best epidemiologic and statistical analytic methodologies to enhance the quality, speed and cost-efficiencies of regulatory science for medical devices.

Regulated Product Submission WG
- Establish a standard system for the electronic exchange of information related to premarket medical device applications.
- Establish Common Data Elements – mapping data types and common vocabularies.
- Define a common ‘Table of Contents’ for medical device regulatory submissions as a first step in defining a common data set for regulatory submissions.
WORKING GROUP GOALS

Unique Device Identification (UDI) WG
Establish a system for the positive identification of medical devices to reduce the risk that a product may be referenced differently in different countries.

Patient Specific Devices WG
*Goals under development

Software as a Medical Device WG
Identify commonalities, establish a common vocabulary and develop approaches for appropriate regulatory controls that promote prospective convergence in areas of advanced and innovative technologies in this topic area
WORKING GROUP GOALS

**National Competent Authority Report (NCAR) WG**
Facilitate the exchange of relevant post market safety information to trigger rapid adoption of field safety corrective actions to avoid death or serious deterioration of health, when relevant.

**Medical Device Single Audit Program WG**
Develop a standard set of requirements for organizations auditing medical device manufacturers' quality management systems, complementing the current ISO13485 revision process under which IMDRF seeks modifications to achieve a harmonized standard amongst its members.
STANDARDS WORKING GROUP

Brazil, Canada, China, DITTA, EU, GMTA, Japan, Russia, US, WHO
New members: Australia and Singapore
Chair: US
STANDARDS WORKING GROUP (SWG)

Goal

- Improve the utility of standards for regulatory use in order to streamline review processes and harmonize regional and national regulatory approaches

Objectives

- Situation Analysis
  - Identify problems in standards development that diminish their regulatory utility
  - Analyze IMDRF member engagement with Standards Developing Organizations (SDOs)
- Draft recommendations for developing ‘regulatory-ready’ standards
- Enhance IMDRF relationships with ISO and IEC
NWIP OUTCOMES

• 2017 Situation Analysis
  – *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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OUTCOME: SITUATION ANALYSIS

• 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 RA 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

- Meeting IMDRF Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (EPs)
  - Demonstrate standards’ alignment with EPs
Performance:
The ability of a medical device to achieve its intended purpose as stated by the manufacturer. Performance may include both clinical and technical aspects.

Example of Essential Principle:
5.1.1 Medical devices and IVD medical devices should achieve the performance intended by their manufacturer…

Technical performance:
Standards conformance demonstrates the ability of a medical device under test to achieve technical goals that are needed to support its intended use.

Clinical performance:
Standards conformance demonstrates the ability of a medical device to provide clinical outcome(s) in its intended use as claimed by the manufacturer. (GHTF/SG5/N1R8:2007, modified)

Example of Essential Principle:
6.2.1 Medical devices emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve ……

Example of Essential Principle:
5.2.1 Where appropriate and depending on jurisdictional requirements, a clinical evaluation may be required. A clinical evaluation should assess clinical data to establish that a favorable benefit-risk determination…

Standards Example:
IEC 60601-1:2005 3rd Ed - Clause 10

Other examples of standards:
IEC 60601-series (General requirements for Basic Safety and Essential Performance
-1-x (collateral general requirement(s)
-2-x (product specific)

Note: the use of device standards that reference the general standard addressing an EPs may provide additional requirements specific to the device under test.


Product specific example:
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 function 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
  – Provide training to interested stakeholders
  – Advance regulatory science
DRAFT PROPOSED DOCUMENT
International Medical Device Regulators Forum

Title: Optimizing Standards for Regulatory Use
Authoring Group: IMDRF Standards Working Group
Date: 14 February 2018
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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 Peter Linders
  – Joint meeting planned for June 2018

• IEC
  – Memo of Understanding under review
  – Possible execution at joint IEC TC62 meeting April 2018
  – Application for Category A liaison status underway
Next Steps

• Short term
  – Public consultation and finalize guidance
  – Promote and educate to the guidance
  – Consider NWIP for standards recognition guidance
  – Effectively represent IMDRF members in standards development priorities
  – Operationalize liaison status and MoU/agreements with SDOs
Next Steps (cont’d)

- **Long term**
  - Analyze standards’ future contributions to IMDRF strategic goal to ‘...accelerate international medical device regulatory convergence...’
  - Capitalize on standards’ central role in IMDRF priorities
    - Essential Principles, MDSAP, UDI and Single Review
    - Advancing regulatory science
  - Determine appropriate future role for standards in IMDRF
    - Liaise with SDOs
    - Lead productive participation in standards development (‘voice of regulators’)
    - Train and support individual RAs and others in effective standards engagement
    - *Drive application of standards to regulatory convergence – how can we put standards to work on behalf of harmonization?*
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Signe Annette Bøgh - Consultant, Dansk Standard

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