IMDRF/DITTA joint workshop on
Optimizing Standards for Regulatory Use

Key note and Panel Discussion

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Moscow, Russia
1. How can Regulatory Authorities and SDOs collaborate more to support each other?

- How IMDRF thinks to best become structurally involved in standards development
- How can IMDRF benefit from its category A liaisons with key technical committees of ISO and IEC?
- Suggestion to support the IMDRF liaison to TC of SDOs?
New Work Item Proposal Goals

- Agreement on how international standards can be improved
- Increase confidence in standards and how they can be better used for regulatory purposes
New Work Item Proposal - Two stages

1. Mapping of technical issues and concerns, with regard to regulatory aspects of standards developed by some major international standardization committees and Explore possibilities for improvement & discuss with stakeholders and SDOs

2. Describe possible actions to take by IMDRF in order to influence and support the development or amendment of standards for regulatory purposes
Member Country Consensus

Unanimous agreement that international standards are critical for:

• Regulating medical devices effectively
• Harmonizing regulation across jurisdictions
### „Regulatory“ Use of Standards

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<td>Singapore</td>
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Number of IMDRF RA experts in ISO/IEC Teams

- 222 respondents
- Caution: responses are self-identified/counted
- ‘None’ responses 58
- Most participate in only 1 (75)
- Second highest is 2 teams (45)

Frequency

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<th>Teams</th>
<th>Count</th>
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<tr>
<td>None</td>
<td>58</td>
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<tr>
<td>1 team</td>
<td>75</td>
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<tr>
<td>2 teams</td>
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<td>11 – 15</td>
<td>4</td>
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<td>16 – 20</td>
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The chart shows the frequency distribution of the number of teams each expert participates in.
Areas of Opportunities

• Participation levels by Regulatory Authorities
• Decision-making in the standards development process
• Usefulness of standards for regulatory use
• Consideration of regulatory and technical environment for product testing during development of a standard
• others
Conclusion:
Standards are not as useful for regulatory purposes as they could be
Conclusion:
Improvement is necessary and in principle possible (actions needed by SDOs and IMDRF)
Conclusion:
Better co-operation and coordination within the IMDRF necessary with regards to international standardisation projects
Recommendations

1. Increase regulators’ engagement with IEC/ISO, TAGs and National Committees (more efficient and effective engagement)

2. Develop resources, knowledge and expertise to improve standards

3. Preparing/Piloting an organisational structure being able to implement recommendations 1 and 2
Develop resources, knowledge and expertise to improve standards

- *Master Guide* for stakeholders to participate in standards development to include: e.g.
  - Essential Principles
  - How-to and/or ‘Best Practices’ for all stakeholders
  - Tools and templates to ensure TCs’ business plans adequately reflect consideration of regulatory needs
  - Templates for test methods (verification and validation) when appropriate
  - Instructions for evaluation and measurement
  - Instructions on conducting an impact assessment of a new standard or NWIP
Increase regulators’ engagement with IEC/ISO, TAGs and National Committees

• Identify gaps in coverage and participation in ISO and IEC; prioritize by ranking important standards by their significance to IMDRF members

• Encourage member engagement with relevant committees (particularly ISO TC 150 and 210 and IEC TC62) in standards development work (joining, liaising, commenting) at both national and international levels

• Establish regular interactions with IEC and ISO; finalize Memos of Understanding

• Partner with SDOs on process improvements for standards development

• Determine appropriate participation for IEC and ISO in future IMDRF standards activities

• Solicit, coordinate and submit IMDRF positions prior to and during standards development activities

• Raise awareness of SWG efforts at the TC/SC/WG levels
Thank you for your attention!