



IMDRF

International Medical
Device Regulators Forum

**IMDRF/DITTA joint workshop on
Optimizing Standards for
Regulatory Use**

Key note and Panel Discussion

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18 March 2019
Moscow, Russia



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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





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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





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Member Country Consensus

Unanimous agreement that international standards are critical for:

- Regulating medical devices effectively
- Harmonizing regulation across jurisdictions





„Regulatory“ Use of Standards

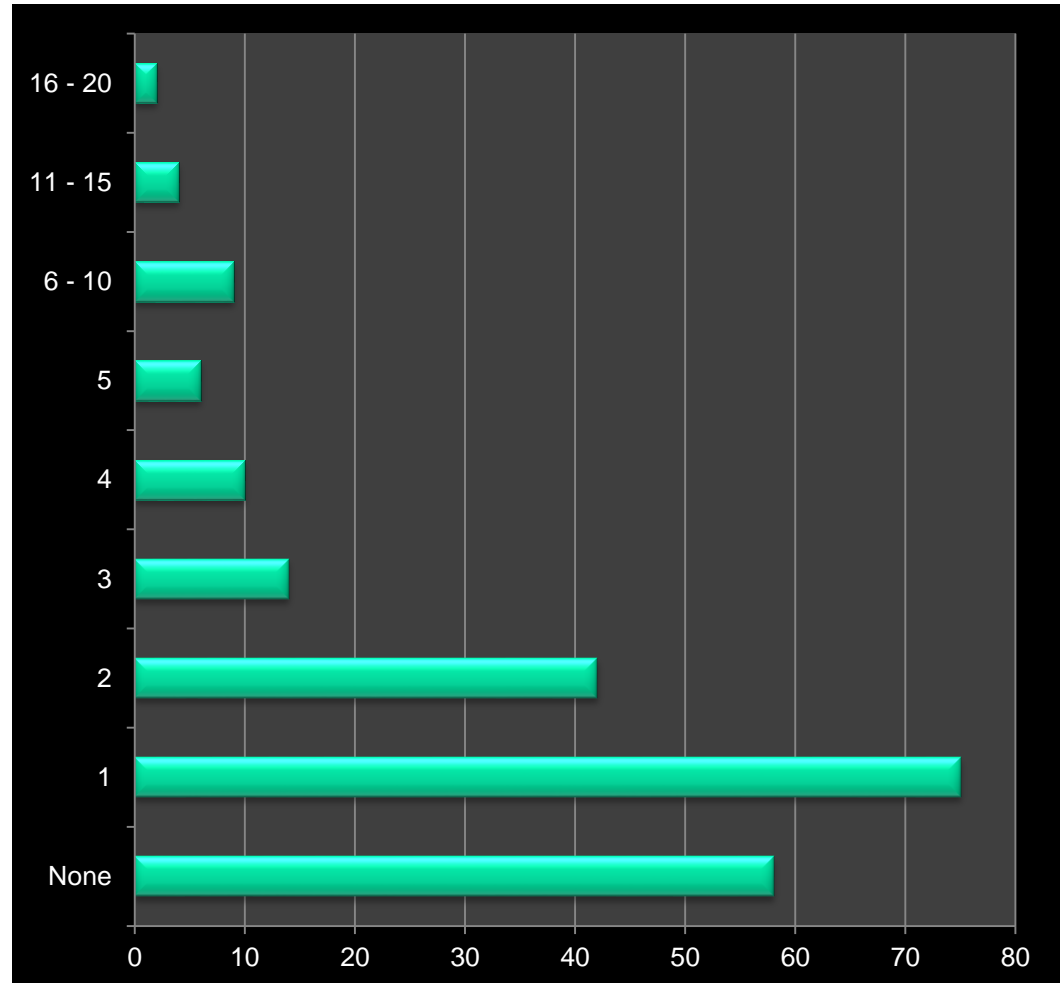
IMDRF RA	Recognition process?	List of recognized standards?	Voluntary use of standards?	Mandatory use of standards?
USA	Yes	Yes	Yes	No
Europe	Yes	Yes	Yes	No
Canada	Yes	Yes	Yes	No
Japan	Yes	No	Yes	No
Russia (EAEU)	Yes	Yes	Yes	No
China	Yes	Yes	Yes	Yes
Brazil	No	No	Yes	Yes
Singapore	No	No	Yes	Yes



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

None	58
1 team	75
2 teams	42
3 teams	14
4 teams	10
5 teams	6
6 – 10	9
11 – 15	4
16 – 20	2





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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**



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Conclusion:

Standards are not as useful for
regulatory purposes as they
could be



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Conclusion:

Improvement is necessary and
in principle possible (actions
needed by SDOs and IMDRF)



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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



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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



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Thank you for your attention !

