IMDRF International Medical Device Regulators Forum

IMDRF Working Group

Improving the Quality of International Standards for Regulatory Use

Progress Report

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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

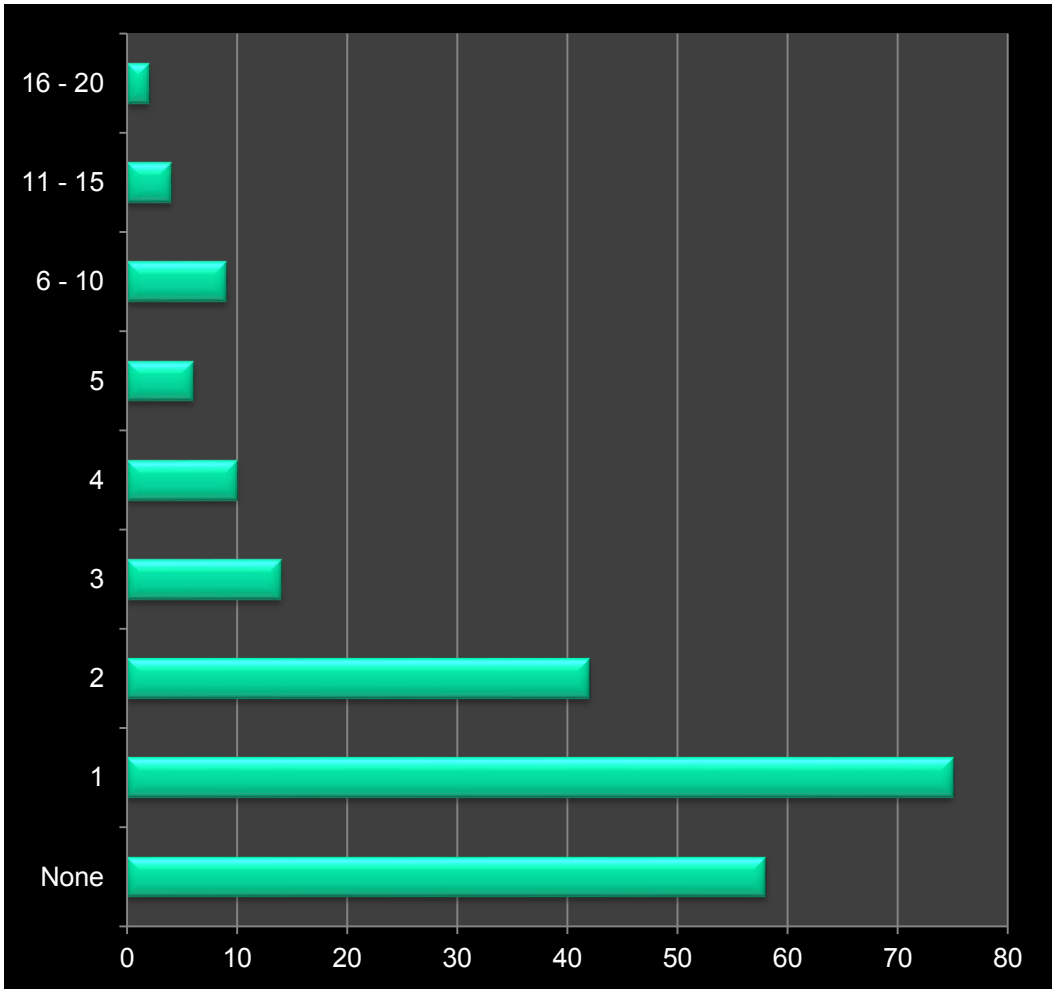
„Regulatory“ Use of Standards

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



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**

Thank you for your attention !