IMDRF International Medical Device Regulators Forum

IMDRF Working Group

Improving the Quality of International Standards for Regulatory Use

Summary and Recommendations

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Brasil, Canada, DITTA, EU, GMTA, Japan, Russia, US, WHO

New Work Item Proposal Goals

- Agreement on how international standards can be improved
- Increase confidence in standards and how they can be 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

First Meeting Objectives

- Share member country experiences
  - Resources, recognition policies, problems using standards for regulatory purposes
- Identify issues of common concern with international standards for regulatory use
- Recommend next steps

Member Country Consensus

Unanimous agreement that international standards are critical for:

- Regulating medical devices effectively
- Harmonizing regulation across jurisdictions

Some Findings

- In all participating IMDRF regions the regulatory use of standards is voluntary. Few exemptions with regards to some standards (e.g. ISO 13485) were e.g. according to the national regulation accreditation of third parties is necessary and those standards become mandatory. (or with respect to the Implementation of the UDI)
- All participating IMDRF regions are assessing standards with regards to compliance with the national/regional regulation.
- Different ways of assessments:
  - Systematic and robust assessment scheme by RA experts and RA expert committees -> regular publication of a list of recognized standards
  - Systematic but more legal formal check of standards -> publication of recognized standard
  - Non- formalized assessment by RA experts dealing with the assessment/market approval of devices -> no official list of recognized standards

Some Findings

- Despite in all IMDRF regions the RAs are doing their best to be involved into international standardization and to assess standards with regards to a possible “recognition” the allocated resources for international standardization work is ranging from
  - ~ 2 FTE to ~ 50 FTE
- Many RA are preferring the (not always efficient) involvement into standardization on the national level (e.g. national “mirror” standard groups)

Member Concerns

Regulators have too little insight and input into standards development

- Lack of resources
- Lack of awareness
- Industry has disproportionate influence

Member Concerns

Current standards frequently contain insufficient direction on how to apply them

Some standards include non-specific pass and fail criteria, or even no pass and fail criteria for technologies,

Requirements of some ISO/IEC standards allowing too much flexibility on requirement interpretation (e.g.: 3rd edition of IEC 60601);

Standards are often written without sufficient knowledge of the legal requirements in IMDRF countries/regions

Other Concerns

- Under-representation of testing houses, clinicians and academia in SDOs
- Participation costs
  - Financial and human
  - Working on international standards and applying them when regulating their products
- Inconsistencies in conformance testing methods across standards
- Lengthy standards creation processes
- …….

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

Analyze regulators' current participation in key international standardization working groups

- Survey and/or other review of committee rosters
- Ensure IMDRF has an accurate understanding of current engagement levels

Recommendations

Form a ‘Standardization Network of RA Experts’

- Develop and maintain a list of IMDRF Recognized Standards
- Serve as educators and resources to other RAs
- Ensure that IMDRF is aware of key device standards activities

Next planned steps

- Providing a report to the IMDRF MC on identified problems
- Getting an overview about IMDRF RA involvement into international standard working groups
- Assessment of the feasibility to establish
  - a network of IMDRF experts on standards
  - a smart and efficient process to assess international standards with respect to their compliance with the essential principles of IMDRF/GHTF

Next planned steps

- Preparing a meeting with SDOs
  - Discussion of problems and possible solutions (out of the hands of the IMDRF RA) also identified by the group
  - possible liaison ?
  - List of essential principles ?
  - Mandating IMDRF standards?
  - …..

Thank you for your attention !