IMDRF WG “Improving the quality of international standards for regulatory use”
- progress report -

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Purpose

To identify and explore possibilities to improve the process of developing international standards used for regulatory purpose in the medical technology domain

1. Mapping of technical issues and concerns, with regard to regulatory aspects of standards developed by some major international standardization committees

2. Explore possibilities for improvement & discuss with stakeholders and SDOs

3. Describe possible actions to take by IMDRF in order to influence and support the development or amendment of standards for regulatory purposes
First Meeting 29-31 August in Berlin

20 Members (17 participants in Berlin)
from: FDA, EU, Health Canada, Roszdravnadzor (Russia), ANVISA (Brasil), PMDA (Japan), DITTA, GMTA
What is the status quo?

1. General description of principles how and which standards are used for regulatory issues

2. Description of procedures to recognise “regulatory” standards or to make standards mandatory

3. General overview on resources allocated by RA to international standardisation processes (E.g. How many experts? How many FTE (Full Time Equivalence)?)
4. General description of identified or perceived problems in international standardisation processes

5. Examples of problems in international standards (in particular standards from ISO TC 210, 194 or IEC TC 62)

6. Examples of reasons why several standards are not recognised or made mandatory
7. First Ideas how IMDRF could improve the quality of international standardisation work
1. General description of principles how and which standards are used for regulatory issues

- In nearly all participating IMDRF Regions standards are considered as translating the mainly non-specific regulatory essential requirements on safety and performance of devices into specific requirements for devices or categories of devices and technologies.

- The same applies for processes or systems required by the regulation
2. Description of procedures to recognise “regulatory” standards or to make standards mandatory

- 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.

- 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 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
3. General overview on resources allocated by RA to international standardisation processes (E.g. How many experts? How many FTE (Full Time Equivalence)?)

- 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)
General description of identified or perceived problems in international standardisation processes

• RA with low participation in comparison to industries in the meetings of the Technical Committees (TC);

• RAs have low influence on decisions in national and international forums that can actually make a difference in the formulation of future standards

• Development of standards is largely driven by industry.

• Too expensive and insufficient involvement of RA and Academics or professional users

• High cost (human and financial resources) for both government and private sectors to participate in the Technical Committees of ISO/IEC.
Some standards include non-specific pass and fail criteria, or even no pass and fail criteria for technologies,

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

Methodology or Process standards do often not include significant confidence that following the procedure will result in a safe and effective Medical Device, within the context of the scope of the standard. Those standards do not always include methodology for setting pass and fail criteria.

Standards are often written without sufficient knowledge of the legal requirements in IMDRF countries/regions.
Conclusion:
Standards are not as useful for regulatory purposes as they could be
Conclusion:
Improvement necessary and in principle possible
Conclusion:
Better co-operation and coordination within the IMDRF
necessary with regards to international standardisation projects
Involvement of RA experts into international standardization is necessary and sensible for each RA.

Only RA having an comprehensive overview of existing problems with devices in the field (due to their surveillance/vigilance role).

Good standards makes it obsolete that the RA has to develop device specific guidelines (for internal and/or external use) on the correct interpretation of the regulatory requirements.

Participation in standardization is an essential tool to ensure that the RA staff is well trained and has state of the art knowledge on medical devices technologies.

Why better co-operation and coordination between IMDRF RA?
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
Recommendations

Obtain formal liaison status for IMDRF to the international SDOs to:

• Access all relevant documentation and meetings
• Nominate experts to participate in working groups
• Amplify our contributions to standards development and harmonization
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
- Outlining a smart and efficient process for establishing, maintaining and (if necessary) correcting a list of IMDRF recognised standards
Next planned steps

• Preparing a next 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!