How standards are used for regulatory purposes among IMDRF members

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Standards are ‘…the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators’.*

Standards Working Group (SWG) Members

- Scott Colburn/FDA/USA, Chair
- Ying Huang/TGA/Australia
- Fabio Quintino/ANVISA/Brazil
- Kevin Day/Health Canada
- Jia Zheng/SDA/China
- Maurizio Andreano/DITTA/Siemens
- Peter Linders/DITTA/Philips
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- Gail Rodriguez/FDA/USA
Role of Standards (IMDRF Model)

Role of Standards in the Assessment of Medical Devices
Study Group 1 Final Document GHTF/SG1/N044:2008

Main purpose: demonstrating conformity with the Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF GRRP WG/N47 FINAL:2018)

Methods:
- use of recognized standards;
- use of non-recognized standards;
- other methods.
Use of recognized standards (IMDRF Model)

Recognition of Standards

The method should include a mechanism of periodic review and realignment of nationally recognised standards to the international standards.

The term “recognised standard” does not imply that such a standard is mandatory.

Use of recognized standards

Recognised standard - standard deemed to offer the presumption of conformity to specific Essential Principles of Safety and Performance.
Use of recognized standards (IMDRF Model)

Revision of Recognised Standards

- a requirement in a specific standard is determined to be inadequate to ensure conformity to a specific Essential Principle;
- one or more of the Essential Principles has changed,
- changes in the state of technology or accepted practice necessitate revising the technical specifications in the standard.

Changes to the Recognition Status

- safety concerns identified through post-market surveillance activities or user experience;
- the availability of a revised version of the standard.
IMDRF Model

Alternative solutions to demonstrate conformity with the Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

- national and international standards that have not been given the status of a "recognised standard" by the Regulatory Authority;
- industry agreed methods;
- internal manufacturer standard operating procedures developed by an individual manufacturer;
- other sources that describe the current state of technology and practice related to performance, material, design, methods, processes or practices.
Use of recognized standards among IMDRF members

- Recognized:
  - Russia (EEU)
  - China
  - Singapore*
  - Canada*
  - Japan*
  - Brazil

- Non-recognized:
  - Australia
  - Korea

- Mandatory:
  - USA
  - Europe

- Voluntary:
  - Brazil

* have one mandatory standard or section of the standard (linked to regulatory framework)
Standards Recognition and Use

Work Item goal: advance harmonized use of standards

- Two objectives
  - Compare RAs’ recognition and utilization policies
  - Update list of commonly recognized standards
- Two elements
  - Survey
  - Checklist of recognized standards
Recognition Program Details

• 7 of the 10 respondents (70%) report that they have a formal standards department or function within their RA

• The lack of a formal department notwithstanding, 9 (90%) have in place formal systems – policies and processes

• Systems identify, recognize and maintain an approved list of standards and encourage their use by manufacturers in device submissions
Recognition Program Details, cont’d

• Most, whether formal or informal, maintain a list of recognized standards that manufacturers may declare conformity to for purposes of device submissions

• Two respondents’ programs are regional programs

• One RA has in place an ad hoc team that plans to transform itself into a formal department in the near future
Recognition Program Details, cont’d

• Many responses appear to be a ‘hybrid’ program, with both formal and informal aspects (e.g., a formal list of recognized standards, but an informal staff and process for producing the list)

• Several mention that they expect further formalization of their standards program in the future

• RAs report both rules/regulations and statutes as the authority for their programs

• National Bodies participate directly in 6 of 10 RAs’ programs (more regulations than statutes)
Managing a Recognition List

- 60% of respondents report they are required to seek outside input into which standards will be recognized.
- Most require a public consultation, at least for list publication.
- Others permit input from the public.
- 90% publish the list of recognized standards; all of those make the list of recognized standards available to all.
- Frequency of list updates ranges from ‘case by case basis’ to ‘periodically’ to ‘at least five yearly’.
How to Gain Recognition

• Again, a wide spectrum of expectations for requesting recognition; some require specific forms and others simply accept a request

• Some have ad hoc or technical teams consider the addition of new standards; some will accept requests from anyone
Partial v Complete Recognition

• 100% (10 respondents) allow partial recognition
Conformity Assessment

• 100% of respondents allow Declarations of Conformity (DoCs)
• 9 of 10 (90%) sometimes require additional documentation to the DoC
  • Generally based upon device risk
  • Testing reports are the most often required documents
• 90% accept test results from other countries in support of a DoC
Thank you for your attention!

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