IMDRF International Medical Device Regulators Forum

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'.*

* https://www.bsigroup.com/en-GB/standards/Information-about-standards/what-is-a-standard/, accessed 15 June 2017

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
- Naoki Marooka/DITTA/Shimadzu
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- Jeff Eggleston/GMTA/Medtronic
- Hideki Asai/GMTA/Hitachi
- Hiroshi Ishikawa/PMDA/Japan
- Madoka Murakami/PMDA/Japan
- Vladimir Antonov/Roszdravnadzor/Russia
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- Christopher Lam/HSA/Singapore
- Kookhan Kim/MFDS/Korea
- Heungil Ryu/MFDS/Korea
- Kyunghyun Kim/MFDS/Korea
- 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

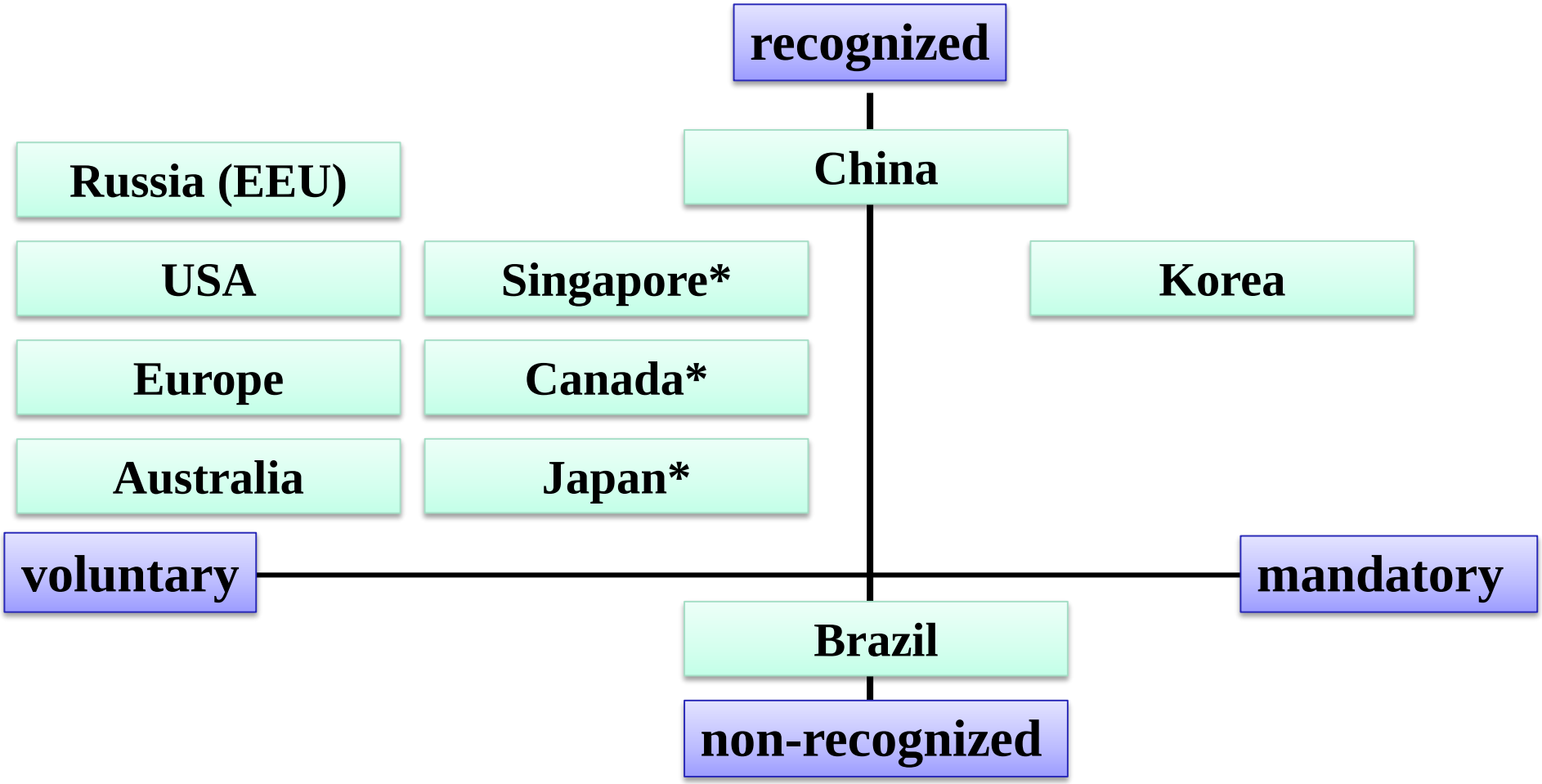
- safety concerns identified through post-market surveillance activities or user experience;
- the availability of a revised version of the standard.

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



* 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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