Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1927-2017 FICCI @90

22nd Asian Harmonization Working Party Annual Meeting

MAKE IN INDIA

MAKE IN INDIA

4-8 December, 2017 I New Delhi

Ministry of Health & Family Welfare
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WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Role of Technical Standards

and

updates on international technical standards

Peter Linders – Philips

AHWP, New Delhi, 4 Dec 2017

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updates on international technical standards

Peter Linders
AHWP, New Delhi

4 December 2017

innovation + you

PHILIPS

Today's menu

- Introduction
- Background
- References international
  - *WTO*
  - *EU*
  - *AHWP Playbook*
  - *ASEAN*
  - *GHTF*
  - *IMDRF*
  - *ISO/IEC*
- Example: ISO/TC 210
- Update on Technical Standards
- Improvement in standards development
- Conclusions

About Peter Linders

- Over 25 years involvement in IEC and ISO
- Involved in regulatory affairs since 1998
- Chair of CENELEC/TC 62
- Chair of ISO/TC 210
- Co-project leader of IEC 82304-1
- COCIR Board member & chair of TRAC
- DITTA member Board of Directors
- Involved in GHTF, IMDRF, and AHWP

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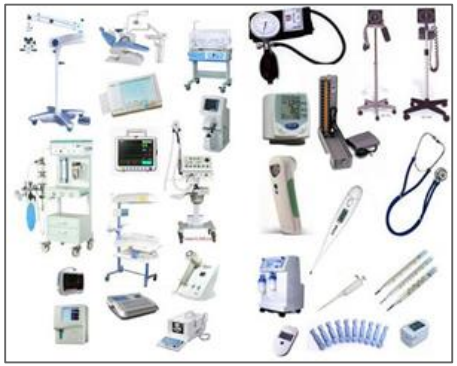
Medical devices: substantial market

Global market size:

Ca. 350 G€ (2015)

Ca. 450 G€ (2020)



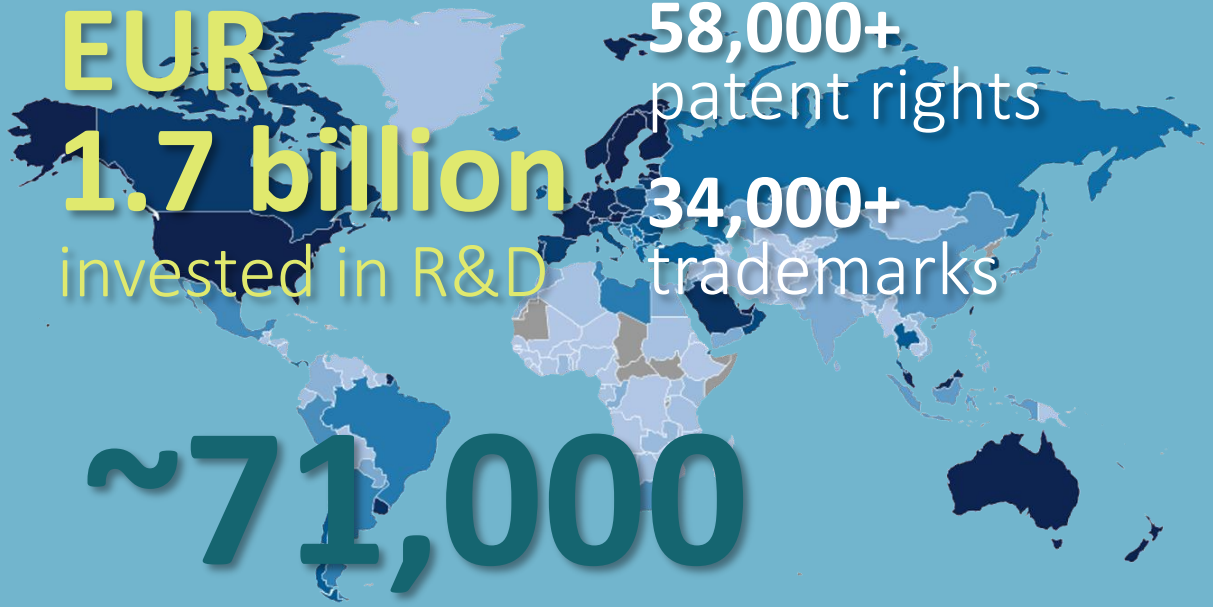
Philips

A focused leader in health technology

With enviable, established positions in the hospital and the home, Philips is entering this next phase in its history determined to extend its leadership in health technology.

Royal Philips in 2016

2.1
billion
lives improved[1]



EUR 1.7 billion
invested in R&D

58,000+
patent rights

34,000+
trademarks

~71,000
employees in over 100 countries

1 Includes contribution of Philips Lighting

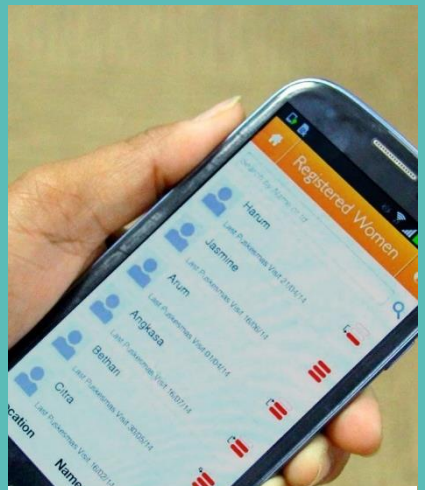
PHILIPS

A selection of our partnerships

Nyeri County Referral Hospital, Nyeri, Kenya, Africa

Karolinska Hospital and Stockholm County Council, Sweden

Hospices Civils de Lyon, France



Bunda Hospital, Padang, Indonesia

We see three major **areas of opportunity**

Personalization of care
Driving convergence of professional healthcare and consumer health

Industrialization/integration of care
Enabling providers to deliver lower-cost care and better outcomes

Inclusive care
Increasing access to affordable care and making care more inclusive

Why International Standards? What is their value?

Access & Time to Market: critical for healthcare system and business

- *Country requirements (laws and regulations) vary*
- *Process and documentation requirements differ*
- *Scope of verification and validation is not unified*
- *Even definition of medical device varies by jurisdiction*

THEREFORE:

Convergence of national requirements through international standards is key

Standards help by bringing:

- *Common & agreed language across stakeholders*
- *Basis for international trade agreements*
- *Testable or auditable requirements (potentially without submitting data)*
- *Cost saving for healthcare: improve patient access*

International standards …

On Technical Standards & Technical Regulation

WTO tells us (https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm):

2.4 Where technical regulations are required, and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

On Technical Standards & Technical Regulation

WTO tells us (https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm):

Technical regulation

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

On Technical Standards & Technical Regulation

WTO tells us (https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm):

2.6 With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.

EU & International Standards

Regulation on standards (EU) 1025/2012

(preamble (6)) Standardisation plays an increasingly important role in international trade and the opening-up of markets. The Union should seek to promote cooperation between European standardisation organisations and international standardisation bodies.

EU & International Standards

Vienna Agreement (ISO-CEN)

The main objective of the Vienna Agreement is to ensure we make the best use of the resources available … and that work does not have to happen twice at the regional or international level.

AHWP Playbook

Chapter 7: Essential Principles of Safety and Performance and Recognition of Standards

So, 2 parts:

1. Essential Principles
2. Standards Recognition

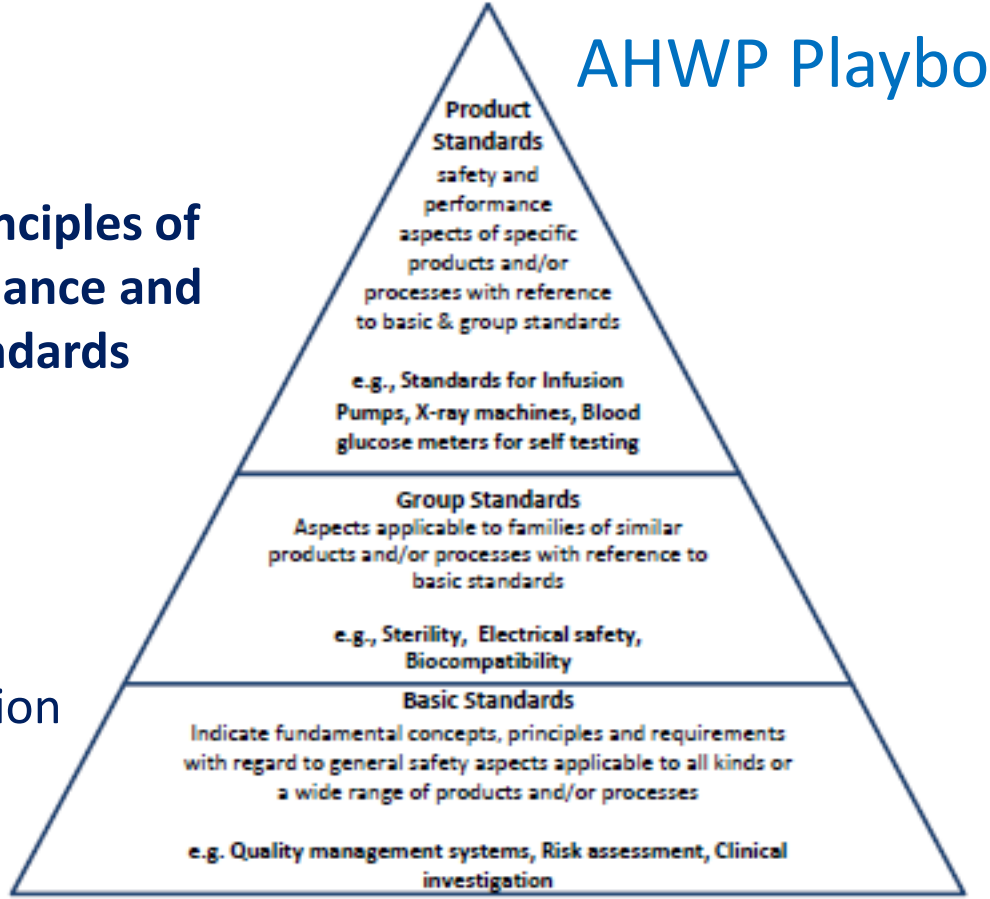
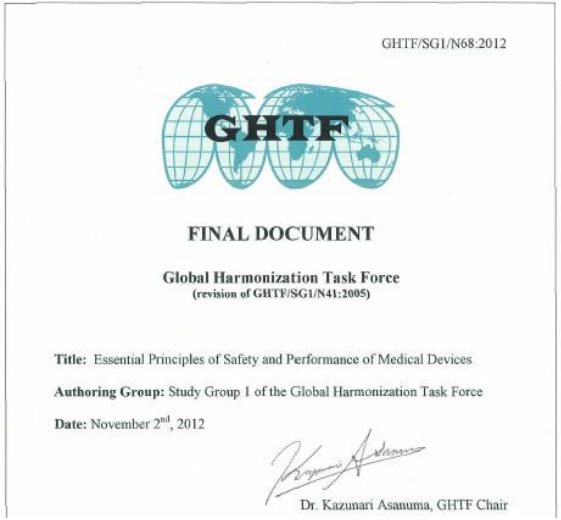


Figure 7: Categories of medical device standards

Chapter 7

Recommend to consider adoption of the **Essential Principles** of safety and performance as developed by the GHTF.

The essential principles comprise six general principles applicable to all medical devices and other principles which only apply, as relevant, to some medical devices.



GHTF/SG1/N68:2012

GHTF

FINAL DOCUMENT

Global Harmonization Task Force
(revision of GHTF/SG1/N41:2005)

Title: Essential Principles of Safety and Performance of Medical Devices

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: November 2nd, 2012

Dr. Kazunari Asanuma, GHTF Chair

Chapter 7

Recognition of standards allows regulatory authorities and other stakeholders to:

- Reduce the burden of regulatory compliance
- Provide for high level of patient safety at reduced cost
- Leverage on consolidated global expertise and experience
- Build confidence and understanding internationally with regulatory authorities and device dealers.

ASEAN MDD and Technical Standards

ASEAN MDD

(http://asean.org/storage/2016/06/22.-September-2015-ASEAN-Medical-Device-Directive.pdf)

ARTICLE 9 - REFERENCE TO TECHNICAL STANDARDS

(1) Medical devices which conform to either the relevant technical standards recognised by the AMDC or other technical standards accepted by the Regulatory Authority of a Member State for the medical device to be placed in the market of that Member State shall be deemed to comply with the applicable essential principles referred to in Article 3.

(2) The AMDC may revise by consensus, the list of recognised technical standards referred to in paragraph 1 of this Article.

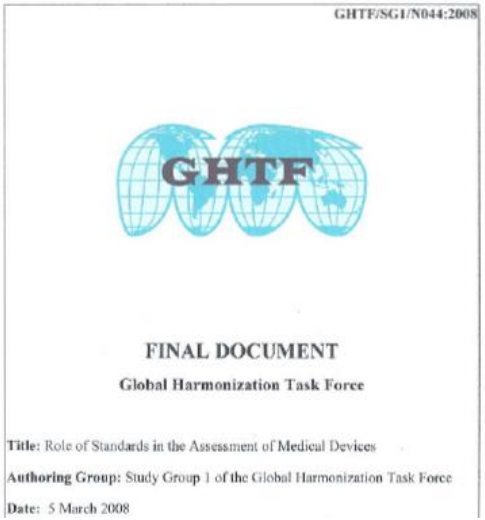
GHTF Guidance Documents

GHTF (1992-2012)

Developed many guidance documents, including Essential Principles, STED (CSDT), and …

SG1/N044: Role of Standards in the Assessment of Medical Devices (2008)

Archive maintained by IMDRF; see:
http://www.imdrf.org/documents/documents.asp#ghtf


GHTF/SG1/N044:2008

GHTF

FINAL DOCUMENT

Global Harmonization Task Force

Title: Role of Standards in the Assessment of Medical Devices

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Date: 5 March 2008

IMDRF – Intl. MD Regulators Forum

IMDRF (2012-21xx)

- Now 9 jurisdictions are member (AU, BR, CA, CN, EU, JP, RU, SG, US)
- AHWP has status as Official Observer
- Industry federations (DITTA, GMTA) have no formal status, but …
- Two plenary meetings per year, incl. Open Stakeholder Meeting
- Active in several programs: MDSAP, RPS, SAMD, UDI, AE-codes, etc.; see http://www.imdrf.org/index.asp

IMDRF – Intl. MD Regulators Forum

IMDRF (2012-21xx)

Programs of interest re. standards:

A. Standards – improvement for regulatory purposes

involve more regulators more in the development of standards so that standards are more easily adopted and 'recognized' for regulatory purposes

B. Essential Principles – revision of GHTF material (regulators only)

review and update the GHTF's Essential Principles to better reflect present day regulatory requirements → better proposition for standards writers!

A standard is …

document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

Note 1 to entry: Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.

(ISO/IEC Directives, part 2, 2016)

International Standards: respecting all interests

From the IEC Statutes (similar in ISO):

"**A National Committee shall be fully representative of national interests in the fields of activity of the Commission.**"

"**The standards work of the Commission shall be carried out through technical committees and subcommittees, composed of representatives of the Full Member National Committees**" (and from Category A liaisons)

Note: National Committees are the members of the TC/SCs. They decide on publications, **not** the drafting groups!

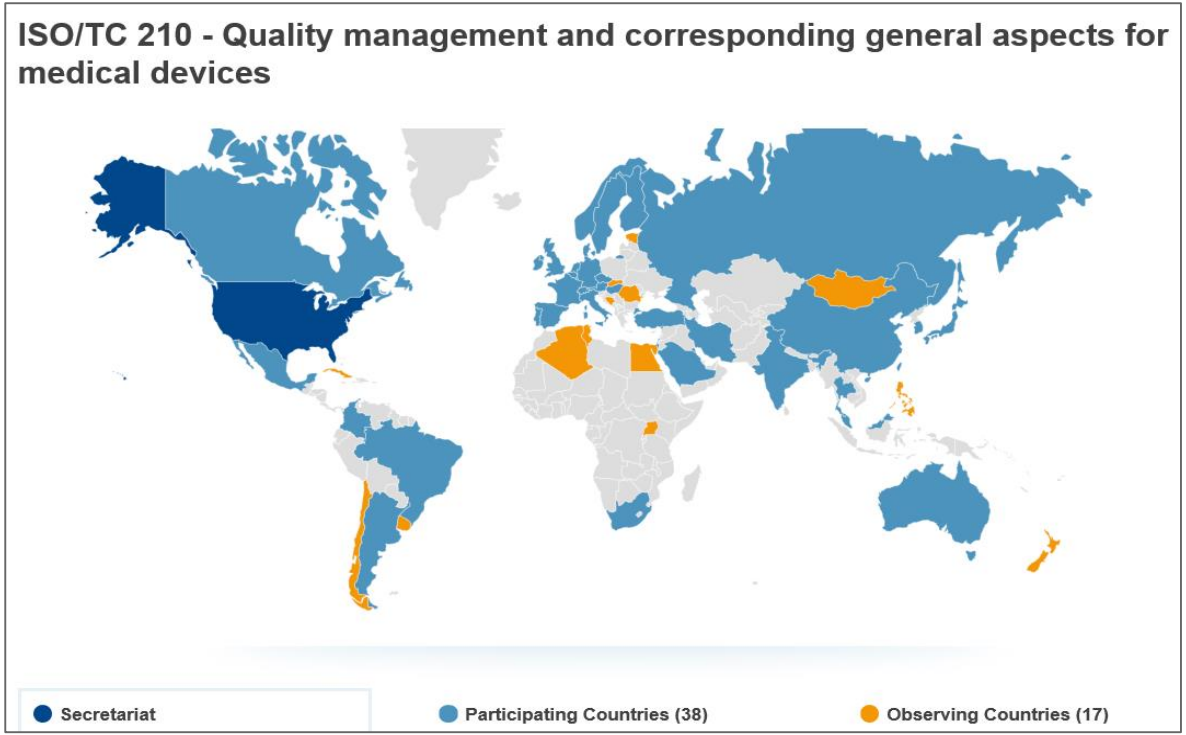
ISO TCs involved in healthcare

Committee	Title	Standards	Work program
TC 76,	Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use	66	16
TC 84,	Devices for administration of medicinal products and intravascular catheters	29	15
TC 94,	Personal safety - Protective clothing and equipment	128	56
TC 106,	Dentistry	171	59
TC 121	Anaesthetic and respiratory equipmen	90	30
TC 150,	Implants for surgery	141	64
TC 157,	Contraceptives/STI	10	8
TC 168,	Prosthetics and orthotics	23	4
TC 170,	Surgical instruments	6	1
TC 172,	Optics and photonics	299	72
TC 173,	Assistive products for persons with disability	83	15
TC 181,	Safety of toys	9	6
TC 194,	Biological evaluation of medical devices	32	15
TC 198,	Sterilization of healthcare products	52	19
TC 210,	Quality management and corresponding general aspects for medical devices	22	17
TC 212,	Clinical laboratory testing and in vitro diagnostic test systems	26	14
TC 215,	Health informatics	151	50
TC 249,	Traditional Chinese medicine	5	30
PC 283	Occupational health and safety management systems	0	5
	Total	**1343**	**496**

Example: ISO/TC 210

- WG 1
- WG 2
- WG 3
- WG 5
- WG 6

- JWG 1
- JWG 2
- JWG 3
- JWG 4



Example: ISO/TC 210

Quality management and corresponding general aspects for medical devices

- Secretariat: ANSI
- Secretary: Mr Wil Vargas
- Chairperson: Mr. P.W.J. Linders until end 2018
- ISO Technical Programme Manager: Dr Mary Lou Pelaprat
- ISO Editorial Programme Manager: M. Vincenzo Bazzucchi

Creation date: 1994

Example: ISO/TC 210

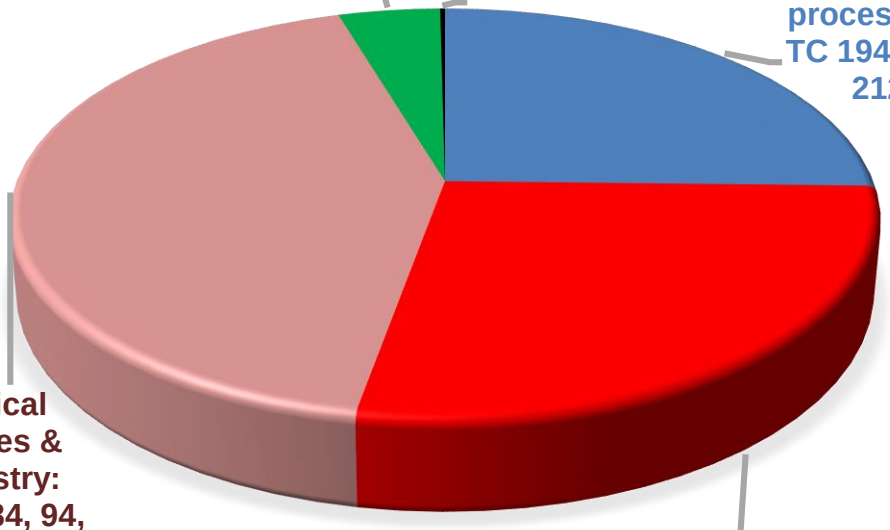
ISO/TC 210 Working groups:

- WG 1 **Application of quality systems to medical devices**
- WG 2 **General aspects stemming from the application of quality principles to medical devices**
- WG 3 **Symbols and nomenclature for medical devices**
- WG 5 **Connectors for reservoir delivery systems**
- WG 6 **Application of post market surveillance systems to medical devices**

Joint Work ISO/TC 210-IEC/TC 62:

- JWG 1 **Application of risk management to medical devices (62A)**
- JWG 2 **Medical device software (62A)**
- JWG 3 **Medical device usability (62A)**
- JWG 4 **Small bore connectors (62D)**

ISO Health standards sold by sector



Standards in Action

ISO 13485
Medical devices — Quality management systems Requirements for regulatory purposes

ISO 14971
Medical devices — Application of risk management to medical devices

ISO 15189
Medical laboratories — Requirements for quality and competence

ISO 15223
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

ISO 11135
Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 10993
Biological evaluation of medical devices

Update on Technical Standards

Standards are regularly reviewed; updated if needed

Key standards under development:

- IEC 60601-1 (Ed 3.1 → Ed 3.2); expect 2019
- IEC 62304 (Ed 1.1 → Ed 2); expect 2019
- ISO 14971 (Ed 2 → Ed 3); expect 2019
- ISO 14155 (Ed 2 → Ed 3); expect 2019 ?
- ISO 10993-series (various parts under revision)

(check IEC and ISO websites for progress)

IMDRF International Medical Device Regulators Forum

Improvement in standards development

Participants:

- 8 of 9 IMDRF jurisdictions (~~AU~~, BR, CA, CN, EU, JP, RU, SG, US)
- WHO
- Industry (DITTA, GMTA)
- (IEC, ISO)

http://www.imdrf.org/docs/imdrf/final/meetings/imdrf-meet-170919-canada-presentation-working-group-update-standards.pdf

IMDRF International Medical Device Regulators Forum

Improvement in standards development

Overview

Regulatory use of standards in WG jurisdictions

Note that the term “Recognized” has multiple meanings

„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

IMDRF International Medical Device Regulators Forum

Improvement in standards development

Observations

By Regulatory Authorities on standards intended for regulatory use

Conclusion

Need guidance for writing standards for regulatory purposes

Selection of observations:

- Regulatory Authorities' experts not sufficiently involved
- Attention for NWIPs: scope & justification must be OK
- Design specification for standards early in process
- Conformity considerations sometimes lacking
- Impact assessment of standards
- Validation of testing: consistency across test labs?
- Flexibility of/built in standards too high?
- Balance between "tried & true" and "new" requirements
- Attention for new technology vs. frequency of change of standards

Conclusions

Developing International Standards for multiple regulatory frameworks is not easy

Because regulations tend to …

- change with no or limited international synchronization in content and timing
- typically develop in a political process, not necessarily involving all stakeholders
- aim for legal integrity, not necessarily practically oriented

Conclusions

Developing International Standards for multiple regulatory frameworks requires …

Ongoing dialogue between:

- Stakeholders, esp. RA, on needs & expectations
- International SDO's on processes

Broadly accepted guidance for RA standards writing

→ Essential Principles of safety & performance V2.0 may help

Thank you