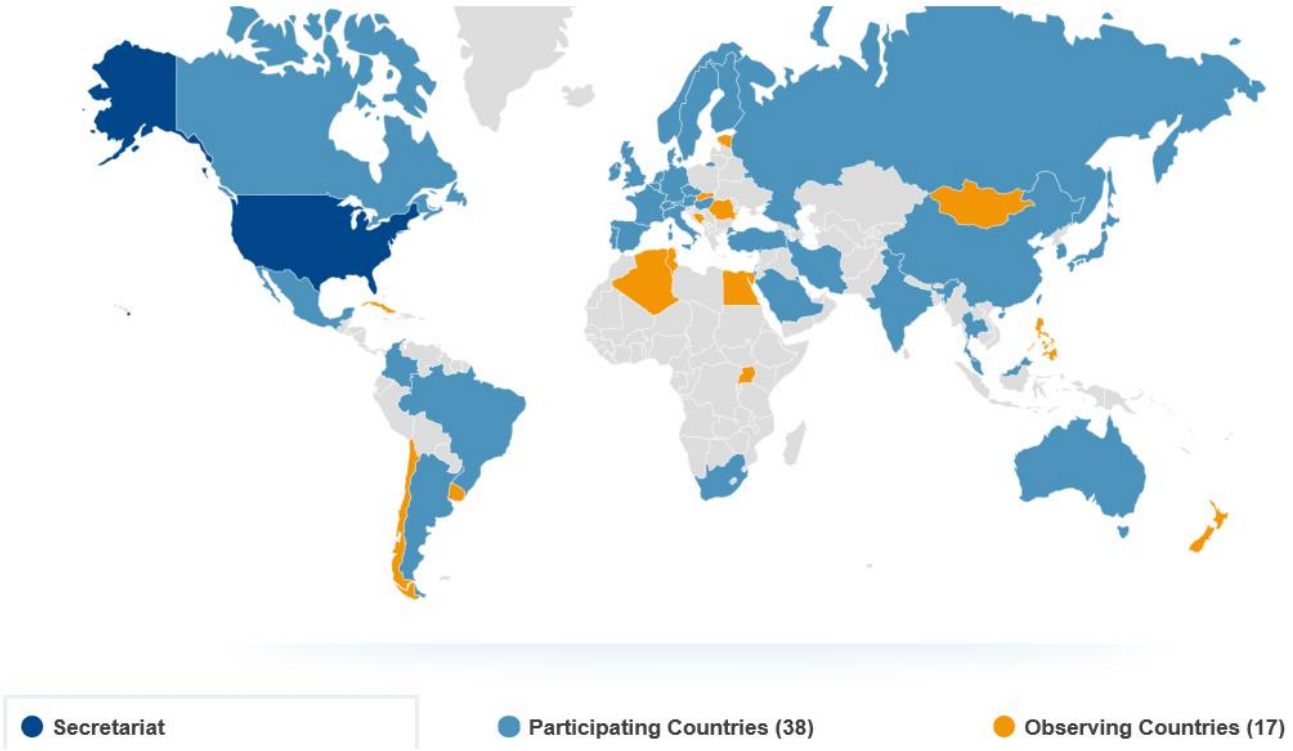
ISO/TC 210 - Quality management and corresponding general aspects for medical devices



Peter Linders, Chair 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

ISO/TC 210 – SCOPE

Standardization of requirements and guidance in the field of quality management and corresponding general aspects for medical devices. Standards for small bore connectors.

Excluded:

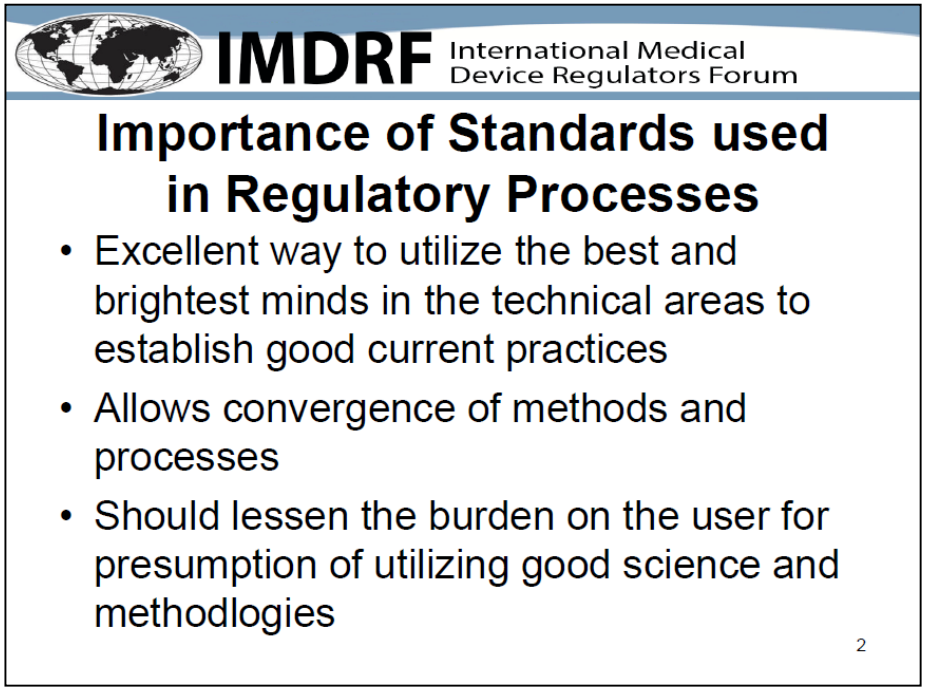
- generic quality management standards dealt with by ISO / TC 176;
- quality management standards for pharmaceutical products;
- technical requirements for specific types of medical devices (Note: Small bore connectors are components of a range of medical devices but are not themselves medical devices).

Note:

In order to promote global harmonization the technical committee may also develop standards on general aspects stemming from the application of quality principles to medical devices, where these are not covered by the scope of another technical committee

ISO/TC 210 – MAIN FOCUS

- Key words
  - For use in regulatory environment
  - Medical devices
  - Quality management
  - Horizontal standards
  - Protect Health & Safety
  - Eliminate trade barriers
  - Global convergence



Kim Trautman (US FDA) in DITTA workshop Kyoto, 2015

ISO/TC 210 – STRUCTURE

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/AhWG **Application of post market surveillance systems to medical devices**

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

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

ISO/TC 210 – CONTEXT & LIAISONS

Co-operate, not work in isolation and avoid duplication of work

- IEC and ISO committees (list)

ISO committees in liaison:

ISO/IEC JTC 1/SC 7, ISO/TC 76, ISO/TC 84, ISO/TC 106, ISO/TC 121, ISO/TC 150, ISO/TC 157, ISO/TC 168, ISO/TC 170, ISO/TC 172/SC 5, ISO/TC 172/SC 7, ISO/TC 173, ISO/TC 173/SC 2, ISO/TC 176, ISO/TC 176/SC 2, ISO/TC 194, ISO/TC 198, ISO/TC 209, ISO/TC 212, ISO/TC 215

IEC committees in liaison:

IEC/TC 56, IEC/TC 62, IEC/SC 62A

- Organizations in liaison

IMDRF (to be invited)

Organizations in liaison (Category A and B):

AHWP, DITTA, EDMA, EUCOMED, EUROM, WFSA, WHO

Organizations in liaison (Category C and D):

GEDSA

Delft meeting (7-11 Nov 2016) decisions

- Increasing ‘grey zone’ between medical and health devices
- “Everything connected to everything else”
- Dialogue with customers & stakeholders

ISO/TC 210 – FUTURE

- Key words
  - Increasing ‘grey zone’ between medical and health devices
  - “Everything connected to everything else”
  - Dialogue with customers & stakeholders

Key decisions from Delft, 11.2016

To revise ISO 14971, Medical devices -- Application of risk management to medical devices, with the following plan:

1. maintain the concepts of and the approach to risk management; no scope change
2. clarify the normative requirements, particularly concerning the following topics:
   - production and post-production information,
   - clinical benefits and risk-benefit analysis,
3. move guidance in the informative annexes to ISO/TR 24971, Medical devices -- Guidance on the application of ISO 14971,
4. keep the annex with the rationale in ISO 14971, Medical devices -- Application of risk management to medical devices,
5. with a 36 month track

Key decisions from Delft, 11.2016

ISO/TC 210 instructs JWG1 to consider the following items regarding the revision of 14971:

1. include references to ISO/TR 24971 and IEC/TR 80002-1, Medical device software -- Part 1: Guidance on the application of ISO 14971 to medical device software;
2. Clarify the relationship with 62366-1, Medical devices -- Part 1: Application of usability engineering to medical devices,
3. Consider to harmonize the vocabulary with ISO 31000, Risk management -- Principles and guidelines , where appropriate,
4. Address data privacy and security.

Key decisions from Delft, 11.2016

Proposal to revise ISO/TR 24971, Medical devices -- Guidance on the application of ISO 14971, and merge guidance in the informative annexes of ISO 14971 into ISO/TR 24971, with the following plan:

1. update the guidance ISO/TR 24971,
2. merge and update guidance from informative annexes of ISO 14971,
3. with no change in scope
4. with a 36 month track

Relation AHWP & ISO/TC 210

- AHWP is a formal liaison organisation to ISO/TC 210
- Mr. Ee Bin Liew has been the voice of AHWP in ISO/TC 210 for quite some time
- Dr Jang-yong Choi (Korea MFDS) appointed AHWP representative in the ISO/TC 210 CAG
- It is expected that they will jointly represent AHWP in ISO/TC 210 for the coming years
- A close link with AHWP WG8 seems appropriate

IMDRF project on standards

IMDRF project on standards

IMDRF International Medical Device Regulators Forum

First Meeting 29-31 August in Berlin

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

IMDRF project on standards

IMDRF International Medical Device Regulators Forum

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

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

CONCERNS, ISSUES, …

FROM DITTA KYOTO 015 WORKSHOP

International standards are very useful, but …

- **Development times are looong**
  IEC 60601-1, 3rd ed. : 10 year; ISO 13485, 3rd ed. : 5 year
- **Multi-part standards come unsynchronized**
  IEC 60601-parts are published almost at random
- **Rules for faster publication result in "submarine documents"**
  NWIPs more often come with a complete draft to "win time"
- **Revisions don't come with change log & rationale**
  For standards users, such revision table is critical

Not always aimed at "optimum community benefits"

COCIR JIRA MEDEC MITA IMEDA 中国医疗器械行业协会 China Association for Medical Devices Industry abimed Kmdica Korea Medical Devices Industrial Coop. Association ITAC health

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

CONCERNS, ISSUES, …

FROM DITTA KYOTO 015 WORKSHOP

International standards are very useful, but …

- **Representing all stakeholders ??**
  regulators, users virtually absent in drafting teams
- **Increasing participation of consultants and pensionado's**
  New business creation? The best experts really hold the pen?
- **Technical Committees don't always follow the directives**
  WGs live "forever"; JWGs act as Technical Committees
- **Turf battle among TC "silo's" does happen**
  some Committees are sort of academic debating clubs

Not always aimed at "optimum community benefits"

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CONCERNS, ISSUES, …

FROM DITTA KYOTO 015 WORKSHOP

International standards are very useful, but …

- **Implementation not synchronized in time**
  Regulators do not synchronize recognition of standards
- **Judgment after standard development is done**
  Regulators (in EU) think about harmonization too late
- **"Country specific" standards are not really standards**
  Implementation can differ by jurisdiction; worse is when …

Not always aimed at "optimum community benefits"

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CONCERNS, ISSUES, …

FROM DITTA KYOTO 015 WORKSHOP

So many standard labels to show eco-friendliness is not sustainable …

IMDRF project on standards

- Next IMDRF STA WG meeting scheduled in Geneva, 21-23 February
- Expect China to join the WG
- Scheduled to meet with SGs of ISO and IEC
- Discussion items include
  - *Process improvement proposals*
  - *IMDRF recognition of standards?*
  - *IMDRF liaison to selected TCs of ISO and IEC*
  - *Establish IMDRF RA standards experts network*

ISO and health

Great things happen **when the world agrees.**

Thank you