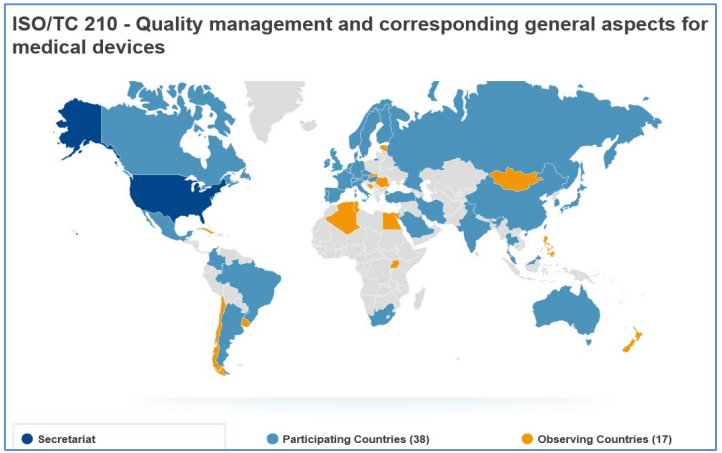
Brief overview of ISO/TC 210

Peter Linders, Chair ISO/TC 210

AHWP – 25 October 2018



About Scott Sardeson …

Scott is on of our TC Advisors

… and convener of WG1 in TC 210

and terribly sorry he can't be here

He says hi to all of you!

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: Mr Ben Carson
- ISO Editorial Programme Manager: M. Vincenzo Bazzucchi

Creation date: 1994

ISO/TC 210 structure

ISO/TC 210/AHG	Ad-hoc group for ISO 22740	Working group
ISO/TC 210/JWG 1	Joint ISO/TC 210-IEC/SC 62A WG : Application of risk management to medical devices	Working group
ISO/TC 210/JWG 2	Joint ISO/TC 210-IEC/SC 62A WG : Medical device software	Working group
ISO/TC 210/JWG 3	Joint ISO/TC 210-IEC/SC 62A WG : Medical device usability	Working group
ISO/TC 210/JWG 4	Joint ISO/TC 210 - IEC/SC 62D WG: Small bore connectors	Working group
ISO/TC 210/WG 1	Application of quality systems to medical devices	Working group
ISO/TC 210/WG 2	General aspects stemming from the application of quality principles to medical devices	Working group
ISO/TC 210/WG 3	Symbols and nomenclature for medical devices	Working group
ISO/TC 210/WG 5	Connectors for reservoir delivery systems	Working group
ISO/TC 210/WG 6	Application of post market surveillance systems to medical devices	Working group

ISO/TC 210 active work program

Standard and/or project under the direct responsibility of ISO/TC 210 Secretariat (10)	Stage	ICS
ISO/DIS 14971 [Under development] Medical devices -- Application of risk management to medical devices	40.60	11.040.01
ISO 18250-1 [Under development] Medical devices -- Connectors for reservoir delivery systems for healthcare applications -- Part 1: General requirements and common test methods	60.00	11.040.25
ISO/DIS 18250-6 [Under development] Connectors for reservoir delivery systems for healthcare applications -- Part 6: Neural applications	40.60	11.040.25
ISO/FDIS 18250-7 [Under development] Connectors for reservoir delivery systems for healthcare applications -- Part 7: Connectors for intravascular infusion	50.20	11.040.25
ISO/AWI TR 20416 [Under development] Medical devices -- Post-market surveillance for manufacturers	20.00	
ISO/CD 20417 [Under development] Medical Devices -- Requirements for general information to be provided by the manufacturer	30.60	11.040.01
ISO/DTR 24971 [Under development] Medical devices -- Guidance on the application of ISO 14971	30.20	11.040.01
IEC 62366-1:2015/DAmd 1 [Under development]	40.20	11.040.01
ISO 80369-1 [Under development] Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements	60.00	11.040.20 11.040.10
ISO 80369-3:2016/FDAmd 1 [Under development]	50.00	11.040.25

ISO/TC 210 key standards

- **ISO 13485** – Quality Management Systems
- **ISO 14971** – Risk Management
- **ISO 15223** – Symbols
- **ISO 16142** – Essential Principles and related standards
- **ISO 18250**-series – reservoir delivery connectors
- **ISO 80369**-series – small bore connectors

And jointly with IEC/SC 62A:

- **IEC 62304** – Medical device software life cycle
- **IEC 62366** – Usability (parts 1 and 2)

ISO/TC 210 – my key messages (1/2)

- Strategic Business Plan 2018 published
- AHWP is active category A liaison
- Strive for category A liaison with IMDRF
- Work to liaise with more medical professionals organizations
- ISO 14971 and ISO/TR 24971 in revision
- ISO/TR 20416: Work on Post-Market Surveillance
- ISO 20417: information to be supplied by the manufacturer
- Exploratory group on medical device life cycle
  - Strong connection with AHWP and MS 2058
  - Focus on availability of and access to safe device
  - Additional focus on environmental aspects

ISO/TC 210 – my key messages (2/2)

Special note on ISO 13485 – Quality Management Systems

- Strong involvement of AHWP
- 2016-edition published and now in transition
- Practical Guide published (2017)
- Survey on transition experience
- Workshop at next meeting in Seoul (12-16 November)
- ISO High Level Structure ??
- IMDRF, MDSAP, Korea will write to **not** adopt HLS in next 5 years
- AHWP-TC invited to express its opinion

ISO and health

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

Thank you