ISO 13485 and other updates by ISO/TC210

Peter Linders – chair ISO/TC 210

Agenda

- Introduction
- Structure
- Publications in 2021
- Current activities (selection)
- New scope text for ISO/TC 210
- Chair Advisory Group
- ISO 13485: future
- Links

Introduction

About Peter Linders

- Over 30 years involvement in IEC and ISO
- Involved in regulatory affairs since 1998
- COCIR Board member & chair of TRAC
- DITTA member Board of Directors
- Involved in GHTF, IMDRF, and GHWP
- Chair of CENELEC/TC 62 - until 01.2022
- Chair of ISO/TC 210

T: +31 6 5182 6428; E: peter.linders@philips.com

Structure

Snapshot from ISO/TC 210 website

STRUCTURE | LIAISONS | MEETINGS

REFERENCE	TITLE
ISO/TC 210/AHG	Ad-hoc group for ISO 22740
ISO/TC 210/AHG 1	High Level Structure Analysis
ISO/TC 210/AHG 2	ISO/TC 210 Scope review
ISO/TC 210/JWG 1	Joint ISO/TC 210-IEC/SC 62A WG : Application of risk management to medical devices
ISO/TC 210/JWG 2	Joint ISO/TC 210-IEC/SC 62A WG : Medical device software
ISO/TC 210/JWG 3	Joint ISO/TC 210-IEC/SC 62A WG : Medical device usability
ISO/TC 210/JWG 4	Joint ISO/TC 210 - IEC/SC 62D WG: Small bore connectors
ISO/TC 210/STTF	Spanish translation task force
ISO/TC 210/WG 1	Application of quality systems to medical devices
ISO/TC 210/WG 2	General aspects stemming from the application of quality principles to medical devices
ISO/TC 210/WG 3	Symbols and nomenclature for medical devices
ISO/TC 210/WG 5	Connectors for reservoir delivery systems
ISO/TC 210/WG 6	Application of post market surveillance systems to medical devices
ISO/TC 210/WG 7	Good engineering maintenance management

2021 publications

ISO #	Title
20417	Medical devices — Information to be supplied by the manufacturer
15223-1	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
80369-5:2016/Cor2	Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications — Technical Corrigendum 2
80369-7	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications

Activities (selection)

Current activities (selection)

- Two PWIs update/revise ISO/TR 20416 (PMS - approved)
- PWI on colour coding in medical applications
- JAG5 (with IEC TC 62) on medical device life cycle aspects
- WG7 project on medical maintenance engineering
- Investigate alternative deliverable for ISO 16142 series
- Study risk management cf. ISO 14971 for "health devices"
- Discuss risk terminology at top level in ISO and IEC JTF
- Investigate opportunity to be involved in future of IEC 62304
- Revision of strategic business plan (SBP)

New scope text

Ballot still open (ISO deadline 15 December 2021)

Current text of ISO/TC 210 scope	Proposed new text for 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.	Guidance and standardization of requirements in the field of quality management and corresponding general aspects, for products with a ~~medical~~ health purpose, including connectors for liquids and gases. Excluded: • generic quality management standards dealt with by ISO/TC 176, and • quality management standards for pharmaceutical products and ~~medical~~ healthcare services.

Chair Advisory Group

Ballot still open (ISO deadline 9 December 2021)

ISO/TC 210 **N 1306**

ISO/TC 210 "Quality management and corresponding general aspects for medical devices"
Secretariat: **ANSI**
Committee Manager: **Munteanu Ovidiu Mr**

Resolution 314, Approval of the DRAFT terms of reference of the Chair Advisory Group (CAG) to ISO/TC 210

Future of ISO 13485

Why would ISO 13485 have to change?

- In 2020, confirmation*) until 2025, *so …*
- Make ISO 13485 HLS/HAMSS compliant ?? *Nah …*
- Link with ISO 9001 ?? *No ISO 9001 revision foreseen …*
- Small updates/clarifications ?? *Ehm, maybe via …*
- … the "Handbook": it is here to help …

Status 2019 - SR

*) See document N1156 of ISO/TC 210, 17 Jan 2020

Future of ISO 13485

Input from stakeholders (with systematic review in 2019) …

MDSAP Consortium Sparks Debate Over Upcoming Revisions to ISO 13485:2016

Japan NC: HLS is not suitable to be used as a base of ISO 13485

UK: ISO 13485:2016 should be confirmed for another five years to allow stability

MDSAP: careful consideration should be given to the need to revise the standard

IMDRF: Imperative that the medical device sector is engaged in any future revisions of the ISO HLS, if there is a desire by ISO TMB that the standard continue to be used for regulatory purposes.

MEDEC: we believe that the maintenance of the status quo and deferring any plans for a revision to ISO 13485 for the time being are in the best interests of both industry and regulatory stakeholders

Links

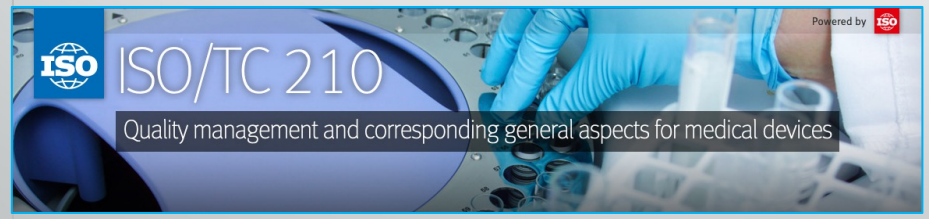
Useful links:

TECHNICAL COMMITTEES

ISO/TC 210

Quality management and corresponding general aspects for medical devices

Official ISO website: https://www.iso.org/committee/54892.html



Public website for ISO/TC 210: https://committee.iso.org/home/tc210

The end

A good ISO 13485,
well implemented,
brings peace of mind
and happiness for all.
Most importantly, for patients across the globe