ISO/TC210

Quality management and corresponding general aspects for medical devices

AI Standard activities

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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 – Structure

ISO/TC 210 Working groups:

- WG 1 **Application of quality systems to medical devices (ISO 13485)**
- 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**
- WG 7 **Good engineering maintenance management**

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

- JWG 1 **Application of risk management to medical devices (ISO 14971)**
- JWG 2 **Medical device software**
- JWG 3 **Medical device usability**
- JWG 4 **Small bore connectors**

ISO/TC 210 – New work in discussion for AI/ML

Possible NP for a standard containing guidance on how to implement ISO 13485 by an organization intending to place AI/ML enabled devices on the market.

This standard would give guidance and specify requirements for an organization to demonstrate its ability to extend its ISO 13485-based/compliant quality management system to medical devices and related services that use artificial intelligence/machine learning methods (AI/ML-MD).

This standard can assist manufacturers, notified bodies and regulatory authorities to assess medical devices in a consistent manner, allowing for a safe, consistent and reliable route to market.

Several jurisdictions and regulatory agencies are in the process of defining and establishing requirements for market access and post-market surveillance of medical devices that use artificial intelligence methods, or machine learning methods to achieve -or in support of achieving- their medical intended use.

Examples are EU Draft AI Regulation, FDA AI/ML SaMD Action Plan, and NMPA Guideline on Artificial Intelligence Medical Devices. The intended deliverable aims to address most of these requirements in a consistent and coherent manner, to benefit all stakeholders.

ISO/TC 210 – Why does the Medical Device sector need this?

ISO/IEC Guide 63:2019, *Guide to the development and inclusion of aspects of safety in International Standards for medical devices*

- Based off of ISO/IEC Guide 51, *Safety aspects – Guidelines for their inclusion in standards,* to address the needs of the medical device sector
- The concept of safety is closely related to protecting patients who are the subjects of medical care, as well as those persons who provide the care and other potentially affected persons. Safety is also related to harm to property or the environment.
- The approach aims to reduce the risk arising during the life cycle of a medical device, including design, production, distribution, installation, use, service, maintenance, and destruction or disposal. The complete life cycle of a medical device (including both the intended use and the reasonably foreseeable misuse) is considered. The goal is to achieve acceptable risk for people, property and the environment.

This same understanding of risk is included in many medical device regulatory frameworks across the globe

Thank you

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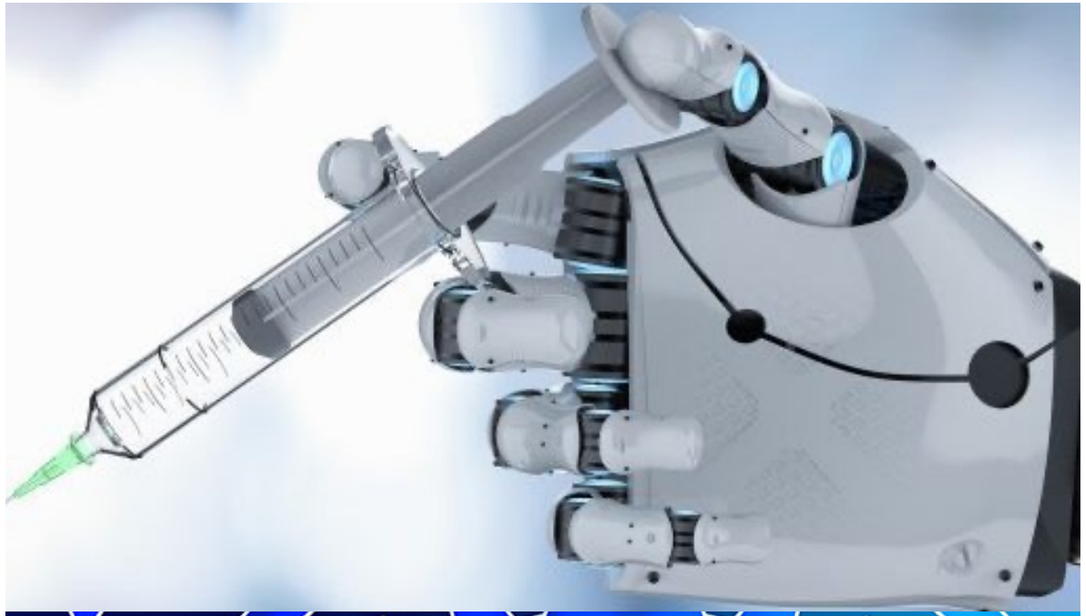

ISO JTC1 IEC
INFORMATION TECHNOLOGY STANDARDS
SC 42 – Artificial Intelligence