BUSINESS PLAN

CEN-CLC/JTC 3
Quality management and corresponding general aspects for medical devices

EXECUTIVE SUMMARY

Business Environment

The area of responsibility of CEN-CLC/JTC 3 *Quality management and corresponding general aspects for medical devices* is related to the European regulatory framework for medical devices.

The existing three Directives on medical devices are:

- EU Directive 93/42/EEC of 14 June 1993 concerning medical devices,
- EU Directive 90/385/EEC of 20 June 1990 concerning active implantable medical devices and
- EU Directive 98/79/EC on in vitro diagnostic medical devices.

The two new Regulations on medical devices, entered into force on 26 May 2017:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

After a transitional period, only the new Regulations will apply. The transitional periods are 3 years after entry into force for the Regulation on medical devices (spring 2020) and 5 years after entry into force (spring 2022) for the Regulation on in vitro diagnostic medical devices. In addition, certificates issued under the Directives can continue to be valid, under certain conditions, for up to a further 4 years after the end of the transitional period for medical devices and a further 2 year for in vitro diagnostic medical devices.

Scope

The scope of CEN-CLC/JTC 3 is standardization of requirements and guidance in the field of quality management and corresponding general aspects for medical devices.

The objective of CEN-CLC/JTC 3 is contributing to and adopting the work of ISO/TC 210, and where necessary draft European standards for quality management and corresponding general aspects for medical devices that cannot be dealt with under the Vienna Agreement. The added value of CEN-CLC/JTC 3 to standards that are developed by ISO/TC 210 under the Vienna Agreement is assuring that the standards are adequate to provide presumption of conformity with the requirements in the European regulatory system.

Benefits

CEN and CENELEC have published technical standards for a large number of medical devices. However, the safety and performance requirements for the complete range of different types of medical devices are greatly enhanced by identifying common quality principles in general standards. Also suitable standards for small bore connectors of medical devices, that are applicable internationally and assuring conformity to the essential requirements of EU Directives will be adopted by CEN-CLC/JTC3.

CEN-CLC/JTC 3 is the single European coordination point whereby national standard bodies can be asked to formally vote and approve proposals for e.g. Annexes Z's and the European Forewords which may provide additional, essential information to the relevant EN ISO standard for quality management or a corresponding general aspect for medical devices.

Priorities

Discussions on the technical content of the standards take place in ISO/TC 210, who develops the standards under the Vienna Agreement (VA). CEN-CLC/JTC 3 will assure that the standards are in conformity with the specific essential requirements of the regulatory framework. In particular it is a priority for CEN-CLC/JTC 3 to assure correct content of the Annexes Z and the European forewords of future revised editions, which may provide additional, essential information for the European market.

For this purpose CEN-CLC/JTC 3 maintains contact with all relevant parties, , making sure the coordination between standardization activities and the regulatory framework is synchronized.

1 BUSINESS ENVIRONMENT OF CEN-CLC/JTC 3

1.1 Description of the Business Environment

The following economic, technical, regulatory, legal, and international dynamics describe the business environment. These may significantly influence the standardization process within the scope of this CEN-CLC/JTC 3.

The area of responsibility of CEN-CLC/JTC 3 *Quality management and corresponding general aspects for medical devices* is related to the two new Regulations and the existing three Directives on medical devices:

- EU Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directive 2007/47/EC,
- EU Directive 90/385/EEC of 20 June 1990 concerning active implantable medical devices,
- EU Directive 98/79/EC on in vitro diagnostic medical devices.

The two new Regulations on medical devices entered into force on 26 May 2017. These replace the existing Directives:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

After a transitional period, only the new Regulations will apply. The transitional periods are 3 years after entry into force for the Regulation on medical devices (spring 2020) and 5 years after entry into force (spring 2022) for the Regulation on in vitro diagnostic medical devices. In addition, certificates issued under the Directives can continue to be valid, under certain conditions, for up to a further 4 years after the end of the transitional period for medical devices and a further 2 year for in vitro diagnostic medical devices.

The main reasons to develop these new Regulations were to ensure:

- a consistently high level of health and safety protection for EU citizens using these products;
- the free and fair trade of the products throughout the EU;
- that EU legislation is adapted to the significant technological and scientific progress in this sector over the last 20 years.

The new Regulations contain a series of changes to modernise the current system:

- stricter ex-ante control for high-risk devices *via* a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level
- the reinforcement of the criteria for designation and processes for oversight of Notified Bodies
- the inclusion of certain aesthetic devices which present the same characteristics and risk profile as analogous medical devices under the scope of these Regulations

- the introduction of a new risk classification system for *in vitro* diagnostic medical devices in line with international guidance
- improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification
- the introduction of an "implant card" containing information about implanted medical devices for a patient
- the reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorisation of multi-centre clinical investigations
- the strengthening of post-market surveillance requirements for manufacturers
- improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance

The role of medical devices is essential to the healthcare of EU citizens. The diversity and innovativeness of this sector contributes significantly to the enhancement of both the quality and efficacy of healthcare in the EU.

Covering a wide range of products, from simple bandages to the most sophisticated life-support equipment, the medical devices sector plays a crucial role in the diagnosis, prevention, monitoring and treatment of diseases. It also helps improve the quality of life of those with disabilities.

[source: European Commission, DG Growth, http://ec.europa.eu/growth/sectors/medical-devices/index_en.htm]

Interested parties include, in the first place, manufacturers of medical devices and their authorized representatives within EU, as well as regulatory authorities, notified bodies, hospitals and other health care facilities, healthcare professionals and patients.

1.2 Quantitative Indicators of the Business Environment

Medical technology is a key driver for Europe's economic well-being, providing quality employment, and a substantial contribution to Europe's balance of trade.

- The industry employs more than 675,000 people,
- The market size is estimated at roughly €110 billion,
- There are almost 27,000 medical technology companies in Europe, of which 95% are Small and Medium-sized Enterprises (SMEs).

[Source: European Commission]

ISO Survey of certifications 2017 - ISO 13485
In 2017, a total of 31520 certificates were issued for ISO 13485, revealing a 7 % growth rate compared to 2016.

[Source:https://www.iso.org/the-iso-survey.html]

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN-CLC/JTC 3

The regulatory framework for Medical Devices is based on the New Approach which utilises standards deemed as “Hamonised Standards”. Such standards provide a “Presumption of Conformity” to the relevant general safety and performance requirements as well as system and process requirements of the Regulations. Application of the Vienna and Dresden Agreements leads to cooperation between CEN & ISO, and IEC & CENELEC, resulting in identical international and European standards which are suitable for all medical devices and optimization of the use of available resources and expertise for the benefit of the stakeholders. Cooperation between CEN & ISO, and IEC & CENELEC facilitates the worldwide exchange of medical devices and improves the economics of the medical device industry as a whole. CEN-CLC/JTC 3, as a joint European Technical Committee, contributes to the elimination of trade barriers and to the quality and safety of medical devices, not only in Europe but also on a global level.

CEN-CLC/JTC 3 acts as the European mirror group of ISO/TC 210 *Quality management and corresponding general aspects for medical devices* and therefore closely cooperates with ISO/TC 210. In principle, the standards are drafted by ISO/TC 210 under the Vienna agreement with ISO-lead, including the parts of the joint work programme with IEC/SC 62A *Common aspects of electrical equipment used in medical practice*, where ISO is leading the projects. If a specific subject is EU-specific to describe the European requirements specifically and cannot be dealt with under VA, CEN-CLC/JTC3 will start such project.

CEN-CLC/JTC3 work programme

Quality Management
The standard EN ISO 13485 ‘Medical Devices - Quality management systems - Requirements for regulatory purposes’ follows the same process-oriented structure as ISO 9001:2008 and add medical device-specific requirements to the elements listed.This standard deviates from ISO 9001:2015 in not following the Annex SL format (so-called High Level Structure),. ISO 13485:2016 is considered fundamental to encouraging and supporting the global harmonization of quality system requirements for medical devices worldwide: it forms the basis for the IMDRF’s medical devices single audit programme (MDSAP). In September 2017, the Handbook 'ISO 13485:2016 - Medical devices – A practical guide' was published to accompany the standard and provide guidance to users. This practical guide is a replacement for ISO/TR 14969, the guidance that was developed for ISO 13485:2003. In March 2018, CEN-CLC/JTC3 published CEN/TR 17223 'Guidance on the relationship between EN ISO 13485: 2016 and European Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation' to provide guidance on the relationship between EN ISO 13485:2016 and the requirements in the European Regulations on Medical Devices (MDR)- Regulation (EU) 2017/745 - and *in vitro* Diagnostic Medical Devices (IVDR) -Regulation (EU) 2017/746.

Risk Management
The regulatory framework requires that the devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety. Furthermore, the manufacturer is required to establish and maintain a risk management system. The standard EN-ISO 14971 “Medical Devices-Risk Management - Application of risk management to medical devices” is harmonised and can be used to demonstrate general compliance with these requirements. Currently, the standard is under revision with target date for publication mid-2019. The revised standard will include new Annex Z for both the Regulations as the Directives.

Information to be supplied by the manufacturer with medical devices

In 2017, a joint project between ISO/TC 210 and CEN-CLC/JTC3 under VA-ISO lead started to develop the new standard EN ISO 20417 *Information to be supplied by the manufacturer with medical devices*, taking into account the existing European standard 1041 on this topic. The aim is to have the new standard recognized as a harmonized standard.

Symbols
The use of harmonized symbols reduces the need for translation into national languages and therefore has a clear economic benefit for the manufacturers, and ultimately, the users. The main standard for this domain is EN ISO 15223-1:2016 'Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements'. In light of the new Regulations, new symbols have been introduced to be assessed for inclusion to this standard. In 2018, experts will continue the discussions to come to a decision if the new symbols will be included into the standard.

Small bore connectors
The standards on small bore connectors of medical devices are applicable internationally and safeguarding conformity to the essential requirements of EU Directives. The standards are needed to ensure the prevention of inadvertent cross-connection between small bore connectors used in different fields of medical applications. It is intended that the complete series will include dimensions and drawings of connectors allocated to specific medical applications.

Post market surveillance (PMS)
A joint project between ISO/TC 210 and CEN-CLC/JTC3 will provide the description of a system that can be used by manufacturers of medical devices to collect and evaluate experiences gained with their devices after placing on the market and to determine if corrective or preventive actions are necessary. Such a system can also be used for improvement of the performance or usability of devices. The informative document provides guidance that can be used to implement a PMS-system to fulfill the national or regional legal requirements.

3 PARTICIPATION IN CEN-CLC/JTC 3

The constitution of a CEN-CLC/JTC 3 arose from the need for a single European coordination body to mirror the work of ISO/TC 210 *Quality management and corresponding general aspects for medical devices*.

Joint Technical Committees and joint Working Groups are to be composed of CEN and CENELEC representatives and are open to all CEN/CENELEC national members, on the basis of only one common delegation per country with representatives appointed by the members of CEN/CENELEC in that country. When forming their delegations to the joint Technical Committee meetings and appointing experts to joint Working Groups, CEN/CENELEC national members shall ensure that all interests affected by the work are properly taken into account.

To participate in the activities of this CEN-CLC/JTC3, please contact the national standards organization in your country.

Organization and structure

In principle the standards are drafted by ISO/TC 210 under the Vienna agreement with ISO-lead, including the joint work programme with IEC/SC 62.

For the main harmonized standards, CEN-CLC/JTC 3 has appointed project leaders who report to the CEN-CLC/JTC 3 meetings.

4 OBJECTIVES OF THE CEN-CLC/JTC 3 AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN-CLC/JTC 3

The foremost aims of standardization in the field of medical technology are to protect the health and safety of patients and (other) users of medical devices, and to eliminate trade barriers for medical devices.

The objectives of CEN-CLC/JTC 3 are:

- Provide a focus for an understanding of the role and application of quality management and the corresponding general aspects of quality principles in standards and guidance required by regulatory authorities and manufacturers;

- Contribute to, and where necessary develop standards and guidance for, and promote adoption of, quality management and the corresponding general aspects of quality principles for medical devices that will effectively address and assuring conformity to the essential requirements of European regulatory framework, and the needs of regulatory authorities and manufacturers;

- Share the quality and risk management principles with other Technical Committees in all sectors of the medical technology field in Europe.

4.2 Identified strategies to achieve the CEN-CLC/JTC 3 defined objectives.

The strategies to reach the objectives are as follows:

1) Utilise the Vienna and Dresden Agreements to achieve consensus and compatibility with ISO/IEC standards for quality management and corresponding general aspects.

2) Liaise with CEN & CLC TC's and other bodies to share the information on the standard activities on quality management and corresponding general aspects in all sectors of the medical technology field. The current liaisons with CEN-CLC/JTC 3 are:

a. CLC/TC 62 Electrical equipment in medical practice
b. CEN/TC 204 Sterilization of medical devices
c. CEN/TC 251 Health informatics
d. European Directorate for the Quality of Medicines & HealthCare (EDQM)
e. ISO/TC 210 Quality management and corresponding general aspects for medical devices

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/CLC TC 3 WORK PROGRAMME

Resources and continued motivation of all parties concerned are crucial factors for the completion of the proposed work programme. It is expected that the necessary resources and expertise will be available in the coming years. Work is also greatly dependent on the imolementation of the new EU legislations, in particular the publication of the Standardization Request. JTC3 is awaiting the SR for MDR/IVDR and where possible, is actively participating in the process..