BUSINESS PLAN

CEN/TC 206
BIOLOGICAL AND CLINICAL EVALUATION OF MEDICAL DEVICES

EXECUTIVE SUMMARY

Business Environment

The task of CEN/TC 206 is to standardize test methods for the biological and clinical evaluation of medical devices. The work of CEN/TC 206 aims to provide the business community with valuable means for demonstration of conformance with the essential requirements of the European Directives on active implantable medical devices (90/385/EEC) and medical devices (93/42/EEC as amended by Directive 47/2007/EC).

This work is done in close cooperation with the corresponding ISO Technical Committee 194 on Biological and clinical evaluation of medical devices.

The parties involved are

- Manufacturers of medical devices
- Contract Research Organisations (CRO)
- Public authorities
- Notified bodies

CEN/TC 206 addresses standards for the protection of the health and safety of the patient, and the appropriate risk-benefits ratio for the patient and the user in order to satisfy the following needs: availability of safe and high quality medical devices, and the facilitation of European and global trade and regulation. Its work is therefore of importance to industry, government regulators, purchasers, and of course the most important end-user, the patient.

Benefits

European Standards created by CEN/TC 206 provide a means to demonstrate compliance with the essential requirements of the European Directives on active implantable medical devices (90/385/EEC) and medical devices (93/42/EEC as amended by Directive 47/2007/EC) and build a framework for a harmonized regulatory process, i. e. testing and certification of these devices.

Close cooperation with ISO/TC 194 "Biological and clinical evaluation of medical devices"" has led to EN ISO standards, improving accessibility of the worldwide market for medical devices.

Priorities

The priority of this Technical Committee is to ensure the safety of medical devices for the patient. The main objective is to improve the availability of safe medical devices on the European Market and, in close cooperation with ISO/TC 194, also on the Global International Market.

1 BUSINESS ENVIRONMENT OF THE CEN/TC 206

1.1 Description of the Business Environment

The following political, economic, technical, regulatory, legal, societal and/or international dynamics describe the business environment of the industry sector, products, materials, disciplines or practices related to the scope of this CEN/TC, and they may significantly influence how the relevant standards development processes are conducted and the content of the resulting standards:

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.

The medical devices sector faces many challenges at national, European and international level, which may have an impact on their innovation capacity and overall competitiveness:

- Public Health Systems - In particular, emerging needs such as developing a shared understanding of healthcare goals, overcoming health inequalities, an ageing society and exploiting the potential of e-health technologies.
- Finding the balance between patient's needs and financial sustainability◦Ensuring that the sector can enhance better access for patients to devices whilst simultaneously ensuring that pricing and reimbursement policies are effective;
- Competitiveness and innovation◦Challenges related to R&D, emerging technologies and the green economy, as well as issues related to the EU's trade and regulatory cooperation globally. SMEs in particular face challenges in this regard.

1.2 Quantitative Indicators of the Business Environment

The following list of quantitative indicators describes the business environment in order to provide adequate information to support actions of the CEN /TC 206:

The medical devices sector helps to save lives by providing innovative health care solutions regarding diagnosis, prevention, monitoring and treatment. The sector has become increasingly important for the healthcare of EU citizens and an influencer on expenditure.

- The medical devices industry is a major employer in Europe, employing 575 000 people in the EU.
- Total sales amount to €100 billion.
- The sector represents some 25 000 companies, of which 95% are Small and Medium-sized Enterprises (SMEs)[1].

[1] http://ec.europa.eu/growth/sectors/medical-devices/index_en.htm

2 BENEFITS EXPECTED FROM THE WORK OF THE CEN/TC 206

The key expected benefits from the work of CEN/TC 206 related to biological evaluation of medical devices are contributions to:

- facilitation of the availability of safe medical devices;
- improvements in the quality of medical devices;
- development of the global market economy.

Focus on new and innovative directions in medical device regulations, biomaterial development, and medical device design. Biocompatibility includes:

- biological evaluation;
- *in vivo* versus *in vitro*;
- design and application of the appropriate tests;
- assessment of bioactivity and tissue response (bioactive materials);
- toxicity testing.

There is a growing public demand for standardized test methods for biological testing and evaluation of medical devices especially for the thousands of new and innovative medical devices entering the healthcare field every year.

Major regulatory requirements which must be considered and reflected in the standards are:

- Essential requirements of the EC Council Directives 90/385 EEC and 93/42/EEC.

Major factors which may have an impact on the development of markets include:

- Concentration of industry into larger units;
- Demographic changes, particularly in the developed nations of the western world. A continuing trend is for the proportion of the elderly in the population to increase, thereby increasing the demand for medical devices worldwide;
- Public concern on quality of medical devices.

The key expected benefits from the work of CEN/TC 206 related to clinical evaluation of medical devices are contributions to:

- increase the quality of clinical investigations for a high level of safety and health requirements by promoting, through the requirements for and the design of a clinical investigation plan, a common approach of clinical investigations by manufacturers and its evaluation by notified bodies;
- ensure that the data obtained by clinical investigations have a sufficient scientific value;
- guarantee that the requirements for clinical investigations provides adequate information for notified bodies in their certification activities and for the competent authorities of the Member States in their market watch and monitoring activities.

Most of the available standards have already been cited in the Official Journal of the European Union under the Directives 90/385 EEC and 93/42/EEC and confer presumption of conformity with Essential Requirements of that Directive.

3 PARTICIPATION IN THE CEN/TC 206

All the CEN national members are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, please contact the national standards organization in your country.

4 OBJECTIVES OF THE CEN/TC AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of the CEN/TC 206

CEN/TC 206 will contribute indirectly to public health and public well-being by developing standards for medical devices. CEN/TC 206 developes standards for biological evaluation that are applicable internationally and relevant to the essential requirements of EU Directives; while standards should indentify safety of medical devices, they should also prevent over-testing. Conformity to the standards by manufacturers will ensure that their products do not compromise the health and well-being of patients. The use of standards therefore contributes to:

- Protection of the health and safety of the patient and user;
- Uniformity of test methods;
- Uniformity of reference materials;
- Uniformity of terminology and definitions;
- Quality of medical devices;
- Effective and efficient use of resources in standards development;
- Elimination of trade barriers through global harmonization.

With regards to clinical evaluation, the standards and deliverables should ensure rigour and scientific value, taking into account the state of the art, when selecting scientific literature and when organizing and performing clinical investigations for:

- the safety and the correct risk-benefits ratio of the patient and the user;
- the assurance, as far as possible, of the appropriate and adequate device performance and function;
- a basis for testing, certification and regulation of devices especially for investigators, producers, notified bodies and regulatory departments; and,
- as consequence, minimizing obstacles to international trade.

4.2 Identified strategies to achieve the CEN/TCs defined objectives.

CEN/TC 206 and ISO/TC 194 are closely co-operating in the development of standards and revisions/improvement of these standards. The environment in which the ISO series of standards are used is characterized by the legislation and by market aspects. These two items differ in various regulatory jurisdictions. As a consequence the series of standards are at this moment not internationally uniformly applied and interpreted. In principle the standards in the area of biological evaluation of medical devices are drafted by ISO/TC 194 under the Vienna agreement with ISO-lead.

To be able to optimise the structure of the present series of standards on biological and clinical evaluation and to harmonize the application and interpretation of the standards, information is needed about the environment in which these standards are used and about the use of the standards themselves. The objective of CEN/TC 206 is to contribute to a further global harmonization of these aspects in close co-operation with ISO/TC 194.

Annexes ZA on the relation between the contents of the standards and the essential requirements of the relevant Directives are prepared by CEN/TC 206 and are included in all published standards. These Annexes on the relation of the essential requirements and the standards are prepared by the project leaders and/or TC secretariat according to CEN procedures.

CEN/TC 206 should also be engaged with the work of other CEN/TCs (and those of ISO), for the adoption of generic standards or adaptation of relevant solutions from other business areas, to circumvent the occurrence of duplicating work already done.

4.3 Environmental aspects

CEN/TC 206 is aware of its responsibility in addressing environmental aspects in the field of biological and clinical evaluation of medical devices.

Every product has an impact on the environment during all stages of its life cycle, e.g. acquisition of raw materials, production, distribution, application/use, up untill the product's final disposal. These impacts range from slight to significant; they can be short-term or long-term; and they occur at global, regional or local level.

Standards writers should consider the need to reduce risks to the environment taking into account the consequences and the likelihood of incidents and accidents. They should as much as possible take into account environmental aspects all along the design, execution, operation and dismantling, and study the assessment of the environmental impact during these different stages.

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

This business plan highlights the context in which CEN/TC 206 has to work. It is indicated by independent reports that the areas tackled are both complex and diverse. As cited above, these reports have concentrated on the barriers, both external and internal to all of the standards development organizations. This section addresses those issues specifically relevant to the CEN/TC 206 work programme and in particular the processes and participation.

The entire work programme of CEN/TC 206, including already published items, clearly forms one package. In fact it even forms one standard in many parts (i.e. the 10993 standards series). It is a challenge to keep this whole package internally consistent and up-to-date. This is particularly so because CEN/TC 206 is focused on an area of rapid scientific development. Early revisions of already published standards have therefore been called for on several occasions already to keep the whole package aligned. Because of the interrelation between all the parts, target dates are often reviewed to enable mutual inclusion of a new development in interlinked parts of the standard. Another challenge for CEN/TC 206 is to achieve on the one hand alignment with the international level and on the other hand to ensure that the documents generated are acceptable to the European Commission as Harmonized Standards. Critical success factor in meeting the above challenges is the continued motivation of all parties concerned to achieve the common goals.

CEN/TC 206 conducts all its work in cooperation with ISO/TC 194 under the Vienna Agreement (VA) with ISO lead. CEN/TC 206 has no editing committee of its own, however, CEN TC 206 can initiate its own working groups on specific subjects, if necessary.

Participation

Active participants in CEN/TC 206 include clinicians, manufacturers, test house, certification body staff, government and regulatory staff. The majority of active Member Bodies come from the more economically developed regions of Europe, but the TC is aware of the needs of less well-developed areas in which the infrastructure necessary for correct operation and maintenance of sophisticated equipment may be less reliable or even absent.

There are relatively many European experts participating in the (international) standards development process domain. All experts active in CEN/TC 206 are also active in the ISO/TC 194 working groups or other SDOs. Whilst this does have the advantage of facilitating effective coordination and collaboration, the disadvantage is that the available expertise is 'spread thinly' over such organizations.