



STRATEGIC BUSINESS PLAN – ISO/TC 210 QUALITY MANAGEMENT AND CORRESPONDING GENERAL ASPECTS FOR PRODUCTS WITH A HEALTH PURPOSE INCLUDING MEDICAL DEVICES

Executive summary

The ISO/TC 210 Strategic Business Plan (SBP) outlines the vision, mission and goals of our Technical Committee (TC). This Executive Summary synthesizes the larger SBP with an overview of our scope, vision and mission while the full Plan provides greater detail to committee members on the context in which the TC operates, including its current structure and representation, as well as the committee goals, priorities, measures, and the expected benefits. This SBP supports the [ISO Strategy 2030](#).

Scope: ISO/TC 210's focus is on products with a medical purpose especially related to general aspects of quality and performance of those products. Our deliverables include standards, guidance documents, and other documents related to quality management, risk management, usability (human factors), symbols, essential principles of safety and performance, product labelling, medical software, post market surveillance, small-bore connectors, and others. ISO/TC 210 pursues some projects in collaboration with other Technical Committees in IEC or ISO.

ISO/TC 210 currently has forty-four [published standards and related documents](#), including guidance documents and technical specifications. At the time of this writing, thirteen [standards are under development](#). These standards reflect important priorities across the medical device community and supports patients and medical providers and the device firms that design, manufacturer and test these products.

Structure: ISO/TC 210 conducts its work through working groups (WG), joint working groups (JWG) with other TCs and the International Electrotechnical Commission (IEC), ad hoc groups (AHG), task forces, a Task Group for strategy development, and the Chairman's Advisory Group.

ISO/TC 210 is proud to have many stakeholder organizations as liaison partners, and we encourage them to contribute to the ongoing projects via the ISO process. For a list of liaison partner committees and organizations [click here](#). ISO/TC 210 is also proud to collaborate with the International Medical Device Regulators Forum (IMDRF) and Global Harmonization Working Party (GHWP) on projects aimed at improving the use of standards for regulatory purposes to accelerate international medical device regulatory harmonization and convergence.

Vision

A globally relevant program of international consensus standards that are flexible and robust in support of patient safety and public health.

Mission

- Provide the forum, direction and expertise for related technical committees and impacted stakeholders to collaborate

- Anticipate opportunities where consensus standards can meet emerging technology needs and develop standards to meet those needs
- Ensure ISO/TC 210 working groups draft and encourage the use of regulatory-ready standards with value throughout the product life cycle
- Review current standards for continued relevance and regulatory-readiness, when applicable
- Advance global harmonization through the use of international consensus standards

ISO/TC 210 Goals

1. Advance conversations between and among Technical Committees, Working Groups and international stakeholders to harmonize and foster communication and complementary efforts in developing standards and other supporting resources.
2. Drive development, application, adoption, awareness and promotion of international standards and other consensus documents in the following substantive areas: quality management, labelling, e-labelling, essential principles, symbols and nomenclature, small-bore connectors, risk management, post-market surveillance, software, usability and human factors, maintenance (good engineering practices) for products with a health focus
3. Lead efforts in supply chain resilience, sustainability, health equity and emerging technologies
4. Modernize policies and processes, e.g., for nominating procedures, resolutions writing, participation expectations, evaluating and approving NWIPs, and ensuring appropriate data-driven analysis and decision-making.

1 Introduction

1.1 ISO technical committees and business planning

The extension of formal business planning to ISO Technical Committees (ISO/TCs) is an important measure which forms part of a major review of business. The aim is to align the ISO work programme with expressed business environment needs and trends and to allow ISO/TCs to prioritize among different projects, to identify the benefits expected from the availability of International Standards, and to ensure adequate resources for projects throughout their development.

1.2 International standardization and the role of ISO

The foremost aim of international standardization is to facilitate the exchange of goods and services through the elimination of technical barriers to trade.

Three bodies are responsible for the planning, development and adoption of International Standards: [ISO](#) (International Organization for Standardization) is responsible for all sectors excluding Electrotechnical, which is the responsibility of [IEC](#) (International Electrotechnical Committee), and most of the Telecommunications Technologies, which are largely the responsibility of [ITU](#) (International Telecommunication Union).

ISO is a legal association, the members of which are the National Standards Bodies (NSBs) of some 164 countries (organizations representing social and economic interests at the international level), supported by a Central Secretariat based in Geneva, Switzerland.

The principal deliverable of ISO is the [International Standard](#).

An International Standard embodies the essential principles of global openness and transparency, consensus and technical coherence. These are safeguarded through its development in an ISO Technical Committee (ISO/TC), representative of all interested parties, supported by a public comment phase (the ISO Technical Enquiry). ISO and its [Technical Committees](#) are also able to offer the ISO Technical Specification (ISO/TS), the ISO Public Available Specification (ISO/PAS) and the ISO Technical Report (ISO/TR) as solutions to market needs. These ISO products represent lower levels of consensus and have therefore not the same status as an International Standard.

ISO offers also the International Workshop Agreement (IWA) as a deliverable which aims to bridge the gap between the activities of consortia and the formal process of standardization represented by ISO and its national members. An important distinction is that the IWA is developed by ISO workshops and fora, comprising only participants with direct interest, and so it is not accorded the status of an International Standard.

2 Business Environment of the ISO/TC

2.1 Description of the Business Environment

The medical device marketplace is a dynamic and growing one, with more than \$500 billion in global sales in 2023 and forecasts of more than \$800 billion by the early 2030s per Fortune Business Insights reporting at <https://www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085>.

Aging populations, greater access to healthcare, growing country wealth, technological advances and an interest in global harmonization among device stakeholders, especially regulatory authorities, set the stage for a healthy market sector poised for steady growth.

2.2 Quantitative Indicators of the Business Environment

With more than thirty published standards, many of which are horizontal and thus apply to the majority of medical devices, ISO/TC 210's influence is broad as well as deep, supporting a global environment that is widely supportive of the use of standards.

This universal support for the use of consensus standards in device development and manufacture extends to regulatory review. Global regulators encourage standards' use and value them for their contributions to regulatory science. In fact, global organizations such as the International Medical Device Regulators Forum (IMDRF), Pan-American Health Organization (PAHO), the Global Harmonization Task Force (GHTF) and others consistently call for harmonizing regulatory practices across jurisdictions by relying upon consensus standards. This ensures patients worldwide can expect safe and effective devices while also reducing regulatory burden for manufacturers.

The international consensus is that standards in general and ISO/TC 210 standards in particular are a prerequisite to medical product quality and safety, and the pillar upon which innovation can bloom. ISO/TC 210's standards are especially relevant to a broad swath of the device marketplace; in particular, ISO 13485 (quality management systems) plays a central role in every corner of the marketplace. Likewise, ISO 14971 (risk management) is the foundational standard to support risk assessment, a critically important element in device design. Other horizontal standards include ISO 15223 (symbols), ISO 20416 (post-market surveillance), ISO 20417 (labelling), ISO/NP 23421 (terminology) and ISO 62366 (usability). The two standards areas not strictly considered horizontal are nonetheless applicable to many devices: ISO 80369 (small bore connector series) and ISO 62304 (medical device software).

3 Representation and participation in the ISO/TC

3.1 Membership

ISO/TC 210's member countries may be found [here](#).

3.2 Analysis of the participation

There are forty 'Participating' members of ISO/TC ISO/TC 210 and twenty-nine 'Observing' members. These members come from all across the globe and when coupled with [liaison organizations](#) represent key internal and external constituencies, including public health professionals, clinicians, regulatory

bodies, academics and industry. This breadth of contributors ensures that ISO/TC 210's documents reflect deep expertise and the most up-to-date data.

3.3 ISO/TC 210 Vision and Mission

Vision

A globally relevant program of international consensus standards that are flexible and robust in support of patient safety and public health.

Mission

- Provide the forum, direction and expertise for related technical committees and impacted stakeholders to collaborate
- Anticipate opportunities where consensus standards can meet emerging technology needs and develop standards to meet those needs
- Ensure ISO/TC 210 working groups draft and encourage the use of regulatory-ready standards with value throughout the product life cycle
- Review current standards for continued relevance and regulatory-readiness
- Advance global harmonization through the use of international consensus standards

3.4 ISO/TC 210 Defined goals

ISO/TC 210's standards and priorities stretch across a wide range of devices. ISO/TC 210 has identified four overarching goals for its work. These goals advance ISO/TC 210's mission which in turn helps meet its vision. ISO/TC 210 has also conducted an in-depth SWOT analysis (strengths, weaknesses, opportunities and threats; see Appendix A). The goals are designed to help address weaknesses and threats while taking advantage of strengths and opportunities.

Since ISO/TC 210's work is accomplished almost exclusively through its subordinate groups (working groups, joint working groups, task forces and ad hoc groups), these four goals are written at a high enough level to accommodate and apply to all the committee's work and specific enough to offer direction to these subordinate groups for their planning purposes. This advances ISO/TC 210's role to provide the virtual space and support to those who contribute to the standards activities.

The goals are:

- Advance conversations between and among Technical Committees, Working Groups and international stakeholders to harmonize and foster communication and complementary efforts in developing standards and other supporting resources
- Drive development, application, adoption, awareness and promotion of standards and other consensus documents in the following substantive areas: quality management, labelling, e-labelling, essential principles, symbols and nomenclature, small-bore connectors, risk management, post-market oversight, software, usability, maintenance (good engineering practices) for products with a health focus
- Lead efforts in supply chain resilience, sustainability, health equity and emerging technologies

- Modernize policies and processes, e.g., for nominating procedures, resolutions writing, participation expectations, evaluating and approving NWIPs, and ensuring appropriate data-driven analysis and decision-making.

As events and priorities change, ISO/TC 210 will revisit these goals and revise if appropriate.

3.5 Identified strategies to achieve the ISO/TC's defined goals

Since ISO/TC 210 is a flat organization whose work is accomplished at the working group level, the Chair and the Chair's Advisory Group (CAG) expect that subordinate groups, including the CAG, will create plans that address the needs of their standards work while conforming to the ISO/TC 210 goals above. The CAG will implement this SBP by communicating directly with each sub-group to explain the process and support the sub-group's own planning processes. These plans will be more objective in nature than the goals outlined in this SBP and should feature a tactical approach that will drive their standards activities.

4 Factors affecting completion and implementation of the ISO/TC work programme

A global TC of 210's size and scope faces complex challenges and opportunities. An analysis of the factors that may impact ISO/TC 210's work appears in Appendix A in the form of a SWOT analysis (strengths, weaknesses, opportunities and threats). ISO/TC 210's goals were established with these factors in mind. The goals capitalize on strengths and opportunities and mitigate weaknesses and threats.

5 Structure, current projects and publications of the ISO/TC

ISO/TC 210's structure, projects and publications may be found on the ISO website. Click on the links below to find the most current information:

- [About](#) (Secretariat, Committee Manager, Chair, Date of creation, Scope, etc.)
- [Contact details](#)
- [Structure](#) (Subcommittees and working groups)
- [Liaisons](#)
- [Meetings](#)
- [Tools](#)
- [Work programme](#) (published standards and standards under development)
- [Get involved](#)

Reference information

[Glossary of terms and abbreviations used in ISO/TC Business Plans](#)

[General information on the principles of ISO's technical work](#)