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STRATEGIC BUSINESS PLAN – ISO/TC 84 (2025 REVISION)

Executive summary

Patient safety always comes first.

ISO/TC 84 is responsible for standardizing devices used for the administration of medicinal products and catheters, and aims to ensure patient safety, improve product reliability, enhance global healthcare quality, and foster innovation in medical device development. The committee focuses on creating and maintaining international standards that drive uniformity, support regulatory compliance, and promote best practices across the healthcare industry. In addition, this committee contributes to sharps injury protection by standardizing sharps containers and sharps injury protection mechanisms.

It is in the best interest of industry, users, patients and governmental agencies to ensure safer and more convenient delivery devices while simplifying and standardizing methods for evaluating dose accuracy relative to the applied medicine and associated patient demographics; also keeping in mind that the devices shall be broadly available, easy to use, cost-effective and suitable for personal use.

Such devices are intended to fulfil the therapy needs while improving the quality of life for the end-user, ultimately contributing to improved health outcomes and related cost reductions. The healthcare sector also benefits from the improvement of such devices through better allocation of limited healthcare resources, contributing to better healthcare outcomes and facilitating the delivery of high-quality care.

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

Drug administration products

Until 1985, the administration of medicinal products was mainly characterized by devices such as needles/syringes and inhalers. During the last two decades, the use of drug delivery devices has significantly increased, for example with the popularity of pen-injectors replacing needles/syringes and refillable dry powder inhalers or non-refillable pressurized metered dose inhalers replacing nebulizers. At the same time self-administration of medicinal products became broader, and the focus shifted from traditional devices to treatments at home with newly developed devices. The reasons behind this are many:

- increasing adoption of home-based medical treatments and telehealth;
- an increased safety and therapeutic effect due to accurate treatment/dosage and an increase in ease of use;
- inclusion of a wider range of users into the scope of the standards;
- reduction in health costs due to improved health outcomes and more efficient allocation of limited healthcare resources.

The market for some of these products used to be limited. However, markets have adapted and evolved rapidly given these new forms of administration. In addition, many of the new drugs (biologics) are not able to be produced as tablets, but rather require subcutaneous or intramuscular injections. Thus, there is a significant growth of treatments requiring ISO/TC 84 devices. Self-administration of medicinal products has developed to include a myriad of products, including pens, auto-injectors, on-body delivery devices (OBDS), pumps, needle-free injectors and inhalers. The boundaries between these device types are disappearing as features once exclusive to reusable devices are found in prefilled devices and as different containers (e.g. cartridges and syringes) with sharps protection features are found in pen-injectors and auto-injectors.

Related ISO/TC 84 products

In addition to injection devices for administration of medicinal products, the scope of ISO/TC 84 also covers catheters, needles, syringes, mechanisms for sharps injury protection and sharps containers.

While the stakeholders have many different interests within this area, Industry requires international guidelines in order to manufacture these products safely. The relevant stakeholders include:

- Government organizations (e.g. WHO, UNICEF, FDA and MDD) and related economic interests;
- Regulatory authorities;
- Industry, as suppliers of medical devices;
- Industry, as suppliers of medicinal products;
- Public interest groups: Organizations such as Diabetes Associations;

– Users, both home-care users (patients) and professional users (e.g. nurses and doctors).

2.2 Quantitative Indicators of the Business Environment

The global market for medical devices and combination products related to the administration of medicinal products and catheters is expected to grow steadily due to increasing healthcare demands, an aging population, and advancements in medical technologies. The rise in chronic diseases and the need for more efficient drug delivery systems further drives the demand for high-quality medical devices. Some sources suggest the market to double within the next ten years.

The following list (not exhaustive) describes the business environment in order to provide adequate information to support the actions of ISO/TC 84:

– needle-based injection systems, where there has been a trend towards the delivery of larger volumes and high viscosity drugs less frequently (once every two weeks, once a month, etc.);
– needle-free injection systems (injecting the medicinal product through the skin by pressure, without penetrating the skin by a needle);
– auto-injectors;
– on-body delivery systems (OBDS);
– inhalers (for delivering drugs either via the oral or nasal route, where there has been a trend towards once or twice per day dosing and the dispensing of one month's supply;
– buccal treatment;
– needles;
– catheters.

There is an increased emphasis on managing cost, improving care and compliance requiring feedback regarding performance of the device before, during and after use. Adding connectivity is thus a major thrust of future development.

The growing complexity of medical devices requires stringent regulatory and standardization measures. Manufacturers apply the requirements of international standards to produce medical devices, catheters and drug/device combinations, called upon by the respective health authorities.

3 Benefits expected from the work of the ISO/TC

As previously noted, a change of product and treatment in this field has resulted with the development from syringes/needles towards the use of needle-based injection systems that are dedicated for specific medicinal treatment, as well as inhaled, transdermal and buccal treatment.

This will require that ISO/TC 84 initiates the preparation of new deliverables whenever new trends or technologies are being developed and introduced for administration of medicinal products. ISO/TC 84 will also need to prepare appropriate new standards to capture connectivity requirements as they pertain to injection systems.

Innovation and emerging technologies are important initiatives that should also be addressed by monitoring and supporting innovations in medical technology, including digital health solutions, AI-driven devices, and personalized drug delivery systems, by ensuring that these innovations are adequately addressed in new standards. Also the fostering of a proactive approach to anticipate emerging trends, such as 3D printing in medical devices, may require new standards.

The benefit is that existing and traditional devices are covered by widely accepted safety requirements and that new forms of administration are covered by requirements at an early stage of development. This facilitates both the process of development as well as the approval

procedure. Users and manufactures benefit greatly, as users are able to purchase safe and functional devices worldwide, and the manufacturers can contribute to the development of requirements and achieve an easier process of approval of their products before launch.

Developing and continuously reviewing ISO standards for devices used in the administration of medicinal products and catheters and establishing a clear process for soliciting feedback from industry stakeholders ensures that standards reflect the latest scientific and technological advancements.

The post-use safety of the sharp's devices is also supported by sharps containers and sharps injury protection mechanisms that have contributed increasing safety from the healthcare professional to the patient and the waste stream workers.

4 Representation and participation in the ISO/TC

4.1 Membership

A full list of P and O members can be accessed here.

4.2 Analysis of the participation

Regulatory bodies, including the US FDA and the European Medicines Agency (EMA), play a crucial role in shaping industry standards.

Greater participation of representatives from national and regional health authorities, the health-care sector and users is desirable. Over the past years, patients and health-care representatives have been active in the development of the standards. Some of those representatives have been supported by the ISO/TC 84 Travel Expense Support (TES) which is an ISO/TC 84 unique tool to facilitate user-representation.

Relevant stakeholders are contacted when new projects within ISO/TC 84 are initiated.

Consistent, sustained involvement from member countries is important to ensure alignment of safety objectives globally. When ISO standards are used as a basis for creation of local or regional standards following the most recent published version without modification is imperative.

5 Objectives of the ISO/TC and strategies for their achievement

5.1 Defined objectives of the ISO/TC

The main objective for the committee is to increase patient safety and limit commercially driven requirements that may conflict with patient safety.

The work is characterized by the enhancement of standards in accordance with the development of new technologies and new device types in the market, and a constant focus on patient safety. ISO/TC 84 develops standards with a high level of safety requirements, which implies that not all products on the market necessarily comply with the requirements, and with a view of inviting industry to develop new and better devices and phase out existing products that may not comply.

ISO/TC 84 intends to develop standards for devices for administration of medicinal products and catheters intended for hospital use. These standards specify performance requirements and dose delivery accuracy assessment as appropriate for the intended therapy and patient.

The committee avoids preparation of de facto standards by following market development and establishes horizontal and functional standards that also provide cost-effective and safe products,

which are required by the users. The objective is to establish performance requirements especially related to the accuracy, robustness, and safety of the devices, and intentionally avoids detailed specifications, which are left to the manufacturers to develop.

5.2 Identified strategies to achieve the ISO/TC's defined objectives

ISO/TC 84 prioritizes its projects to reflect market needs and market impacts (e.g. pandemics) and safeguards active participation from all relevant stakeholders to take an active part in the development of the various deliverables in the committee (manufacturers, authorities, end-users, patients, healthcare personnel, etc.).

In order to get participation from users/patients, a Travel Expense Support fund was established in 2010 to provide travel funding in areas where this is needed in the working groups (e.g. nurses, persons with visual impairment, etc.).

The committee has decided to establish work item study groups for each new idea/proposal for new work items in order to ensure consensus on the objective to be achieved and to ensure that a future document will be globally relevant in accordance with the global relevance policy of ISO.

ISO/TC 84 supports action on UN Sustainable Development Goal 3 'Good health and well-being'.

In 2024, ISO/TC 84 formed an Advisory Group (Expert Panel) to manage external inquiries about its documents, simplifying the internal process for publishing responses and providing a direct communication channel to experts of the TC.

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

ISO/TC 84 believes that there is great expertise to be recruited for the advancement of its projects. However, knowledge could be lacking within areas where research is yet to be done. The merging of technologies requires exhaustive collaboration among experts and regulatory bodies to facilitate exchange of knowledge.

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

Information on ISO online

The link below is to the TC's page on ISO's website:

ISO/TC 84 on ISO Online

Click on the tabs and links on this page to find the following 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)

Reference information

Glossary of terms and abbreviations used in ISO/TC Business Plans

General information on the principles of ISO's technical work