Executive summary

Patient safety always comes first.

ISO/TC 84 works to increase patient safety and ensure high quality of devices used for administration of medicinal products and catheters.

It has been the interest for industry, users, patients and governmental agencies to ensure safer and more convenient delivery devices and at the same time achieve simple and standardized 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, inexpensive and suitable for personal use.

Such devices are intended to provide a dose accuracy fulfilling the therapy needs while improving the quality of life for the end-user; ultimately contributing to improved health outcomes and related cost reductions. The health-care sector also benefits from the use of such devices through better allocation of limited healthcare resources.

The demand for devices covered by ISO/TC 84 continues to grow at over 15% annually.
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:

Until 1985, the administration of medicinal products was mainly characterized by devices such as needles/syringes and inhalers. During the years, the use of drug administration devices has 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. The self-administration of medicinal products was to become broader and shift the focus from traditional devices to treatments at home with newly developed devices. In recent years the trend has been towards the use of devices with replaceable containers or prefilled devices. The reasons behind this are many:

- The treatment is transferred from hospitals to self-administration in the home;
- The method of treatment at home is more convenient for the user leading to better compliance;
- An increased safety and therapeutic effect due to accurate treatment/dosage;
- The health costs are reduced due to improved health outcomes and more efficient allocation of limited healthcare resources.

The market for some of these products used to be rather 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 as medicines for SC or IM 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 device are found in prefilled devices and as different containers (e.g. cartridges and syringes) are sharps protection features are found in pen-injectors and auto-injectors.

In addition to injection devices for administration of medicinal products, the scope also covers catheters.

While the stakeholders have many different interests within this area, Industry needs 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 being suppliers of medical devices;
- Industry being suppliers of medicinal products;
- Public interest groups: Organizations such as Diabetes Associations;
- Users being both home-care users (patients) and professional users (e.g. nurses and doctors).
2.2 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 ISO/TC 84:

The trend is moving from use of traditional syringes and needles towards the below mentioned metering devices:
- 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.);
- pumps for catheters;
- 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);
- transdermal treatment (e.g. by the use of patches);
- buccal treatment.

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.

Today, 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 is due with the development from the use of 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. The work in relation to on-body delivery systems is an example. ISO/TC 84 will also need to prepare appropriate new standards to capture connectivity requirements as they pertain to injection systems.

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 marketing.
4 Representation and participation in the ISO/TC

4.1 Membership

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

4.2 Analysis of the participation

Greater participation of representatives from national and regional health authorities, the health-care sector and users would be 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.

In principle, relevant stakeholders are contacted when new projects within ISO/TC 84 are initiated. It is estimated that more than 90 % of the global manufacturers are represented in the various working groups and national mirror committees.

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 avoid commercial driven requirements.

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

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.

ISO/TC 84 avoids preparation of de facto standards by following the market development and establishes horizontal and functional standards that also provide inexpensive 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 decide.

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 TC 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 global 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’.

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 elaboration of the TC’s projects. However, knowledge could be lacking within areas where research is yet to be done. The merging technologies require exhaustive collaboration among experts and 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