STRATEGIC BUSINESS PLAN
ISO/TC 76
Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use

EXECUTIVE SUMMARY

The work programme of ISO/TC 76 is focused on primary packaging materials and on non-active devices for the administration of medicinal products as well as parenteral solutions, enteral feeding preparations, and diagnostic materials. Primary packaging materials have a steadily growing potential in a global market with a noticeable need of worldwide standardization and harmonization.

ISO/TC 76 International Standards will help the manufacturer of primary packaging materials and medical devices, the pharmaceutical industry, the end user of the products as well as analytical laboratories for a better understanding of the mutual needs to improve the product quality and to harmonize analytical methods. Additionally, the standardization work of ISO/TC 76 facilitates a worldwide exchange of goods and know-how transfer, thus improving the economics of existing and future business.

International Standards and harmonization will contribute to establish or maintain a high level of quality, which is an important prerequisite for primary packaging materials and administration devices.

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 76

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:

2.1.1 Existing International Standards of ISO/TC 76 and worldwide harmonization in the field of primary packaging materials for medicinal products and harmonization of medical devices will contribute to ensure a high quality level of the products.

2.1.2 GMP principles in production and control of primary packaging materials are of great importance for the safety of a patient using the medicinal product, because of its direct product contact.

2.1.3 In the field of growth hormones and vaccines, the conventional application system (vial, closure, cap, injection needle) are more and more replaced by prefillable syringes.

2.1.4 The relevant stakeholders are the following:

- Regulatory authorities, e. g. WHO, FDA, EC
- Pharmaceutical industry
- Manufacturers of primary packaging materials
- Suppliers of application systems
- Notified bodies resp. test houses
- Public interest groups, e. g. ICSH, ISBT

2.1.5 The concerns and perceptions of stakeholders mentioned in 2.1.4 are quite different from each other. ISO/TC 76 standards address safety aspects, health and environmental issues as well as material specific requirements and test methods.

2.1.6 International Pharmacopoeias, e. g. USP, Ph. Eur., JP. have to be taken into consideration because these regulations are mandatory in various countries.

2.1.7 The European Directive on "Medical devices" has to be taken into consideration when creating new ISO/TC 76 standards. The essential requirements of the MDD should be met, otherwise discrepancies of the technical content between ISO and EN standards can occur.

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 the ISO/TC 76:

2.2.1 At the present, the biggest markets for primary packaging materials as well as for administration devices are in U.S.A., Western Europe and Japan. However, China, Eastern Asia and South America are increasing markets.

2.2.2 It is almost impossible to correctly assess the total sales in this field because there are no full international records available to the public. The total sales volume, however, is estimated in the range of about US $ 6-10 billion.

2.2.3 The evaluation of relative market shares makes only sense when comparing the materials utilized. Materials made of plastics and glass play a predominant role, whereas rubber and metal contribute to a lesser degree.

2.2.4 In a certain way, the numbers of containers and devices grow in parallel at a rate of about 5 % per year globally. However, the average growth does not reveal the fact that innovative products grow faster, whereas commodities are losing market shares gradually.

2.2.5 There is a noticeable concentration of suppliers in the U.S.A., Japan and Central Europe. Especially in the field of packaging components such as glass containers, rubber elements and sealing caps. Most of the global business is in the hands of a few globally operating U.S., Japanese and European companies. In the case of administration devices, the situation is quite different with no real concentration effects (with the exception of blood collecting tubes).

3. BENEFITS EXPECTED FROM THE WORK OF THE ISO/TC 76

3.1 Safety of the patient
A performance quality level and the consistency of it over a long period contributes to the quality of medicinal products, diagnostics and administration devices, thus ensuring the patients overall safety.

3.2 Economy
Standardization of components facilitates the availability of those parts worldwide and improves the machinability (filling and assembly lines).

3.3 Market access
ISO standards enable manufacturers, e.g. in developing countries, to export into highly industrialized countries.

3.4 Auditing
ISO standards provide a common platform for the evaluation of products, set up internationally accepted quality levels, and create a basis for auditing activities, e.g. by notified bodies or test houses.

3.5 Complementary support
Promptly updated ISO standards reflect the state of the art and they complement national regulations. An example is the provision of complementary tests for packaging components that are typically not included in a Pharmacopoeia, e.g. fragmentation test for rubber closures, penetration force test of infusion sets.

4. REPRESENTATION AND PARTICIPATION IN THE ISO/TC 76

4.1 Membership

Countries/ISO members bodies that are P and O members of the ISO committee

4.2 Analysis of the participation

4.2.1 ISO/TC 76 represents a high degree of the worldwide market share. Many producers, some hospital representatives and analytical experts take an active role in the work.

4.2.2 Geographically, most contributions to the standardization work come from the U.S.A. and Western Europe, followed by China. Active contribution from e.g. Russia and Japan has been missing in the past.

4.2.3 Developing countries do not yet take an active part in the work of TC 76.

5. OBJECTIVES OF THE ISO/TC 76 AND STRATEGIES FOR THEIR ACHIEVEMENT

5.1 Defined objectives of the ISO/TC 76

5.1.1 The main objective of ISO/TC 76 standardization work is to develop International Standards that will support manufacturer's effort to ensure the safety and high functionality of their products for the benefit of the patient.

5.1.2 To develop International Standards in the field of primary packaging materials and medical devices that will effectively address the requirements of users, regulatory authorities and manufacturers.

5.1.3 To consider the application of ISO 9001 in conjunction with GMP aspects as the basis for a quality assurance standard in the field of primary packaging materials.

5.1.4 To develop International Standards that will simultaneously meet or at least not conflict with the essential requirements of the corresponding European Directive, of the American FDA and of the Japanese MHW.

5.1.5 To co-operate with International Pharmacopoeia Commissions, e.g. U.S.P., Ph. Eur., in order to be in line with regulatory requirements.

5.1.6 To liase with other ISO/TC´s , e.g. ISO/TC 84 in order to avoid duplication of work and to ensure compatibility with other International Standards, e. g. with ISO/TC 194 regarding biological test methods.

5.1.7 To review all published International Standards of ISO/TC 76 at an earlier stage as required in the ISO/IEC Directives and if necessary to revise them as soon as possible in order to meet the market actualities.

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

5.2.1 ISO/TC 76 holds plenary meetings only if the progress of work being made by the various working groups justifies such a meeting. A great deal of standardization work is done by correspondence.

5.2.2 In order to speed up the work the ISO/TC 76 Secretariat has introduced electronic means of communication, e. g. ISO/TC 76 is going to test the efficiency of more and more WebEx.

5.2.3 ISO/TC 76 is taking widely used national or regional standards as a basis for new ISO standards. A close co-operation has been established with the European Standardization body CEN/TC 205. As far as possible the "Vienna Agreement" under the leadership of ISO is applied.

5.2.4 More and more ISO/TC 76 has to take into consideration microbiological aspects and questions of biocompatibility, brought up by national authorities. Therefore, it is necessary to have a close liaison with ISO/TC 194 in order to be in line with the requirements and test methods laid down in International Standards of this Technical Committee. Further liaisons with other ISO/TC´s, e.g. ISO/TC 84, ISO/TC 176/SC 2, ISO/TC 198 and ISO/TC 210 are very important.

5.2.5 The structure of ISO/TC 76 is well established and will be reviewed from time to time. At the moment there is no reason to change it.

5.2.6 ISO/TC 76 will continue to seek to expand its membership and encourage active involvement from member bodies not currently participating in its work.

6. FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE ISO/TC 76 WORK PROGRAMME

6.1 Due to financial reasons it is more and more difficult to find experts from the user side, e. g. clinicians, scientists etc., who are able to attend international meetings. In the long term the possibility exists that ISO standards will not be balanced anymore.

6.2 Experts representing the industry are permanently overloaded with the daily work in their companies and very often do not have the time and capacity to complete a special task transferred to them during a TC or WG meeting within an agreed time frame. Consequently, the agreed target dates by the TC cannot be met.

6.3 The competition between companies on the global market becomes harder and harder. Insufficient financial support and reduced man power when investigating special details on agreed items implemented in the programme of work of the TC can cause delays in finishing some work items or can make it possible to bring them to an end.

7. STRUCTURE, CURRENT PROJECTS AND PUBLICATIONS OF THE ISO/TC 76

This section gives an overview of the ISO/TC's structure, scopes of the ISO/TCs and any existing subcommittees and information on existing and planned standardization projects, publication of the ISO/TC and its subcommittees.

7.1 *Structure of the ISO committee*

7.2 *Current projects of the ISO technical committee and its subcommittees*

7.3 *Publications of the ISO technical committee and its subcommittees*

Reference information

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

General information on the principles of ISO's technical work