

# 1 QUALITY MANAGEMENT SYSTEMS IN TISSUE BANKING

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## Abstract

Over the last, decade the concept of standardisation and quality management has gained increasing importance in tissue banking.

There are several reasons for this development:

- increasing demand for human and other biological tissue;
- increasing risk of viral infections;
- progress in medical, pharmaceutical and technical sciences related to tissue banking;
- centralisation in tissue banking;
- international co-operation and networking;
- international harmonisation by standards and guidelines.

The General and Specific Standards for Tissue Banking cover national and/or international requirements and are accompanied by technical manuals related to methodology of tissue banking (donor selection, processing, preservation, sterilisation, storage, and distribution). These standards and technical

manuals shall ensure the quality of tissue banking. Such a quality system is very specific.

To establish a quality framework that covers the specific methodology as well as general aspects of quality management (research & development, design control, education and training, documentation, traceability, management control, corrective action, etc.), tissue banks can use an international standard: ISO 9000.

This article explains the individual elements of the quality management system (QMS) according to ISO 9000 and gives examples of selected points.

This QMS, once it is introduced, is subject to regular auditing by an international certification network. The authors recommend this QMS be used as an instrument for harmonisation and international co-operation in tissue banking.

## **1. Introduction**

In the last decade in particular, rapid progress in the medical, pharmaceutical and technical sciences, including biotechnology, has taken place, exerting a considerable effect on what is generally known as tissue banking. But new demands and challenges for this special field have arisen through new developments in the industrial area and through internationally changing social and political structures as well. Tissue banking is medically interdisciplinary and even more reliant than other specialised fields upon the application of knowledge from other branches of science and even more influenced by them. A further difference to other medical disciplines is the urgent necessity of the inclusion of norms, standards and statutory regulations in the daily work of a tissue bank. As far as that goes, tissue banking has many similarities with the pharmaceuticals and medical devices manufacturing industry, in particular, as regards safety aspects.

For ease of understanding, definitions of terms which are of importance within the framework of the following exposition, are included at this point.

*Tissue banking* is a specialised medical discipline, which, in accordance with generally recognised ethical principles and conscious that tissue donation from the population is carried out for unselfish or charitable reasons, is concerned with the organisation and coordination of the tissue removal, processing and preservation of tissues, their quality assurance, as well as the storage and distribution of these final products for therapeutic, diagnostic, teaching and research purposes and is controlled and licensed by official and competent national or other authorities. In this regard, the term “tissue” includes all cells and tissue as well as cell and tissue replacement materials of biological origin.

*Quality of a tissue* is the totality of its qualities and characteristics which make it suitable to fulfil the demands made upon it.

*Quality assurance in tissue banking* in the most general sense includes “the totality of all activities of quality management, quality planning, quality control and quality testing in order to verify tissue banking so that the entire operation is in conformity with the standards and regulations valid for this process and so that the condition of the finished tissue in regard to its suitability for all previously established and expected demands is fulfilled” (Fig. 1).

<b>Q U A L I T Y</b>	<b>Donation</b>	<b>A S S U R A N C E</b>
	<b>Procurement</b>	
	<b>Preparation</b>	
	<b>Preservation</b>	
	<b>Application</b>	

Fig. 1. Quality assurance in tissue banking.

The above-mentioned quality-specific aspects are accompanied by a further very important phenomenon, namely, the steady increase in requirements for cells and tissue for clinical use and for their use as parent material for other preparations, for example, within the framework of biotechnological processes.

The changing qualitative as well as the quantitative demands on tissue banks, can no longer be realised by locally-acting banks, for example, in hospitals. Without centralisation (concentration of resources) on the one hand and specialisation (concentration of know-how) on the other, the existing discrepancy is not to be overcome. Indispensable instruments for the solution of this problem are centralisation at the national level and co-operation at the international level. Impediments to such a development are currently the absence in many countries of laws and means of regulation for dealing with biological materials, in particular, human tissue. In other countries, tissue is dealt with very differently and its handling is regulated, namely, as tissue, transplant, pharmaceutical or medical device. In addition, there are very clear differences in the logistics and quality assurance of tissue banks in various regions of our globe. This complicates considerably co-operation between tissue banks.

In order to solve this problem, medical-scientific specialist societies were founded at national and international levels. One of their most important goals was and is the development of quality standards and ethical rules for tissue banking. In this way, one of the most important instruments for comprehensive co-operation has now been created: a common platform for quality assurance on the basis of general acceptance by the experts and in accordance with the principle of "standards as high as necessary but not as high as possible". A multitude of tissue banks now work on the basis of these standards recommended by, for example, the American Association of Tissue Banks and European Association of Tissue Banks. Many governments have taken on these standards or used them in the development of national regulations.

Tissue banks face the problem of organising all internal processes and implementing them in the daily routine in such a way that they

are in agreement with the national laws and are able in the same manner, to take into account the standards developed in the international scientific societies. In the last few years, an overlapping system of national and international regulations has developed from this (Fig. 2), the observance of which presents the tissue bank with ever higher organisational and professional demands.

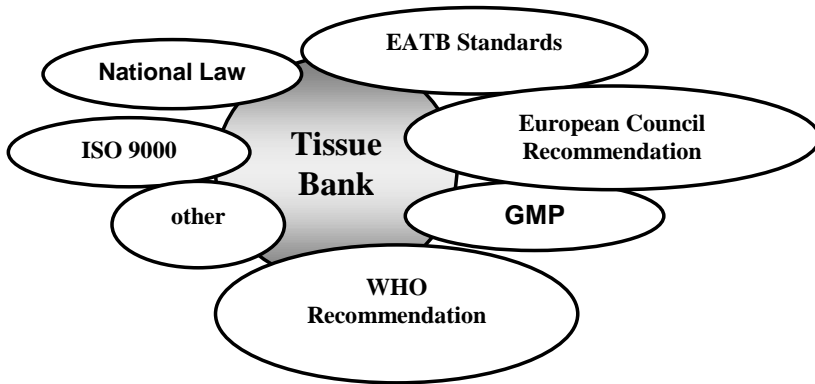


Fig. 2. Overlapping system of national and international regulations for tissue banks.

In addition to these important aspects, there are now additional goals directly connected with the idea of quality, such as:

- improvement of transplant characteristics,
- innovation, new products (biotechnology!),
- increasing productivity and efficiency,
- lowering of costs (self sufficiency!),
- satisfaction of the surgeons,
- public awareness,
- competitiveness,
- globalisation, international co-operation,
- improvement of the “working atmosphere” etc.

These goals and concepts would not necessarily have been associated with tissue banking up to a few years ago.

Oftentimes, nowadays, the old organisational structures are no longer sufficient to correspond to the changed philosophy of the "QUALITY" concept – to always and everywhere be at the centre of endeavours.

The General and Specific Standards for Tissue Banking cover national and/or international requirements and are accompanied by technical manuals related to methodology of tissue banking (donor selection, processing, preservation, sterilisation, storage, and distribution). These standards and technical manuals shall ensure the quality of tissue banking. Such a quality system is very specific.

To establish a quality framework that covers the specific methodology as well as general aspects of quality management (research & development, design control, education and training, documentation, traceability, management control, corrective action, etc.), the focus of tissue bankers when developing quality management systems (QMS) has now been on the models according to ISO 9000. A few of the tissue banks have their QMS certified by an accredited agency.

### **1.1. Structure of the ISO 9000 standard series**

The quality management system (QMS) in accordance with the ISO 9000 international standard series, which has been introduced as a regional, for example, European, standard series EN ISO 9000 and as a national standard series (e.g. DIN EN ISO 9000 in Germany), with its extensive platforms, today forms the most general foundation for the creation of quality management systems. It describes recommendations for the construction of such systems and supplies an extensive description of the duty of care for quality management and quality assurance. The structure of the standard series, which consists of five standards, is shown in Fig. 3.

The five standards describe:

ISO 9000: Guidelines for selection and use of the standards  
ISO 9000 to 9004

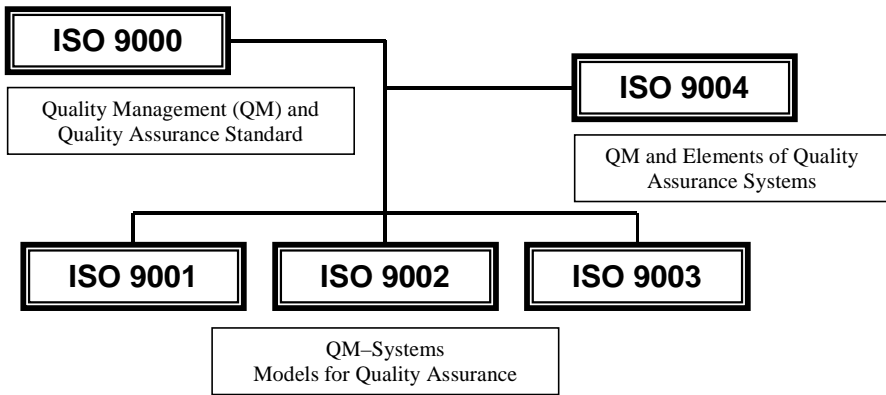


Fig. 3. Structure of ISO 9000 system.

ISO 9004: General guidelines to quality management and the elements of a quality assurance system;

**ISO 9001:** *Quality systems – Model for quality assurance in design, development, production, installation and servicing;*

**ISO 9002:** *Quality systems – Model for quality assurance in production, installation and servicing;*

ISO 9003: Quality systems – Model for quality assurance in final inspection and testing.

Should a tissue bank decide to establish a QMS on the basis of the ISO 9000 standard series, then in principle, the models in accordance with ISO 9001 or ISO 9002 would be possibilities, according to whether the profile of the tissue bank also included activities in research and development.

The inner structure of the models in accordance with ISO 9001 to ISO 9003 is described through quality assurance *elements*. The most extensive model according to ISO 9001 consists of 20 elements (see Fig. 4).

If a quality management system in accordance with ISO 9002 is established, quality assurance element No. 4 “Design Control” is not required.

Management Responsibility	Quality System	Contract Review	Design Control
Document and Data Control	Purchasing	Control of Customer-supplied Products	Product Identification and Traceability
Process Control	Inspection and Testing	Control of Inspection, Measuring and Test Equipment	Inspection and Test Status
Control of Non-conforming Products	Corrective and Preventive Action	Handling, Storage, Packaging, Preservation and Delivery	Control of Quality Records
Internal Quality Audits	Training	Servicing	Statistical Techniques

Fig. 4. Quality Assurance Elements ISO 9001.

## 1.2. The structure of the documentation

The implementation of a quality management system in a tissue bank according to ISO 9000 presupposes the complete description of the system in accordance with the standard performance target on the basis of the 19 (ISO 9002) or 20 (ISO 9001) quality assurance elements. The very general nature of the quality assurance elements as structural performance targets is the basis for the fact that a quality management system according to ISO 9000 is describable for every subject-specific enterprise and thus also for tissue banking.

An important starting point is the drafting of a documentation structure adequate and suitable in scale to tissue banking. The format, in principle of the documentation structure, can be seen in Fig. 5.

The *Quality Manual* describes the QMS in its most general form with very little depth of detail. The structure as regards content of the quality manual should thus correspond to the structure of the 19 or 20 quality assurance elements. Because of the low depth of

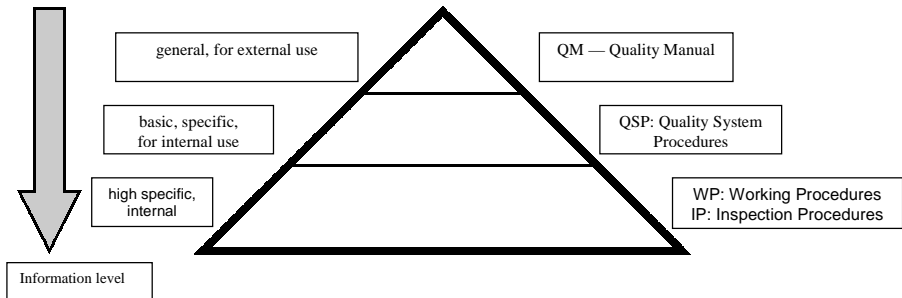


Fig. 5. Principal document structure describing ISO 9000 Quality Management Systems.

detail (for example, no description of know-how in processing), the quality manual is very suitable for external presentation of the quality-oriented structure of the tissue bank both to the authorities and within the framework of cooperation with other tissue banks.

## 2. The Quality Assurance Elements in Tissue Banking

In this section, the central aspects of the individual quality assurance elements are described and a connection to tissue banking established.

### 2.1. Element 1: Management responsibility

A core concept of QMS according to ISO 9000 consists of the fact that the responsibility for quality lies with the management (administrators/directorship) of an enterprise (tissue bank). The management is obligated through the standard to draw up a declaration on quality policy: this is binding for staff. They are obliged to its fulfilment. In tissue banking, the high ethical demands in dealing with tissue of human origin and the state-of-the-art professional level are among the outstanding features of a quality policy.