

2.20. Element 20: Statistical techniques

Statistical techniques can be very useful for supplying information on correctly functioning processes. The standard always requires the use of statistical methods in areas where they can be sensibly utilised. Not just mathematical–statistical techniques in a narrow sense are meant in these cases. Surveys, market analyses and other methods are also included.

3. Reflections on the ISO 9000 Standard Series from the Point of View of Tissue Banking (Conclusions)

The construction of a QMS on the basis of the ISO 9000 standard series in tissue banking is still at its very beginning. Up to now, to the author's knowledge at the time of the drafting of this manuscript, there are two tissue banks in Europe and one in the United States which are certified. In Vietnam, one tissue bank works according to a national standard which practically corresponds to the ISO standard. In other branches of business, however, there are umpteen numbers which have experience with this standard extending back to the 1980s.

On the basis of our own experience, it can be said in summary that ISO 9000 is also well suited for the formation of the basis for implementing a QMS for tissue banking. The advantages of this standard series being very generally formulated, that is to say without any relation to a particular branch of business, and at the same time, exhibiting a high degree of complexity, speak for this recommendation.

In implementing a QMS in accordance with ISO 9000, the goal is normally, after the system comes into force, to bring evidence through an audit by an accredited certification body that the system is in conformity with the standard, is effective, fully established and finally, that the certificate is issued. On the other hand, this goal can only be achieved by means of a substantial personnel and financial expenditure. Therefore, there is the legitimate question as to whether for the reasons mentioned, the ISO 9000 standard series is appropriate

to serve as the basis in tissue banking in view of international harmonisation and further quality-oriented development in the area. This question can however be answered with an unequivocal yes. In the first phase, the auditing and certification must not be seen as the highest goal. Then, the other advantages move more clearly to the fore. These include coming into a harmonised “language” in regard to quality assurance and quality management in tissue banking. Then, one is in a position to see the realisation of individual important elements as a positive result. The most important aspect of a consensus in tissue banking would then be the acceptance of the principles of the ISO standard series and the selective, step-by-step realisation of individual elements, so that every tissue bank, wherever it is located, could take part in the harmonisation.

4. Acknowledgement

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5. Bibliography

DIZG German Institute for Cell and Tissue Replacement: Quality Management Manual.

DIZG German Institute for Cell and Tissue Replacement: Procedure Manuals.

European Association of Tissue Banks: Ethical Code.

European Association of Tissue Banks: General Standards.

European Association of Tissue Banks/European Association of Musculo-Skeletal Transplantation: Common Standards for Musculo-Skeletal Tissue Banking.