

From Quality to Quality Management in European Blood Establishments: Council of Europe's contribution

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The Council of Europe, based in Strasbourg (France), was founded in 1949 and has 47 Member States with some 820 million citizens.

The European Directorate for the Quality of Medicines & HealthCare (EDQM), a Directorate of the Council of Europe, is a leading organisation that protects public health. One of its responsibilities is to develop guidance, standards and operational activities in the field of Blood Transfusion.

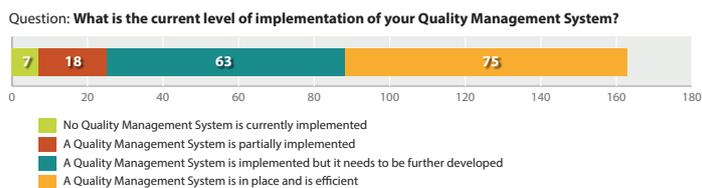
Background

During the last decade, the concept of quality in the field of blood transfusion has evolved greatly, while European Blood Establishments (BEs) have been required to comply with new regulatory requirements. Transfusion is a procedure that carries intrinsic risks and the implementation of a **Quality Management System (QMS)** in BEs is key to managing these risks and ensuring the efficacy, quality and safety of blood. Whereas Quality Assurance (QA) implies the development of procedures to ensure that requirements are fulfilled, a QMS additionally implies a quality policy and objectives, risk-management and continuous improvement to direct all processes towards quality. Implementation of a QMS is required by EU Directive 2002/98/EC, is prescribed in the Council

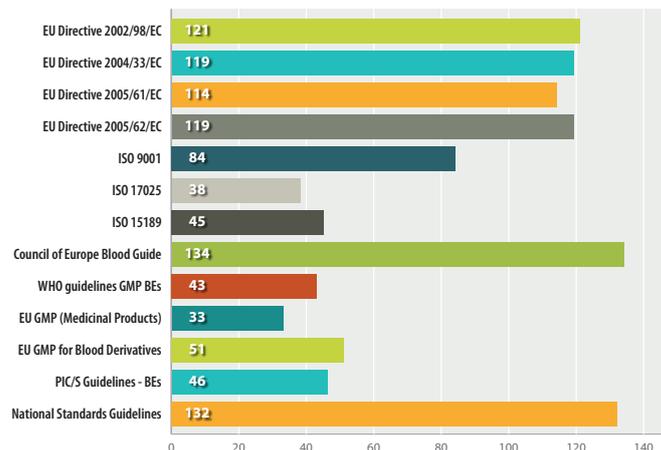
of Europe's *Guide to the Preparation, Use and Quality Assurance of Blood Components* and defined in EU GMP, PIC/S guidelines and ISO Standards. Nevertheless, the concept is not always entirely understood and is often seen as a burden owing to a lack of appropriate on-site support. This was confirmed in a survey performed by the EDQM in 2012. The data collected from 186 BEs (33 countries) and observations recorded during on-site visits provide evidence of the difficulties encountered in understanding quality concepts and developing an integrated QMS, and show that existing systems tend to be blood product quality-oriented. Additionally, it was observed that the use of existing standards varies between countries and even within countries (Figure 1).

Figure 1 – 2012 Survey Results

(Results are given in absolute numbers of Blood Establishments)



Question: **Which of the following standards are used in your Blood Establishment in order to implement a Quality Management System?**



RESULTS

Since 2012, the EDQM has run **9 B-MJVs**, **4 B-TVs** and organised **1 Training Course**. BEs recognise this programme as essential, given the increasing relevance of QMS, the complexity of the activities undertaken and the difficulties in implementing all standards applicable in this field.

Observations recorded during the schemes ranged from critical to minor. A classification of the non-conformities observed during these schemes is shown in Figure 3. The majority of the non-conformities found were related to management and continuous improvement requirements which shows that

systems are still QA based.

Participating BEs were able to take measures, switch from a quality- to a QM-oriented system and/or improve their QMS. The first European Training Course on Quality Management for BEs took place in April 2015. Its content is provided in Figure 4.

Figure 3 – Classification of non-conformities observed during on-site schemes*



Aim

In order to assist BEs with the development and implementation of an integrated QMS, in 2012, the EDQM launched an educational programme called the **Blood Quality Management Programme (B-QM)**.

Methods

The B-QM Programme delivers on-site training or assessment schemes as well as learning tools as described in Figure 2.

Figure 2 – B-QM programme activities

(Participation in the B-QM schemes is open to all European Blood Establishments and is free of charge)

Learning Tools

- Training Courses
- Manual on QMS (Ongoing activity)

On-site Training & Assessment Schemes

- Blood Training Visits (B-TV):**
An on-site visit is performed. Training sessions then take place on technical and QMS issues based on the observed non-compliances during the visit.
- Blood Mutual Joint Visits (B-MJVs):**
These are visits intended to advise BEs and help them implement and/or improve their QMS.
- Blood Mutual Joint Audit (B-MJAs):**
These check that the implemented QMS complies with the requirements of the Standards and Regulations implemented in the BE (Minimum standards to be implemented: EU Blood Directives and Council of Europe's *Guide to the Preparation, Use and Quality Assurance of Blood Components*).

The on-site scheme type is selected based on a prior assessment of the existing QMS. The process- and risk-based approach is taken, allowing BEs to rethink their system, consider the criticality of their processes, develop a risk-based QMS and focus on continuous improvement.

Conclusion

Blood quality can only be guaranteed through the development of a **common European approach and operational tools** in the field of QM, together with the implementation of an integrated QMS.

The EDQM B-QM programme is the first of its kind in Europe and provides **non-reprobativ** support to BEs.