Guidelines for the Blood Transfusion Services

2.4: Systems

http://www.transfusionguidelines.org/red-book/chapter-2-quality-in-blood-and-tissue-establishments-and-hospital-blood-banks/2-4-systems

2.4: Systems

2.4.1: Quality management system

Within a Blood/Tissue Establishment an effective quality management system (QMS) is a well-designed, structured and organised method of quality assuring the provision of consistent, safe and efficacious products. It also covers all diagnostic activities, reagent production, clinical trials and R&D. It provides both a means to confirm to regulatory bodies, management and customers that the establishment's service is in compliance with relevant standards, and also a basis whereby improvement in quality may be demonstrated.

The European Blood and Safety Quality Directives require that a quality system is to be applied for any blood and blood components circulating in the EC and that member states therefore should ensure that for all blood and blood components including those coming from third countries there is a quality system in place for Blood Establishments equivalent to the quality system provided under these Directives.

The EU Tissues and Cells Directives have equivalent requirements for the provision of a quality management system. These are defined as follows: 'an efficient QMS comprises a series of inter-related elements and a quality system for Blood/Tissue Establishments should embrace the principles of quality management, quality assurance, and continuous quality improvement, and should include personnel, premises and equipment, documentation, collection, testing and processing, storage and distribution, contract management, non-conformance and self-inspection, quality control, blood component recall, and external and internal auditing'.

2.4.2: Good manufacturing practice

The application of GMP is the cornerstone of an effective QMS and provides the structure upon which the elements of the quality system can be built. The objective of GMP is formally stated as being 'to assure the quality of the medicinal product for the safety, well-being and protection of the patient'.[17] The BSQR requires that Blood Establishments and hospital blood banks meet the requirements of good practice. This is taken by the MHRA to mean that Blood Establishments and hospital blood banks should comply with all relevant sections of the EC Guidelines to GMP.[18] This applies to hospital blood banks, even though they are not manufacturing anything, but are part of the distribution chain which is defined as part of the overall manufacturing process.

The EC Guidelines to GMP are described more fully in section 2.6 using the quality system format provided by Directive 2005/62/EC.[6] Elements are presented under separate headings, and in practical terms all of these must be considered for each and every procedure or process to conform to the principles of good manufacturing practice.