



Managing the “cold chain”



GMP

GMP & BSQR

- BSQR Article 22: Storage, transport and distribution – all blood and blood products are stored appropriately and storage conditions monitored
- GMP Guide - Chapter 3: Premises and Equipment – ensure premises and equipment is designed and constructed to ensure products are safe for use.

1. Quality Management System

- Satisfy regulatory/accreditation requirements
- “owned” and understood by the workforce
- Is an integral part of how everyone works
- GMP focused
- Ensures the delivery of high quality products and/or services
- Commitment from everyone is vital

Quality Management System for BSQR

- Quality Incident Reports Chapter 1 GMP
- Self Inspection Chapter 9 GMP
- Technical Agreements Chapter 7 GMP
- Complaints Chapter 8 GMP
- Component Recall Chapter 8 GMP
- **Receipt & storage of components**
Chapter 5 GMP
Chapter 4 GMP
- Traceability Chapter 8 GMP
- Adverse reactions & events Chapter 8 GMP

Quality Management System for BSQR

- Quality manual incorporating specifications agreed with MHRA Chapter 1 - GMP
- Access to Quality Manager with designated responsibility Chapter 1 - GMP
- Staff are provided with timely, relevant and regularly updated training Chapter 2 - GMP
- Document control system Chapter 4 - GMP
- Traceability requirements are met Chapter 4 - GMP
- Regular performance reviews of QMS Chapter 1 - GMP

Quality Management System for BSQR

- **SOPs for the storage, distribution & transport of blood/blood components within & outside hospital**
Chapter 5 - GMP
- **SOPs covering temperature controlled storage, its monitoring and management of the “cold chain”**
Chapter 5 - GMP
- **Standard procedures for the validation & calibration of processes & equipment**
Chapter 5 - GMP
- SOPs for the notification of serious adverse events & reactions
Chapter 5 - GMP
- SOPs that allow the accurate, efficient & verifiable withdrawal of blood/blood components if notified of a quality issue
Chapter 5 - GMP

3.Premises and Equipment - GMP

- There should be defined storage areas for quarantine, released, rejected and recalled materials.
- Where specific storage conditions are required these should be provided, checked and monitored for compliance.
- Storage areas should be secure, restricted to authorised person access.

WORKSHOPS

Yellow Team

Purchasing and installing a new fridge/freezer

Blue Team

Routine management of fridge/freezer

Red Team

Management of unit between lab and patient

Green Team

Management of satellite banks