Regulation in Transfusion

"Become a blood boffin"

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Regulatory and Governance Bodies

- Medicines and Healthcare Regulatory Authority (MHRA)
- Serious Hazards of Transfusion (SHOT)
- British Committee for Standards in Haematology (BCSH)
- Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO)

Why?

- Patient safety

  - Blood Banks store, process and distribute products for clinical treatment which are highly specialised, fragile and dangerous (if processed/ handled/ used incorrectly)

MHRA

- Government organisation which oversees Pharmaceutical production, medical devices and blood.
- Competent body
- Ensures compliance to Blood Safety and Quality Regulations 2005 No 50 (Directive 2002/98/EC – setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components)

Who does it cover?

- “Blood Establishments”
- NHSBT (NBS) – Collection, Storage,Production, Testing, Distribution
- Hospitals - Processing (crossmatching), Storage, Distribution

BSQR

- Traceability of blood from donor to recipient
  - Audit trail
  - Fate
  - Cold chain transport/storage
  - recall

- EudraLex – Volume 4 good manufacturing practice
  - Quality management system
  - Personnel
  - Premises and equipment
  - Documentation
  - Production
  - Quality control
  - Complaints and product recall
  - Self Inspection (internal audit)
- Orange Book – Rules and Guidance for Pharmaceutical Manufacturers and Distributers

Compliance

- Yearly submission of compliance report required by every “Blood Establishment” in UK.
- Signed by CEO as responsible person
- Falsification or knowingly providing inaccurate information – criminal offence
- Decision to inspect based on report
- “control sites”

Inspection

- Power to enforce “cease and desist” order
- Required to submit corrective actions to non conformances within specified time
- Depending on severity may be subjected to repeat inspections

SABRE/SHOT

- Serious Adverse Blood Reactions or Event
  - Website entry of incidents
  - Split into:
    - Serious Adverse Reactions SAR (to transfusions)
    - Serious Adverse Events (SAE) (any thing else that goes wrong)
  - SAR may also be reported to SHOT

Purpose

- Risk reduction
- Collation of data
  - Trends
  - Basis for guidelines and recommendations
  - Ensure root cause is properly identified
  - Ensure corrective action is effective