

Regulation in Transfusion

“Become a blood boffin”

12/06/13

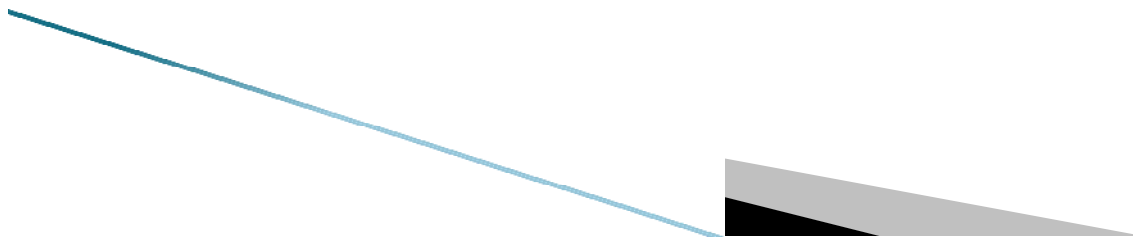
Steve Tucker

Colchester University Hospitals



Regulatory and Governance Bodies

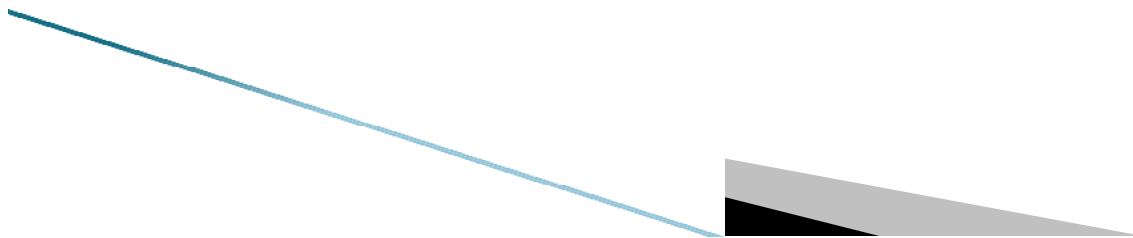
- ▶ Medicines and Healthcare Regulatory Authority (MHRA)
- ▶ Serious Hazards of Transfusion (SHOT)
- ▶ British Committee for Standards in Haematology (BCSH)
- ▶ Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO)



Why?

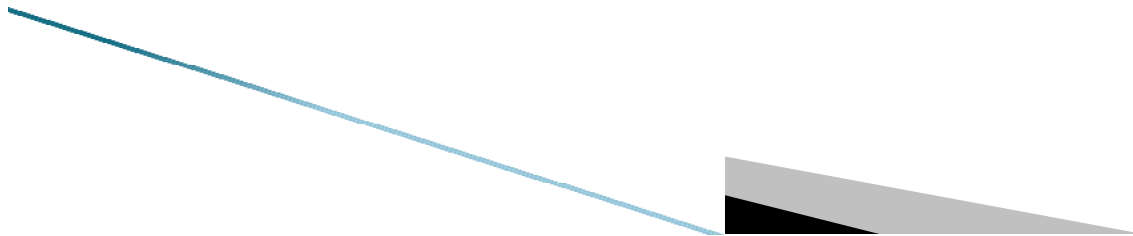
▶ Patient safety

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



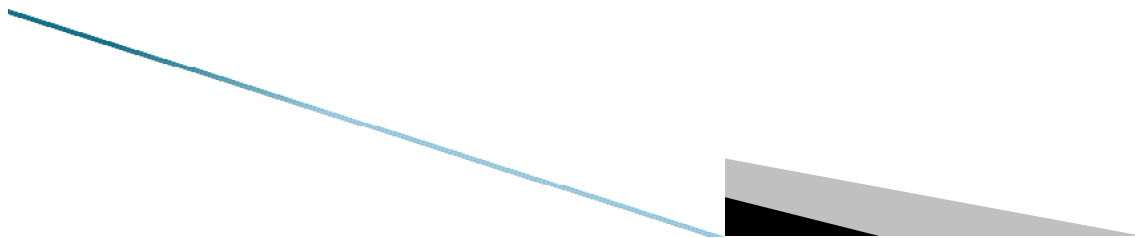
MHRA

- ▶ 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

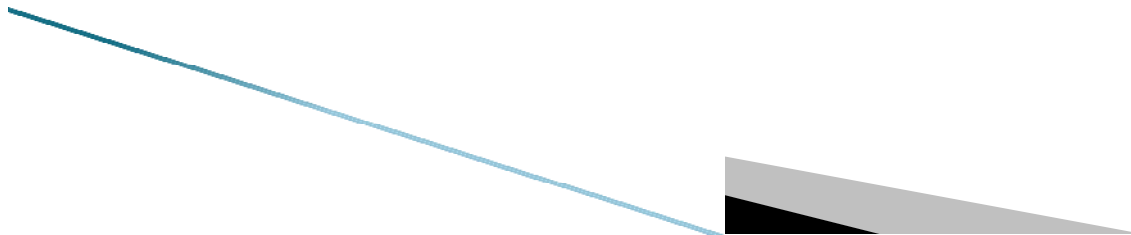


BSQR

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

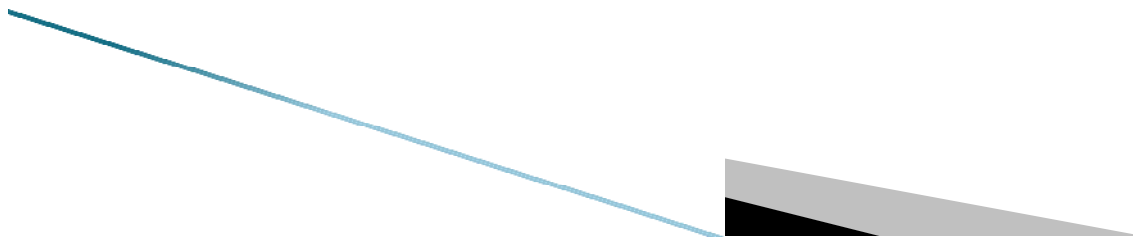
- ▶ EudraLex – Volume 4 good manufacturing practice
 - Quality management system
 - Personnel
 - Premises and equipment
 - Documentation
 - Production
 - Quality control
 - Complaints and product recall
 - Self Inspection (internal audit)

- ▶ Orange Book – Rules and Guidance for Pharmaceutical Manufacturers and Distributors



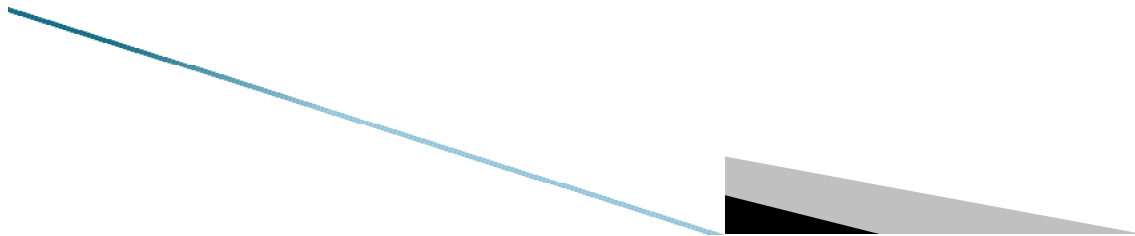
Compliance

- ▶ 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”



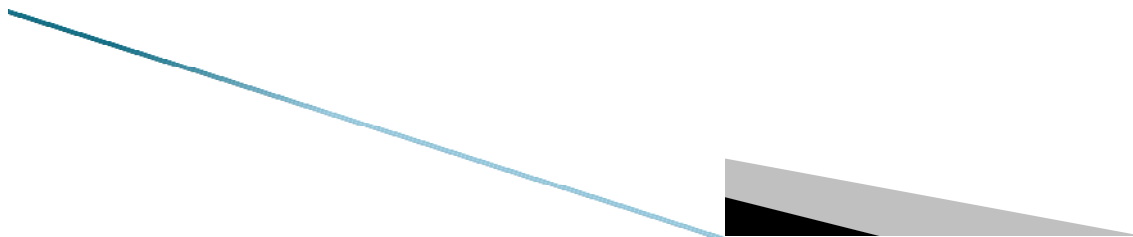
Inspection

- ▶ 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

