

# The MHRA Experience

The view from the gallows!

WASPS USER DAY

13<sup>th</sup> June 2006

# MHRA

- Medicines & Healthcare products Regulatory Agency
- An executive agency of the DoH
- Designated by Secretary of state as interim Competent Authority for the safety and quality of blood and blood components.
- The Blood Safety and Quality Regulations
  - EUD 2005/61 & 62, SI 2005 No 50, February 2005 & 8 November 2005.

# MHRA requirements

- Regulatory oversight.
  - Performing compatibility testing, storing and distributing blood and blood components
- Submitted a compliance report (Dec 2005)
- To show self assessment of compliance with the regulations
- Over 400 compliance reports assessed.

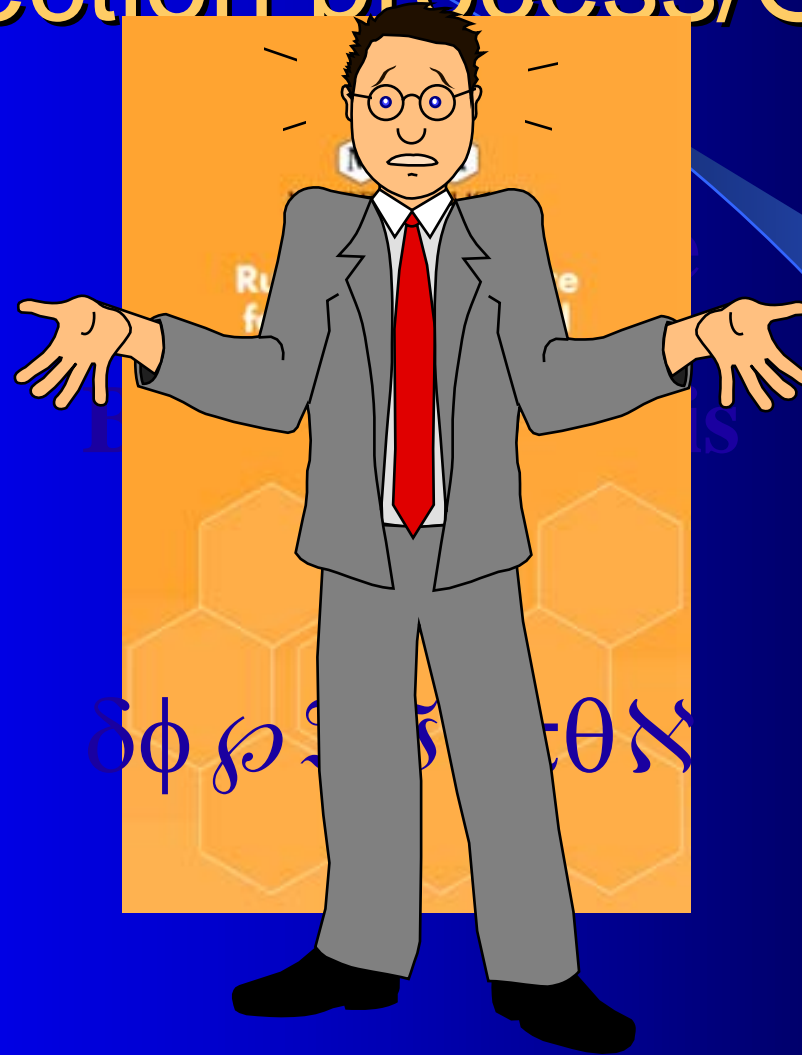
# MHRA Inspections

- 67 establishments designated for inspection
- 3 hospitals chosen for initial inspections
  - 1 each in Northern Ireland, England & Wales
- Wrexham Maelor 3<sup>rd</sup> on the list
- 2 weeks notice

# Reasons for inspection

- “Expired” CPA accreditation
- SABRE incident
  - Private Hospital
  - Blood storage / fridge failure

# Inspection process/GMP



# Inspection process

- To GMP standards
  - “The Orange book”
  - EU GMP Guide
- Quality system
- Pre transfusion testing
- Warehousing & storage
- Secondary processing
- Release of components
- Distribution of components
- Transport
- Facilities
- IT

# QUALITY SYSTEMS

- SOP's
- SABRE reporting - SOP required
- Self inspection process/Audit
  - Detail required
  - Ownership
  - Risk register?
- Service level agreements - Essential
- “Complaints” - incident reporting - SOP
- Record retention

# Document & Change control

- Document Control and Change Control
- Change control (Internal & External)
  - Computer “tweaks”
  - System changes
  - Upgrades
- Master copies - control & printing
- Staff notification
- Training records / distribution
- Independent review of SOPs is required

# QUALITY SYSTEMS

- Traceability system/Lookbacks
  - Not main focal point!
- Equipment
  - Maintenance
  - Calibration
  - Validation
- Process records
- Staff training

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# Staff Training

- GMP training required
- Training records (& Competency Assessment)
  - Porters
  - Lab staff
  - Out of hours
  - Nurses
- Complete record
  - Tasks and SOP numbers
  - Method of assessment

Blood bank register

# QUALITY SYSTEMS

- Quality Incident Reports
  - Process Deviations
- Recall procedures
  - External & *Internal*
- Records and investigations
  - Storage systems, length of time

# PRE-TRANSFUSION TESTING

- Sample acceptance
  - Barcodes
- Batch acceptance
  - Does it do what it says on the tin.
  - CE marking, IVDD



## Compatibility testing

Electronic or Manual

## ABO Rh and Screen

Test methodology

## Validation of test methods used

# PRE-TRANSFUSION TESTING

- Results Transfer/Recording for component release
  - Interface validation
- Back –up systems
  - In the event of routine system failure
  - Essential power supply
- Equipment
  - Maintenance,
  - Calibration
- External QC Accreditation schemes
  - NEQUAS, WASPS

# WAREHOUSING & STORAGE

- Inventory control systems!
- Temperature monitoring
  - Focus of attention!
  - **Blood boxes**
  - **Portable blood banks**
- Control of critical supplies
  - Cool packs!

# SECONDARY PROCESSING OF COMPONENTS

- Critical process controls
  - Temperature monitoring
- Equipment used
  - Maintenance records
- Inspection of components
  - In specific SOP's or separate
- Release process controls
  - Criteria
  - Still frozen - concessionary release
- Production of labels

# LABELLING & RELEASE

- Inspection of Components
- Concessionary / exceptional release!
  - Uncross-matched issue\*
  - Emergency O Negatives
  - Incompatible units
  - Partially defrosted products
- Process controls
- Line clearance
- Back-up system in the event of routine system failure

# DISTRIBUTION & TRANSPORT

- Where to & how?
- Delivery processes
  - Blood boxes
  - Portable blood banks
- Order receipt
  - Request forms
  - Telephone records
- Stock controls
- Storage of Components

# FACILITIES & IT

- Temperature & monitoring
- Backup power supplies
- Preventative maintenance
- Security
- Data archives/storage
- Change control (& validation)
  - LIMS
  - Analyser

# Closing meeting

- Formal feedback on inspection findings
  - critical/ major/ other
- Positives and negatives
- Explain next steps – report

# Non compliances

- Critical finding
  - patient safety implications or regulatory offence or casts doubt on validity of data
- Major finding
  - non-compliance with regulations that could have impact or a combination of “other” non compliances
- Other
  - minor non-compliance. Lots of minor non-compliance may add up to a major non-compliance

# Our report

- No Criticals
- One Major
- Two Others

# Major

- Training
  - GMP training not yet performed
  - Porters training records not available for review
  - Procedure for notifying personnel of requirements to be trained against a new SOP not detailed in an SOP.
  - Training record reviewed did not record SOPs numbers against which she had been trained
  - Method of assessment not recorded

# Major

- Control of SOPs
  - Master copies with lists of locations to which copies had been issued were not always evident.
  - Copies of SOPs did not always print with the footer instruction to destroy unauthorised copies
  - At time of inspection no record of review on “uncross-matched issue” SOP
  - SOPs not always independantly reviewed

# Major

- Self inspection process
  - There was not a fully defined schedule for self inspection.
  - The self inspection procedure lacked sufficient detail for the performance recording and follow up of self inspections.

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# Other

- Maintenance & calibration of temperature monitoring system
  - At the time of inspection, there was no evidence that calibration of complete system was performed
  - There was no evidence that “as found calibration” was performed and reported to BBM
  - An appropriate representative did not review the calibration and maintenance reports for the NEXT system
  - SOP for Computerised temperature monitoring not followed (record of corrective action).

# Comments

- A number of procedures were noted as being in draft form at the time of the inspection
- It was noted that Quality Control Data (Certificate of Analysis) was not available for reagents and controls used for the Ortho Autovue Innova. This data must be available for each lot number used.

# Respond to report

- Itemised response
- Within 28 days
- Action plan
- Supplementary evidence



Thank you