Blood Bank Inspections

Common Deficiencies

Stephen Grayson
March to October 2012

• Insufficient sites inspected since the March BCC meeting to give a meaningful picture.

• Thus is in part due to the inspection cycle which starts after BCR review in August and finishes in March.

• Presentation will thus focus on the inspectors’ key areas of concern
Key Concerns

Computerised Documentation Control

- A misconception that the computerised system “is the system” rather than the tool.

- Sites either being unfamiliar with the system in place or incorporating inadequate controls within the system to facilitate compliance.
Key Concerns

Computerised system controls

- Unidirectional interfaces where two or more automated systems are present and part used cards are reused and are thus unknown by the alternate analysers

- Control of the LIMS database with respect to duplicate patient records. Lack of robust management through merging or linking records
Key Concerns

- Deviations - investigation and remediation
  - Still weak on a number of sites with inadequate root cause analysis, evidence and robustness of actions.
  - Use of hospital risk management systems which tend to focus on actual harm with little consideration for the potential for harm
Key Concerns

- Complaints & Recall
  - Various weaknesses in the overall management of these events

- Process Validation
  - Ensuring that processes are initially validated and then revalidated at defined frequencies, not just in reaction to change

- Change Control
  - Often absent or not robust
  - Tend to focus on approval of changes rather than the management of change from inception to introduction and beyond.
Key Concerns

• Maintenance of equipment
  - Ensuring that equipment is maintained in a compliant state.
  - Inadequate review prior to bringing back into use after planned and reactive maintenance
  - Missed preventative maintenance and calibrations not adequately addressed
Key Concerns

• Laboratory
  • Adhesive on labels attached to frozen samples not designed for this use resulting in label detachment

• Samples run in the same session as QC being accepted when the QC fails
Thank You

Questions?
Crown copyright 2012

The materials featured within this MHRA presentation are subject to Crown copyright protection for this event. Any other copy or use of Crown copyright materials featured in this presentation, in any form or medium, is subject to prior approval of the MHRA which has Delegated Authority from Her Majesty's Stationery Office (HMSO) to administer Crown copyright for MHRA originated material. Applications should be in writing, clearly stating the proposed use/reuse of the information, and should be sent to the MHRA at the following address: Conference and Education Function, 16th Floor, MHRA, 1 Nine Elms Lane, London SW8 5NQ. Fax 020 7084 3522 or e-mail speakers@mhra.gsi.gov.uk. You may not sell or resell any information reproduced to any third party without prior agreement. The permission to reproduce Crown copyright protected material does not extend to any material in this pack which is subject to a separate licence or is the copyright of a third party. Authorisation to reproduce such material must be obtained from the copyright holders concerned.