Blood Bank Inspections
Common Deficiencies

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October 2011
March to October 2011

• 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’ perception of where sites were failing in the data presented in March.

• Please note that the data presented relates to Major and Critical deficiencies only.

• A single Major or Critical deficiency may have several sub points and thus may contribute to more than one citation within the MHRA’s deficiency database.
Hospital Blood Banks

HBB Top 10 Deficiencies

- Computerised systems – documentation and control
- Self inspection
- Equipment validation
- Complaints and Product recall
- Personnel issues – training
- Quality management
- CAPA
- Documentation - Procedures & Worksheets
- Change Control
- Investigation of anomalies

% of Total Citations

Apr09 to Mar10
Apr10 to Mar11

Stephen Grayson
Slide 3
6th October 2011
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Hospital Blood Bank Commentary

• Data from 38 inspections completed

• New categories in the top 10

• Self Inspection
  • This is typically a lack of adequate resource to establish an effective and ongoing commitment to performing self inspections.

• Computerised Documentation Control
  • In this area there is a misconception on some sites that the computerised system “is the system” rather than the tool.
  • There were also issues of sites either being unfamiliar with the system in place or incorporating inadequate controls within the system to facilitate compliance.
Blood Establishments

UK BEA Top 10 Deficiencies

- Documentation - procedures/PSF/TAs
- Contamination, microbial – potential for
- Complaints and Product recall
- Calibration of measuring and test equipment
- Quality management – change control
- Process validation
- Investigation of anomalies
- Documentation – manufacturing
- Design and maintenance of equipment
- Quality management

Apr09 to Mar10
Apr10 to Mar11
UK BEA Commentary

- Data from 10 inspections completed
- New categories in the top 10
  - Complaints & Recall
    - This relates to 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
UK BEA Commentary - continued

• Maintenance of equipment
  - Ensuring that equipment is maintained in a compliant state.
  - Signed back into use after planned and reactive maintenance
  - Missed preventative maintenance and calibrations not adequately addressed

• Quality Management
  - Generally a number of concerns regarding the overall quality management system. No common theme with respect to specific failure topics
Overseas Plasma

Overseas Plasma Top 10 Deficiencies

- Donor eligibility assessment
- Failure to respond to previous inspection findings
- Supplier and contractor technical agreements
- Design and maintenance of equipment
- Calibration of measuring and test equipment
- Investigation of anomalies – CAPA
- Investigation of anomalies
- Documentation - procedures/PSF/TAs
- Quality management
- Quality management – change control

Apr09 to Mar10
Apr10 to Mar11
Overseas Plasma Commentary

• Data from 17 inspections completed
• This is principally Plasma for Fractionation, not Transfusion and is likely to be Plasma for Fractionation only in the future

New categories in the top 10:
• Quality Management
  - Generally a number of concerns regarding the overall quality management system. No common theme with respect to specific failure topics

• Documentation – Procedures, TA’s and Supplier and contractor technical agreements
  - Either an absence of the required documents or a failure to keep such documents up to date.
Overseas Plasma Commentary - continued

• Investigation of anomalies & CAPA
  - Lack of robustness in investigations and CAPA
  - Lack of suitable effectiveness checks

• Failure to respond to previous inspection findings
  - Previous commitments not complied with (action or timeframe).

• Donor eligibility assessment
  - Failures in the assessment of donor eligibility such as key questions not asked, or donors advising that they had read and understood documents, salient details of which they could not recollect when questioned
Thank You

Questions ?
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