Blood Bank Inspections

Common Deficiencies

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2009/10 Inspection Summary

- 72 sites were selected for inspection during 2009/10
- 9 further sites were selected as controls
- Deficiency data is now being collated by inspectors for Critical and Major deficiencies raised. This data informs which types of deficiencies are most prevalent in any given period and forms the basis of this summary.
- A Note of Caution - This presentation does not include MHRA expectations however these will be discussed as necessary.
Deficiency Database

- Database set up originally for EU GMP inspections
- Specific blood related categories added to database in 2009
- This is the first year blood data has been collected in this manner
- The following graphs are based on the top 10 deficiencies by percentage of those raised in Critical and Major deficiencies.
Hospital Blood Banks

Hospital Blood Banks - Inspections April 2009 to March 2010

Top Ten - % of deficiency citations (within Critical & Major deficiencies only)

- Investigation of anomalies: 14.0%
- Change Control: 8.0%
- SABRE reporting: 6.0%
- Quality Management: 4.0%
- Equipment Validation: 4.0%
- Complaints and Product Recall: 4.0%
- CAPA: 2.0%
- Traceability: 0.0%
- Documentation: 0.0%
- Training: 0.0%
Blood Establishments

Blood Establishments - Inspections April 2009 to March 2010

- Documentation – manufacturing
- Contamination, microbial – potential for
- Computerised systems – validation
- Computerised systems – documentation and control
- Calibration of measuring and test equipment
- CAPA
- Change Control
- Failure to respond to previous inspection findings
- Documentation – procedures/PSF/TAs
- Investigation of anomalies

Top 10 - % of deficiency citations (within Critical & Major deficiencies only)
Overseas Plasma - Inspections April 2009 to March 2010

- Documentation – manufacturing
- Design and maintenance of equipment
- Computerised systems – validation
- Calibration of measuring and test equipment
- Validation master plan and documentation
- Process validation
- Design and maintenance of premises
- Contamination, microbial – potential for
- Equipment Validation
- Change Control

Top 10 - % of deficiency citations (within Critical and Major deficiencies only)
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