GLP Deficiency Data
2017 / 2018 Inspection Year Analysis
(01 Apr 2017 – 31 March 2018)
Breakdown of GLP findings in 2017/18

16 critical findings were raised in the 2017/18 inspection year, broken down as follows:

- 1 was raised under the heading of 'Computerised Systems'
- 1 was raised under the heading of 'Organisation & Personnel'
- 5 were raised under the heading of 'Quality Assurance'
- 9 were raised under the heading of 'Study Conduct'
65 Inspection Majors in 2017/18

- Archives: 2
- Computerised systems: 3
- Facilities: 1
- Organisation & Personnel: 6
- Quality Assurance: 14
- SOP’s: 0
- Study Conduct: 39
Note: there were no major findings attributed to categories: SOPs
Breakdown of 39 Study Conduct Majors in 2017/18

- (Study Management & Conduct) Other
- Multi-site aspects
- Deviations
- Amendments
- SD / PI not discharging duties
- Study plan
- Unable to reconstruct study activities / insufficient details recorded
- Errors, discrepancies in study data
- QA statement
- Compliance statement
- Errors, omissions or discrepancies in the report
- Issues with method validation performance or documentation
- (Data Integrity Controls) Other
- Inappropriate access rights / No user permissions
- incomplete review of data (i.e. not looking at audit trails)
- Printouts insufficient to classify as raw data
- (Data Integrity) Other
- Missing data
- Acquired data not secure
Breakdown of 14 Quality Assurance Majors in 2017/18

- Risk based QA issues / Management of QA programme
- Process based audit programme
- Study based / critical phase audit programme
- Failure to comply with own procedures
- Delay / failure to undertake corrective & preventative actions
- Issues related to the inspection of QA
- Quality Assurance (Other)
Breakdown of 12 additional Majors in 2017/18

- Training (GXP)
- Training (specific)
- (Organisation, Personnel, Delegation & Responsibilities) Other
- Conflict of Interest
- Equipment related - calibration
- Inadequate or no validation
- Delays in Archiving

Bar chart showing the breakdown with Inadequate or no validation being the most common issue.
469 Inspection Deficiencies in 2017/18
% Breakdown of GLP Deficiency Findings in 2017/18

- Study Conduct: 41%
- Archives: 9%
- Computerised systems: 3%
- Facilities: 10%
- Organisation & Personnel: 13%
- Quality Assurance: 12%
- SOP's: 12%

Total: 469 Deficiencies
2017/18 Archiving Deficiencies

- Total: 42 Deficiencies
- Procedures for archiving
- Procedures for loans including extensive loan periods
- Delays in archiving
- Facilities
- Unable to locate archived records
- Electronic archiving
- Archiving (other)
2017/18 Computerised Systems Deficiencies

Total: 15 Deficiencies
# 2017/18 Facilities Deficiencies

Total: 47 Deficiencies

<table>
<thead>
<tr>
<th>Category</th>
<th>Deficiencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilities (other)</td>
<td>5</td>
</tr>
<tr>
<td>Labelling / identification of samples / reagents / expired reagents etc</td>
<td>1</td>
</tr>
<tr>
<td>Doc control/storage - methods, validation or calibration docs</td>
<td>1</td>
</tr>
<tr>
<td>Equipment related – fridge / freezer storage and monitoring</td>
<td>11</td>
</tr>
<tr>
<td>Equipment related – other</td>
<td>7</td>
</tr>
<tr>
<td>Equipment related – maintenance</td>
<td>3</td>
</tr>
<tr>
<td>Equipment related – calibration</td>
<td>7</td>
</tr>
<tr>
<td>General housekeeping</td>
<td>3</td>
</tr>
</tbody>
</table>
2017/18 Organisation & Personnel Deficiencies

Total: 63 Deficiencies
2017/18 Quality Assurance Deficiencies

Total: 54 Deficiencies
2017/18 SOP Deficiencies

- SOPs (other)
- Overdue SOP reviews
- SOP content
- SOP review
- SOP administration and control

Total: 55 Deficiencies
2017/18 Study Conduct Deficiencies

- Lack of SLA / contract
- Contracts & Agreements (other)
- Time stamp not secure
- Data Integrity (other)
- Incomplete review of data (i.e. not looking at audit trails)
- Use of shared passwords / logins
- SD / PI not discharging duties
- Source / Raw Data (other)
- Unable to attribute data to an individual
- Problems with supporting records
- Reporting (other)
- QA statement
- Errors, omissions or discrepancies in the report
- Failure to assess validation status of method
- Data Integrity Controls (other)
- Use of shared passwords / logins
- Incomplete review of data (i.e. not looking at audit trails)
- Data Integrity (other)
- Time stamp not secure
- Contracts & Agreements (other)
- Lack of SLA / contract

Total: 193 Deficiencies
Trend analysis

Inspection Year 2014/15 to Inspection Year 2017/18
Number of GLP Inspections 2014/15 – 2017/18
Trend Analysis of Major Deficiencies 2014/15 - 2017/18
Trend Analysis of Deficiencies 2014/15 - 2017/18

Number Raised

- Archives
- Computerised Systems
- Facilities
- Organisation & Personnel
- Quality Assurance
- SOPs
- Study Conduct

2014/15 2015/16 2016/17
Trend Analysis of All Deficiencies 2014/15 - 2017/18

The graph shows the number of deficiencies over the years 2014/15 to 2017/18. The deficiencies are categorized into Major, Critical, Deficiency, and Total. The trend indicates a decrease in the number of deficiencies from 2015/16 to 2017/18.
Trend Analysis of Major and Critical Deficiencies 2014/15 – 2017/18
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