MHRA Desktop Inspections

Ewan Norton - Lead Senior GMDP Inspector
Presentation Outline

- How it started….
  - What we decided to do…
    - What went well…
      - What we learned…
    - What now and where next…
How it started…

OBI

Process
How it started…
How it started…

- Potential challenges with desktop inspections:
Presentation Outline

• How it started…

• What we decided to do…

• What went well…

• What we learned…

• What now and where next…
Pre-Inspection Letter
**Pre – Inspection Requests**

**IMPORTERS**

Cut and paste the first table below into the Pre-Inspection Letter (which can be found in this folder - [LINK](#))

<table>
<thead>
<tr>
<th>Request</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Site Master File</td>
<td></td>
</tr>
<tr>
<td>2. Completed pre-inspection compliance report (see link in letter).</td>
<td></td>
</tr>
<tr>
<td>a. list of batches certified in the last</td>
<td>Excel or Word</td>
</tr>
<tr>
<td>4. PQR procedure</td>
<td></td>
</tr>
<tr>
<td>a. List of Product Quality Reviews showing target date and completion date since last inspection and copies of relevant PQR’s available.</td>
<td>Excel or Word</td>
</tr>
<tr>
<td>5. Deviation procedure</td>
<td></td>
</tr>
<tr>
<td>a. List of deviations since the last inspection - formatted to show classification, root cause, date opened, planned closure date and actual date closed.</td>
<td>List in Excel</td>
</tr>
<tr>
<td>6. CAPA procedure (if separate from the deviation procedure)</td>
<td></td>
</tr>
<tr>
<td>a. list of CAPA since the last inspection at your site formatted to show date opened, planned closure date and actual date closed</td>
<td>List in Excel</td>
</tr>
<tr>
<td>7. Change control procedure</td>
<td></td>
</tr>
<tr>
<td>a. List of change controls since the last inspection formatted to show classification, date opened, planned closure date and actual date closed.</td>
<td>List in Excel</td>
</tr>
<tr>
<td>8. OOS procedure</td>
<td></td>
</tr>
<tr>
<td>a. List of all OOS investigations (not just confirmed OOS) since last inspection formatted to show investigation conclusion, root cause, date opened and actual date closed.</td>
<td>List in Excel</td>
</tr>
<tr>
<td>9. Procedure identifying process for assessing EU importation testing results against manufacturer C of A</td>
<td></td>
</tr>
<tr>
<td>10. List of batches rejected since last inspection.</td>
<td>Excel or Word</td>
</tr>
<tr>
<td>11. Complaints procedure and list of complaints since last inspection - formatted to show classification, root cause, date opened and date closed.</td>
<td>List in Excel</td>
</tr>
<tr>
<td>12. Recall procedure and list of any recalls since the last inspection.</td>
<td>Excel or Word</td>
</tr>
<tr>
<td>13. Quality agreements procedure</td>
<td></td>
</tr>
<tr>
<td>a. List of agreements held identifying review dates.</td>
<td>List in Excel</td>
</tr>
<tr>
<td>14. List of procedures including version number, effective dates and review dates.</td>
<td>Excel or Word</td>
</tr>
<tr>
<td>15. Update on commitments since last inspection identifying dates communicated to previous inspector for completion and actual completion dates</td>
<td></td>
</tr>
<tr>
<td>16. Supplier Qualification procedure</td>
<td></td>
</tr>
<tr>
<td>a. Approved supplier list</td>
<td></td>
</tr>
<tr>
<td>b. List of supplier audits planned for last year and this year showing the status of the audits and whether they were physical or paper-based audits.</td>
<td></td>
</tr>
<tr>
<td>c. Supplier complaint procedure</td>
<td></td>
</tr>
<tr>
<td>d. List of open supplier complaints</td>
<td></td>
</tr>
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</table>
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16. Supplier Qualification procedure
   a. Approved supplier list
   b. List of supplier audits planned for last year and this year showing the status of the audits and whether they were physical or paper-based audits.
   c. Supplier complaint procedure
   d. List of supplier complaints (if not incorporated in deviation process)

17. Customer approval procedure, including Bona Fide confirmation process

18. Training procedure.

19. Self inspection procedure

20. Self inspection schedule for this year and last year showing dates each carried out

21. Management review procedure

22. TSE procedure

23. Procedure that identifies approach to Excipient risk assessments

24. Procedure that identifies approach to Elemental Impurities (ICH Q3D)

25. Sampling procedure identifying where samples are taken i.e. at site or upon importation

26. Artwork control procedure

27. A number of photographs of key areas from different angles (please identify the areas in the file title, or on the pictures themselves)
   a. Warehouse areas (if applicable)
   b. QC areas (if applicable)
   c. Stability Storage areas (if applicable)
   d. Retention sample storage area

28. Governing (top level) procedure for distribution and shipments

29. Indication of current staffing levels
Pre-Inspection Letter
DWP Certificate
This certificate is issued based on a remote inspection of DWP compliance during COVID-19 travel restrictions. A risk-based site inspection programme remains in place.
Pre-Inspection Letter
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What went well…
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What we learned…
**Presentation Outline**

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  - What now and where next…
What now and where next… (I)
What now and where next… (II)
Thank you for listening.