INSPECTION METHODS
INSPECTION: METHODS

- TRACE FORWARD
- TRACE BACK
- PRODUCT SPECIFIC
- DEVIATION / COMPLAINT-BASED
- PRODUCT LICENCE (Market Authorisation)
- DOCUMENT TRAIL
- THE CHECKLIST AUDIT
- RANDOM
TRACE FORWARD AUDIT

WAREHOUSE ➔ DISPENSARY ➔ PRODUCTION ➔ QUALITY CONTROL ➔ FINISHED GOODS

- vendors
- calibration
- documentation
- validation
- sampling
- utilities
- GCLP

+ • favoured method
  • easy to plan
  • logical
  • easy for auditee

- • becomes routine
  • miss the unexpected
The Trace Forward logic applied to a single unit operation

- Materials
- Documentation
- Personnel

- SOP xxx
- Cleaning dispensary

- Completed logbook
TRACE BACK AUDIT

• Essentially the reverse of trace forward

  +

  • Easy to plan
  • Logical
  • Can be used to vary approach

  -

  • No major disadvantages
PRODUCT-SPECIFIC AUDIT

+ • highly specific  
  • logical  
  • detailed

- • time consuming  
  • not everything noted  
  • confined to specific  
  • product
COMPLAINT / DEVIATION-BASED AUDIT

- PARTICLES
- PACKAGING PROBLEMS
- MISSING TABLETS
- MISSING LABEL
- LEAKING CONTAINERS

+ Learn from mistakes
+ Allows improvement

- Specific
- Considers small part of operation
- No value as compliance audit
COMPLAINT AUDIT

• Can be extended to **internal** as well as **external** complaints, e.g.
  – Deviations/failure investigations
  – OOS investigations
  – CAPA programme

HIGH CALORIE DIET FOR AUDITORS!
MARKET AUTHORISATION No. 544321

+ • Compliance • Clear requirements • Easy to perform

- • No real disadvantages

RAW MATERIALS
PRODUCTION METHOD
EQUIPMENT

IN PROCESS TESTS
END TESTS
DOCUMENTATION
CONTRACT BASED AUDIT

• Can be used for external audits, e.g.
  – Supply level agreements with suppliers
  – Service level agreements with contractors
  – Quality agreements
  – contracts

Any officially / legally binding document provides starting point for audit
THE CHECKLIST AUDIT

• CRITERIA CHECKLIST (e.g. EU GMPs, CFRs etc.)
• DEPARTMENTAL CHECKLIST
• COMPANY-SPECIFIC

+  
• Easy to use 
• Avoids missing issues 
• Good for inexperienced auditors 
• Easier for auditee 
• Allows quantification; GMP rating system

-  
• Restrictive for experienced auditors 
• Reduces complex issues to YES or NO 
• Reflects preconceived ideas 
• Focus of audit is more on checklist, rather than operators 
• Allows quantification; GMP rating system
DOCUMENTATION AUDIT

**ALL BATCH - SPECIFIC**

**+**
- Good insight into QS
- Easy to perform
- Specific

**-**
- Difficult for auditee
- No plant tour
- Focuses on human error
TYPICAL AUDIT STRUCTURE

ORGANISATION

SYSTEM 1

TRACE FORWARD

DOCUMENTS FOR SPECIFIC ISSUES

SYSTEM 2

COMPLIANCE

SYSTEM 3

COMPLAINTS

DOCUMENTS FOR SPECIFIC ISSUES
<table>
<thead>
<tr>
<th>Announced</th>
<th>Unannounced</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Right people present</td>
<td>• Possible key people absent</td>
</tr>
<tr>
<td>• Allows auditee to plan</td>
<td>• No time for planning</td>
</tr>
<tr>
<td>• Allows “clean up”</td>
<td>• “As is” situation</td>
</tr>
<tr>
<td>• Shows trust</td>
<td>• Demonstrates suspicion</td>
</tr>
<tr>
<td>• Length can be set in advance</td>
<td>• Unpredictable</td>
</tr>
<tr>
<td>• Cooperative</td>
<td>• Adversarial</td>
</tr>
</tbody>
</table>
INSPECTION DEPTH

Audit Depth

ABSENCE
- Fast
- Easy
- Indisputable

ADHERENCE
- Slower
- Compliance check

ADEQUACY
- Complex
- Slow
- Expertise required
- Much discussion/opinion

Audit Progress
REMARKS

• Any inspector does have its own interest (background) and strong/weak points

• Any inspector/inspection might use one of the approaches discussed and “skip” as a result other approaches.

• You may not consider a situation being “approved by an inspector”, if she/he has made no comments.

• Neither: while one inspector may have no comments, another might give you a critical/major/minor observation/483
THANK YOU FOR YOUR ATTENTION