GMP Training Course
Inspections from an industry perspective

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Objective

- To provide an insight into how arranged inspections are prepared and managed.
- To share my industry experience of inspections.
- To discuss potential areas of conflict.
Preparation

• A positive inspection outcome is crucial to the reputation of the company as an ethical manufacturer
• Planning prevents poor performance

• Corporate Policy & Local Procedures
• Personnel will be trained
  • ‘How to conduct yourself in an inspection’
Preparation

- Scope & Timing
- Communication Cascade
- Inspector Intelligence
- Corporate Audit
- ‘4 Week Plan’ Initiation
  - Site / Areas within scope & other potential areas
Site Inspection Team

- Technical
- Laboratory (Analytical Microbiology)
- Global Systems / Group
- QMS BPO
- QMS BPO Complaints APR Stability
- QMS BPO Release Regulatory
- QMS BPO Deviation Validation Change Control

Business Process Owner Initial Action Plan
- Set up weekly ‘Plan Do Review’ meetings
- Check profile of the inspectors
- Establish contacts list
- Review site inspection history
- Check availability of primary / deputy contacts
- Communicate inspection dates& scope to other teams. Arrange their availability as appropriate
- Current Issue Management & Position statements
- Inspection Strategy
  - Number inspectors vs. War Room & personnel
- Launch Event
- Initiate weekly area tours
- Communication with Leadership Team
Local Inspection Team

- Typical Representation
- Local individual 4 week plans will be initiated
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<thead>
<tr>
<th>Action</th>
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<tbody>
<tr>
<td>Establish contact with site inspection team</td>
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<tr>
<td>Establish contacts list</td>
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<tr>
<td>Check availability of primary / deputy contacts</td>
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<tr>
<td>Check that contacts are trained. ‘How to be behave in an inspection’ – arrange if necessary</td>
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<tr>
<td>Generate list of key SOPs &amp; Forms</td>
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<td>Review and update SOPs, as necessary</td>
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<tr>
<td>Check any existing Position Statements vs. current situation</td>
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<td>Review any open deviations and progress or document rationale for being open</td>
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<tr>
<td>Review any audit actions &amp; any actions required before inspection?</td>
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<td>Review change control – any significant changes relevant to the inspection?</td>
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<td>APR /PQR status</td>
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<tr>
<td>Review key system personnel training records / job descriptions</td>
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<td>Review training material and update if necessary</td>
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<tr>
<td>Initiate weekly area tours</td>
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<td>Generate lists of Deviations / Change Controls</td>
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<td>Collate validation documents</td>
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### Week 3

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<tr>
<td>Review week 4 actions for completion</td>
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<tr>
<td>Review and update relevant system access</td>
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<td>Determine (and provide if necessary) whether war room needs any additional system access.</td>
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<td>Review and update expert packages</td>
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<td>Review of documentation – any updates required?</td>
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<tr>
<td>Send contacts list (with contact numbers) to the War Room</td>
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<td>Review controlled document binders (SOPs, awareness forms, reading, housekeeping of documents)</td>
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<tr>
<td>Review Key Investigations</td>
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<td>Generate list of Technical Documents and send to War Room</td>
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<td>Assess requirements for documents i.e. on site or off site from archive</td>
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<td>Start to populate war room with controlled documents and generate document inventory</td>
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**Week 2**

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<tr>
<td>Review week 3 actions for completion</td>
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<tr>
<td>Check requirement for demo PC and printers</td>
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<tr>
<td>Confirm requirements for tours, who will do them, route, etc?</td>
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<tr>
<td>Transfer Hard copies of Expert Packages to the War Room</td>
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<tr>
<td>Ensure a ‘demo’ PC is available, if required</td>
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<tr>
<td>Walk Route with QA/QP – Mock Inspection</td>
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### Week 1

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<th>Action</th>
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<tbody>
<tr>
<td>Review week 2 actions for completion</td>
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<tr>
<td>Send inspection relevant user messages</td>
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<tr>
<td>Expert Packages and SOP content familiarisation</td>
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<tr>
<td>Communicate Inspection Plan to team, if known</td>
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<tr>
<td>Walk Route with QA/QP – Mock Inspection</td>
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Expert Packages

• Presentation
• Describes the company approach
• High level overview
• Sets the scene
• Lists key procedures
• Is it an introduction, a way in or a stalling tactic?
Inspection Personnel

- Head of QA
- QP
- Senior Management – Production
- Secretary / Scribe
- Runners
- Back Room Personnel
- Key Contacts & Deputies

Can have up to 50+ personnel involved each day
Inspection Control Centre
The HUB/ The Control Room / The War Room

• Dedicated communication links
• Electronic Request System
  – (Back up paper request system & sufficient runners)
• Access to all systems
• Booking In / Out Process & Review Process
  – Status & Location of every document requested tracked throughout the inspection
  – Documents reviewed → Risks ? Where next ?
• Processes trailed and tested prior to inspection.
• Personnel dedicated to inspection, removed from routine duties
Opening Meeting

- Agenda
- Confirm Scope
- Confirm key personnel are available
- Company Introductions
- Company Presentation / Overview
- Ascertain initial documentation requests
Inspection – Week 0

• Be prepared for all aspects to be inspected:
  – Quality Management System Review
  – Facility Tours
  – Documentation Review
  – System Demonstrations
  – QC testing to be observed e.g. Sterility Test
  – Access to controlled areas
  – Personnel Interviews
Inspection – Week 0
Re-communicate Inspection Plan to team

• Communication is key!
  – Stand down / up
  – Location of Inspector
  – Daily Debriefs / Summary reports
  – Primary contacts / Deputies availability
  – Inspection Wrap Up Mtg

• Personnel available and suitably prepared to represent company
Closing Meeting

• Deficiencies should hopefully be clear and apparent
• These should have been openly discussed

• Negotiation  NO! --- Correct Misconceptions YES
Deficiencies & Post Inspection Follow Up

- Correct as many deficiencies during inspection

**Post Inspection:**

Deficiency Assessed

Response Collated & Holistically Assessed

Reviewed by senior management and endorsed

Reviewed by Corporate QA Endorsement – Global Implications?

Finalised and Approved Response

Communicated back to relevant Health Authority

Deficiency Action Plan implemented & tracked to completion
Areas of Conflict

• Controlling ?
  – Agenda, Availability Personnel

• Time Wasting ?
  – Getting on site – ‘the security video’
  – The lengthy company overview presentation
  – Over use of expert packages
  – Repeated documentation requests
Areas of Conflict

• Complexity
  – Procedures
  – Terminology/ Jargon

• Corporate QA presence
  – Not allowing site personnel to respond i.e. theory vs. actual
  – Defending corporate position

• Number of people involved
Some of the Challenges

• The number documents that can be requested
• Historical documentation – off site archives
  – Timelines for retrieval
• Access to controlled areas ?
  – Allow access or follow standard procedures
• Personality Conflicts
  QA/Inspector
Thank You for Listening

Questions ?