



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

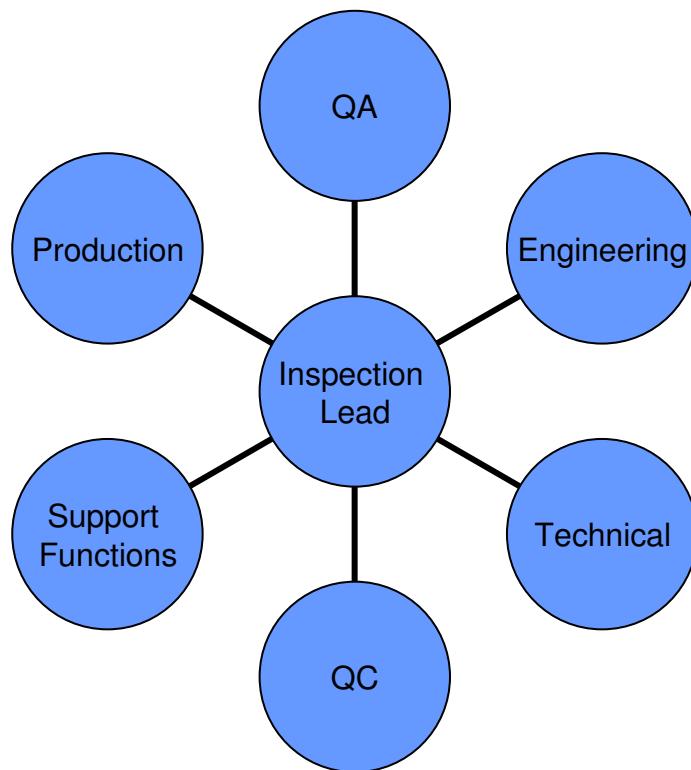
Site Inspection Team



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
<ul style="list-style-type: none"> 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



Week 4

Action
Establish contact with site inspection team
Establish contacts list
Check availability of primary / deputy contacts
Check that contacts are trained. 'How to be behave in an inspection' – arrange if necessary
Generate list of key SOPs & Forms
Review and update SOPs, as necessary
Check any existing Position Statements vs. current situation
Review any open deviations and progress or document rationale for being open
Review any audit actions & any actions required before inspection?
Review change control – any significant changes relevant to the inspection?
APR /PQR status
Review key system personnel training records / job descriptions
Review training material and update if necessary
Initiate weekly area tours
Generate lists of Deviations / Change Controls
Collate validation documents

Week 3

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



Week 2

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



Week 1

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



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

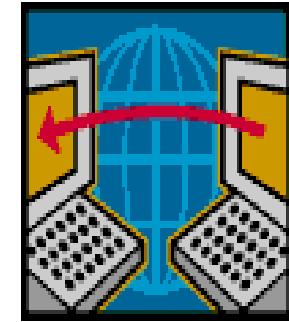
- Head of QA
- QP
- Senior Management – Production
- Secretary / Scribe
- Runners
- Back Room Personnel
- Key Contacts & Deputies

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 ?