Types of GMP Inspection

Types of GMP Inspection

Objectives

1. To review the different types of inspection
2. To examine when each is appropriate
3. To discuss inspections in your country

Types of GMP Inspection

Objective of the inspection

- Routine inspection
- Concise inspection
- Follow-up inspection
- Special inspection
- Quality systems review

Types of GMP Inspection

Routine Inspection

- Full inspection of all components of GMP
- Newly established manufacturer
- Renewal of a license
- Changes:
  - ↗ *new product or product lines*
  - ↗ *modifications to manufacturing methods*
  - ↗ *key personnel, premises or equipment*
- History of non-compliance with GMP
- Not inspected in the last 3-5 years

Types of GMP Inspection

Concise Inspection

- Consistent record of compliance with GMP
- Focus on limited number of GMP requirements
  - ↗ *selected as indicators*
- Identify significant changes
- Indicate attitude towards GMP
- Non-compliance
  - ↗ *should trigger comprehensive inspection*

Types of GMP Inspection

Follow-up Inspection

- Reassessment or re-inspection
- Monitor result of corrective actions
- 6 weeks to 6 months after initial inspection
  - *nature of defects*
  - *work undertaken*
- Specific GMP requirements
  - not observed
    - *not adequately implemented*

Types of GMP Inspection

Special Inspection

- Spot check focusing on
  - *one product, a group of related products*
  - *specific operations, e.g. mixing, labelling*
- Complaints or recalls
- Adverse drug reactions
- Marketing approval or export certificate
- Information or investigation
  - *specific information*
  - *advice on regulatory requirements*

Types of GMP Inspection

Quality Systems Review

- Assess the quality assurance (QA) system
- Description of the QA system (e.g. manual)
- Policy and standards to be observed
- Management structure
  - *implementation*
- Procedures
  - *quality standards set for products*
  - *correctly defined manufacturing processes*
  - *records kept*
  - *QC and QA functions are performed*

Types of GMP Inspection

Frequency of Inspections

- Depends on type of inspection
- Inspectorate resources (e.g. workload, number of inspectors)
- New facilities - before licensed
- All companies - regular schedule
  - *ideally annual*
- Large companies
  - *several visits over a period, e.g. 5 years*
  - *validity of manufacturing license or GMP certificate*

Types of GMP Inspection

Duration of Inspections

- Depends on type of inspection
- Inspectorate resources (e.g. workload, number of inspectors)
- Size of the company
- Purpose of the visit
- Days to weeks
- Number of inspectors
  - ↗ *including specialist support*

Types of GMP Inspection

Announced and unannounced inspections

- Depends on type of inspection
- Announced
  - *comprehensive inspection*
- Unannounced
  - *routine inspection (depending on country policy)*
  - *concise inspection*
  - *follow-up inspection*
  - *special inspection*

Types of GMP Inspection

Regulatory Actions

- Based on national regulations
- Correction of unsatisfactory situations
- Closing down of a factory
- Withholding of authorizations
- Product recall

Types of GMP Inspection

Group Session

- The inspectorate received a complaint that an injectable product (water for injection (WFI), 10ml ampoule) is possibly contaminated with microorganisms. You have to organize an inspection of the company in question
- What type of inspection would be performed?
- Will the inspection be announced or unannounced?
- Who will be part of the inspection team?
- What will you consider in preparation for the inspection?

Types of GMP Inspection

Possible Issues

- Purpose of the inspection
- Notification (or not) of the company in advance
- Make-up of the team
- Programme for the inspection
- Sterility test, leak test and visual inspection
- Validation and qualification
- Documentation review