Training Handbook							
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Auditor Training Handbook

Presented By
Maria Mylonas

Table of Contents

1. GMP – Ten Golden Rules

Summarise the Ten Golden Rules of GMP in the table below:

Rule No.	Summary
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

2. Inspector Attributes

In your small groups list the desirable and undesirable characteristics / mind-set of an inspector:

Desirable characteristics / mind-set

Undesirable characteristics / mind-set

3. Preparing for a self-inspection

You have been assigned the responsibility of conducting a periodic audit on one of your departments. The last audit was conducted 6 months ago by another member of your company.

1. Determine how you would go about preparing for the audit.
2. Determine how you would conduct the audit and record your points below.

Preparing for the audit
Conducting the audit

4. Questioning Styles

Question Style	Examples of Questions
Closed	
Open	
Probing	
Hypothetical	
Leading	
Reflective	
Paraphrase	
Clarifying	

5. Audit Plan

You have been asked to conduct an audit of one of your suppliers.

Task – Create your proposed audit plan for this audit using the worksheet provided.

Consider the following:

- Number of days needed
- Number of auditors
- Types of skills/knowledge the auditors will require
- Which areas you will focus on
- Duration in each area

6. Medicine inspection deficiencies

A **Critical Deficiency** is a deficiency when it is observed that:

- A practice or process has produced, or may result in, a significant risk of producing a product that is harmful to the user; and/or
- The manufacturer has engaged in fraud, misrepresentation or falsification of products or data.

A **Major Deficiency/Nonconformity** is a non-critical deficiency/nonconformity that:

- Has produced or may produce a product which does not comply with its marketing authorisation (in some circumstances this could be critical); and/or
- Indicates a major deviation from the Code of GMP or QMS standard; and/or
- Indicates a major deviation from the terms of the manufacturing licence, GMP approval (overseas manufacturers), or Conformity Assessment Certificate; and/or
- Indicates a failure to carry out satisfactory procedures for release of batches; and/or
- Indicates a failure of the person responsible for QA/QC to fulfil his/her duties; and/or
- Consists of several other deficiencies/non conformities, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such.

1. Review the 9 inspection findings below. Determine if each one is a critical deficiency or a major deficiency, based on the definitions above.
2. Discuss with your group and record your results below.

Inspection Finding	Deficiency (Critical or Major)
Raw materials not tested (including proper identification testing) to ensure compliance with specifications	
Cleaning program not followed and evidence of dirty premises/equipment or non-validated cleaning procedures	
Water system for sterile products not validated	
Falsification or misrepresentation of analytical results or records	
Damage (holes, cracks, peeling paint) to walls/ceilings in manufacturing areas where product is exposed	
Test methods not validated	
Stored equipment not protected from contamination	
Complex production processes for non-critical products not validated	
Evidence of gross pest infestation	

7. Audit Report Review

Review your chosen FDA Warning Letter and list the main deficiencies cited in the audit report.

Company Name	

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