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Sterile-Production Area Audit Checklist

Practical 21 - Audit case-study practical

Aim

To create and apply an evidence-based audit checklist for the specified facility or supplier.

Principle

An audit evaluates objective evidence against defined criteria and scope. A checklist supports consistent coverage but does not replace risk-based sampling, interviews and corroboration of actual practice.

Materials and Requirements

- Fictional site profile, applicable current requirements and SOPs
- Audit plan, checklist and finding templates
- Selected records and interview notes
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Define purpose, scope, products, jurisdictions, auditor roles and sampling rationale.
3. For each question specify the requirement, objective evidence and record to inspect; trace one selected batch or transaction end to end.
4. Classify each observation using the approved system and describe the evidence, requirement and gap without speculation.
5. Prepare an exit summary and proposed action follow-up with responsibility, due dates and effectiveness evidence.
6. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Audit question / criterion	Evidence sampled	Finding / risk	Action / verification
Governance / scope	Identify records	Assess	Assign
Selected process	Trace evidence	Assess	Assign
Follow-up	Review closure	Assess	Verify

Calculations

- Closure completion (%) = verified closed actions / actions due for closure x 100

Worked Example

Illustrative 8 actions are due and 6 have verified closure: completion = 75%.
The two remaining actions must be evaluated by risk; the percentage does not itself establish site compliance.

Audit scope: Sterile production

• Contamination-control strategy; facility and personnel qualification; environmental monitoring; aseptic-process simulation where applicable; sterilisation and integrity evidence; interventions and investigations.
• For each listed area record the criterion, selected evidence, actual observation, risk and follow-up.

Result and Interpretation

• Deliver a traceable checklist, factual finding statements and a risk-based follow-up plan.

Precautions

• Avoid patient or commercial identifiers in teaching records.
• Do not confuse absence of evidence with proof of conformity.
• Do not claim an audit is a regulatory certification.

Viva Questions and Answers

What makes a finding defensible?

A clear criterion, objective evidence and a described gap.

Why sample records?

A reasoned sample examines actual implementation within the audit scope.

Is an action closed when promised?

Closure requires verified implementation and, where relevant, effectiveness.

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