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Out-of-Specification Investigation

Practical 10 - Quality case-study practical

Aim

To investigate a defined pharmaceutical-quality case and prepare a defensible decision record.

Principle

A quality-system decision connects evidence, patient or product risk, cause assessment, authorised action and effectiveness. A suspected cause is a hypothesis until supported by evidence.

Materials and Requirements

- Fictional case pack, batch history and applicable SOP
- Investigation, risk and action templates
- Trend data and a documented approval pathway
- 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. Construct a factual timeline and distinguish facts from assumptions.
3. Identify affected batches, containment and immediate product-risk questions.
4. Gather relevant laboratory, equipment, personnel and manufacturing evidence and test plausible causes.
5. Propose justified actions with owners, dates and effectiveness measures; record disposition and closure through authorised roles.
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.

Finding / evidence	Risk / impact	Action / owner	Effectiveness evidence
Observed problem	Assess	Assign	Define
Cause hypothesis	Test	Assign	Verify
Product disposition	Justify	Approve	Record

Calculations

- Recurrence rate = repeated events / defined opportunities x 100
- State the observation period and denominator when comparing rates.

Worked Example

Illustrative 6 documentation omissions in 200 records give 3.0%. After an intervention, 1 in 200 gives 0.5%. Review comparable workload and surveillance before attributing improvement to the action.

Case assignment

- Assay result outside the approved specification

• Secure preparations and data, perform a timely laboratory assessment, then extend to manufacturing as warranted.
• A retest requires scientific justification; a passing retest does not erase the original result.

Result and Interpretation

• Produce a signed-role investigation summary with evidence, unresolved questions and justified closure criteria.

Precautions

• Do not invent a root cause or delete contrary evidence.
• Distinguish containment from permanent correction.
• Do not use repeated testing to obtain a passing result.

Viva Questions and Answers

What distinguishes correction from corrective action?

Correction addresses the immediate problem; corrective action addresses its cause.

What closes an action effectively?

Evidence that it was implemented and achieved the intended sustained result.

Why assess product impact early?

Containment and disposition may be needed before the investigation is complete.

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