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Good Distribution Practice - Four Case Studies

Practical 4 - Regulatory documentation practical

Aim

To investigate four cases under the assigned good-practice framework.

Principle

GMP, nonclinical GLP, computerised-laboratory data controls and GDP cover different activities. Apply the relevant legal scope and quality system rather than treating the acronyms as interchangeable certifications.

Materials and Requirements

- Fictional product or study case and controlled document templates
- Current official requirements for the specified jurisdiction and product category
- Requirement-to-evidence and gap-assessment worksheet
- 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 product category, intended use, jurisdiction, application type and the date of the regulatory check. Keep this as an offline training exercise with no filing, fees or real applicant information.
3. For each of four cases create a timeline and identify the applicable requirement and affected records.
4. Evaluate immediate risk and containment and gather evidence that can test the proposed cause.
5. Propose specific corrective/preventive actions and a predeclared effectiveness check for each case.
6. Perform an independent consistency and completeness check. Record evidence, gaps, owners and the exact approval or permission still required.
7. 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.

Requirement / dossier element	Document / evidence	Gap / responsible role	Readiness decision
Administrative scope	Identify	Assess	Record
Scientific / quality evidence	Map	Assess	Record
Submission / lifecycle	Validate	Assess	Record

Worked Example

Each assigned case below is fictional. Missing evidence must remain a documented gap; do not manufacture a compliant record retrospectively.

Four GDP case assignments

- 1. Transport temperature excursion: Assess actual time/temperature and stability evidence, quarantine and authorised disposition.
- 2. Untraceable wholesaler: Review authorisations, transaction records and product authenticity safeguards.

• 3. Returned stock mixed with saleable stock: Segregate, document condition and evaluate suitability through the approved process.
• 4. Recall traceability failure: Reconcile distributed quantities, identify recipients and test the communication and effectiveness-check system.

Result and Interpretation

• Produce four separate case reports with evidence, impact, actions and closure criteria.
• A complete training checklist is not an authorisation, licence or guarantee of acceptance.

Precautions

• Distinguish scientific content requirements from electronic-publishing rules.
• Recheck current forms, amendments, scope and local requirements at actual filing.
• Do not invent approval numbers, signatures, fees or deadlines.

Viva Questions and Answers

Why define the application type first?

It determines the legal route and required evidence.

Does a valid file format prove scientific adequacy?

Technical validation and substantive review are separate.

Why retain requirement versions?

Regulations and submission specifications can change.

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