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Quality-Control Documentation Across Dosage Forms

Practical 5 - Regulatory documentation practical

Aim

To compile QC records across solid oral, oral liquid and sterile dosage forms.

Principle

Laboratory documentation connects an approved specification and sampling instruction to raw observations, calculations, review and an authorised certificate or decision.

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 dosage form list identity, content, uniformity or performance and route-specific tests with methods and criteria.
4. Prepare a controlled worksheet containing preparation details, reference potency, instrument/reagent identity, raw readings, formulas and independent review.
5. Create a fictional certificate and connect every reported result to the underlying record, including deviations and any OOS investigation.
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

Illustrative tablet mass compliance cannot replace content uniformity; an oral-liquid appearance result cannot replace microbial-quality testing; clear sterile-product appearance cannot establish sterility.

Result and Interpretation

- Deliver three dosage-form record sets and a traceable result-to-raw-data map.
- 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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