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Indian CTD Dossier and SUGAM Training Exercise

Practical 12 - Regulatory documentation practical

Aim

To compile an Indian CTD training dossier and SUGAM field map.

Principle

The CTD organises scientific content while national administrative requirements remain jurisdiction-specific. SUGAM is an application platform; uploading files is not scientific approval.

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. Define application category and map current Indian administrative forms and portal fields.
4. Organise Module 1 regional material, Module 2 summaries, Module 3 quality, Module 4 nonclinical and Module 5 clinical evidence as applicable.
5. Check cross-document product identity, manufacturers, strength, version and signature-role consistency.
6. Create an offline portal-field map and gap checklist without logging in or submitting a real application.
7. Perform an independent consistency and completeness check. Record evidence, gaps, owners and the exact approval or permission still required.
8. 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 quality section names one manufacturing site while the application form names another. The discrepancy must be reconciled before a readiness conclusion.

Result and Interpretation

- Deliver a structured dossier index and offline application-field mapping.
- 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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