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Import of Drugs for Research and Development

Practical 11 - Regulatory documentation practical

Aim

To prepare an Indian research-drug import documentation exercise.

Principle

Import requirements depend on drug category and intended use. An import permission for trial or examination material is not marketing authorisation.

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 the material, quantity justification, supplier, site, intended study and existing permissions.
4. For new-drug or related material within the relevant NDCT scope map the CT-16 application and CT-17 licence evidence and current CDSCO checklist.
5. Prepare fictional quality, labelling, accountability, storage, transport and unused-material disposition records and assess consistency.
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

Fictional requirement is 200 units for a defined study and justified reserve. Reconcile requested, received, used, retained and disposed quantities and document why the import quantity is needed.

Result and Interpretation

- Deliver an offline import pack and accountability plan with the correct category and permission distinctions.
- 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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