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FDA eCTD Publishing Exercise

Practical 5 - Regulatory documentation practical

Aim

To publish and validate an offline electronic CTD training sequence.

Principle

eCTD adds machine-readable structure and lifecycle operations to the CTD content. Regional Module 1, accepted versions and validation rules differ; a set of PDF folders alone is not a valid eCTD.

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. Select receiving agency, accepted technical version and current regional specifications.
4. Create a fictional sequence plan and document placement with searchable, navigable PDFs and appropriate metadata.
5. Validate required structure, metadata, checksums/identifiers and lifecycle operations using the specification appropriate to the chosen version.
6. Review technical findings and manually check hyperlinks, bookmarks, readability and scientific consistency; create no live gateway submission.
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 a replacement document references the wrong predecessor. The lifecycle link must be corrected even if the PDF opens successfully.

Agency publishing check

• Identify current FDA regional Module 1 and technical validation specifications and use a supported submission version.
• As checked in November 2026, FDA supports eCTD 3.2.2 and 4.0 in their applicable scopes; do not assume 4.0 is already the only permitted version. Confirm lifecycle/forward-compatibility rules for the actual application.

Result and Interpretation

• Deliver a publishing plan, validation finding log and offline sequence index.
• 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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