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ANDA Submission Checklist

Practical 18 - Regulatory documentation practical

Aim

To prepare a Abbreviated New Drug Application evidence checklist.

Principle

IND, NDA, ANDA and BLA have distinct purposes and legal bases. Scientific, administrative, manufacturing and electronic requirements must be mapped to the selected application and product.

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. Determine product centre, application type, development stage and the relevant current guidance.
4. Build a section-level index connecting each requirement to an evidence document and responsible role.
5. Check product consistency, study traceability, manufacturing scope, labelling and electronic technical requirements.
6. Prepare a readiness summary distinguishing missing studies, missing documents and publishing defects.
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

Fictional dossier has a complete table of contents but lacks a validated potency method. Index completeness does not resolve the scientific evidence gap.

Abbreviated New Drug Application

• Reference listed drug/comparator and eligibility, pharmaceutical equivalence, quality/manufacturing, appropriate BE evidence, labelling and patent/exclusivity certifications as applicable.
• Abbreviated does not mean quality evidence is optional or that a full new-drug efficacy programme is always repeated.

Result and Interpretation

• Deliver a purpose-specific checklist, evidence map and priority gap report.
• 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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