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M.Pharm Practical Notes

Pharmaceutical Regulatory Affairs Practicals I

Semester 1

Contents

The contents page numbers refer to the numbered notes pages, excluding the promotional pages.

Good Manufacturing Practice - Four Case Studies 2
Good Laboratory Practice - Four Case Studies 4
Good Automated Laboratory Practice - Four Case Studies 6
Good Distribution Practice - Four Case Studies 8
Quality-Control Documentation Across Dosage Forms 10
SOPs and Analytical Stability and Validation Reports 12
Master Batch and Distribution Records 14
Brand and Generic Labelling Comparison 16
Clinical Trial Protocol for India 18
BA and BE Study Registration in India 20
Import of Drugs for Research and Development 22
Indian CTD Dossier and SUGAM Training Exercise 24
Intellectual Property Registration in India 26
CDSCO GMP Audit Requirements 28
Indian Patent Application Documentation 30
IND Submission Checklist 32
NDA Submission Checklist 34
ANDA Submission Checklist 36
Scientific Response to a Warning Letter 38
Investigational Medicinal Product Dossier for the EU 40
Comparison of EU Marketing Authorisation Routes 42
Drug Master File Systems in the US EU and Japan 44
Electronic CTD Publishing Exercise 46
Clinical Trial Application for the US 48
Clinical Trial Application for the EU 50
Clinical Trial Applications in the US EU and Japan 52
Clinical Trial Regulatory Checklist for India 54
Clinical Trial Regulatory Checklist for the EU 56
Clinical Trial Regulatory Checklist for the US 58

Good Manufacturing Practice - Four Case Studies

Practical 1 - Regulatory documentation practical

Aim

To investigate four cases under the assigned good-practice framework.

Principle

GMP, nonclinical GLP, computerised-laboratory data controls and GDP cover different activities. Apply the relevant legal scope and quality system rather than treating the acronyms as interchangeable certifications.

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 of four cases create a timeline and identify the applicable requirement and affected records.
4. Evaluate immediate risk and containment and gather evidence that can test the proposed cause.
5. Propose specific corrective/preventive actions and a predeclared effectiveness check for each case.
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

Each assigned case below is fictional. Missing evidence must remain a documented gap; do not manufacture a compliant record retrospectively.

Four GMP case assignments

- 1. Line-clearance omission: Contain the batch risk, reconstruct objective evidence and assess potential mix-up before authorised disposition.

• 2. Uncontrolled process change: Review change approval, risk, validation and affected registrations; an informal instruction is insufficient.
• 3. Unqualified supplier: Review material status, source qualification, traceability and product impact; define evidence before release.
• 4. Missing cleaning entry: Retain original records, investigate actual cleaning evidence and assess contamination risk without backdating.

Result and Interpretation

• Produce four separate case reports with evidence, impact, actions and closure criteria.
• 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.

Good Laboratory Practice - Four Case Studies

Practical 2 - Regulatory documentation practical

Aim

To investigate four cases under the assigned good-practice framework.

Principle

GMP, nonclinical GLP, computerised-laboratory data controls and GDP cover different activities. Apply the relevant legal scope and quality system rather than treating the acronyms as interchangeable certifications.

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 of four cases create a timeline and identify the applicable requirement and affected records.
4. Evaluate immediate risk and containment and gather evidence that can test the proposed cause.
5. Propose specific corrective/preventive actions and a predeclared effectiveness check for each case.
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

Each assigned case below is fictional. Missing evidence must remain a documented gap; do not manufacture a compliant record retrospectively.

Four GLP case assignments

- 1. Study-plan change without approval: Identify the applicable nonclinical GLP scope, study-director responsibilities and amendment/deviation controls.

• 2. Reference-material identity gap: Trace characterisation, storage and test-system suitability before interpreting study data.
• 3. Missing raw observations: Preserve available source data, assess reconstruction limits and involve the independent quality-assurance function.
• 4. Archive retrieval failure: Evaluate record retention, indexing, access and recoverability against the actual GLP requirements.

Result and Interpretation

• Produce four separate case reports with evidence, impact, actions and closure criteria.
• 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

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Does a valid file format prove scientific adequacy?

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Why retain requirement versions?

Regulations and submission specifications can change.

Good Automated Laboratory Practice - Four Case Studies

Practical 3 - Regulatory documentation practical

Aim

To investigate four cases under the assigned good-practice framework.

Principle

GMP, nonclinical GLP, computerised-laboratory data controls and GDP cover different activities. Apply the relevant legal scope and quality system rather than treating the acronyms as interchangeable certifications.

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 of four cases create a timeline and identify the applicable requirement and affected records.
4. Evaluate immediate risk and containment and gather evidence that can test the proposed cause.
5. Propose specific corrective/preventive actions and a predeclared effectiveness check for each case.
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

Each assigned case below is fictional. Missing evidence must remain a documented gap; do not manufacture a compliant record retrospectively.

Four GALP case assignments

• 1. Shared laboratory login: Establish unique attribution, access roles, review and a supported corrective action.
• 2. Audit trail not reviewed: Assess relevant data changes, review scope and product impact; merely enabling a feature is insufficient.
• 3. Spreadsheet formula changed: Evaluate validation, version control, locked calculations and independent verification.
• 4. Backup cannot be restored: Test the controlled recovery process and verify complete, readable records rather than checking only backup existence.

Result and Interpretation

• Produce four separate case reports with evidence, impact, actions and closure criteria.
• 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?

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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.

Good Distribution Practice - Four Case Studies

Practical 4 - Regulatory documentation practical

Aim

To investigate four cases under the assigned good-practice framework.

Principle

GMP, nonclinical GLP, computerised-laboratory data controls and GDP cover different activities. Apply the relevant legal scope and quality system rather than treating the acronyms as interchangeable certifications.

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 of four cases create a timeline and identify the applicable requirement and affected records.
4. Evaluate immediate risk and containment and gather evidence that can test the proposed cause.
5. Propose specific corrective/preventive actions and a predeclared effectiveness check for each case.
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

Each assigned case below is fictional. Missing evidence must remain a documented gap; do not manufacture a compliant record retrospectively.

Four GDP case assignments

- 1. Transport temperature excursion: Assess actual time/temperature and stability evidence, quarantine and authorised disposition.
- 2. Untraceable wholesaler: Review authorisations, transaction records and product authenticity safeguards.

• 3. Returned stock mixed with saleable stock: Segregate, document condition and evaluate suitability through the approved process.
• 4. Recall traceability failure: Reconcile distributed quantities, identify recipients and test the communication and effectiveness-check system.

Result and Interpretation

• Produce four separate case reports with evidence, impact, actions and closure criteria.
• 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.

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.

SOPs and Analytical Stability and Validation Reports

Practical 6 - Regulatory documentation practical

Aim

To prepare an SOP and connected analytical, stability and validation report structures.

Principle

An SOP prescribes an approved process; a report states what was done and what the evidence supports. Protocol acceptance criteria must be defined before the validation or study results are judged.

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. Draft an SOP with purpose, scope, roles, materials, procedure, calculations, records, deviations, approvals and revision control.
4. Draft an analytical report with preparation traceability, method suitability, raw results and reviewed calculations.
5. Draft stability and validation reports that map each protocol objective and criterion to actual observations, deviations, conclusions and restrictions.
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 validation report states recovery results and the prespecified criterion; it must not silently widen the criterion after seeing a failed result.

Result and Interpretation

- Deliver one controlled SOP and three linked report templates with a completed fictional example section.
- 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.

Master Batch and Distribution Records

Practical 7 - Manufacturing-document practical

Aim

To prepare connected master, batch and distribution records for a model product.

Principle

The batch manufacturing record records what actually happened for a specific batch, including material lots, actual quantities, equipment, times, checks, yields, deviations and authorised review. It references the approved master instructions.

Materials and Requirements

- Approved model tablet formulation and batch-size basis
- Material specifications and equipment list
- Document-control and process-control templates
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Identify product, batch number, master-document revision and manufacturing dates.
2. Record actual material lots, quantities, status and independent checks against the master formula.
3. Enter equipment identification, cleaning and line clearance, actual process parameters, times and in-process results contemporaneously.
4. Reconcile stage yields and packaging components, attach analytical records and document deviations and quality disposition.
5. Correct errors with a traceable procedure; retain original entries and approval history.

Observations and Record

Enter actual measurements or the supplied teaching data. Record the method, material identity, conditions and units.

Material / stage	Quantity or instruction	Control / criterion	Authorised role
Active / placebo marker	Calculate	Identity / potency	Assign
Excipients	Calculate	Specification	Assign
Process stages	Specify	Parameters / checks	Assign

Calculations

- Stage yield (%) = actual acceptable output / theoretical output x 100

Worked Example

Illustrative theoretical blend 4.000 kg and recovered acceptable blend 3.920 kg give a 98.0% yield. Record 0.080 kg loss with a documented explanation rather than silently adjusting the theoretical quantity.

Distribution traceability

- Record batch, released quantity, customer or depot, dispatch date, quantity and storage or transport conditions.
- Reconcile released, distributed, returned and retained quantities and demonstrate how affected customers would be identified in a recall exercise.

Result and Interpretation

• Deliver an executed, traceable fictional batch record with actual quantities, process observations, yields, deviations and authorised review status.
• Distinguish the approved master instruction from the evidence of what happened for this batch.

Precautions

• Record observations contemporaneously and preserve traceable corrections.
• Do not replace actual values with master targets or backdate signatures.
• Escalate discrepancies and deviations through the controlled quality process.

Viva Questions and Answers

How does a BMR differ from an MFR?

The MFR is the approved master instruction; the BMR records execution of a particular batch.

Why record actual quantities and times?

They provide evidence of the real process and support reconciliation and investigations.

How are errors corrected?

Use the approved attributable correction process while retaining the original information and reason.

Brand and Generic Labelling Comparison

Practical 8 - Regulatory documentation practical

Aim

To compare brand and generic product labels without confusing identity, claim and presentation.

Principle

Labels are approved product-specific information. Equivalent active-ingredient names do not by themselves establish identical indication, formulation, excipients or authorised instructions.

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. Choose actual approved comparator labels of the same ingredient, strength and dosage form and retain their dates.
4. Compare composition, indication, dose instructions, contraindications, warnings, storage, manufacturer and regulatory identifiers.
5. Distinguish permitted presentation differences from potentially meaningful clinical or legal discrepancies and prepare a clarification log.
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 two packs state the same active and strength but different release types. They cannot be treated as automatically interchangeable from the ingredient line alone.

Result and Interpretation

• Produce a side-by-side field comparison and explain what additional equivalence or substitution evidence is needed.
• 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.

Clinical Trial Protocol for India

Practical 9 - Regulatory documentation practical

Aim

To draft a review-ready fictional clinical study protocol.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

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 a scientifically justified question and one measurable primary endpoint, with a feasible and ethical comparator.
4. Specify design, eligibility, allocation, blinding and study schedule, including withdrawals and safety escalation.
5. Write a justified sample-size and analysis plan with missing-data handling, monitoring, data integrity and consent arrangements.
6. Map the protocol to the assigned jurisdiction and assemble the supporting dossier and review checklist.
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 parallel-group question compares mean change in a defined validated endpoint. A proposed 100 participants per arm is a planning placeholder until supported by effect, variability, type-I error, power and attrition assumptions.

Required protocol sections

- Scientific rationale, objectives, population and primary/secondary endpoints.
- Design, comparator, allocation, blinding, eligibility, study visits and procedures.
- Intervention accountability and product quality; safety monitoring, stopping rules and reporting responsibilities.
- Sample-size justification, analysis population, estimand or question, missing-data and multiplicity handling as appropriate.
- Consent, privacy, participant care, compensation/insurance as required, ethics oversight and dissemination.

Jurisdiction: INDIA

- Use current Indian NDCT rules and CDSCO requirements for the actual trial category. Map CT-04 application and CT-06 permission where applicable, registered ethics-committee review and prospective CTRI registration obligations.
- Address injury care/compensation, safety reporting, investigator and site suitability, product import/manufacture permissions and applicable record retention.

Result and Interpretation

- Deliver a protocol synopsis, schedule of assessments, safety plan and requirement-to-document 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.

BA and BE Study Registration in India

Practical 10 - Regulatory documentation practical

Aim

To assemble an Indian BA/BE permission, ethics and registration readiness pack.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

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 a scientifically justified question and one measurable primary endpoint, with a feasible and ethical comparator.
4. Specify design, eligibility, allocation, blinding and study schedule, including withdrawals and safety escalation.
5. Write a justified sample-size and analysis plan with missing-data handling, monitoring, data integrity and consent arrangements.
6. Map the protocol to the assigned jurisdiction and assemble the supporting dossier and review checklist.
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 parallel-group question compares mean change in a defined validated endpoint. A proposed 100 participants per arm is a planning placeholder until supported by effect, variability, type-I error, power and attrition assumptions.

Indian BA/BE readiness

• Identify the product and exact study category and apply current NDCT rules and CDSCO guidance, including any centre registration requirements within scope.

• Distinguish regulatory permission, registered ethics-committee approval and prospective CTRI registration requirements. Verify all prerequisites before first participant enrolment where required.

• Use fictional offline form fields and attach a product, protocol, investigator, bioanalytical and safety evidence checklist; do not submit or create a live registration.

Result and Interpretation

• Deliver a protocol synopsis, schedule of assessments, safety plan and requirement-to-document 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.

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.

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.

Intellectual Property Registration in India

Practical 13 - Regulatory documentation practical

Aim

To distinguish and document appropriate Indian intellectual-property routes.

Principle

Patent, trademark, copyright and design protection concern different subject matter. A patentability search is different from a freedom-to-operate assessment and neither is a marketing licence.

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. Classify a fictional invention, brand, artwork and product appearance by the potentially relevant protection route.
4. Record ownership, inventorship or authorship and confidentiality before public disclosure.
5. For the chosen route map current official forms, evidence and examination/registration stages and identify specialist questions.
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 tablet-process invention and FirstHope-style brand name involve different possible rights. A granted trademark would not establish patent rights in the process.

Result and Interpretation

- Produce a subject-matter-to-route matrix and a documented search and application checklist.
- 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.

CDSCO GMP Audit Requirements

Practical 14 - Audit case-study practical

Aim

To create and apply an evidence-based audit checklist for the specified facility or supplier.

Principle

An audit evaluates objective evidence against defined criteria and scope. A checklist supports consistent coverage but does not replace risk-based sampling, interviews and corroboration of actual practice.

Materials and Requirements

- Fictional site profile, applicable current requirements and SOPs
- Audit plan, checklist and finding templates
- Selected records and interview notes
- 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 purpose, scope, products, jurisdictions, auditor roles and sampling rationale.
3. For each question specify the requirement, objective evidence and record to inspect; trace one selected batch or transaction end to end.
4. Classify each observation using the approved system and describe the evidence, requirement and gap without speculation.
5. Prepare an exit summary and proposed action follow-up with responsibility, due dates and effectiveness evidence.
6. 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.

Audit question / criterion	Evidence sampled	Finding / risk	Action / verification
Governance / scope	Identify records	Assess	Assign
Selected process	Trace evidence	Assess	Assign
Follow-up	Review closure	Assess	Verify

Calculations

- Closure completion (%) = verified closed actions / actions due for closure x 100

Worked Example

Illustrative 8 actions are due and 6 have verified closure: completion = 75%.
The two remaining actions must be evaluated by risk; the percentage does not itself establish site compliance.

Audit scope: Indian GMP inspection readiness

• Applicable current Indian manufacturing requirements; licences and product scope; pharmaceutical quality system; premises and equipment; production and laboratory controls; complaints, recalls and data integrity.
• For each listed area record the criterion, selected evidence, actual observation, risk and follow-up.

Result and Interpretation

• Deliver a traceable checklist, factual finding statements and a risk-based follow-up plan.

Precautions

• Avoid patient or commercial identifiers in teaching records.
• Do not confuse absence of evidence with proof of conformity.
• Do not claim an audit is a regulatory certification.

Viva Questions and Answers

What makes a finding defensible?

A clear criterion, objective evidence and a described gap.

Why sample records?

A reasoned sample examines actual implementation within the audit scope.

Is an action closed when promised?

Closure requires verified implementation and, where relevant, effectiveness.

Indian Patent Application Documentation

Practical 15 - Regulatory documentation practical

Aim

To prepare a fictional Indian patent application documentation pack.

Principle

Patent examination considers statutory patentability and disclosure requirements. A broad claim without enabling support or a novelty search is not a defensible application.

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. Describe the problem, prior art, inventive concept and supporting experimental evidence without disclosing a real confidential invention.
4. Draft title, field, background, summary, detailed description, examples, claims, abstract and drawings as appropriate.
5. Map Form 1 application, Form 2 provisional/complete specification and examination request Form 18/18A where eligible, plus other applicable declarations and ownership evidence.
6. Review clarity, support, unity and the current statutory exclusions and procedural requirements with the appropriate specialist role.
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 claim covers every formulation of a drug but examples support only one narrow matrix. Identify the support gap rather than copying the broad claim into a filing.

Result and Interpretation

- Deliver an offline draft structure and a current-form readiness checklist; no legal right is created by the exercise.
- 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.

IND Submission Checklist

Practical 16 - Regulatory documentation practical

Aim

To prepare a Investigational 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.

Investigational New Drug application

• Investigational plan, investigator information, relevant prior human and nonclinical evidence, CMC adequate for the phase, protocols and participant protection.
• IND supports clinical investigation subject to applicable requirements; it is not marketing approval.

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.

NDA Submission Checklist

Practical 17 - Regulatory documentation practical

Aim

To prepare a 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.

New Drug Application

• Administrative and prescribing information, integrated summaries, quality, nonclinical and clinical evidence appropriate to the legal basis, manufacturing and risk-management evidence.
• A marketing application needs the relevant evidence standard; do not treat every development programme as having identical study-count requirements.

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.

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.

Scientific Response to a Warning Letter

Practical 19 - Regulatory documentation practical

Aim

To draft an evidence-based scientific response to a fictional warning letter.

Principle

A useful response addresses each observation, product impact, containment, investigation, systemic cause, corrective action and effectiveness with verifiable evidence. A promise without scope and dates is incomplete.

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. Break each fictional observation into its factual allegation, affected scope and requirement.
4. Describe immediate containment and retrospective product/data impact, including what remains unknown.
5. Prepare a point-by-point cause assessment and actions with accountable owners, deliverables and realistic committed dates.
6. Map completed evidence and future milestones, distinguishing implemented corrections from planned actions and independent verification.
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 observation concerns deleted analytical runs. Preserve all recoverable data, assess batch impact and system access/audit controls, and propose independently verified remediation; do not merely retrain one analyst.

Result and Interpretation

- Deliver a response matrix and evidence annex index with honest status reporting.
- 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.

Investigational Medicinal Product Dossier for the EU

Practical 20 - Regulatory documentation practical

Aim

To create an EU Investigational Medicinal Product Dossier training index.

Principle

An IMPD supports the quality, nonclinical and clinical evidence relevant to an investigational product and proposed trial. The amount and type of evidence depend on development stage and available justified references.

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 investigational product, dosage form, manufacture, trial phase and prior knowledge.
4. Map drug substance and product quality, manufacture, controls and stability to the proposed clinical use.
5. Summarise relevant nonclinical and prior clinical evidence and justify how it supports the proposed exposure and risk controls.
6. Connect the IMPD with protocol, investigator brochure and applicable CTIS trial application requirements.
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 stability data support only three months under the proposed storage conditions, while the trial supply plan assumes twelve months. Identify the supply and evidence gap.

Result and Interpretation

- Deliver an IMPD index, evidence map and trial-use risk/gap assessment.
- 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.

Comparison of EU Marketing Authorisation Routes

Practical 21 - Regulatory documentation practical

Aim

To compare EU centralised, decentralised, mutual-recognition and national authorisation routes.

Principle

Route eligibility depends on product and legal basis. In the centralised route EMA performs scientific assessment and the European Commission grants the authorisation; other routes involve national competent authorities.

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 a fictional product and assess whether centralised authorisation is mandatory or available.
4. Compare centralised assessment with national authorisation, decentralised simultaneous applications and mutual recognition of an existing national authorisation.
5. Map participating states, responsible authority, dossier and lifecycle implications without assigning unverified timelines.
6. Recommend a route with an eligibility rationale and identify missing information.
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 product already nationally authorised in one state may be considered for mutual recognition in other states if eligible. A not-yet-authorised product may fit a decentralised route if outside mandatory centralised scope.

Result and Interpretation

- Deliver a four-route comparison and a justified product-specific recommendation.
- 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.

Drug Master File Systems in the US EU and Japan

Practical 22 - Regulatory documentation practical

Aim

To compare US DMF, EU ASMF and Japanese MF systems.

Principle

Master-file mechanisms permit confidential quality information to support a referenced application under jurisdiction-specific arrangements. Registration or filing of a master file is not an independent product marketing 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 the drug substance or other material and the application referencing it.
4. Map US DMF type and letter-of-authorisation requirements; for the EU distinguish applicant and restricted parts of an ASMF.
5. Map Japanese MF registration and relevant reference/access and local procedural requirements.
6. Compare holder/applicant responsibilities, change notification and consistency of the applicant-accessible information.
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 supplier sends the applicant only a master-file number. The applicant still needs suitable accessible quality information and the relevant authorisation/access arrangements; the number alone is insufficient.

Result and Interpretation

- Deliver a three-jurisdiction responsibility and document matrix.
- 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.

Electronic CTD Publishing Exercise

Practical 23 - 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 chosen receiving agency regional Module 1 and technical validation specifications and use a supported submission version.

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.

Clinical Trial Application for the US

Practical 24 - Regulatory documentation practical

Aim

To draft a review-ready fictional clinical study protocol.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

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 a scientifically justified question and one measurable primary endpoint, with a feasible and ethical comparator.
4. Specify design, eligibility, allocation, blinding and study schedule, including withdrawals and safety escalation.
5. Write a justified sample-size and analysis plan with missing-data handling, monitoring, data integrity and consent arrangements.
6. Map the protocol to the assigned jurisdiction and assemble the supporting dossier and review checklist.
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 parallel-group question compares mean change in a defined validated endpoint. A proposed 100 participants per arm is a planning placeholder until supported by effect, variability, type-I error, power and attrition assumptions.

Required protocol sections

- Scientific rationale, objectives, population and primary/secondary endpoints.
- Design, comparator, allocation, blinding, eligibility, study visits and procedures.
- Intervention accountability and product quality; safety monitoring, stopping rules and reporting responsibilities.
- Sample-size justification, analysis population, estimand or question, missing-data and multiplicity handling as appropriate.
- Consent, privacy, participant care, compensation/insurance as required, ethics oversight and dissemination.

Jurisdiction: US

- Determine whether an IND is required or an exemption applies; map FDA application responsibilities and IRB review with informed consent.
- Include CMC appropriate to phase, nonclinical and prior-human support, investigator information, safety reporting, registration/results obligations where applicable and current electronic requirements.

Result and Interpretation

- Deliver a protocol synopsis, schedule of assessments, safety plan and requirement-to-document map.
- A complete training checklist is not an authorisation, licence or guarantee of acceptance.

Precautions

- Distinguish scientific content requirements from electronic-publishing rules.
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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.

Clinical Trial Application for the EU

Practical 25 - Regulatory documentation practical

Aim

To draft a review-ready fictional clinical study protocol.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

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.
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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 parallel-group question compares mean change in a defined validated endpoint. A proposed 100 participants per arm is a planning placeholder until supported by effect, variability, type-I error, power and attrition assumptions.

Required protocol sections

- Scientific rationale, objectives, population and primary/secondary endpoints.
- Design, comparator, allocation, blinding, eligibility, study visits and procedures.
- Intervention accountability and product quality; safety monitoring, stopping rules and reporting responsibilities.
- Sample-size justification, analysis population, estimand or question, missing-data and multiplicity handling as appropriate.
- Consent, privacy, participant care, compensation/insurance as required, ethics oversight and dissemination.

Jurisdiction: EU

- Map the Clinical Trials Regulation and CTIS application with Part I scientific and Part II member-state/ethical elements as applicable.
- Keep IMPD, protocol, investigator brochure, consent, product accountability, safety reporting and national requirements consistent; CTIS is not a marketing-authorisation route.

Result and Interpretation

- Deliver a protocol synopsis, schedule of assessments, safety plan and requirement-to-document 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.

Clinical Trial Applications in the US EU and Japan

Practical 26 - Regulatory documentation practical

Aim

To compare trial-application requirements across three named jurisdictions.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

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.
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5. Write a justified sample-size and analysis plan with missing-data handling, monitoring, data integrity and consent arrangements.
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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 parallel-group question compares mean change in a defined validated endpoint. A proposed 100 participants per arm is a planning placeholder until supported by effect, variability, type-I error, power and attrition assumptions.

Comparison deliverable

• Use the same fictional product, phase and population. Compare authority, legal route, ethics, scientific dossier, product permission, consent, safety and registration obligations.

• Add a separate responsibility and evidence column for each jurisdiction rather than treating one approval as universal.

Assigned jurisdictions

• US

• EU

• Japan

• For Japan distinguish PMDA scientific consultation/review roles and applicable MHLW/ethics requirements; for each jurisdiction verify the current product-specific procedure.

Result and Interpretation

• Deliver a protocol synopsis, schedule of assessments, safety plan and requirement-to-document 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.

Clinical Trial Regulatory Checklist for India

Practical 27 - Regulatory documentation practical

Aim

To prepare a jurisdiction-specific clinical-trial regulatory readiness checklist.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

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.
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Worked Example

Illustrative parallel-group question compares mean change in a defined validated endpoint. A proposed 100 participants per arm is a planning placeholder until supported by effect, variability, type-I error, power and attrition assumptions.

Required protocol sections

- Scientific rationale, objectives, population and primary/secondary endpoints.
- Design, comparator, allocation, blinding, eligibility, study visits and procedures.
- Intervention accountability and product quality; safety monitoring, stopping rules and reporting responsibilities.
- Sample-size justification, analysis population, estimand or question, missing-data and multiplicity handling as appropriate.
- Consent, privacy, participant care, compensation/insurance as required, ethics oversight and dissemination.

Jurisdiction: INDIA

- Use current Indian NDCT rules and CDSCO requirements for the actual trial category. Map CT-04 application and CT-06 permission where applicable, registered ethics-committee review and prospective CTRI registration obligations.
- Address injury care/compensation, safety reporting, investigator and site suitability, product import/manufacture permissions and applicable record retention.

Result and Interpretation

- Deliver a protocol synopsis, schedule of assessments, safety plan and requirement-to-document map.
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Precautions

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Viva Questions and Answers

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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.

Clinical Trial Regulatory Checklist for the EU

Practical 28 - Regulatory documentation practical

Aim

To prepare a jurisdiction-specific clinical-trial regulatory readiness checklist.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

Materials and Requirements

- Fictional product or study case and controlled document templates
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Procedure

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Jurisdiction: EU

• Map the Clinical Trials Regulation and CTIS application with Part I scientific and Part II member-state/ethical elements as applicable.
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Why retain requirement versions?

Regulations and submission specifications can change.

Clinical Trial Regulatory Checklist for the US

Practical 29 - Regulatory documentation practical

Aim

To prepare a jurisdiction-specific clinical-trial regulatory readiness checklist.

Principle

A protocol connects the research question to participant protection, design, procedures, analysis and operational controls. Regulatory permission, ethics approval and registration are separate requirements.

Materials and Requirements

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• Determine whether an IND is required or an exemption applies; map FDA application responsibilities and IRB review with informed consent.
• Include CMC appropriate to phase, nonclinical and prior-human support, investigator information, safety reporting, registration/results obligations where applicable and current electronic requirements.

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