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M.Pharm Practical Notes

Pharmaceutical Regulatory Affairs Practicals II

Semester 2

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Change-Control and Deviation Case Studies

Practical 1 - Quality case-study practical

Aim

To investigate a defined pharmaceutical-quality case and prepare a defensible decision record.

Principle

A quality-system decision connects evidence, patient or product risk, cause assessment, authorised action and effectiveness. A suspected cause is a hypothesis until supported by evidence.

Materials and Requirements

- Fictional case pack, batch history and applicable SOP
- Investigation, risk and action templates
- Trend data and a documented approval pathway
- 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. Construct a factual timeline and distinguish facts from assumptions.
3. Identify affected batches, containment and immediate product-risk questions.
4. Gather relevant laboratory, equipment, personnel and manufacturing evidence and test plausible causes.
5. Propose justified actions with owners, dates and effectiveness measures; record disposition and closure through authorised roles.
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.

Finding / evidence	Risk / impact	Action / owner	Effectiveness evidence
Observed problem	Assess	Assign	Define
Cause hypothesis	Test	Assign	Verify
Product disposition	Justify	Approve	Record

Calculations

- Recurrence rate = repeated events / defined opportunities x 100
- State the observation period and denominator when comparing rates.

Worked Example

Illustrative 6 documentation omissions in 200 records give 3.0%. After an intervention, 1 in 200 gives 0.5%. Review comparable workload and surveillance before attributing improvement to the action.

Case assignment

- Planned mixer change versus an unplanned mixing departure

• Create separate change-control and deviation records; connect their risk assessment, approvals and validation evidence.
• A retrospective change request cannot replace an honest deviation record.

Result and Interpretation

• Produce a signed-role investigation summary with evidence, unresolved questions and justified closure criteria.

Precautions

• Do not invent a root cause or delete contrary evidence.
• Distinguish containment from permanent correction.
• Do not use repeated testing to obtain a passing result.

Viva Questions and Answers

What distinguishes correction from corrective action?

Correction addresses the immediate problem; corrective action addresses its cause.

What closes an action effectively?

Evidence that it was implemented and achieved the intended sustained result.

Why assess product impact early?

Containment and disposition may be needed before the investigation is complete.

Corrective and Preventive Action Case Study

Practical 2 - Quality case-study practical

Aim

To investigate a defined pharmaceutical-quality case and prepare a defensible decision record.

Principle

A quality-system decision connects evidence, patient or product risk, cause assessment, authorised action and effectiveness. A suspected cause is a hypothesis until supported by evidence.

Materials and Requirements

- Fictional case pack, batch history and applicable SOP
- Investigation, risk and action templates
- Trend data and a documented approval pathway
- 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. Construct a factual timeline and distinguish facts from assumptions.
3. Identify affected batches, containment and immediate product-risk questions.
4. Gather relevant laboratory, equipment, personnel and manufacturing evidence and test plausible causes.
5. Propose justified actions with owners, dates and effectiveness measures; record disposition and closure through authorised roles.
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.

Finding / evidence	Risk / impact	Action / owner	Effectiveness evidence
Observed problem	Assess	Assign	Define
Cause hypothesis	Test	Assign	Verify
Product disposition	Justify	Approve	Record

Calculations

- Recurrence rate = repeated events / defined opportunities x 100
- State the observation period and denominator when comparing rates.

Worked Example

Illustrative 6 documentation omissions in 200 records give 3.0%. After an intervention, 1 in 200 gives 0.5%. Review comparable workload and surveillance before attributing improvement to the action.

Case assignment

- Recurring line-clearance documentation omissions

• Define the problem and product impact, investigate causes, assign corrective and preventive actions with owners.
• Verify implementation and effectiveness against a preselected recurrence measure.

Result and Interpretation

• Produce a signed-role investigation summary with evidence, unresolved questions and justified closure criteria.

Precautions

• Do not invent a root cause or delete contrary evidence.
• Distinguish containment from permanent correction.
• Do not use repeated testing to obtain a passing result.

Viva Questions and Answers

What distinguishes correction from corrective action?

Correction addresses the immediate problem; corrective action addresses its cause.

What closes an action effectively?

Evidence that it was implemented and achieved the intended sustained result.

Why assess product impact early?

Containment and disposition may be needed before the investigation is complete.

Raw-Material Analysis Documentation

Practical 3 - Analytical practical

Aim

To plan and document the official assay and identification evidence required for a raw material.

Principle

A titration relates analyte amount to the amount of standard reagent required by a defined reaction. Reaction stoichiometry, endpoint selection, blank consumption and reagent standardisation determine the calculation. The test preparation, blank, calibration or titrant standardisation and independent controls are part of the measurement. State the actual concentration units, test conditions and adopted method before interpreting the result.

Materials and Requirements

- Selected official compound and adopted monograph
- Appropriate standardised titrant and primary-standard record
- Endpoint indicator or potentiometric system
- Qualified balance and volumetric equipment
- Controlled method and raw-data worksheet

Procedure

1. Identify the material, intended attribute, method version and acceptance criteria. Record preparation and instrument or reagent identities.
2. Prepare the prescribed blank and reference or standardised reagent. Verify the measurement with an independent check where applicable.
3. Prepare a representative weighed test portion in the specified solvent. Ensure the reaction conditions and dissolution are appropriate.
4. Titrate using the defined endpoint, recording initial and final burette readings and a reagent blank.
5. Repeat on independent portions and calculate the content using the reaction stoichiometry and the actual titrant concentration.
6. Record individual readings for independently prepared test portions. Keep all raw observations, including unsuccessful measurements and their investigation.
7. Calculate the result on the stated mass, volume or area basis, including dilution, blank and recovery corrections as justified.
8. Compare the evidence with the applicable criteria and write a conclusion limited to the tested preparation and conditions.

Observations and Record

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

Preparation / attribute	Method condition	Raw measurement	Calculated result
Titrant standardisation	Record	Record	Calculate
Blank	Record	Record	Calculate
Test portion 1	Record	Record	Calculate

Preparation / attribute	Method condition	Raw measurement	Calculated result
Test portion 2	Record	Record	Calculate

Calculations

• Analyte amount (mol) = blank-corrected titrant volume (L) x actual titrant molarity x stoichiometric ratio
• Assay (%) = measured analyte mass / weighed preparation mass x 100

Worked Example

Illustrative 1:1 reaction: corrected titrant volume 10.00 mL, molarity 0.1000 mol/L and analyte molar mass 180.16 g/mol.

Measured analyte = 0.01000 x 0.1000 x 180.16 = 0.18016 g.

For a 0.1820 g test portion, assay = 98.99% approximately. This example does not assign the reaction to a particular official drug.

Monograph-to-record mapping

• Identify the current applicable monograph, material grade and any water, solvent or purity correction.
• Map identity, assay and impurity requirements to method records and raw data. A supplier certificate supports the record but does not replace required receipt testing.

Result and Interpretation

• State the endpoint and stoichiometric basis, including whether water or other correction factors are required by the monograph.
• Report replicate variability and the evidence that the method can measure the intended attribute in this matrix.

Precautions

• Use the actual standardised reagent concentration.
• Avoid endpoint overshoot and parallax.
• Select a blank with the same reagent and solvent conditions.
• Use the adopted laboratory procedure, suitable controls and the designated waste arrangements.

Viva Questions and Answers

Why standardise a titrant?

Its actual concentration can differ from the nominal preparation.

Why is stoichiometry essential?

The reagent-to-analyte mole relationship determines the mass calculation.

Why correct for the blank?

Other components may consume titrant.

Multi-Agency Audit Checklist

Practical 4 - 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: Multi-agency inspection readiness

• Map one core quality system to the actual jurisdiction-specific scope. Record each requirement source and date rather than claiming that one checklist guarantees every agency outcome.
• 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.

FDA eCTD Publishing Exercise

Practical 5 - Regulatory documentation practical

Aim

To publish and validate an offline electronic CTD training sequence.

Principle

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

Materials and Requirements

- Fictional product or study case and controlled document templates
- Current official requirements for the specified jurisdiction and product category
- Requirement-to-evidence and gap-assessment worksheet
- Approved method or teaching-data pack and a dated record sheet

Procedure

1. Define the preparation or dataset, study question and method version. Record identities, units and the criteria to be used before examining the outcome.
2. Define product category, intended use, jurisdiction, application type and the date of the regulatory check. Keep this as an offline training exercise with no filing, fees or real applicant information.
3. Select receiving agency, accepted technical version and current regional specifications.
4. Create a fictional sequence plan and document placement with searchable, navigable PDFs and appropriate metadata.
5. Validate required structure, metadata, checksums/identifiers and lifecycle operations using the specification appropriate to the chosen version.
6. Review technical findings and manually check hyperlinks, bookmarks, readability and scientific consistency; create no live gateway submission.
7. Perform an independent consistency and completeness check. Record evidence, gaps, owners and the exact approval or permission still required.
8. Retain the original observations and calculations. State deviations, missing information and the limits of the conclusion; do not replace measured values with expected results.

Observations and Record

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

Requirement / dossier element	Document / evidence	Gap / responsible role	Readiness decision
Administrative scope	Identify	Assess	Record
Scientific / quality evidence	Map	Assess	Record
Submission / lifecycle	Validate	Assess	Record

Worked Example

Illustrative a replacement document references the wrong predecessor. The lifecycle link must be corrected even if the PDF opens successfully.

Agency publishing check

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

Result and Interpretation

• Deliver a publishing plan, validation finding log and offline sequence index.
• A complete training checklist is not an authorisation, licence or guarantee of acceptance.

Precautions

• Distinguish scientific content requirements from electronic-publishing rules.
• Recheck current forms, amendments, scope and local requirements at actual filing.
• Do not invent approval numbers, signatures, fees or deadlines.

Viva Questions and Answers

Why define the application type first?

It determines the legal route and required evidence.

Does a valid file format prove scientific adequacy?

Technical validation and substantive review are separate.

Why retain requirement versions?

Regulations and submission specifications can change.

EMA eCTD Publishing Exercise

Practical 6 - 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 EMA / EU 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.

MHRA eCTD Publishing Exercise

Practical 7 - 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 MHRA regional Module 1 and technical validation specifications and use a supported submission version.
• Keep the UK application route and electronic specification separate from EU/EMA requirements; check the current MHRA guidance for the exact product and application.

Result and Interpretation

• Deliver a publishing plan, validation finding log and offline sequence index.
• A complete training checklist is not an authorisation, licence or guarantee of acceptance.

Precautions

• Distinguish scientific content requirements from electronic-publishing rules.
• Recheck current forms, amendments, scope and local requirements at actual filing.
• Do not invent approval numbers, signatures, fees or deadlines.

Viva Questions and Answers

Why define the application type first?

It determines the legal route and required evidence.

Does a valid file format prove scientific adequacy?

Technical validation and substantive review are separate.

Why retain requirement versions?

Regulations and submission specifications can change.

Biologics License Application Checklist

Practical 8 - Regulatory documentation practical

Aim

To prepare a Biologics License 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.

Biologics License Application

• Biological-product identity, manufacturing/control strategy, potency, safety and clinical evidence, facilities and product-specific lifecycle controls.
• A biological product may require product- and pathway-specific evidence; do not assume an ANDA route applies.

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.

Vaccine Product Approval Documentation

Practical 9 - Regulatory documentation practical

Aim

To compile a vaccine product-approval evidence checklist.

Principle

Vaccine quality evaluation includes biological identity, manufacturing consistency, potency, purity, safety and stability along with the appropriate nonclinical and clinical evidence. Requirements are platform- and jurisdiction-specific.

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 vaccine platform, intended population, route and regulatory pathway without designing a biological agent.
4. Map source-material and cell/substrate controls, manufacturing stages and validated control strategy from supplied records.
5. Review potency, consistency, contamination controls, stability/cold chain and relevant nonclinical/clinical evidence.
6. Connect labelling, pharmacovigilance and lot-release obligations where applicable to the chosen jurisdiction.
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 lot meets total-protein content but lacks qualified potency evidence. Content alone cannot establish vaccine potency or approval readiness.

Result and Interpretation

- Deliver a platform-specific evidence map and gap assessment, using only supplied product records.
- 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.

Biologic Trial Applications in the US EU and India

Practical 10 - 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.
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.

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

• India

• 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.

Blood and Blood-Product Registration Checklist

Practical 11 - Regulatory documentation practical

Aim

To prepare a blood and blood-product registration and traceability checklist.

Principle

Whole blood/components, plasma-derived medicinal products and recombinant products may follow different frameworks. Donor, collection, testing, manufacturing and traceability requirements must match the exact category.

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 the fictional product and identify the relevant regulator and establishment/product permissions.
4. Review supplied donor/source eligibility, testing, collection and storage evidence where applicable, keeping personal data absent.
5. For a plasma-derived product map manufacturing, validated pathogen-safety controls, identity, potency, impurities and stability evidence without describing pathogen procedures.
6. Assess traceability, haemovigilance/pharmacovigilance, recall and product-information obligations.
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 pack lacks a link to its source lot and distribution record. A passing assay does not repair the traceability gap.

Result and Interpretation

- Deliver a category-specific registration and traceability evidence 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.

Five-Market Registration Comparison and WHO Guidance

Practical 12 - Regulatory documentation practical

Aim

To compare medicine-registration requirements across the assigned markets.

Principle

Regional formats and reliance mechanisms do not make all markets identical. Product classification, applicant role, quality evidence, local administration and lifecycle responsibilities must be assessed separately.

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 the same fictional product and legal basis for each named market and identify the official competent authority.
4. Build a matrix for applicant/local representation, dossier format, language, quality/GMP, stability, clinical/BE, labels and pharmacovigilance.
5. Check current regional versus national requirements and distinguish WHO guidance or prequalification from national marketing authorisation.
6. Prepare an evidence-gap and sequencing plan with no invented fees, deadlines or automatic approvals.
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.

Market / framework	Authority / scope	Dossier and local evidence	Gap / action
Kenya	Pharmacy and Poisons Board	Verify current requirements	Record
Ghana	Food and Drugs Authority	Verify current requirements	Record

Market / framework	Authority / scope	Dossier and local evidence	Gap / action
Nigeria	NAFDAC	Verify current requirements	Record
Egypt	Egyptian Drug Authority	Verify current requirements	Record
South Africa	SAHPRA	Verify current requirements	Record

Worked Example

Fictional product has an ICH CTD quality package but lacks one market local-language product information and stability justification. Shared scientific data do not eliminate those gaps.

Five-market scope

• These are five explicitly selected illustrative markets, not a formal WHO category of five emerging markets. WHO guidance/prequalification and national registration are separate.

Result and Interpretation

• Deliver a country-by-country requirements matrix with dated verification fields.
• 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.

Registration Comparison for the Original BRICS Markets

Practical 13 - Regulatory documentation practical

Aim

To compare medicine-registration requirements across the assigned markets.

Principle

Regional formats and reliance mechanisms do not make all markets identical. Product classification, applicant role, quality evidence, local administration and lifecycle responsibilities must be assessed separately.

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 the same fictional product and legal basis for each named market and identify the official competent authority.
4. Build a matrix for applicant/local representation, dossier format, language, quality/GMP, stability, clinical/BE, labels and pharmacovigilance.
5. Check current regional versus national requirements and distinguish WHO guidance or prequalification from national marketing authorisation.
6. Prepare an evidence-gap and sequencing plan with no invented fees, deadlines or automatic approvals.
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.

Market / framework	Authority / scope	Dossier and local evidence	Gap / action
Brazil	ANVISA	Verify current requirements	Record
Russia	Applicable national / EAEU framework	Verify current requirements	Record

Market / framework	Authority / scope	Dossier and local evidence	Gap / action
India	CDSCO and relevant authorities	Verify current requirements	Record
China	NMPA / CDE	Verify current requirements	Record
South Africa	SAHPRA	Verify current requirements	Record

Worked Example

Fictional product has an ICH CTD quality package but lacks one market local-language product information and stability justification. Shared scientific data do not eliminate those gaps.

Historical grouping

• This exercise uses the original five BRICS markets named in the curriculum context; it is not a statement of current BRICS membership.

Result and Interpretation

• Deliver a country-by-country requirements matrix with dated verification fields.
• 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 Registration in China and South Korea

Practical 14 - Regulatory documentation practical

Aim

To compare medicine-registration requirements across the assigned markets.

Principle

Regional formats and reliance mechanisms do not make all markets identical. Product classification, applicant role, quality evidence, local administration and lifecycle responsibilities must be assessed separately.

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 the same fictional product and legal basis for each named market and identify the official competent authority.
4. Build a matrix for applicant/local representation, dossier format, language, quality/GMP, stability, clinical/BE, labels and pharmacovigilance.
5. Check current regional versus national requirements and distinguish WHO guidance or prequalification from national marketing authorisation.
6. Prepare an evidence-gap and sequencing plan with no invented fees, deadlines or automatic approvals.
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.

Market / framework	Authority / scope	Dossier and local evidence	Gap / action
China	NMPA / CDE	Verify current requirements	Record
South Korea	MFDS	Verify current requirements	Record

Worked Example

Fictional product has an ICH CTD quality package but lacks one market local-language product information and stability justification. Shared scientific data do not eliminate those gaps.

Result and Interpretation

- Deliver a country-by-country requirements matrix with dated verification fields.
- 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.

ASEAN Drug Registration Checklist

Practical 15 - Regulatory documentation practical

Aim

To compare medicine-registration requirements across the assigned markets.

Principle

Regional formats and reliance mechanisms do not make all markets identical. Product classification, applicant role, quality evidence, local administration and lifecycle responsibilities must be assessed separately.

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 the same fictional product and legal basis for each named market and identify the official competent authority.
4. Build a matrix for applicant/local representation, dossier format, language, quality/GMP, stability, clinical/BE, labels and pharmacovigilance.
5. Check current regional versus national requirements and distinguish WHO guidance or prequalification from national marketing authorisation.
6. Prepare an evidence-gap and sequencing plan with no invented fees, deadlines or automatic approvals.
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.

Market / framework	Authority / scope	Dossier and local evidence	Gap / action
ASEAN framework	ACTD / ACTR plus each member authority	Verify current requirements	Record
Selected national case	HSA Singapore or another explicitly chosen member	Verify current requirements	Record

Worked Example

Fictional product has an ICH CTD quality package but lacks one market local-language product information and stability justification. Shared scientific data do not eliminate those gaps.

ACTD distinction

• ACTD has four parts: administrative/product information, quality, nonclinical and clinical. ICH CTD has five modules; map the structures correctly and verify each national accepted format.

Result and Interpretation

• Deliver a country-by-country requirements matrix with dated verification fields.
• 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.

GCC Drug Registration Checklist

Practical 16 - Regulatory documentation practical

Aim

To compare medicine-registration requirements across the assigned markets.

Principle

Regional formats and reliance mechanisms do not make all markets identical. Product classification, applicant role, quality evidence, local administration and lifecycle responsibilities must be assessed separately.

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 the same fictional product and legal basis for each named market and identify the official competent authority.
4. Build a matrix for applicant/local representation, dossier format, language, quality/GMP, stability, clinical/BE, labels and pharmacovigilance.
5. Check current regional versus national requirements and distinguish WHO guidance or prequalification from national marketing authorisation.
6. Prepare an evidence-gap and sequencing plan with no invented fees, deadlines or automatic approvals.
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.

Market / framework	Authority / scope	Dossier and local evidence	Gap / action
Gulf Health Council	GCC central registration scope	Verify current requirements	Record
Saudi Arabia	SFDA national requirements	Verify current requirements	Record
Other selected GCC state	Its national competent authority	Verify current requirements	Record

Worked Example

Fictional product has an ICH CTD quality package but lacks one market local-language product information and stability justification. Shared scientific data do not eliminate those gaps.

Result and Interpretation

- Deliver a country-by-country requirements matrix with dated verification fields.
- 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.

US Medical Devices - 510k and PMA Checklists

Practical 17 - Regulatory documentation practical

Aim

To compare US 510(k) and PMA evidence requirements for a fictional medical device.

Principle

A 510(k) seeks a substantial-equivalence determination to an appropriate legally marketed predicate; PMA requires an independent safety/effectiveness demonstration under its framework. The pathway depends on classification and the actual device.

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 intended use, users, technology, classification and product code and identify whether an exemption or other route is relevant.
4. For a 510(k) map predicate, intended-use and technological comparisons and the required bench, biological, software or clinical evidence as applicable.
5. For PMA map valid scientific evidence, manufacturing and quality-system information, labelling and post-approval obligations.
6. Assess current FDA technical submission and quality-system requirements; QMSR became effective on 2 February 2026.
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 device shares a shape with a predicate but has a different intended use. Shape alone cannot establish substantial equivalence.

Result and Interpretation

- Deliver two distinct checklists and a justified route-assessment record.
- 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.

EU Medical Devices - CE Conformity Checklist

Practical 18 - Regulatory documentation practical

Aim

To prepare an EU medical-device conformity and CE-marking checklist.

Principle

EU device conformity is assessed under the applicable MDR or IVDR framework, device classification and intended purpose. CE marking is not an EMA medicine 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. Classify the fictional product as a device or IVD and document the applicable classification rule and intended purpose.
4. Map general safety/performance requirements to risk management, verification/validation, clinical evaluation or performance evidence and technical documentation.
5. Identify the appropriate conformity-assessment route and notified-body involvement where required, plus declaration, labelling and registration obligations.
6. Prepare post-market surveillance, vigilance and clinical/performance follow-up plans and check current transition rules for the actual case.
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 Class III implant has bench evidence but no justified clinical evaluation. A completed checklist cannot replace the missing clinical evidence or notified-body assessment.

Result and Interpretation

- Deliver a conformity-assessment map with requirement-to-evidence traceability.
- 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.

Class III Device Technical Documentation and STED Mapping

Practical 19 - Regulatory documentation practical

Aim

To map a Class III device technical dossier and legacy STED headings to current requirements.

Principle

EU device conformity is assessed under the applicable MDR or IVDR framework, device classification and intended purpose. CE marking is not an EMA medicine 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. Classify the fictional product as a device or IVD and document the applicable classification rule and intended purpose.
4. Map general safety/performance requirements to risk management, verification/validation, clinical evaluation or performance evidence and technical documentation.
5. Identify the appropriate conformity-assessment route and notified-body involvement where required, plus declaration, labelling and registration obligations.
6. Prepare post-market surveillance, vigilance and clinical/performance follow-up plans and check current transition rules for the actual case.
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 Class III implant has bench evidence but no justified clinical evaluation. A completed checklist cannot replace the missing clinical evidence or notified-body assessment.

Technical-documentation mapping

• Organise device description, design/manufacturing, safety/performance checklist, risk management, verification/validation, clinical evidence and post-market plans.
• Treat STED as a summary structure. Map it to the actual jurisdiction current technical-documentation requirements; for EU MDR include Annex II and III scope rather than assuming STED alone is legally sufficient.

Result and Interpretation

• Deliver a conformity-assessment map with requirement-to-evidence traceability.
• 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.

Medical Device Facility Audit Checklist

Practical 20 - 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: Medical device facility

• Intended use and design controls; risk management; supplier and production controls; software validation where applicable; complaint, vigilance and corrective-action systems; traceability and change control.
• 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.

Clinical Investigation Plan for a Medical Device

Practical 21 - Regulatory documentation practical

Aim

To draft a clinical investigation plan for a fictional medical device.

Principle

A device investigation must connect intended purpose, risks, device performance and participant protection. Device-specific design and operator effects can require controls different from a medicine trial.

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 device/version, intended purpose, scientific rationale and the applicable jurisdiction and device-GCP requirements.
4. Specify objectives, endpoints, comparator, population, operator training and the investigation schedule.
5. Prepare sample-size/analysis, device accountability, adverse-event and device-deficiency reporting, stopping and monitoring plans.
6. Connect consent, ethics/regulatory review, risk management and follow-up to the device version and intended claim.
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 device version changes mid-study. Assess whether risk, comparability, protocol, consent and regulatory approvals need revision before combining outcomes.

Result and Interpretation

- Deliver a plan synopsis, assessment schedule, device-accountability form and safety 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.

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