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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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