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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.

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