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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.

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