



REPUBLIC OF KOREA IVD REGULATORY MAP

A practical orientation for global RA teams entering the Republic of Korea

START HERE: WHAT IS THE PRODUCT IN KOREA?

1 Confirm Korean regulatory identity

Confirm the intended use, product family, and whether the item is an IVD reagent, analyzer/instrument, or software/other. Classification and licensing route depend on intended use, risk, and MFDS framework.



IVD reagent



Analyzer / instrument



Software / other

2 Choose the regulatory route

CLASS I



Low risk

Generally low individual risk to the public.
Generally follows **notification**.

CLASS II



Low-moderate risk

Moderate individual risk.
Route may be certification or approval depending on product.

CLASS III



High risk

High individual risk.
Generally requires **approval** under MFDS.

CLASS IV



Highest risk

Highest individual risk.
Generally requires **approval** under MFDS.

3 Build the Korea market-access infrastructure



MFDS framework

Understand the IVD Act, MFDS classification, licensing model, review pathways, and guidance.



Korea in-country license holder / local setup

Appoint a Korean license holder (if required) and ensure capable local representation and QMS accountability.



KGMP / technical dossier readiness

Establish KGMP compliance and prepare a complete technical dossier aligned with MFDS expectations.



Korean labeling / commercialization readiness

Ensure Korean labeling, package leaflets, IFU, and promotional claims meet MFDS requirements.

4 Build the evidence stack



Administrative

Forms, device licence application materials, site information, and market history.



Quality / KGMP-QMS

KGMP-complaint QMS aligned to Korean standards (e.g., ISO 13485).



Analytical performance

Method performance, precision, accuracy, reportable range, interference, and comparability.



Clinical / scientific performance

Clinical performance or scientific evidence supporting intended use, risk controls, and claims.



Labeling & IFU

Korean labeling and package leaflet (KR), warnings, claims, and instructions.



RA TRAP TO AVOID

Do not begin with "What is the Korea timeline?" Begin with product identity → classification → licensing route → Korean labeling → market-access infrastructure → evidence gaps.
The timeline is the result of those decisions.



STRATEGIC INSIGHT:

In Korea, route selection, local representation, KGMP compliance, and technical-document review are key drivers of review time and outcome. Plan early to avoid costly delays.



REPUBLIC OF KOREA IVD: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch

A Program flow



B What gets heavier as the class rises?

Signal	CLASS I	CLASS II	CLASS III	CLASS IV
Pathway intensity	Notification	Certification	Approval	Approval
Analytical performance	Basic ●●○○○	Moderate ●●●○○	High ●●●○○	Very high ●●●●○
Clinical / scientific support	Not usually required ○○○○	Limited / targeted ●●○○○	Moderate ●●●○○	Extensive ●●●●○
QMS / KGMP readiness	Basic ●●○○○	Moderate ●●●○○	High ●●●○○	Very high ●●●●○
Post-market control	Lower ●●○○○	Moderate ●●●○○	Higher ●●●○○	Highest ●●●●○

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on product complexity, evidence quality, application completeness, review workload, and other factors.



Certification review target: 5 days from receipt of a complete application.	Approval review target: 10 days from receipt of a complete application (excluding technical document review).	Technical-document review target: 55 days (clock may stop for supplement requests).	Clinical-report review target: 70 days where clinical evidence review is required.
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These published review targets are planning cues. Actual timing varies.

D Labeling & language essentials

Korean-language support Key labeling, IFU, and instructions must be in Korean. Bilingual use may be required.	Product labeling Accurate, unambiguous labeling with proper warnings, precautions, and symbols.	Instructions for use (IFU) Provide clear IFU in Korean. Include intended use, procedures, and interpretation guidance.	Claims control Claims must be supported by evidence and consistent with intended use.	Product identifier / traceability docs Include UDI/DI, lot/serial info, and traceability documentation as required.
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PRIMARY RESOURCES USED FOR THIS TRAINING AID

- Ministry of Food and Drug Safety (MFDS) — Medical Devices: <https://www.mfds.go.kr/eng/index.do?mid=727>
- MFDS — e-MDR (G-Pass) Medical Device Information System: <https://emed.mfds.go.kr>
- MFDS — Review & Approval Procedures for Medical Devices: https://www.mfds.go.kr/eng/brd/m_99/view.do?seq=40822
- MFDS — Medical Device QMS (KGMP) Guidance: https://www.mfds.go.kr/eng/brd/m_99/view.do?seq=40829
- Honestone Capital & Consulting: <https://hopestonecapital.com>



IMPORTANT: Product-specific Korean requirements, current MFDS guidance, and applicable laws govern.

Always confirm your classification, route, evidence needs, labeling, and timelines with official MFDS sources before execution.



STRATEGIC INSIGHT:

Plan early, align evidence to the route, and track MFDS guidance updates to keep your timeline on target.