JAPAN IVD REGULATORY MAP

A practical orientation for global RA teams entering Japan

START HERE: WHAT IS THE PRODUCT IN JAPAN?

1 Confirm Japanese regulatory identity

EU/FDA assumptions do not transfer directly. Confirm whether the product is an IVD reagent, analyzer/instrument, or software/other, because Japan route and nomenclature can differ.

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS I

Lower diagnostic-information risk

Notification / self-certification

Todokede route; no PMDA technical review.

CLASS II

Controlled IVD

Certification OR approval

If certification standards apply -> Registered Certification Body (Ninsho). Otherwise -> MHLW approval after PMDA review.

CLASS III

Higher diagnostic-information risk

Ministerial approval

PMDA review -> MHLW approval; novel markers, genetic/cancer tests and CDx commonly sit here.

Japan IVDs are classified into Classes I – III only (no Class IV).

3 Build the Japan market-access infrastructure

J-MAH

Japan-based Marketing Authorization Holder manages the route and post-market obligations.

Foreign manufacturer registration

Required manufacturing sites/processes must be appropriately registered for Japan.

QMS

Japan QMS Ordinance / MO169; inspection may be document-based or on-site; MDSAP reports may support conformity.

Japanese localization

Application content, labeling/package insert and operating documents require planned Japanese localization.

4 Build the evidence stack

Administrative
MAH/manufacturing sites/application forms/foreign-market history.

Quality
Specifications/stability/manufacturing method/QMS evidence.

Performance
Analytical performance/correlation/reference methods/risk management.

Clinical / scientific
Clinical performance when needed; higher scrutiny for novel, genetic, cancer and CDx claims.

Labeling & IFU
Japanese labeling, package insert, operating instructions, intended use wording, claims control.

RA TRAP TO AVOID

Do not begin with "What is the Japan timeline?" Begin with product identity -> Japanese classification/nomenclature -> applicable standard -> route -> evidence gap -> MAH/site readiness. The timeline is a result of those decisions.

STRATEGIC INSIGHT:

Analyzer/instrument pathways without assay-specific diagnostic claims can be simpler and faster than full assay routes.

JAPAN IVD: HOW THE WORK ACTUALLY FLOWS

From strategy to authorization — with the decision points a newer RA professional should watch

A Program flow

1. **Scope** — IVD vs device? Intended use?
2. **Classify** — Class I / II / III Japanese category
3. **Standards** — Certification or approval criteria?
4. **Local setup** — J-MAH + site registration + QMS
5. **Evidence** — Analytical + correlation + clinical
6. **Submit** — Todokede / Ninsho / Shonin
7. **Launch** — Japanese labeling + post-market system

B What gets heavier as the class rises?

Signal	CLASS I	CLASS II	CLASS III
Premarket pathway	Todokede	Ninsho or Shonin	Shonin
Evidence intensity	Lower ●○○○○	Moderate ●●○○○	High ●●●●○
Analytical / correlation	Core ●●○○○	Stronger support ●●●○○	Detailed ●●●●●
Comparator strategy	Simple ●○○○○	Comparator support important ●●●○○	Multiple comparators may be needed ●●●●○
Clinical / scientific support	Selective ●○○○○	Sometimes needed ●●○○○	Often important ●●●●●
Manufacturing / QMS readiness	Basic-moderate ●●○○○	High ●●●●○	Very high ●●●●●
Post-market control	Lower ●○○○○	Higher ●●●○○	Highest ●●●●●

C Indicative route-based planning ranges

Illustrative planning ranges for timing only — actual timing depends on MAH readiness, FMR, QMS, translation/localization, comparator strategy, and study requirements.

Classes I–II may use notification or certification routes depending on category and standards.

Ordinary PMDA approval targets are often cited around 7 months; expert-review or CDx products around 12 months, but total project timing can be longer.

D Labeling & language essentials

- Plan Japanese support for the submission and commercialization package.
- Product labeling should reflect the approved Japanese intended use and classification.
- Package insert / instructions for use / operating manuals are required.
- Claims control matters — commercial claims must stay aligned with the approved indication and dossier.
- Verify JMDN/ category, standards, and product-specific documentation expectations case by case.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- PMDA review services: pmda.go.jp/english/review-services/reviews/0004.html
- PMDA IVD overview: pmda.go.jp/files/000266824.pdf
- PMDA foreign manufacturer registration information
- Hopestone Capital & Consulting: hopestonecapital.com
- Template also reflects screening-level requirement tags from Hopestone's internal global device requirements workbook.

Important: Product-specific Japan notifications, standards and recent regulatory changes govern. Confirm current requirements before execution.

