



JAPAN MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Japan



START HERE: WHAT IS THE PRODUCT IN JAPAN? ▶

1 Confirm Japan regulatory identity

Confirm intended use, users, device or SaMD status, invasiveness, implantability, sterility, active/electrical features, whether applicable certification standards exist, and whether claims fit a known device category.



General medical device



Sterile / implantable / invasive



SaMD / active / special

2 Choose the regulatory route

CLASS I



Extremely low risk

Notification route

Notification to PMDA through a Japan MAH.

CLASS II



Low risk

Certification or approval

If certification standards exist, use Registered Certification Body (RCB) certification; otherwise MHLW approval after PMDA review.

CLASS III



Medium risk

Certification or approval

Some devices with certification standards may be certified; other products require MHLW approval after PMDA review.

CLASS IV



High risk

Approval route

MHLW approval after PMDA review, usually with the highest evidence burden.

In Japan, both class and certification-standard availability drive the pathway.
Not every Class II or Class III device follows the same route.

3 Build the Japan market-access infrastructure



PMD Act / PMDA + MHLW

Use the PMD Act framework; PMDA performs reviews and post-market safety work, while MHLW grants approvals.



Japan MAH / D-MAH

Foreign manufacturers commercialize through a Japan-based Marketing Authorization Holder or Designated MAH.



Foreign manufacturer + QMS readiness

Confirm foreign-manufacturer accreditation status and prepare for QMS conformity assessment and site oversight.



Japanese labeling / launch readiness

Build Japanese labeling, package-insert, and commercialization readiness into the plan.

4 Build the evidence stack



Administrative

Device description, intended use, class rationale, route logic, and application records.



Quality / QMS

Design and manufacturing controls, supplier oversight, and QMS documentation.



Nonclinical / V&V

Bench, electrical safety, EMC, biocompatibility, sterilization, software V&V, and usability as applicable.



Clinical evaluation

Literature, clinical evaluation rationale, and clinical evidence or trial support where needed.



Labeling & IFU

Japanese labeling, package insert, warnings, precautions, and instructions aligned to the approved content.



RA TRAP TO AVOID

Do not assume all Class II devices are third-party certifiable. Check certification-standard availability and precedent first.



STRATEGIC INSIGHT

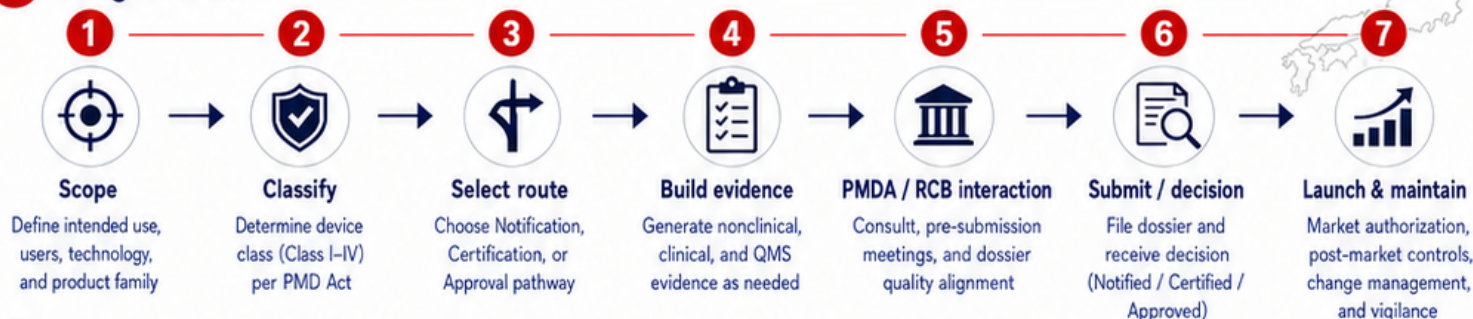
A clean early decision on certification-standard availability can save major time and cost in Japan.



JAPAN MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

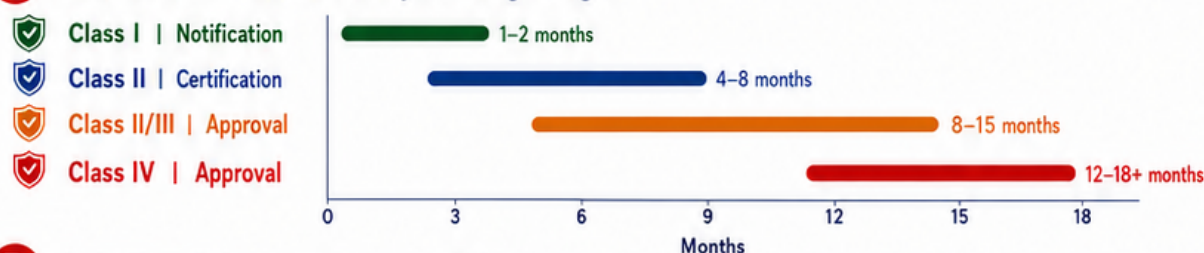


B What gets heavier as the class rises?

Signal	Class I	Class II	Class III	Class IV
Pathway intensity	Notification ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Nonclinical evidence	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical evidence	Usually limited ● ● ● ● ●	Case-dependent ● ● ● ● ●	Often stronger ● ● ● ● ●	Strongest ● ● ● ● ●
QMS scrutiny	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Post-market control	Lower ● ● ● ● ●	Moderate ● ● ● ● ●	Higher ● ● ● ● ●	Highest ● ● ● ● ●

i Note: Some Class II and Class III devices may follow certification or approval depending on certification-standard availability.

C Indicative route-based planning ranges



Planning ranges are Hopestone estimates, not PMDA or MHLW review promises. Actual duration depends on route, dossier maturity, QMS readiness, translations, and questions during review.

D Labeling & language essentials



Japanese-language labeling & IFU
Labeling and IFU must be in Japanese and consistent with the approved or certified content.



Package insert alignment
Ensure Japanese package insert matches approved/certified information exactly.



Claims control
Claims must be supported by approved evidence and limited to authorized performance statements.



Product-specific warnings / symbols
Include required warnings, precautions, contraindications, and symbol labeling per Japanese requirements.

E Primary resources used for this training aid



- **PMDA Device Reviews (Overview)**
pmda.go.jp/english/review-services/reviews/0004.html
- **PMDA Review Process (Consultation & Pre-submission)**
pmda.go.jp/english/review-services/reviews/0009.html

- **PMDA QMS / GMP / GCTP Guidance**
pmda.go.jp/english/review-services/gmp-qms-gctp/0003.html
- **About PMDA (Roles & Functions)**
pmda.go.jp/english/about-pmda/0004.html



IMPORTANT:

Product-specific classification, certification standards, and current PMDA / MHLW expectations govern. Confirm current route before execution.



JAPAN MEDICAL DEVICE: EXECUTION DETAILS & HIGH-RISK DECISION POINTS

Use this page to identify the issues most likely to change route, evidence burden, or launch timing.



E Country-specific decision points

1 Certification standards check For Class II and some Class III devices, confirm early whether a certification standard exists. This determines RCB certification versus approval.	2 Implantable / invasive use Implantability, invasiveness, duration of contact, and user setting can elevate class and evidence needs.	3 Sterile products Sterile claims raise expectations for sterilization validation, packaging integrity, shelf life, and related controls.
4 Active / software / connected Electrical safety, EMC, usability, cybersecurity, and software lifecycle documentation may become central dossier elements.	5 Clinical evaluation route Decide whether literature, equivalent-device experience, or direct clinical data will be necessary to support safety and effectiveness.	6 Japan-market setup Clarify J-MAH or D-MAH roles, foreign manufacturer accreditation, QMS conformity, import setup, and local responsibilities.

F Regulatory readiness checklist

- ☐ 1. Intended use and claims frozen
- ☐ 2. Classification and route logic documented
- ☐ 3. Certification-standard availability checked
- ☐ 4. J-MAH or D-MAH assigned
- ☐ 5. QMS and manufacturing evidence ready
- ☐ 6. Clinical evaluation strategy defined
- ☐ 7. Japanese labeling/IFU/package-insert plan ready
- ☐ 8. Change control and vigilance responsibilities mapped

G High-impact practical notes

 Change control Approved/certified products need disciplined management of changes and amendments.	 Post-market vigilance The MAH and related parties must manage adverse event reporting and post-market actions.	 SaMD / special technologies Software and connected products require special attention to lifecycle documentation and review expectations.
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USE THE TIMELINES AS PLANNING RANGES, NOT REGULATORY PROMISES

Actual duration depends on classification, route, dossier quality, translations, QMS readiness, and PMDA / MHLW or RCB review questions.



Accuracy review basis: current official PMDA / MHLW sources accessed Aug 2026. Verify product-specific requirements at execution.

