UNITED STATES IVD REGULATORY MAP

A practical orientation for global RA teams entering the U.S.

START HERE: WHAT IS THE PRODUCT IN THE U.S.?

1 Confirm product identity & intended use

Confirm the intended use, target population, and operating environment. Determine whether the item is an IVD reagent, analyzer/instrument, software/other, or potentially Laboratory Use / Research Use Only (RUO) outside IVD regulatory scope.

Boundary check: Could this be Laboratory Use (RUO/LDT) rather than an IVD?

- IVD reagent
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS I

Lowest risk

Exemptions may apply

Subject to general controls (e.g., QSR, labeling) and product code–specific exemptions.

CLASS II

Moderate risk

Usually 510(k)

Substantially equivalent to a predicate device. Some novel devices may qualify for De Novo.

CLASS III

Highest risk

PMA or other high-scrutiny pathway

Premarket Approval (PMA) typically required. Substantial clinical evidence and manufacturing controls. HDE or other routes may apply.

3 Build the U.S. market-access infrastructure

FDA regulatory framework

Understand device classification, listing, and submission requirements. Use the Right Combination (product code) to define the pathway.

U.S. Agent / local setup

Foreign manufacturers must designate a U.S. Agent. Establish commercial presence or distributor strategy as needed.

Establishment registration & device listing

Register the manufacturing site(s) with FDA and list each device (with product codes) prior to submission and before commercialization.

Labeling & commercialization readiness

Ensure U.S. labeling, UDI, and claims alignment. Prepare for imports, distribution, and post-market reporting obligations.

4 Build the evidence stack

Administrative
Forms, commitments, device description, predicate information, checklists, and cover letters.

Quality
QMS per 21 CFR 820 (QSR), processes, risk management, and CAPA.

Analytical performance
Verification & validation data, accuracy, precision, robustness, and method comparison.

Clinical / scientific
Clinical studies or literature, usability, interference, and benefit–risk support.

Labeling & IFU
U.S. labeling and IFU with intended-use & claims aligned to the product code.

RA TRAP TO AVOID

Do not begin with "What is the U.S. timeline?"
Begin with product identity → product code (Right Combination) → predicate strategy → intended-use wording → evidence gaps.
The route and timeline are the result of those decisions.

STRATEGIC INSIGHT

Product code, predicate strategy, and intended-use wording drive the pathway, submission type, and review clock.
Get these right first.

Training overview — verify current device-specific requirements with FDA and your U.S. Agent. Not legal advice.

UNITED STATES IVD: HOW THE WORK ACTUALLY FLOWS

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

A Program flow

1. **Scope** — IVD use? Intended use?
2. **Classify / Product code** — Determine class and product code
3. **Predicate strategy** — Identify predicate or De Novo path
4. **Local setup** — U.S. agent, registration & UDI
5. **Evidence** — Analytical + clinical as needed
6. **Submit** — 510(k), De Novo or PMA
7. **Launch / maintain** — Communicate, monitor, update

B What gets heavier as the class rises?

Signal	CLASS I	CLASS II	CLASS III
Premarket pathway	Exempt entry (no premarket submission)	510(k)	PMA
Evidence intensity	Low ●○○○○	Moderate ●●●○○	High ●●●●●
Analytical performance	Basic ●○○○○	Moderate ●●●○○	Extensive ●●●●●
Clinical / scientific support	Not typically required ●○○○○	Often needed ●●●○○	Typically required ●●●●●
Manufacturing / QMS readiness	Basic ●○○○○	Moderate ●●●○○	High ●●●●○
Post-market control	General controls ●○○○○	Special controls ●●●○○	Intensive controls ●●●●●

C Indicative route-based planning ranges

Illustrative planning ranges for training only — actual timing depends on product type, predicate availability, data complexity, FDA review, third-party timelines, and study requirements.

Ranges reflect typical U.S. experiences only. Complexity, completeness, and FDA workload can materially change timelines.

Priority review targets (e.g., 180 days for PMA) apply only after FDA acceptance of a complete application and are not reflected in the above planning ranges.

D Labeling & language essentials

- Use U.S. labeling conventions and U.S. English.
- Instructions for use (IFU) must be complete, accurate, and consistent with the labeling.
- Claims control matters — claims must be supported and consistent with the intended use.
- Device listing, registration, and UDI per 21 CFR Part 807.
- Product-specific documentation expectations vary by class, pathway, and FDA program.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- FDA Medical Devices overview: *www.fda.gov/medical-devices*
- 510(k) Program: *www.fda.gov/medical-devices/premarket-submissions/510k*
- De Novo Classification Request Program: *www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-requests*
- Premarket Approval (PMA): *www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma*
- FDA Registration & Listing: *www.fda.gov/medical-devices/device-registration-and-listing*
- Hopestone Capital & Consulting: hopestonecapital.com

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

