MEXICO IVD REGULATORY MAP

A practical orientation for global RA teams entering Mexico.

1 START HERE: WHAT IS THE PRODUCT IN MEXICO?

Confirm the intended use and product family, and whether the item is an IVD reagent/kit, analyzer/instrument, or software/other. Commercialization of IVDs in Mexico is overseen by **COFEPRIS**.

- IVD reagent / kit
- Analyzer / instrument
- Software / other

2 Choose the regulatory route

CLASS I

Low risk

Sanitary registration route

Least complex dossier. Typical for lower-risk IVDs with well-established performance.

CLASS II

Moderate risk

Sanitary registration route

Stronger technical and performance evidence. Greater review depth by COFEPRIS.

CLASS III

High risk

Sanitary registration route

Highest evidence requirements and review intensity. For life-supporting or high-impact IVDs.

For eligible products, Mexico may also allow a **Vía Reliance / abbreviated route** based on approvals from recognized reference authorities. Confirm eligibility with current **COFEPRIS** criteria.

3 Build the Mexico market-access infrastructure

COFEPRIS framework
Comply with the General Health Law, Health Regulations on Medical Devices, and applicable Official Mexican Standards (NOMs) overseen by COFEPRIS.

Mexican registration holder / local representative
Appoint a Mexican legal entity or *importador autorizado* responsible for registration, importation, post-market compliance, and vigilance.

Spanish localization & submission language
Prepare the dossier in Spanish. All labeling, IFU, and promotional materials must be in Spanish for review and market.

Product-specific testing / standards / QMS readiness
Align testing with NOMs and international standards where accepted. Ensure QMS compliance (e.g., ISO 13485) and audit readiness.

4 Build the evidence stack

Administrative
Application forms, product details, legal certificates, free sale certificate, PoA, and local representative docs.

Quality
QMS (ISO 13485), design controls, manufacturing controls, supplier management, and risk management.

Analytical performance
Analytical sensitivity & specificity, precision, accuracy, cut-offs, interferences, reportable range, and stability.

Clinical / scientific
Clinical or scientific evidence supporting safety and performance based on risk and intended use.

Labeling & IFU
Spanish labeling and IFU with intended use, indications, contraindications, warnings, precautions, symbols, and UDI (if applicable).

RA TRAP TO AVOID

Do not start with timeline assumptions. Begin with product identity → classification → regulatory route (including reliance eligibility) → Spanish-ready documentation. The timeline is the result of those decisions.

STRATEGIC INSIGHT

Product class, reliance eligibility, and Spanish-ready documentation are the biggest drivers of timing and review outcomes. Plan early and align to COFEPRIS expectations.

Training overview — verify current product-specific requirements with COFEPRIS and local experts. Not legal advice.

MEXICO 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** — Define intended use, population, and specimen type.
2. **Classify** — Determine risk class (I, II, or III) per COFEPRIS rules.
3. **Local holder setup** — Establish or confirm Mexico registration holder (RA & QPPV as applicable).
4. **Testing / standards** — Plan tests & compliance to Mexican Official Standards (NOMs) and applicable guidance.
5. **Evidence** — Compile technical file in Spanish with performance & safety evidence.
6. **Submit** — File dossier in Spanish via COFEPRIS eCOFEPRIS platform (ventanilla única).
7. **Launch & maintain** — Obtain sanitary registration; fulfill post-market obligations and renewals.

B What gets heavier as the class rises?

Signal	CLASS I	CLASS II	CLASS III
Premarket pathway	Simplified notification pathway	Sanitary registration	Sanitary registration
Evidence intensity	Low ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High ● ● ● ● ○
Analytical performance	Basic ● ○ ○ ○ ○	Moderate ● ● ○ ○ ○	High / comprehensive ● ● ● ● ○
Clinical / scientific support	Not usually required ● ○ ○ ○ ○	Limited as applicable ● ● ○ ○ ○	Extensive ● ● ● ● ○
Manufacturing / QMS readiness	Basic ● ○ ○ ○ ○	Strong ● ● ● ○ ○	Very strong ● ● ● ● ●
Post-market control	Basic vigilance ● ○ ○ ○ ○	Enhanced vigilance ● ● ● ○ ○	Intensive vigilance ● ● ● ● ●

C Indicative route-based planning ranges

These are Hopestone planning estimates, not official review clocks. Actual duration depends on class, dossier quality, COFEPRIS workload, and reliance eligibility.

D Labeling & language essentials

- **Spanish-language support** — All labels, IFU, and dossier documents must be in Spanish.
- **Product labeling** — Labels must include mandatory Spanish information per COFEPRIS rules and align with approved intended use.
- **Instructions for use** — Spanish IFU required with clear instructions, symbols, and safety information.
- **Claims control** — Claims must align to approved intended use and be truthful, verifiable, and not misleading.
- **Product identifier & documentation** — Use traceable Unique Device Identifier (UDI) and maintain records with document control.

PRIMARY RESOURCES USED FOR THIS TRAINING AID

- COFEPRIS device information pages: gob.mx/cofepris/en/tramites-y-servicios/informacion-de-dispositivos-medicos
- **Sanitary registration pages** (national & foreign products): gob.mx/cofepris/en/tramites-y-servicios/registros-sanitarios
- **Via Reliance page:** gob.mx/cofepris/en/tramites-y-servicios/via-reliance
- **Technovigilance page:** gob.mx/cofepris/en/tramites-y-servicios/tecnovigilancia
- Hopestone Capital & Consulting: hopestonecapital.com

IMPORTANT: Product-specific requirements, standards, and current regulatory changes govern. Confirm current requirements before execution.

