



# MEXICO MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering Mexico

## START HERE: WHAT IS THE PRODUCT IN MEXICO? ▶

### 1 Confirm Mexican regulatory identity

Confirm intended purpose, users, claims, technology, and whether the item is a medical device under COFEPRIS expectations. Identify whether it is equipment, implant/prosthetic or other specialty type, consumable/material, or software/connected technology. Determine the risk classification and whether the product may use the abbreviated RELIANCE route based on recognized foreign approvals.



General medical device



Class / specialty check



Software / other

### 2 Choose the Mexican regulatory route

#### CLASS I



Lowest risk

Well-known products with lower risk.

#### CLASS II



Moderate risk

Moderate risk with broader technical requirements.

#### CLASS III



Highest risk

Highest risk or more novel devices with the deepest review.

#### RELIANCE



Abbreviated route

Abbreviated route based on recognized foreign approvals/equivalency where eligible.

Class, product type, and route eligibility determine the submission path.

### 3 Build the Mexico market-access infrastructure



#### COFEPRIS framework

Sanitary registration through COFEPRIS.



#### Mexican registration holder / importer

Define the local registration holder and import responsibilities.



#### Technical dossier / GMP readiness

Prepare technical-scientific evidence, manufacturing information, and good manufacturing / quality support.



#### Spanish labeling / launch readiness

User materials, instructions / manuals, and key labeling content should be ready in Spanish.

### 4 Build the evidence stack



#### Administrative

Company details, device description, intended use, claims, classification, and regulatory history.



#### Quality / GMP / QMS

QMS aligned with ISO 13485, GMP certificates, supplier controls, process validation, and CAPA.



#### Safety / performance

Bench testing, biocompatibility, EMC/electrical safety, sterilization, software validation, usability, and risk management.



#### Clinical / technical support

Clinical evaluation, literature, bench data, and performance evidence per COFEPRIS expectations.



#### Labeling & IFU

Spanish labeling and IFU with safety warnings, claims, and use instructions.



#### RA TRAP TO AVOID

Do not start with "What is the Mexico timeline?" Start with device type, class, and whether RELIANCE is available; local-holder setup and Spanish documentation drive timing.



#### STRATEGIC INSIGHT:

Where eligible, RELIANCE can compress timelines, but non-eligible or higher-risk products need fuller technical review.



# MEXICO MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

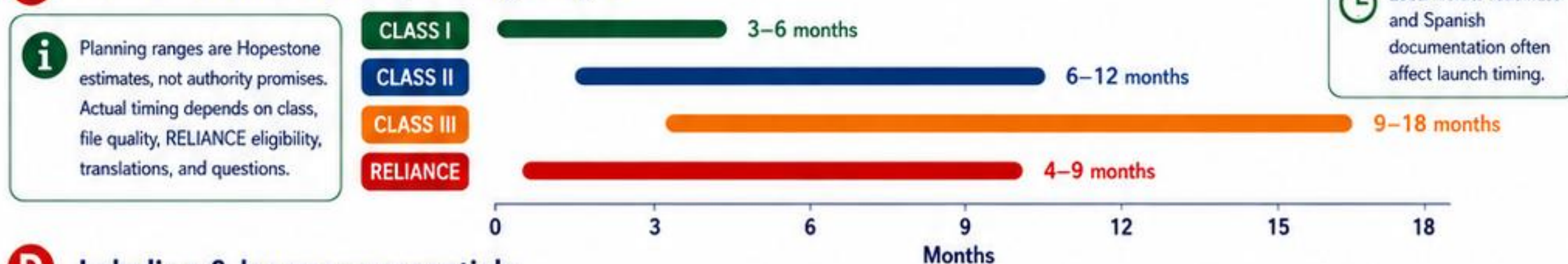
From classification to commercialization — with the decision points a newer RA professional should watch



## B What changes as route complexity rises?

| Signal                        | CLASS I                   | CLASS II           | CLASS III             | RELIANCE                                           |
|-------------------------------|---------------------------|--------------------|-----------------------|----------------------------------------------------|
| Pathway intensity             | Lowest ● ● ● ● ●          | Moderate ● ● ● ● ● | High ● ● ● ● ●        | Reduced when eligible ● ● ● ● ●                    |
| Evidence intensity            | Basic ● ● ● ● ●           | Moderate ● ● ● ● ● | High ● ● ● ● ●        | Reduced duplicative review when eligible ● ● ● ● ● |
| Clinical / scientific support | Usually limited ● ● ● ● ● | Targeted ● ● ● ● ● | Significant ● ● ● ● ● | Targeted ● ● ● ● ●                                 |
| Quality system readiness      | Basic ● ● ● ● ●           | Moderate ● ● ● ● ● | High ● ● ● ● ●        | Moderate-high ● ● ● ● ●                            |
| Post-market control           | Lower ● ● ● ● ●           | Moderate ● ● ● ● ● | Higher ● ● ● ● ●      | Moderate-high ● ● ● ● ●                            |

## C Indicative route-based planning ranges



## D Labeling & language essentials

**Spanish-language support**  
All labeling, IFU, and promotional materials must be in Spanish and clear for intended users.

**Labeling content**  
Include required info: intended use, warnings, precautions, storage, symbols, manufacturer, local holder, and registration number.

**Instructions / manual**  
Provide complete Spanish IFU with use, limitations, setup, maintenance, and troubleshooting.

**Claims control**  
Claims must match approved indications and be consistent across labeling, IFU, and promotional content.

**Registration / records**  
Maintain current registration documents, variations, renewals, and correspondence for at least 5 years.



### PRIMARY RESOURCES USED FOR THIS TRAINING AID

- COFEPRIS – Dispositivos Médicos (Información para la salud)  
<https://www.gob.mx/cofepris/acciones-y-programas/dispositivos-medicos>
- COFEPRIS – RELIANCE (Reconocimiento de Autoridades Reguladoras)  
<https://www.gob.mx/cofepris/acciones-y-programas/reliance>
- COFEPRIS – Trámites: Registro Sanitario de Dispositivos Médicos  
<https://www.gob.mx/cofepris/tramites-y-servicios/registro-sanitario-de-dispositivos-medicos>
- Hoystone Capital & Consulting — [hopestonecapital.com](https://hopestonecapital.com)



### IMPORTANT

Product-specific Mexican requirements and current COFEPRIS expectations govern. Confirm current requirements before execution.