LATAM REGULATORY GUIDES · MEXICO

COFEPRIS Regulatory Translation Requirements: The Complete Guide for Drugs and Medical Devices in Mexico

The Reglamento de Insumos para la Salud rule set — Arts. 16, 24, 161 fr. III and 179 — plus Tercero Autorizado routing, dual-body ethics review, and Mexican-variant terminology.

Julio G. Martinez-Clark · CEO bioaccess® · Founder Amavita Sciences ·

Last updated August 25, 2026 · ~29 min read · Version 1.5.0

ON THIS PAGE

The direct answer

The Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) is Mexico's health regulator, established by presidential decree as an *órgano desconcentrado* of the Secretaría de Salud with technical, administrative, and operational autonomy (Decreto de creación de COFEPRIS). The controlling translation instrument is the Reglamento de Insumos para la Salud (RIS): Art. 16 RIS requires that all documentation used in the manufacturing and commercialization process of health supplies be in Spanish, Art. 24 RIS and Art. 179 fr. II–III RIS require Spanish labeling and Spanish *instructivo*/operating manual for devices, and Art. 161 fr. III RIS requires that representation letters from foreign entities be in Spanish or translated by a

perito traductor (court-authorized expert translator) and authenticated per the country of origin (RIS). Clinical trials run through COFEPRIS with parallel dual-body ethics review — a Comité de Ética en Investigación (CEI) plus the institution's research committee — and only Spanish versions of protocol, Investigator's Brochure and ICF are approved (ClinRegs Mexico). COFEPRIS is one of the two LATAM regulators with the highest RFI rates on translation grounds in Amavita's 24-month internal casework (Amavita, RFI Anatomy).

This guide is a complete reference for Spanish (Mexican variant) regulatory translation into the COFEPRIS framework — drugs and devices, market access, market clearance, and clinical research. It is written for sponsors, CROs, in-house regulatory affairs teams, and CMOs conducting Mexican market entry or maintaining Mexican registrations.

A. Regulator profile

Agency name: Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS) — Federal Commission for Protection against Sanitary Risk.

Establishing statute: Presidential decree creating COFEPRIS as an *órgano desconcentrado de la Secretaría de Salud* with technical, administrative, and operational autonomy (Art. 1 of the creation decree) (Decreto de creación).

Jurisdictional scope: Art. 2 of the creation decree assigns sanitary regulation, control, and promotion over medicines and *insumos para la salud* (health supplies), food, beverages, cosmetics, tobacco products, pesticides, biotechnology products, and occupational and environmental health risks. Art. 10 assigns the device dossier evaluation function, the pharmacovigilance programme, and the authorization of *terceros autorizados* (authorized third-party reviewers) (Decreto de creación).

Official website: gob.mx/cofepris

Headquarters: Oklahoma 14, Col. Nápoles, Alcaldía Benito Juárez, CP 03810, Ciudad de México (ClinRegs Mexico).

Adjacent bodies you must coordinate with

Body	Role
Comité de Ética en Investigación (CEI) — institution-level	Ethics approval mandatory and parallel to COFEPRIS; must approve the Spanish ICF before COFEPRIS authorization; only Spanish versions of protocol, IB and ICF are approved (ClinRegs Mexico)

Body	Role
Institutional research committee and biosafety committee	Second and third parallel institutional reviews required alongside CEI ethics review (ClinRegs Mexico)
Consejo de Salubridad General (CSG)	Maintains the *Compendio Nacional de Insumos para la Salud* — the national listing instrument for public-sector market access; inclusion requests are filed by the *Representante Legal* by e-mail, with a public consultation portal at acnis.csg.gob.mx (CSG)
Comisión Coordinadora para la Negociación de Precios (CCNPMIS)	Sole federal body authorized to negotiate, annually, prices of patented or single-source medicines and health supplies purchased by the public system; created by presidential agreement published in the *Diario Oficial de la Federación* on 26 February 2008; members include Hacienda, Economía, Salud, IMSS, and ISSSTE (CCNPMIS)
Centro Nacional de Farmacovigilancia (CNFV)	Receives adverse-event notifications, periodic safety reports (*RPS*), and clinical-study safety reports under NOM-220-SSA1-2016 (DOF, NOM-220-SSA1-2016)

Mexican submissions do not go to COFEPRIS alone. A properly-executed Mexican trial or registration requires coordinated filings across COFEPRIS (regulatory), CEI plus the institutional research committee (dual ethics), CSG plus CCNPMIS (economic and public-sector access), and CNFV (pharmacovigilance). Vendors who treat COFEPRIS as a single-agency submission produce packages that fail cross-body review.

B. Official language requirements

Mexico's official working language for regulatory submissions is Mexican Spanish, and the controlling instrument is the Reglamento de Insumos para la Salud (RIS).

The general rule — RIS Art. 16

All specifications, analytical techniques, and documentation used in the manufacturing and commercialization process of health supplies must be in Spanish (RIS).

Labeling — RIS Art. 24

Labels of health supplies must be in Spanish (RIS).

Devices — RIS Art. 179 fr. II–III

For medical devices, the label and the *instructivo* / operating manual must be presented in Spanish. Arts. 184 and 205 duplicate this Spanish-labeling obligation across the affected supply categories (RIS).

Foreign-authority documents — RIS Art. 161 fr. III

Representation letters and other legal-status instruments issued by foreign authorities must be in Spanish or translated by a *perito traductor* and authenticated per the law of the country of origin (RIS).

The technical-content practical band

For CTD technical modules, Amavita's regulator comparison records COFEPRIS as accepting English technical content with a Spanish summary, while legal-status documents require Spanish sworn translation (Amavita, Which Regulators Accept English Dossiers).

The preclinical/technical carve-out

For preclinical reports, Art. 153 RIS and the DOF procedure catalogue are the operative references: a *perito traductor* is required only for documents issued by a foreign authority, and *traducción simple* endorsed by the *responsable sanitario* is accepted otherwise (Amavita, Preclinical LATAM).

Clinical trial specifics

- Protocol, Investigator's Brochure, and ICF: Spanish required; only Spanish versions are approved by the CEI and research committee (ClinRegs Mexico)
- Foreign-Regulatory-Authority (FRA) reliance route: certified/legalized/apostilled copy of the foreign authorization with Spanish translation; protocol and IB may be filed in English with Spanish translations
- Foreign documents supporting investigational-product import: Spanish translation by an "expert translator"
- Pharmacovigilance reports under NOM-220-SSA1-2016: MedDRA-coded clinical manifestations required (§8.1.10.1); ICH-E2B-compliant formats required (§8.1.12.2); the norm as fetched does not state an explicit Spanish-language mandate for *RPS*/PSUR/PBRER — practical band is Spanish because the receiving agency is CNFV (DOF, NOM-220)

Register and terminology expectations

- All dossiers are reviewed in Mexican Spanish — the delivery variant. Vendors who deliver *castellano* (Iberian Spanish) or *español rioplatense* introduce register mismatch that COFEPRIS reviewers flag (Amavita, Regulatory Language Infrastructure).
- NOM-220-SSA1-2016 mandates MedDRA for adverse event terminology.
- Numeric format defect risk is elevated for Mexican submissions: decimal-comma vs decimal-point defects are a documented COFEPRIS RFI trigger (see Section F).

C. Sworn vs certified vs simple translation

Document tier	Requirement	Legal basis
Foreign legal instruments (representation letters, foreign-authority certificates, GMP certificates, CPPs)	Spanish or translated by a *perito traductor* and authenticated per the law of the country of origin	RIS Art. 161 fr. III (RIS)
Narcotics import invoices	Consular-certified invoice	RIS Art. 134-B fr. II (RIS)
Foreign clinical-trial authorization (FRA reliance)	Certified/legalized/apostilled copy of the foreign authorization with Spanish translation	ClinRegs Mexico
Foreign documents supporting investigational-product import	Spanish translation by an "expert translator"	ClinRegs Mexico
Technical/preclinical reports	No sworn translator required; *traducción simple* endorsed by the *responsable sanitario*	Amavita, Preclinical LATAM
ICF (Spanish)	Prepared in Spanish and approved by CEI before COFEPRIS authorization; no sworn translation of the ICF itself	ClinRegs Mexico

Who qualifies as *perito traductor*

A *perito traductor* is authorized at state judicial level — not federal. Each state's Tribunal Superior de Justicia (or equivalent) maintains its own registry of court-authorized expert translators. Documents used for CPPs, GMP certificates, and legal-representation instruments require translation by a *perito traductor* from a state registry (Amavita, Sworn vs Certified).

Apostille sequencing

The correct order is original → apostille → sworn translation → binding. Sworn translation applies only to documents that create or prove legal standing (powers of attorney, corporate authorizations, health-authority certificates). Vendors who sworn-translate the apostille itself, or who apply sworn translation to technical CMC content, waste 30-70% of translation cost and produce packages that add cost without adding compliance value (Amavita, Costly Translation Mistakes).

Document currency (seventh QC gate)

Foreign certificates, apostilles, and notarized instruments must be within their jurisdictional validity window at the time of submission. Mexico's rule set does not carry an explicit expiry statute the way Peru does (2-year foreign-document expiry), but stale foreign-authority certificates trigger COFEPRIS deficiency notices. Amavita's seventh QC gate — Document Currency — verifies that each foreign instrument in the submission set is still within the issuing jurisdiction's validity window before release (Amavita, Translation QC).

D. Preclinical / non-clinical documentation — the three operational questions

Mexico is the jurisdiction where sponsors most often assume the worst case — full perito traductor certification of the entire non-clinical stack — and pay for it. The statute is narrower than the assumption.

D.1 Do we have to translate every page of the preclinical stack?

No. Article 153 of the Reglamento de Insumos para la Salud (RIS) scopes sworn translation to documents issued by a foreign authority: foreign marketing authorizations, certificates of free sale, GMP certificates, apostilled corporate instruments. It does not convert privately generated technical evidence — GLP toxicology reports, pharmacology and safety-pharmacology studies, ADME, toxicokinetics, biocompatibility testing — into perito-traductor territory.

What replaces the perito for technical evidence is the responsable sanitario endorsement. This is not a rubber stamp and it is not a translation certification: it is a substantive technical attestation by the Mexican-licensed responsible pharmacist or physician that the dossier content is accurate and complete as presented. The signer carries professional and administrative liability for what is inside the binder. That is why COFEPRIS can accept an English non-clinical body of evidence with a Spanish overview: an accountable Mexican professional has attested to it.

D.2 If translation IS required — is it text-only, or does it require DTP?

Text-only for everything in the perito tier — foreign authority documents are certified as running text with the perito's name, credential number, signature, and date. DTP applies elsewhere: Spanish labelling, IFU, and patient-facing material, where the deliverable is authorized artwork rather than a text file. Preclinical figures and tables reproduced inside a Spanish non-clinical summary require table-fidelity work (numeric integrity, unit consistency), but not full artwork rebuild.

D.3 If translation is NOT required — what substitutes for it?

Three substitutes carry Mexican filings: (1) a Spanish non-clinical overview per study, signed off under the responsable sanitario endorsement; (2) CTD Module 2.4 / 2.6 in Spanish over an English Module 4; (3) a Spanish study-index table mapping each untranslated report to the safety claim it supports. Regional variant matters here even in the summary layer — Mexican medical usage, not peninsular or South American Spanish, because variant drift is a first-cycle RFI driver.

The two regulatory pathways trigger different translation obligations

Every LATAM regulator operates two related but separate regulatory pathways for a sponsor's product: (1) clinical-trial authorization, which is what allows the investigational product to enter a clinical study on the sponsor's timeline; and (2) market-access / sanitary registration, which is what allows the commercial product to be sold. These pathways trigger different translation obligations. The most common sponsor error is applying a market-access translation obligation (device IFU, primary label, secondary packaging) to a clinical-trial dossier where that obligation is not yet in force.

Pathway 1 — clinical-trial authorization

- Protocol, IB, and ICF must be in Spanish for CEI / institutional research committee approval.
- Foreign health-authority letters (FDA IDE, GMP, CFS, CPP) as perito traductor translation per Art. 161 fr. III RIS.

Pathway 2 — market-access / sanitary registration

- Full Spanish labelling per NOM-072-SSA1 (drugs) and NOM-137-SSA1 (devices).
- Spanish *instructivo* / IFU per Art. 24 and Art. 179 fr. II–III RIS (DTP required).

For each document class in this guide's consolidated preclinical instruction table below, check which pathway it is scoped to before authorizing translation. A document that requires DTP-scope translation for market registration may require only text-flow translation — or no translation at all — for clinical-trial authorization.

D.4 Consolidated preclinical instruction table

Document class	Spanish required?	Statutory basis	Certification tier	DTP?	Substitute deliverable
GLP toxicology / pharmacology reports	No	Art. 153 RIS scope split	Responsable sanitario endorsement	No	Spanish Module 2.4/2.6
ADME / toxicokinetics	No	Art. 153 RIS	Responsable sanitario endorsement	No	Spanish tabulated summary
Biocompatibility (devices)	No	Art. 153 RIS	Responsable sanitario endorsement	No	Spanish justification table
Foreign marketing authorization / CPP	Yes	Art. 153 RIS	Perito traductor	No	None
GMP certificate from foreign authority	Yes	Art. 153 RIS	Perito traductor	No	None
Powers of attorney, apostilles	Yes	Art. 153 RIS + notarization	Perito traductor	No	None
Labelling, IFU, patient material	Yes	Labelling NOM + RIS	Certified + regulatory review	Yes	None
Reliance route (COFEPRIS-04-010-A) — Investigator's Brochure	Bilingual mandatory — English source + Spanish translation	Acuerdo DOF 24/03/2025, Art. 7 fr. III	None specified for the IB translation; certification/legalization/apostille attaches only to the foreign authorization letter	No	None
Reliance route (COFEPRIS-04-010-A) — research protocol	Bilingual mandatory — English source + Spanish translation	Acuerdo DOF 24/03/2025, Art. 7 fr. III	None specified	No	None

Document class	Spanish required?	Statutory basis	Certification tier	DTP?	Substitute deliverable
Reliance route (COFEPRIS-04-010-A) — foreign authority authorization letter (≤ 12 months old)	Yes (Spanish)	Acuerdo DOF 24/03/2025, Art. 7 fr. II	Certified / legalized / apostilled	No	None

Where the preclinical translation risk actually sits

In the boundary line of Art. 153, not in the volume of pages. Sponsors who send the entire non-clinical stack to a perito overspend by an order of magnitude; sponsors who treat a foreign-authority certificate as "technical" and skip the perito get a *prevención* that restarts the clock. The responsable sanitario endorsement is the load-bearing control — it must be issued by someone who actually read the untranslated evidence.

CATEGORY 1: DRUGS

D1. Drugs — Market access (pricing, reimbursement, HTA)

Mexico separates market clearance (COFEPRIS *registro sanitario*) from market access, which runs through two non-COFEPRIS bodies:

Listing — Consejo de Salubridad General (CSG)

The Compendio Nacional de Insumos para la Salud is the national listing instrument for public-sector market access. Inclusion is requested by the *Representante Legal* by e-mail, with a public consultation portal at acnis.csg.gob.mx. The CSG page carries the date 01 April 2024; the specific documents required for an inclusion request and the statutory decision timeline are not published on that page (CSG).

Price negotiation — CCNPMIS

The Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud negotiates annually the prices of patented/single-source medicines and supplies included in the *Cuadro Básico* (first level of care) and the *Catálogo de Insumos* (second and third levels), for products subject to direct award under the *Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público*. Its work is supported by a Comité Técnico Clínico, a Comité de

Evaluación Económica, and a Comité de Análisis de Precios y Patentes, coordinated by a *Secretario Técnico*. Patent-validity input comes from IMPI and sanitary-registration input from COFEPRIS (CCNPMIS).

Translation load for market access

The RIS Art. 16 rule (all commercialization-process documents in Spanish) covers the dossier that underpins CSG listing (RIS). Documents specific to the CCNPMIS economic dossier — pricing files, reference-country comparators, budget-impact analyses — are not enumerated in fetched sources.

Timelines

Negotiation frequency is annual; the Commission's presidency runs for two years; no per-application review timeline in days is stated (CCNPMIS).

D2. Drugs — Regulatory submissions for market clearance

The RIS sets statutory review clocks per pathway, and a distinctive Mexican feature: shortened clocks where a Tercero Autorizado (TA) — authorized third-party reviewer — has issued a favourable opinion.

Pathway	Statutory deadline	With Tercero Autorizado / international body	RIS article
Medicine whose active ingredient(s) are already registered in Mexico	40 days	20 days	Art. 166 (RIS)
New active ingredient already registered / freely sold abroad, or new indication	60 days	20 days	Art. 166 (RIS)
New molecules	90 days	n.a.	Art. 166 (RIS)
Enteral formulas	60 days	15 days	Art. 171 (RIS)
Vitamins	45 days	15 days	Art. 172 (RIS)
Homeopathic medicines	45 days, deemed approved if no answer	15 days	Art. 173 (RIS)
Herbal remedies	45 days	15 days	Art. 174 (RIS)
Biomedicamentos (biologics)	90 days	n.a.	Art. 177 (RIS)
Post-modification sell-off of prior labelling/stock	120 days	—	Art. 189 (RIS)

Generic interchangeability route

Inclusion in the Catálogo de Medicamentos Genéricos Intercambiables, which the CSG compiles and publishes periodically in the DOF (Art. 74 RIS). Holders of valid *registros sanitarios* apply and must show compliance with Art. 75 requirements (Art. 77 RIS) (RIS).

Documents requiring translation

- Full manufacturing/commercialization documentation set in Spanish (Art. 16 RIS)
- Spanish labelling (Art. 24 RIS)
- Spanish or *perito traductor*-translated and country-authenticated representation letters (Art. 161 fr. III RIS)
- CPPs and GMP certificates: *perito traductor* Spanish translation
- CTD technical modules: English content with Spanish summary is the practical band; sworn Spanish for legal-status documents (Amavita, Which Regulators Accept English Dossiers)

Empirical timelines

No verified empirical (as-observed) COFEPRIS market-clearance clock was found in fetched sources. The only empirical Mexican figures verified are RFI-cycle figures (see Section F).

Pediatric / orphan / biosimilar extras

For orphan medicines, NOM-220-SSA1-2016 §8.2.7 requires semi-annual *RPS* for the first 2 years and annual thereafter (DOF, NOM-220). *Biomedicamentos* have their own 90-day clock (Art. 177 RIS). Pediatric-specific translated-document requirements are not enumerated in fetched sources.

D3. Drugs — Clinical research trial submissions

Authorizing agency: COFEPRIS, via the health-research authorization procedure; modifications use *homoclave* COFEPRIS-09-012 (ClinRegs Mexico).

Ethics framework

Dual approval — an institutional Comité de Ética en Investigación (CEI) plus the institution's research committee (and biosafety committee where applicable). The CEI must approve the Spanish ICF, and only Spanish versions of protocol, IB and ICF are approved (ClinRegs Mexico).

Amavita's amendment analysis records that CEI approval of the ICF must precede COFEPRIS filing, adding roughly +30 days to the amendment path when the ICF changes (Amavita, Amendment Cascade).

Documents requiring translation

- Protocol, Investigator's Brochure, ICF in Spanish (Mexican variant)

- For the FRA reliance route: certified/legalized/apostilled copy of the foreign authorization with Spanish translation; protocol and IB may be filed in English with Spanish translations
- Foreign documents supporting IP import: Spanish translation by an expert translator

Amendments

Mexico has no substantial vs non-substantial amendment framework — all amendments run the same 30-calendar-day path (ClinRegs Mexico).

Statutory timelines

- 30 business days under the *Reglamento de la Ley General de Salud en Materia de Investigación para la Salud*
- 30 calendar days under the *Acuerdo* governing research-protocol procedures (also applicable to amendments)
- 45 calendar days for the FRA-reliance route
- **10-day* prevención** (deficiency) notice with a 5-business-day response window; requests are deemed denied** absent a response
- 10 days for IP import authorization, deemed approved (ClinRegs Mexico)

Trial safety timelines under NOM-220-SSA1-2016

- Serious ADR/AE: 7 calendar days
- Non-serious ADR/AE: at study end
- Two or more similar serious cases at the same site with the same product and lot: immediately, within 48 hours
- Annual study safety report from first national authorization (§8.3.3.3.1)
- Notice of cancellation/suspension/resumption of sponsored trials: 15 business days (§§7.4.2.10, 7.5.2) (DOF, NOM-220)

PV report language

NOM-220-SSA1-2016 requires MedDRA-coded clinical manifestations (§8.1.10.1) and ICH-E2B-compliant formats (§8.1.12.2); the norm as fetched does not state an explicit Spanish-language mandate for *RPS*/PSUR/PBRER. Practical band is Spanish because CNFV is the receiving agency (DOF, NOM-220).

CATEGORY 2: MEDICAL DEVICES

E1. Devices — Market access

Same two-track structure as drugs: listing via the Compendio Nacional de Insumos para la Salud at the CSG (CSG), and price negotiation for patented/single-source *insumos* via the CCNPMIS, whose mandate explicitly covers "medicamentos y otros insumos para la salud" in the *Cuadro Básico* and *Catálogo de Insumos*, purchased under direct award (CCNPMIS).

Translation load: RIS Art. 16 (Spanish for all commercialization documentation) covers devices as *insumos para la salud*. Hospital-tender-specific translated-document lists are not enumerated in fetched sources.

Timelines: annual negotiation cycle; no per-application day-count.

E2. Devices — Regulatory submissions for market clearance

Classification (Art. 83 RIS) (RIS):

Class	Definition
Clase I	Supplies known in medical practice, with proven safety and efficacy, and generally not introduced into the body
Clase II	Supplies known in medical practice that may vary in material or concentration and are generally introduced into the body remaining less than 30 days
Clase III	New or recently accepted supplies, or those introduced into the body and remaining more than 30 days

Note: Mexico's three-class scale is not identical to Brazil's four-class scale (I/II/III/IV) or to Colombia's I/IIa/IIb/III scale. Vendors submitting the same device in multiple LATAM markets must reclassify per jurisdiction — a defect class Amavita's inventory gate catches upstream of submission.

Art. 82 RIS enumerates the supply categories requiring *registro sanitario*: medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical material, wound-care material, hygiene products, and other medical-use devices (RIS).

Statutory review clocks (Art. 179 RIS) (RIS):

Pathway	Deadline	Effect of silence
Clase I	30 days	Application deemed granted (positive silence)

Pathway	Deadline	Effect of silence
Clase II	35 days	No automatic approval stated
Clase III	60 days	No automatic approval stated
Any class with favourable Tercero Autorizado opinion	≤15 days	—
Foreign-manufactured supplies (Chapter IX, Title Two)	Same clocks as Art. 179 (Art. 180)	—
Modification of registration conditions	22 days (Art. 188), deemed granted on silence; prior authorization required (Art. 184)	Deemed granted

Renewal/prórroga: The RIS text as fetched does not establish a device-registration renewal term or procedure; Art. 157 only allows the authority to review sanitary authorizations at any time.

Per-class translated documents

- Spanish label and Spanish *instructivo*/operating manual (Art. 179 fr. II–III RIS)
- Spanish labelling generally (Art. 24 RIS)
- All manufacturing/commercialization documentation in Spanish (Art. 16 RIS)
- Representation letters per Art. 161 fr. III RIS (RIS)

Device IFU and labelling must be in the national language in every LATAM jurisdiction — no English-only concession, no bilingual concession (Amavita, Which Regulators Accept English Dossiers).

Empirical device timelines

The only verified empirical Mexican device figure is the RFI cycle in Section F: Class II infusion pump, +50 calendar days (Amavita, RFI Anatomy).

IVD / SaMD / combination-product extras

The RIS text as fetched does not carry IVD- or software-specific classification rules — vendors bringing in-vitro diagnostics or Software-as-a-Medical-Device products need to confirm current COFEPRIS classification guidance separately.

E3. Devices — Clinical research trial submissions

Mexico does not operate a separate device-trial statute in the fetched sources: health research on humans (including with devices) runs the same COFEPRIS protocol-authorization route plus CEI review documented in D3 (ClinRegs Mexico). Device-specific first-in-human vs pivotal vs post-market distinctions, and device-trial-specific timelines, are not enumerated in fetched sources.

F. Common RFI / rejection patterns

Amavita's RFI casework records that COFEPRIS and ANVISA have the highest rates of RFIs issued on translation grounds in Amavita's 24-month internal dataset (Amavita, RFI Anatomy).

Documented COFEPRIS case — Class II infusion pump

A Class II infusion pump submitted through DIGIPRiS. A decimal-comma conversion defect rendered a range of 0.1–999 mL/h as "999 ml/hr" — the decimal comma from the English source ("0.1") was interpreted as a thousands separator in the Spanish rendering, and the range collapsed to a single ceiling value.

Sequence:

1. Submission
2. *Prevención* (deficiency notice) issued citing the numeric integrity defect
3. Sponsor responded on day 22 of the 30–45 calendar-day response window
4. Re-review took 28 days
5. Total delay: +50 calendar days

DIGIPRiS permits one prevention and one response. A second defect would have terminated the process.

The six recurring defect classes (COFEPRIS-applicable)

The six recurring defect classes Amavita identifies across LATAM regulators apply to COFEPRIS filings (Amavita, Amendment Cascade; Amavita, Regulatory Language Infrastructure):

1. Numeric integrity — decimal separators, unit conversions (the infusion-pump case)
2. Negation preservation — "not less than" ↔ "at least" flips, "should not be diluted" losing the *no*
3. Readability below INFLESZ 55 — ICF register mismatch triggering CEI escalation
4. Terminology inconsistency — MedDRA drift within the same dossier
5. Structural inventory — missing sections in the Spanish-language delivery
6. Jurisdictional adaptation — *castellano* (Iberian) delivered where Mexican Spanish required

The seventh defect class Amavita has added — Document Currency — captures stale foreign certificates, apostilles, and notarizations that were valid when translated but expired between

translation and submission.

For the full case-by-case RFI Anatomy analysis, see the six LATAM regulator rejections deconstructed blog post.

G. Timelines summary — COFEPRIS

Sub-category	Item	Statutory	Empirical
D1	CCNPMIS price negotiation	Annual cycle (CCNPMIS)	n.a.
D1	Compendio inclusion	n.a.	n.a.
D2	Medicine, registered active ingredient	40 days; 20 with TA (RIS Art. 166)	n.a.
D2	New active / new indication	60 days; 20 with TA (RIS Art. 166)	n.a.
D2	New molecules	90 days (RIS Art. 166)	n.a.
D2	Biologics (*biomedicamentos*)	90 days (RIS Art. 177)	n.a.
D3	Protocol authorization	30 business days / 30 calendar days (ClinRegs Mexico)	n.a.
D3	FRA reliance route (COFEPRIS-04-010-A)	45 días naturales for COFEPRIS resolution; "insufficient/unclear information" trigger under Art. 10 (Acuerdo DOF 24/03/2025, Arts. 8 and 10)	n.a.
D3	Amendment (all)	30 calendar days; +~30 days for prior CEI ICF approval (ClinRegs Mexico; Amavita)	n.a.
D3	*Prevención* response window	5 business days (ClinRegs Mexico)	n.a.
D3	IP import authorization	10 days, deemed approved (ClinRegs Mexico)	n.a.

Sub-category	Item	Statutory	Empirical
E2	Device Clase I	30 days, deemed granted (RIS Art. 179)	n.a.
E2	Device Clase II	35 days (RIS Art. 179)	n.a.
E2	Device Clase III	60 days (RIS Art. 179)	n.a.
E2	Any class + Tercero Autorizado	≤15 days (RIS Art. 179)	n.a.
E2	Device modification	22 days, deemed granted (RIS Art. 188)	n.a.
E2	RFI cycle (Class II)	*prevención* window 30–45 calendar days (Amavita)	+50 calendar days (Amavita)
E3	Device trials	Same as D3; device-specific: n.a.	n.a.

Where an item is marked n.a., that timeline is not stated in the fetched primary sources. Marking absences explicitly is part of Amavita's citation discipline — vendors should not infer timelines from adjacent pathways.

H. Recent regulatory changes 2023–2026

24 March 2025 — Acuerdo DOF 24/03/2025 (FRA reliance route created)

The DOF publishes the *Acuerdo por el que se establecen los criterios para la autorización de protocolos de investigación en seres humanos que cuenten con la autorización previa por una autoridad reguladora extranjera*, signed by the Secretario de Salud on 18 March 2025. This introduces Mexico's first formal reliance route for clinical protocols — recognising EMA (centralized), FDA, MHRA and Health Canada — and with it Mexico's first explicit bilingual-submission requirement for the Protocol and Investigator's Brochure (Art. 7 fr. III). Homoclave COFEPRIS-04-010-A, Modalidad A. COFEPRIS decision clock: 45 días naturales. Entered into force 60 días hábiles after publication (June 2025). (DOF 24/03/2025.)

- The CSG's Compendio Nacional de Insumos para la Salud page carries the date 01 April 2024, with the ACNIS consultation portal live at acnis.csg.gob.mx (CSG).
- Amavita's August 2026 preclinical analysis positions Art. 153 RIS plus the DOF procedure catalogue as the current operative basis for limiting *perito traductor* use to foreign-authority documents (Amavita, Preclinical LATAM).

- No 2023–2026 amendment to the RIS device or drug clocks was verified in fetched sources — the RIS clocks in this guide (Arts. 166, 171–177, 179, 188) are the current controlling clocks.
- Context — Argentina's ANMAT has adopted ICH E6(R3) via Disposición 7516/2025 effective 1 December 2025 (Boletín Oficial). COFEPRIS has not yet adopted E6(R3); Mexico's GCP framework remains anchored in NOM-012-SSA3-2012 and the current NOM-220-SSA1-2016 pharmacovigilance rules. The E6(R3) gap is a widening standard-alignment issue that sponsors running multi-country LATAM trials should track.

I. Amavita library cross-references

- Which Regulators Accept English Dossiers — COFEPRIS band: English technical + Spanish summary; Spanish sworn for legal documents
- Sworn vs Certified Translation — *perito traductor* authorized at state judicial level
- RFI Anatomy — six LATAM regulator rejections deconstructed — Class II infusion pump decimal-comma *prevención*, +50 calendar days
- Amendment Cascade — CEI-before-COFEPRIS ICF sequencing, +~30 days
- Preclinical Translation Requirements — 9 LATAM Regulators — Art. 153 RIS, *traducción simple* endorsed by *responsable sanitario*
- INFLESZ Threshold for Spanish ICFs — COFEPRIS-linked CEI escalation adds 30–90 calendar days
- Regulatory Language Infrastructure vs Traditional Translation — Mexican Spanish variant delivery
- Three Bands of LATAM Regulatory Translation — 12-regulator scope framing
- Translation QC for Regulatory Dossiers — seven QC gates including Document Currency
- Costly Translation Mistakes — apostille sequencing

FAQ

Does COFEPRIS accept English-language dossiers?

Practical band: English technical modules with a Spanish summary are accepted in CTD Modules where content is technical rather than legal. Legal-status documents — powers of attorney, corporate authorizations, health-authority certificates, CPPs, GMP certificates, representation letters from foreign entities — require *Spanish sworn translation by a perito traductor*** and country-of-origin authentication per RIS Art. 161 fr. III (RIS; Amavita, Which Regulators Accept English Dossiers).

What is a perito traductor and why does it matter?

A perito traductor is a court-authorized expert translator registered at the state judicial level — not federal. Each state's Tribunal Superior de Justicia (or equivalent) maintains its own registry. Documents used for CPPs, GMP certificates, and legal-representation instruments require translation by a perito traductor on a state registry. Federal-level "certified translator" credentials do not satisfy the RIS Art. 161 fr. III standard (Amavita, Sworn vs Certified).

What is a Tercero Autorizado and does using one really cut review time in half?

A Tercero Autorizado (TA) is a third-party reviewer authorized by COFEPRIS per Art. 10 of the creation decree. For most drug pathways, a favourable TA opinion cuts the statutory review clock from 40–60 days to 20 days (Art. 166 RIS), and for device pathways from 30–60 days to ≤15 days (Art. 179 RIS) (RIS). New molecules and biologics do not have a TA-shortened path.

How does COFEPRIS handle informed consent forms — does an ICF have to be sworn-translated?

No. The ICF must be prepared in Spanish (Mexican variant) and approved by the CEI before COFEPRIS authorization of the protocol. Sworn translation applies to legal-status documents, not to the ICF itself. The ICF language risk is register mismatch — ICFs that read like a translated protocol rather than a patient-facing document trigger CEI escalation, which adds 30–90 calendar days (Amavita, INFLESZ Threshold).

What does the Foreign Regulatory Authority (FRA) reliance route change about translation load?

Under the FRA reliance route, the foreign clinical-trial authorization must be filed as a certified/legalized/apostilled copy with Spanish translation, and protocol plus IB may be filed in English with Spanish translations — cutting the translation load on technical modules while keeping the full Spanish requirement on the legal tier. The statutory clock is 45 calendar days (ClinRegs Mexico).

The governing instrument: Acuerdo DOF 24/03/2025

The FRA reliance route was created by the Acuerdo por el que se establecen los criterios para la autorización de protocolos de investigación en seres humanos que cuenten con la autorización previa por una autoridad reguladora extranjera, published in the Diario Oficial de la Federación on 24 March 2025 and signed by the Secretario de Salud on 18 March 2025. It entered into force 60 días hábiles after publication per Transitorio Primero, which places its operational start in June 2025. The homoclave for filings on this route is COFEPRIS-04-010-A, Modalidad A (Medicamentos, Biológicos o Biotecnológicos) per Transitorio Segundo. The four foreign authorities the Acuerdo recognizes, per Arts. 4–5, are: - EMA — European Medicines Agency, centralized procedure only - FDA — U.S. Food and Drug Administration - MHRA — U.K. Medicines and Healthcare products Regulatory Agency - Health Canada Approvals from any other authority — including national EMA member-state agencies, PMDA, TGA, ANMAT, ANVISA, INVIMA — do not confer reliance eligibility on this route. The verbatim bilingual Protocol and Investigator's Brochure clause is Acuerdo Art. 7 fr. III: > "Copia en inglés y traducción al español del Protocolo y Manual del investigador con los cuales se obtuvo la autorización de conducción (solo se requerirá que la versión en español cuente con la aprobación de los respectivos comités en México)." Three operational reads matter: 1. Bilingual is mandatory on this route, not optional. The English source must travel with the Spanish translation; a Spanish-only file is non-compliant on this route. This is the closest thing published in LATAM to an explicit preclinical-translation mandate, because the Investigator's Brochure carries the non-clinical safety package (pharmacology, toxicology, PK/PD, prior clinical experience). 2. Only the Spanish version is presented to the CEI. Per Art. 7 fr. III, "solo se requerirá que la versión en español cuente con la aprobación de los respectivos comités en México." The English version travels for reference and audit; ethics approval attaches to the Spanish text. 3. No translator tier is specified for the Protocol or IB translation on this route. Certification, legalization, and apostille attach only to the foreign authority's authorization letter under Art. 7 fr. II — and the letter is subject to a document-staleness rule: "no deberá exceder más de un año de su expedición." The Protocol and IB translation itself carries no perito traductor obligation on the reliance route. COFEPRIS decision clock on the reliance route: "La COFEPRIS tendrá un término máximo de 45 días naturales para emitir la resolución correspondiente" (Art. 8). COFEPRIS retains a broad "insufficient/unclear information" trigger under Art. 10, which mirrors NOM-012-SSA3-2012 numeral 7.4.3. Scope limits worth surfacing on the sponsor's routing call: - The route is limited to medicamentos, biológicos y biotecnológicos — medical devices are excluded (Art. 5). A device sponsor filing at COFEPRIS does not have a reliance pathway and does not inherit the bilingual Protocol/IB mandate. - The route is limited to Phase III, non-adaptive designs, ordinary approval pathway — Phase I, II, IV, pilot studies, adaptive designs, master protocols, and accelerated/conditional foreign approvals do not qualify (Art. 5 frs. I–III). - 12 therapeutic areas named. The Acuerdo restricts the route to a defined set of therapeutic areas listed in Art. 4; sponsors outside those areas file under the standard route. For device and Phase I studies — which sit outside this route — no published Mexican instrument specifies a translation rule for the Protocol or IB by name. The default posture is (a) file in Spanish per the CEI's Guía nacional and (b) apply RIS perito traductor only where RIS Art. 161 fr. III attaches (foreign health-authority letters, GMP, CFS, CPP, FDA IDE), not to the scientific reports themselves.

Are protocol amendments in Mexico substantial vs non-substantial?

No. Mexico has no substantial vs non-substantial amendment framework — all amendments run the same 30-calendar-day path (ClinRegs Mexico). This is different from Argentina and Brazil, where the substantial/non-substantial distinction changes the clock and the required documentation. When the amendment touches the ICF, CEI approval of the revised ICF must precede COFEPRIS filing, adding roughly +30 days (Amavita, Amendment Cascade).

What device classification does COFEPRIS use?

Three classes under Art. 83 RIS: Clase I (known devices, not introduced into the body), Clase II (known devices introduced into the body <30 days), Clase III (new devices or devices remaining >30 days). Statutory clocks are 30 / 35 / 60 days; ≤15 days with a favourable Tercero Autorizado; Clase I is deemed granted on silence at 30 days (RIS).

What Spanish variant does COFEPRIS expect?

Mexican Spanish. Not castellano (Iberian), not español rioplatense (Argentine/Uruguayan). Vendors who deliver Iberian Spanish or generic "Latin American Spanish" introduce register mismatch that triggers RFI (Amavita, Regulatory Language Infrastructure).

What is the highest-risk defect class for COFEPRIS submissions?

Numeric integrity — specifically decimal-comma vs decimal-point conversion defects. Amavita's documented Class II infusion pump case cost +50 calendar days when a decimal-comma defect collapsed a 0.1–999 mL/h range to "999 ml/hr" (Amavita, RFI Anatomy). DIGIPRiS permits one prevención and one response; a second defect terminates the process.

Has COFEPRIS adopted ICH E6(R3)?

Not yet. Argentina's ANMAT is the first LATAM regulator to adopt E6(R3) via Disposición 7516/2025, effective 1 December 2025 (Boletín Oficial). Mexico's GCP framework remains anchored in NOM-012-SSA3-2012 and the current NOM-220-SSA1-2016 pharmacovigilance rules. Sponsors running multi-country LATAM trials should track this widening standard-alignment gap.

About the author

Julio G. Martinez-Clark is CEO of bioaccess®, Latin America's leading medical-device clinical research organization, and founder of Amavita Sciences, the multilingual clinical operations platform. He has led first-in-human trial operations across 12 LATAM jurisdictions and built the seven-gate translation QC pipeline behind Amavita's regulatory language infrastructure.

Version history

This guide is version **1.5.0**, last updated August 25, 2026. Every substantive change to the COFEPRIS requirements on this page is recorded below.

v1.5.0 August 25, 2026

- Anchored the FRA reliance route to the Acuerdo DOF 24/03/2025 by name: the four recognized foreign authorities (EMA centralized, FDA, MHRA, Health Canada), the verbatim Art. 7 fr. III bilingual Protocol/IB clause, homoclave COFEPRIS-04-010-A Modalidad A, the 60-día-hábil entry into force, the 45-día-natural decision clock (Art. 8), the Art. 10 information trigger, and the ≤12-month staleness rule on the foreign authorization letter (Art. 7 fr. II).
- Surfaced reliance-route scope limits (medicamentos/biológicos/biotecnológicos only, Phase III only, 12 named therapeutic areas) and added reliance rows to the Section D.4 table plus the Section G and Section H entries.

v1.3.0 August 22, 2026

- Split the Section D exception list into clinical-trial authorization and market-access / sanitary registration pathways, immediately before the consolidated preclinical instruction table.
- Clarified that device IFU and labelling obligations activate at device registration, not at clinical-trial authorization.

v1.2.0 August 22, 2026

- Added Section D — Preclinical / non-clinical documentation (D.1–D.4), placed between Section C and Category 1: Drugs.
- Consolidated the sworn vs. certified vs. simple translation instruction table.
- Regenerated the downloadable PDF so it matches the on-page text.

v1.1.0 August 11, 2026

- Migrated QC copy from six gates to the seven-gate architecture (adds Document Currency).
- Added FAQ block with structured data and a pre-submission QC checklist download.

v1.0.0 July 28, 2026

- Initial publication of the regulator translation requirements guide.