LATAM REGULATORY GUIDES · LATIN AMERICA

LATAM Regulatory Translation for Life Sciences: The Complete Reference Hub

The doorway to all six regulator-specific reference guides: language rules, sworn-translation tiers, document-currency windows, and the seven QC gates that hold a LATAM dossier together.

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

Last updated August 11, 2026 · ~18 min read · Version 1.1.0

Pillar guide

ON THIS PAGE

The direct answer

Latin America has six major life-sciences regulators — ANVISA (Brazil), COFEPRIS (Mexico), INVIMA (Colombia), ANMAT (Argentina), ISP (Chile), and DIGEMID/ANM (Peru) — plus a long tail of smaller authorities. No two share the same language rule. ANMAT requires a *traductor público matriculado* register hit for every foreign-authority document. DIGEMID accepts *traducción simple* but invalidates any foreign document older than two years. ISP lets a company officer sign the translation. ANVISA gives Portuguese, Spanish, or English acceptance zones per document type. COFEPRIS names the *perito traductor*. INVIMA requires *traducción oficial* with consular legalization or apostille and gives pharmaceutical CPPs a one-year currency window. Between them, they generate the seven distinct QC gates — structural inventory, numeric integrity, unit

consistency, negation preservation, entity mapping, adversarial back-translation, and Document Currency — that Amavita's regulatory language infrastructure runs on every dossier. This hub page is the doorway to the six regulator-specific reference guides that operationalize each one.

Section 1. The six regulators at a glance

The Big 6 govern roughly 80% of LATAM's pharmaceutical and medical-device market volume. Every foreign sponsor entering the region touches at least three of them, and most touch all six.

Regulator	Country	Establishing statute	Translation standard	Foreign document age limit
ANVISA — Agência Nacional de Vigilância Sanitária	Brazil	Lei 9.782/1999	Portuguese for forms/IFU/user manuals/labelling; other documents may be Portuguese, Spanish, or English; sworn translation or consular certification for revalidation statements (RDC 751/2022)	No general statutory age limit for the fetched articles
COFEPRIS — Comisión Federal para la Protección contra Riesgos Sanitarios	Mexico	Ley General de Salud + RIS	*Perito traductor* (court-authorized expert) for foreign-authority documents; *traducción simple* endorsed by the *responsable sanitario* for technical content (RIS Art. 161 fr. III)	Not stated as a general age limit; document-specific windows apply
INVIMA — Instituto Nacional de Vigilancia de Medicamentos y Alimentos	Colombia	Ley 100/1993 · Decreto 677/1995 · Decreto 4725/2005	*"Traducción oficial"* with consular legalization or apostille (Decreto 677/1995 Arts. 31 §2, 45 §2, 56, 67 §1; Decreto 4725/2005 Art. 44)	≤ 1 year for drug CPPs

Regulator	Country	Establishing statute	Translation standard	Foreign document age limit
ANMAT — Administración Nacional de Medicamentos, Alimentos y Tecnología Médica	Argentina	Decreto 1490/1992 · Ley 16.463	Strictest: legalization plus translation by *traductor público matriculado* for any non-Spanish document from a foreign authority (Disposición 5755/1996 Art. 8)	Not stated as a general age limit
ISP — Instituto de Salud Pública de Chile	Chile	Código Sanitario (DFL 725) · DS 3/2010	Spanish or translated **under the signature of the* representante legal*, a designated company professional, or the* Director Técnico*** — no translator credential named (DS 3/2010 Art. 29 No. 10)	Not stated as a general age limit
DIGEMID / ANM — Dirección General de Medicamentos, Insumos y Drogas	Peru	Ley 29459 · DS 016-2011-SA	Most permissive: *traducción simple al idioma español* for all foreign documents; English acceptance set by ANM *comunicado* (DS 016-2011-SA Art. 28)	≤ 2 years from issue date, unless the document itself states a validity

The three bands. Amavita's Three Bands of LATAM Regulatory Translation framework consolidates these into three operational tiers based on translator qualification, authentication burden, and English acceptance. ANMAT + INVIMA (top of the strictness curve). ANVISA + COFEPRIS (mid-band, document-type-specific). ISP + DIGEMID (permissive on translator qualification, but with their own hard constraints — officer liability in Chile, calendar currency in Peru).

No two regimes are identical. A dossier that clears ANMAT will not automatically clear DIGEMID (calendar problem), will not automatically clear INVIMA (apostille problem), and will not automatically clear ANVISA (Portuguese label problem). A dossier optimized for DIGEMID will fail ANMAT on translator credential. This is the structural reason why LATAM regulatory translation is not "translate once, submit six times."

Section 2. Two categories, six regulators, three regulatory motions

Every regulator page in this reference library is structured around the same two-category × three-motion matrix, so a sponsor can find the same subsection across all six guides.

Two categories:

- Drugs — pharmaceutical products, including biologicals and biosimilars.
- Medical devices — the four-class regime (in ANVISA, COFEPRIS, INVIMA, DIGEMID) or the developing framework (in Chile, where D.Ex. 25/2026 extends control to devices generally).

Three motions per category:

1. Market access — pricing, reimbursement, HTA, national list inclusion.
2. Regulatory submissions for market clearance — the primary registration or authorization pathway.
3. Clinical research trial submissions — the authorization to conduct human clinical research.

That gives six subsections per regulator — D1 through D3 for drugs, E1 through E3 for devices — plus the cross-cutting sections on language rules, sworn vs certified translation, RFI patterns, and consolidated timelines. Every reference guide in this library follows that layout, so a sponsor comparing "device clinical-trial authorization in Argentina vs Brazil" can jump straight to the E3 section in the ANMAT guide and the E3 section in the ANVISA guide.

Seven per-regulator guides:

- ANVISA Regulatory Translation Guide (Brazil) — the RDC 751/2022 device framework, RDC 837/2023 DICD clinical-investigation dossier, RDC 947/2024 trials framework, CMED pricing.
- COFEPRIS Regulatory Translation Guide (Mexico) — NOM-072, NOM-220, RIS Art. 161, CCNPMIS pricing, IETS-adjacent HTA infrastructure.
- INVIMA Regulatory Translation Guide (Colombia) — Decreto 677/1995 pharmaceutical framework, Decreto 4725/2005 device framework, CNPMDM pricing, IETS HTA.
- ANMAT Regulatory Translation Guide (Argentina) — the ICH E6(R3) transition via Disposición 7516/2025 effective 1 December 2025, Disposición 5755/1996 sworn-translation rule, Disposición 2318/2002 device framework.
- ISP Regulatory Translation Guide (Chile) — DS 3/2010 pharmaceutical framework, Ley 20.850 (Ley Ricarte Soto) high-cost access, D.Ex. 25/2026 device-registration generalization.
- DIGEMID Regulatory Translation Guide (Peru) — DS 016-2011-SA registration framework, INS/DIIS/SUDEC two-agency trial architecture, Comunicado 008-2022-DIGEMID English acceptance perimeter.

- SRS Regulatory Translation Guide (El Salvador) — the DNM → SRS succession under Legislative Decree No. 891 effective 7 August 2024, RTCA 11.03.59:18 Mutual Recognition, RTS 11.03.02:21 §6.3.4.d castellano-or-ISO-15223-1 labelling rule.

Section 3. The seven QC gates

Amavita's regulatory language infrastructure operates on seven gates. The first six emerged from Amavita's six defect classes — the pattern of translation defects that trigger RFIs across all six regulators. The 7th gate — Document Currency — was added in 2026 after the DIGEMID two-year rule and the INVIMA one-year CPP rule produced defect patterns not captured by the first six.

Gate 1 — Structural inventory. Every document required by the regulator is present, and no unauthorized document is filed. The failure mode is a missing CLC, a missing CPP, a missing GMP certificate — or their inverse: filing a document not called for by the specific pathway.

Gate 2 — Numeric integrity. Every numeric value in the translation matches the source. Amavita's canonical case is the COFEPRIS infusion-pump *"999 ml/hr"* decimal-comma error, where the Spanish comma and the English decimal disagreed — filed as documented in RFI Anatomy.

Gate 3 — Unit consistency. SI vs Imperial, mmHg vs kPa, µg vs mg, g vs kg. Every unit is verified against the source and against the target-country pharmacopoeial convention.

Gate 4 — Negation preservation. *"Do not exceed"* vs *"exceed only if"*. A single dropped negation in an IFU or ICF is a safety defect on its face, and is one of the highest-severity translation defects any regulator will flag.

Gate 5 — Entity mapping. Names — of the manufacturer, of the holder, of the technical director, of the manufacturing site, of the product family, kit, set, system — must be identical across the CPP, the CLC, the GMP certificate, the dossier body, the IFU, and the labelling. Peru's Art. 122 CLC-anchoring rule and Argentina's Disposición 5755/1996 sworn-translation register make entity-mapping drift directly detectable.

Gate 6 — Adversarial back-translation. The target-language text is translated back into the source language by an independent linguist without sight of the source. The two source-language versions are then compared. Semantic drift, ambiguity, and terminology inconsistency surface here that no forward-only QC will catch.

Gate 7 — Document Currency (new in 2026). Every foreign-issued document in the dossier — CPP, CLC, GMP certificate, ISO 13485 certificate, FDA documentation, apostille or consular legalization — sits within its own jurisdictional validity window at the moment of filing. DIGEMID's 2-year rule and INVIMA's 1-year CPP rule are the primary drivers; ANVISA revalidation statements and Chile's Art. 47 fee-payment clock also engage this gate.

Each gate is a pass/fail check with a documented output. The seven gates together are the final release-layer commitment recorded in the cryptographic audit ledger — the receipt sponsors need when a regulator asks how a specific dossier was quality-controlled.

See Blog corrections + seventh QC gate rollout for the operational architecture of Gate 7 and the two blog corrections it drove (Chile Art. 92 → 74 item 5 / 29 No. 10 / 78; Argentina Disposición 6677/2010 repealed by Disposición 7516/2025).

Section 4. The six defect classes and how each regulator triggers them

Amavita's Amendment Cascade analysis documents six recurring defect classes that trigger regulator RFIs. Each regulator exposes these differently:

Defect class	Where it hits hardest	Statutory anchor
Numeric integrity	COFEPRIS (documented case)	Amavita RFI Anatomy
Negation preservation	All six — but ANMAT and INVIMA are strictest on IFU/ICF language	Amavita, INFLESZ Threshold
Readability below INFLESZ 55	INVIMA and ISP have documented ICF readability RFIs	Amavita, INFLESZ Threshold
Terminology inconsistency	Peru's Art. 130 vs Art. 137(a) vs Arts. 124–127 three-way consistency requirement is the paradigm case	DS 016-2011-SA
Structural inventory	Colombia's Decreto 677/1995 pharmaceutical dossier + Decreto 4725/2005 device dossier have the longest per-item checklists	Decreto 677/1995
Jurisdictional adaptation	ANVISA's Portuguese-only zones (forms, IFU/user manuals, labelling models) under RDC 751/2022 Art. 10 §9	RDC 751/2022
Document currency (7th gate, new)	DIGEMID (2-year rule) and INVIMA (1-year CPP rule)	DS 016-2011-SA Art. 28; Decreto 677/1995

Amavita's RFI Anatomy deconstructs six real regulator rejections. The Chile case in that post has been corrected in the current version — the operative citation is DS 3/2010 Arts. 74 item 5 / 29 No. 10 / 78, not Art. 92 (which governs *sublotes*). The correction was driven by Gate 5 (Entity mapping) applied to the Amavita library itself.

Section 5. Recent regulatory changes 2023–2026

The last three years compressed more LATAM regulatory change than the prior decade. The four items below are the most consequential for a sponsor's LATAM translation program.

1. Argentina — ICH E6(R3) via Disposición 7516/2025. Argentina became the first LATAM regulator to formally adopt ICH E6(R3). Disposición 7516/2025 Art. 7 repealed the older Disposición 6677/2010, effective 1 December 2025 (Boletín Oficial). Every sponsor with active or planned Argentine trials must reconcile protocol, IB, and ICF templates to the E6(R3) framework. See the ANMAT guide for the full transition matrix.

2. Brazil — RDC 837/2023 DICD framework + RDC 947/2024 general trials. ANVISA restructured the medical-device clinical-investigation pathway with RDC 837/2023, formalizing the DICD (*Dossiê de Investigação Clínica de Dispositivo Médico*) (ANVISA announcement). RDC 947/2024 consolidates the general clinical-trial framework. E6(R3) adoption is pending. See the ANVISA guide.

3. Chile — D.Ex. 25/2026 generalizes device registration. Chile has historically operated a ten-category device-registration regime. D.Ex. 25/2026 extends control to medical devices and IVDs generally — the single largest expansion of Chile's device registration perimeter in decades. D.Ex. 5/2025 brought immunohematology reagents under registration (in force 21 February 2026), and D.Ex. 31/2026 brought IVD reagents for microbiological qualification of blood donations under registration (ISP ANDIM). See the ISP guide.

4. Peru — Comunicado 008-2022-DIGEMID formalizes English-acceptance perimeter. Comunicado 008-2022-DIGEMID permits English for CTD Modules 3, 4, and 5 (Amavita, Preclinical LATAM). It is a *comunicado*, not a decree — exactly the administrative instrument Art. 28 DS 016-2011-SA designates for setting the English-acceptance perimeter. DS 028-2023 and Resolución 184-2023 established the amendment/modification distinction with associated notice and decision windows (ClinRegs Peru). See the DIGEMID guide.

Mexico and Colombia have not published equivalent LATAM-first changes in the same period; their operative frameworks — NOM-072, NOM-220, RIS Art. 161 for Mexico; Decreto 677/1995, Decreto 4725/2005 for Colombia — remain the governing texts.

Section 6. Cross-regulator comparison — the fast reference

For sponsors sizing a multi-country LATAM program, this section is the pivot. Every row is verified against the per-regulator guide.

Translator qualification standard

Regulator	Standard for foreign-authority documents	Key instrument
ANVISA	Free translation permitted absent a specific rule to the contrary; sworn or consular certification for revalidation statements	RDC 751/2022 Art. 27(I)
COFEPRIS	*Perito traductor* (court-authorized expert)	RIS Art. 161 fr. III
INVIMA	*Traducción oficial* + apostille or consular legalization	Decreto 677/1995 Arts. 31 §2, 45 §2
ANMAT	*Traductor público matriculado* + legalization	Disposición 5755/1996 Art. 8
ISP	Officer signature (representante legal, designated professional, or Director Técnico)	DS 3/2010 Art. 29 No. 10
DIGEMID	*Traducción simple* (unqualified)	DS 016-2011-SA Art. 28

Foreign document age limits

Regulator	Age limit	Statutory hook
ANVISA	Not identified as general statutory age limit	RDC 751/2022
COFEPRIS	Not stated as a general age limit	RIS
INVIMA	≤ 1 year for drug CPPs	Decreto 677/1995
ANMAT	Not stated as a general limit	Disposición 5755/1996
ISP	Art. 47 fee-payment clock starts the six-month registration timeline	DS 3/2010
DIGEMID	≤ 2 years from issue date for all foreign documents	DS 016-2011-SA Art. 28

Device classification systems

Regulator	Classes	Reference
ANVISA	Four (I, II, III, IV) with IMDRF alignment; SaMD-specific rule at RDC 751/2022 Art. 8 §4	RDC 751/2022
COFEPRIS	Three (Clase I, II, III)	LGS + regulations
INVIMA	Four (I, IIa, IIb, III)	Decreto 4725/2005
ANMAT	Four (I, II, III, IV)	Disposición 2318/2002
ISP	Historically 10 controlled categories; D.Ex. 25/2026 extends control to devices and IVDs generally	ISP ANDIM
DIGEMID	Four (Clase I–IV)	DS 016-2011-SA Art. 136

Clinical-trial authorizing agency

Country	Agency	Notes
Brazil	ANVISA (COINP)	RDC 947/2024 general framework; RDC 837/2023 DICD for devices
Mexico	COFEPRIS	Single agency
Colombia	INVIMA	Ethics + regulator dual approval
Argentina	ANMAT	E6(R3) framework as of 1 December 2025
Chile	ISP	Provisional-use authorization; CEC opinion required first
Peru	INS (DIIS/SUDEC) — not DIGEMID	DIGEMID contributes investigational-product opinion + import auth

Section 7. What the Amavita library contains

Beyond the six regulator reference guides, the Amavita library carries deeper analytical work on the mechanics of LATAM regulatory translation. Every piece below is cross-linked from the relevant regulator guides.

Foundational framework:

- Three Bands of LATAM Regulatory Translation — the operational tiering of the six regulators by translator qualification, authentication burden, and English acceptance.
- Regulatory Language Infrastructure vs Traditional Translation — why LATAM life-sciences translation is a systems problem, not a document problem.
- Which Regulators Accept English Dossiers — document-by-document, regulator-by-regulator English-acceptance matrix.

Translation authentication:

- Sworn vs Certified Translation for Regulatory Submissions — the terminology, and where each regulator sits.
- Costly Translation Mistakes in Regulatory Submissions — apostille sequencing, notary chains, and the failure modes at each step.

Quality control mechanics:

- Translation QC for Regulatory Dossiers — the foundational QC discipline behind the seven gates.
- RFI Anatomy — Six LATAM Regulator Rejections Deconstructed — six worked case studies with statutory citations.
- Amendment Cascade — One Protocol Change × 12-Country LATAM Stack — why one protocol change generates 12+ downstream translation tasks.
- Blog corrections + seventh QC gate rollout — the operative account of Gate 7 (Document Currency) and the two blog corrections that motivated it.

Preclinical translation:

- Preclinical Translation Requirements — 9 LATAM Regulators — CTD Module 4 translation matrix.
- Preclinical Translation Requirements — Global Regulators — comparative treatment.

Clinical readability:

- INFLESZ Threshold — Spanish ICF Readability Compliance — the ≥ 55 benchmark and why it applies across all Spanish-speaking regulators.

Section 8. How to use these guides

Sponsors typically arrive at these guides in one of three scenarios.

Scenario 1 — Entering a single LATAM country. Load the relevant regulator guide (ANVISA, COFEPRIS, INVIMA, ANMAT, ISP, or DIGEMID) and work section by section. Section B tells you the language rule. Section C tells you sworn/certified/simple. Sections D1–D3 or E1–E3 tell you what documents need translation per pathway. Section F tells you the common RFI patterns. Section G is the timeline table for planning.

Scenario 2 — Planning a regional program. Read this hub first. Use Section 6 to size the translator-qualification and document-currency delta between the countries you're entering. Then open the relevant regulator guides for the specific pathways. The seven QC gates (Section 3) tell you what the release-layer commitment looks like across the whole program.

Scenario 3 — Fixing an active RFI. Load the regulator's guide (Section F on RFI patterns), read the RFI Anatomy blog for the closest case study, and check the cure window in Section G. Peru's 2-business-day trial-file correction window and Colombia's 30-day cure windows are the tightest.

When the workflow crosses two or more regulators — which it usually does — the seven QC gates are the shared discipline. The specifics change per country. The gates do not.

FAQ

How many life-sciences regulators are there in LATAM?

Six major regulators cover roughly 80% of the market volume: ANVISA (Brazil), COFEPRIS (Mexico), INVIMA (Colombia), ANMAT (Argentina), ISP (Chile), and DIGEMID/ANM (Peru). A long tail of smaller authorities governs the remaining countries.

Which LATAM regulator is strictest on translation credentials?

ANMAT (Argentina). Disposición 5755/1996 Art. 8 requires legalization plus translation by a traductor público matriculado — a court-registered public translator — for any non-Spanish document from a foreign authority (Disposición 5755/1996).

Which LATAM regulator has the most permissive translation rule?

DIGEMID (Peru). Art. 28 DS 016-2011-SA accepts traducción simple for all foreign-issued documents (DS 016-2011-SA) — but the same article invalidates any foreign document older than two years, so the credential rule is permissive while the calendar rule is unforgiving.

Can any LATAM regulator accept an English-only dossier?

No regulator accepts a fully English dossier. DIGEMID accepts English for CTD Modules 3, 4, and 5 per Comunicado 008-2022-DIGEMID. ANVISA accepts English, Spanish, or Portuguese for most non-forms/non-labelling documents. ISP accepts English technical content with a Spanish summary. All six require the informed-consent form, labelling, and IFU in the local language.

What is the "7th QC gate"?

Document Currency — the verification that every foreign-issued document in the dossier (CPP, CLC, GMP certificate, ISO 13485, FDA documentation, apostille) sits within its own jurisdictional validity window at the moment of filing. Added to Amavita's original six defect classes in 2026 after DIGEMID's 2-year rule and INVIMA's 1-year CPP rule produced defect patterns not captured by the original six. See Blog corrections + seventh QC gate rollout.

Which LATAM regulator was first to adopt ICH E6(R3)?

Argentina. Disposición 7516/2025 Art. 7 repealed the older Disposición 6677/2010, effective 1 December 2025 (Boletín Oficial). Brazil has adopted E6(R2) with E6(R3) pending. No other LATAM regulator in the Big 6 has formally adopted E6(R3) as of August 2026.

Where do I start if I only have a Certificate of Pharmaceutical Product for one country?

Start with the INVIMA guide if you're entering Colombia (1-year CPP rule) or the DIGEMID guide if you're entering Peru (2-year rule). Both are the calendar-driven regimes. The other four regulators do not tie a general age limit to the CPP in the fetched articles.

How do these guides get updated?

Every guide is refreshed when a governing statute changes. The ANMAT guide was rewritten to reflect Disposición 7516/2025. The ISP guide was rewritten to reflect D.Ex. 25/2026. The blog corrections + seventh QC gate rollout post documents the two most recent corrections. Amavita commits every guide version to a cryptographic audit ledger so sponsors can verify which version informed their submission.

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 **1.1.0**, last updated August 11, 2026. Every substantive change to the LATAM requirements on this page is recorded below.

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.