AMAVITA SCIENCES™ · TRANSLATIONAL SERVICES

COFEPRIS vs ANVISA

Clinical trial translation requirements checklist

A practical side-by-side of what Mexico's COFEPRIS and Brazil's ANVISA expect from Spanish and Portuguese clinical trial documentation — drawn from the Amavita regulatory guides.

Dimension	COFEPRIS · Mexico	ANVISA · Brazil
Regulator	Comisión Federal para la Protección contra Riesgos Sanitarios. Regulates medicines, devices, biologics, trials, and sanitary registrations.	Agência Nacional de Vigilância Sanitária. Regulates marketing authorizations, Phase III trials, devices, and post-market surveillance.
Target language	Mexican regulatory Spanish — not neutral LatAm Spanish.	Brazilian Portuguese — Portugal-PT terminology is rejected.
Documents that must be translated	Protocol · ICF · Investigator's Brochure · CRFs · SUSAR/SAE narratives · lab manuals · IFUs · registration labeling, CMC, stability.	Protocol · ICF (Termo de Consentimento) · IB · safety narratives · IFUs · bula (labeling) · CMC & stability for MA · CEP/CONEP appendices.
Certification of translation	Perito traductor / public translator for legal instruments (POAs, apostilled docs). Technical docs require qualified medical translators with certified sign-off.	Tradutor público juramentado for legal instruments. Technical dossier translations must be MD- or specialist-reviewed and consistently attested across the package.
Controlled terminology	Align with COFEPRIS-accepted Spanish nomenclature; MedDRA LLTs in Spanish where applicable; consistent drug/device naming across dossier.	Vocabulário Controlado ANVISA · CID-10 · MedDRA PT-BR where required; drug names per DCB (Denominações Comuns Brasileiras).
English-only submissions?	Not accepted. All review happens in Spanish.	Not accepted. All review happens in Brazilian Portuguese.
Common failure modes	Literal back-translation of clinical terms · inconsistent drug/device names · missing signatures/dates on certificates · broken source pagination · untranslated appendices → oficios / requerimientos.	AI-only translation of safety narratives · Portugal-PT leakage · mismatched CMC units · missing bula sections · inconsistent DCB naming → exigências that reset the review clock.
Impact of MD-led review	Catches clinical-intent errors pre-submission, reduces clarification rounds, protects protocol authorization timeline.	Aligns terminology with ANVISA controlled vocabulary, prevents Phase III and MA delays from linguistic exigências.

PRE-SUBMISSION CHECKLIST

Two dossiers, two languages, one QC pass

COFEPRIS · Mexico

- ☐ Protocol, ICF, and IB fully translated into Mexican regulatory Spanish.
- ☐ SUSAR/SAE narratives and lab manuals translated with MedDRA-aligned terminology.
- ☐ IFUs and device labeling adapted to Mexican regulatory expectations.
- ☐ Legal instruments (POAs, apostilled documents) certified by a perito traductor.
- ☐ Drug and device nomenclature consistent across every dossier document.
- ☐ Every appendix, footnote, and figure caption translated — no source-language leakage.
- ☐ Pagination and table structure preserved to match source formatting.
- ☐ Translator attestation and signature present on all required certificates.
- ☐ MD-led clinical review completed before submission to prevent oficios / requerimientos.

ANVISA · Brazil

- ☐ Protocol, TCLE (ICF), and IB translated into Brazilian Portuguese — no Portugal-PT.
- ☐ Safety narratives reviewed by a physician, not AI-translated alone.
- ☐ Terminology aligned with Vocabulário Controlado ANVISA and CID-10.
- ☐ Drug names follow DCB (Denominações Comuns Brasileiras) consistently.
- ☐ Bula (labeling) sections complete and formatted per ANVISA structure.
- ☐ CMC and stability data translated with units and formats verified.
- ☐ CEP/CONEP appendices translated and cross-referenced.
- ☐ Sworn (juramentado) translation attached for legal instruments.
- ☐ Consistent translator attestation across the full submission package.
- ☐ MD-led QC pass completed to prevent exigências that reset review timelines.

SCOPE A PILOT

Share one protocol or registration dossier for Mexico or Brazil. Our team will reach out within 2 business days with a scoped pilot proposal and timeline.

amavitasciences.com/start-your-latam-pilot

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