LATAM REGULATORY GUIDES · BRAZIL

ANVISA Regulatory Translation Requirements: The Complete Guide for Drugs and Medical Devices in Brazil

Brazil's language regime by document type: RDC 947/2024 acceptance zones, the RDC 200/2017 sworn carve-out, RDC 751/2022 device Portuguese rules, and the CEP/CONEP clock.

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

Last updated August 25, 2026 · ~34 min read · Version 2.0.0

ON THIS PAGE

The direct answer

The Agência Nacional de Vigilância Sanitária (ANVISA) is Brazil's health regulator, established by Law No. 9.782 of 26 January 1999 with jurisdiction over drugs, biologics, medical devices, cosmetics, and clinical research. For regulatory submissions, ANVISA accepts documents in Portuguese, Spanish, or English under RDC 947/2024, with sworn Portuguese translation limited to health-authority-issued documents under RDC 200/2017 Art. 6. Medical device application forms, IFUs, and labeling must be in Portuguese (RDC 751/2022 Art. 10 §9). Clinical trial submissions run through ANVISA in parallel with ethics review by a CEP via Plataforma Brasil — and since Decreto nº 12.651, de 7 de outubro de 2025 Art. 40, CONEP is an appeals-only instance while the Instância Nacional de Ética em Pesquisa (INAEP) takes over norm-setting, *credenciamento* and *acreditação* under Lei nº 14.874, de 28 de maio de 2024, with a 90-business-day statutory review clock and a 30-business-day *exigência* (technical requirement) cycle that resets the clock (ClinRegs Brazil; Amavita, ANVISA guide).

This guide is a complete reference for Portuguese regulatory translation into the ANVISA 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 Brazilian market entry or maintaining Brazilian registrations.

A. Regulator profile

Agency name: Agência Nacional de Vigilância Sanitária (ANVISA) — National Health Surveillance Agency.

Establishing statute: Law No. 9.782 of 26 January 1999, effective 27 January 1999 (ClinRegs Brazil).

Jurisdictional scope: Health surveillance across medicines, medical devices, biologics, cosmetics, foods with health claims, and clinical research. ANVISA is an ICH member and has adopted ICH E6(R2); as of August 2026 it has not yet implemented E6(R3) — a widening gap now that Argentina's ANMAT has adopted E6(R3) via Disposición 7516/2025 (ClinRegs Brazil; Disposición 7516/2025).

Official website: gov.br/anvisa

Headquarters: SIA Trecho 5, Guará, Brasília-DF, CEP 71205-050 (ClinRegs Brazil).

Adjacent bodies you must coordinate with

Body	Role
CEP (Comitê de Ética em Pesquisa) — site-level	Ethics approval mandatory and parallel to ANVISA; protocol submitted in Portuguese via Plataforma Brasil; completeness check 10 working days, opinion 30 days (ClinRegs Brazil)
CONEP (Comissão Nacional de Ética em Pesquisa) — national	National ethics escalation triggered by protocol category or CEP-flagged substantive amendments; adds 30–90 days (Amavita, Amendment Cascade)
CMED (Câmara de Regulação do Mercado de Medicamentos)	Economic regulation of the medicines market — pricing, adjustments, ceilings. Created by Art. 5 of Lei nº 10.742/2003; hosted on ANVISA's website at gov.br/anvisa/pt-br/assuntos/medicamentos/cmed
DDCM / DEEC review units	Drug Clinical Development Dossier (*Dossiê de Desenvolvimento Clínico de Medicamento*) and Specific Clinical Trial Dossier (*Dossiê Específico de Ensaio Clínico*) review under RDC 945/2024 and RDC 585/2021 (ClinRegs Brazil)

Brazilian submissions do not go to ANVISA alone. A properly-executed Brazilian trial or registration requires coordinated filings across ANVISA (regulatory), CEP/CONEP (ethics), and — for pharmaceuticals with pricing implications — CMED (economic). Vendors who treat ANVISA as a single-agency submission produce packages that fail cross-body review.

B. Official language requirements

Brazil's official language is Brazilian Portuguese, and ANVISA reviews dossiers in Brazilian Portuguese. But the language rule is more nuanced than "translate everything to Portuguese," and vendors who don't understand the nuance either over-translate (wasting cost) or under-translate (triggering RFIs).

The general rule — RDC 947/2024

Documents must be in Portuguese, but English and Spanish are accepted, with translation subject to ANVISA request. In the absence of a specific rule requiring sworn translation, a free translation may be accepted (ClinRegs Brazil).

The English/Spanish exemption — RDC 25/2011 (as amended by RDC 50/2013)

"Os documentos apresentados nos idiomas inglês e espanhol estão dispensados desta exigência" — documents in English and Spanish are exempted from the sworn-translation requirement (Amavita, Preclinical LATAM).

The sworn-translation carve-out — RDC 200/2017 Art. 6

Sworn translation is required for documents issued by health authorities, plus contracts, powers of attorney, and corporate authorizations. RDC 403/2020 granted further waivers citing the cost of sworn translation (Amavita, Preclinical LATAM).

The device carve-in — RDC 751/2022

For medical devices, RDC 751/2022 Art. 10 §9 requires that application forms, IFUs (Instructions for Use / user or operator manuals), and labeling models must be presented in Portuguese. Under Art. 10 §10, all other device documents may be presented in Portuguese, Spanish, or English, according to rules defined in specific regulation (RDC 751/2022, English text).

Clinical trial specifics

- Protocol, PDME (product development plan), and IB: Portuguese recommended per G-DDCMManual (ClinRegs Brazil)
- CEP filing (Plataforma Brasil): Portuguese protocol required
- TCLE (Termo de Consentimento Livre e Esclarecido — informed consent): fully revised in Portuguese — no partial Portuguese, no bilingual submission
- Investigational-product labeling: must be in local language — "all of the text labeling must be written in Portuguese"
- Imported human biological material labels: English and Portuguese dual-language required
- DSUR: may be forwarded to ANVISA in English upon request — the clearest English-accepting safety-reporting rule among the six LATAM regulators covered in this guide series (ClinRegs Brazil)

Register and terminology expectations

- All dossiers are reviewed in Brazilian Portuguese — not European (Iberian) Portuguese. Vendors who pivot through European Portuguese introduce register mismatch that ANVISA reviewers flag.
- ANVISA maintains a Vocabulário Controlado — a controlled terminology glossary that dossiers should conform to.

- Adverse event terminology must align with MedDRA.
- ANVISA generally accepts English technical content with a Portuguese summary in the CTD Modules where the content is technical rather than legal, with Portuguese sworn translation required for the legal tier (Amavita, Which Regulators Accept English Dossiers).

The A4 margin rule

The Guia CTD specifies A4 margin and legibility standards. This is a printing rule only — not a language requirement. Module 2 Portuguese is recommended rather than required (Amavita, Preclinical LATAM). Vendors sometimes conflate this printing spec with a language requirement, generating unnecessary translation cost.

C. Sworn vs. certified vs. simple translation — the ANVISA tier rules (sanitary layer)

The sworn-translation regime described below is entirely sanitary-layer (ANVISA RDC 200/2017, RDC 25/2011). It does not transfer to CEP/INAEP ethics filings.

Brazil operates a three-tier translation system, and mismatches between the document tier and the translation type are one of the most common — and most preventable — RFI triggers.

Document type	Translation tier required	Statutory hook
Contracts, powers of attorney, corporate authorizations	Tradutor público juramentado registered with a state Junta Comercial — cannot be replaced by in-house or agency certification	Amavita, ANVISA guide; Amavita, Sworn vs Certified
Health-authority-issued documents (foreign approvals, GMP certificates, CFS)	Sworn translation	RDC 200/2017 Art. 6 (Amavita, Preclinical LATAM)
Device revalidation manufacturer declaration	Consular or certified statement issued by the legal manufacturer, in Portuguese/English/Spanish, or accompanied by sworn translation, signed for max 2 years where no validity is stated	RDC 751/2022 Art. 27(I)
English or Spanish documents generally	Exempt from sworn translation; free translation acceptable absent a specific sworn requirement	RDC 25/2011 (as amended by RDC 50/2013); RDC 947/2024

Document type	Translation tier required	Statutory hook
TCLE (patient informed consent)	Brazilian Portuguese, fully revised, patient-comprehensible register	Amavita, INFLESZ — no Portuguese-validated equivalent of INFLESZ exists, so adapted Flesch is used

The Junta Comercial registration point

A common vendor error is delivering a "sworn translation" produced by a translator who is not registered with a Junta Comercial. In Brazil, the *tradutor público juramentado* is a state-registered public office — the translator holds a *matrícula* number issued by the state's commercial registry (Junta Comercial). A translation without a valid Junta Comercial matrícula is not a sworn translation, regardless of what the delivery document claims. ANVISA reviewers can and do verify matrícula numbers against state registries.

The ethics layer: institutional identity and legal basis (CONEP → INAEP)

Field	Value
Full legal name (PT)	Comissão Nacional de Ética em Pesquisa (CONEP)
English gloss	National Research Ethics Commission
Parent institution	Directly linked to the Conselho Nacional de Saúde (CNS), Ministério da Saúde
Successor body (2025→)	Instância Nacional de Ética em Pesquisa (INAEP), órgão colegiado no âmbito do Ministério da Saúde
Statutory basis of the system	Lei nº 14.874/2024, Art. 5º — creates the Sistema Nacional de Ética em Pesquisa com Seres Humanos, segmented into (I) a national ethics instance and (II) local CEPs
Implementing decree	Decreto nº 12.651, de 7 de outubro de 2025 — regulates Lei nº 14.874/2024
Ethics resolutions still in force	Res. CNS 466/2012 (general guidelines); Res. CNS 251/1997 (new drugs, medicines, vaccines and diagnostic tests); Res. CNS 674/2022 (research typing and protocol routing)
Savings clause for CNS norms	Decreto 12.651/2025, Art. 39 — CNS norms remain valid until INAEP publishes replacements, insofar as they do not contradict Lei 14.874/2024 or the Decreto

Field	Value
Most recent legal-instrument update	Decreto nº 12.651/2025, DOU 08/10/2025
Submission portal	Plataforma Brasil — national unified base for all Sistema CEP/Conep registrations
Successor platform mandated	Decreto 12.651/2025, Art. 8º — the Ministério da Saúde will maintain an integrated electronic platform for registration, protocol, information and analysis of research
Current CONEP role	Appeals-only instance during the INAEP transition per Decreto 12.651/2025, Art. 40 — CONEP acts *"como instância recursal até a posse dos membros da Instância Nacional de Ética em Pesquisa"*
Sanitary regulator	ANVISA (Agência Nacional de Vigilância Sanitária) — separate authorisation track under Lei 14.874/2024 Art. 58
Statute entered into force	90 days after publication (Lei 14.874/2024, Art. 65) — ~28 August 2024

Brazil's ethics layer was restructured in 2024–2025. Lei 14.874/2024 created a two-tier Sistema Nacional de Ética em Pesquisa (SINEP): a national instance (INAEP) and local CEPs. Decreto 12.651/2025 gave INAEP the norm-setting, *credenciamento* and *acreditação* powers previously exercised by CONEP within the CNS structure. CONEP was reduced to an appeals instance for the duration of the transition (Art. 40). Existing CEPs are grandfathered as *credenciados*/*acreditados* until INAEP re-evaluates them (Art. 37). CNS resolutions — 466/2012, 251/1997, 674/2022 — remain in force under the savings clause of Art. 39 for anything they cover that INAEP has not yet re-legislated. INAEP has already issued its Regimento Interno (Res. INAEP 01/2026, 02/04/2026) and a Despacho de Orientação nº 2/2026 harmonising Art. 14 deadline counting (DOU 28/04/2026, in force 05/05/2026).

What Brazilian ethics instruments *do* and *do not* say about translation

No fetched Brazilian ethics instrument prescribes a language for the technical dossier or requires translation of preclinical documentation. Lei 14.874/2024 and Decreto 12.651/2025 are silent. Res. CNS 466/2012, 251/1997 and 674/2022 are silent. The only language-adjacent obligations are *comprehensibility* rules directed at participant-facing documents: the informed consent form must use *"linguagem clara e objetiva, de fácil entendimento"* (Lei 14.874/2024, Art. 2º LIII), adapted to local culture where cooperation is international (Res. CNS 466/2012, item IV.5(b)). No such rule attaches to a toxicology report, an IND, or an Investigator's Brochure at the ethics layer.

Instrument	Requirement for translation?	Language requirement?	Verbatim scope
Lei nº 14.874/2024	None	None	The single "língua" hit at Art. 9 §2 II refers to a *consultant familiar with the language of the community* — not to submission documents
Decreto nº 12.651/2025	None	None	Zero occurrences of *tradução*, *tradutor*, *idioma*, *língua* as document-language requirements
Res. CNS 466/2012	None	None	The single "tradu" hit is item III.2(l), *"as pesquisas em comunidades... traduzir-se-ão em benefícios"* — not a document rule
Res. CNS 251/1997	None	None	5 pages, zero occurrences
Res. CNS 674/2022	None	None	11-page DOU republication, zero occurrences

> The operative lever — Lei 14.874/2024, Art. 14 §8 *"§ 8º Todos os documentos requisitados pelo CEP deverão estar previstos em ato do Poder Executivo, em regulamento ou no regramento do próprio CEP e ter pertinência com a matéria analisada."*

Read together with Art. 13 (the document list is deferred to specific regulation), this means any CEP demand for a Portuguese translation of a preclinical report must rest on a written instrument the sponsor is entitled to inspect.

> **The* diligência*-registration duty — Despacho de Orientação nº 2/2026 do Colegiado da INAEP (DOU 28/04/2026, in force 05/05/2026) Each* diligência *must be formally recorded in the official routing system* "com indicação clara das exigências formuladas, do prazo concedido e da data de comunicação."*

Any translation demand made by a CEP after 05/05/2026 must therefore be memorialised in Plataforma Brasil with a written basis and deadline — a document trail Amavita Sciences uses to scope work precisely and to challenge out-of-scope demands.

Preclinical-package composition at the ethics layer (Res. CNS 251/1997)

Brazil is unusually explicit about what a preclinical package must contain — and the source is a 1997 CNS resolution that remains in force under Decreto 12.651/2025 Art. 39's savings clause.

Item	Verbatim requirement (PT)	Amavita commentary
IV.1(a)	*"Especificação e fundamentação da fase de pesquisa clínica na qual se realizará o estudo, demonstrando que fases anteriores já foram cumpridas."*	Gate on prior phases
IV.1(b)	*"Descrição da substância farmacológica ou produto em investigação, incluindo a fórmula química e ou estrutural e um breve sumário das propriedades físicas, químicas e farmacêuticas relevantes."*	CMC / physicochemical
IV.1(c)	*"Apresentação detalhada da informação pré-clínica necessária para justificar a fase do projeto, contendo relato dos estudos experimentais (materiais e métodos, animais utilizados, testes laboratoriais, dados referentes a farmacodinâmica, margem de segurança, margem terapêutica, farmacocinética e toxicologia, no caso de drogas, medicamentos ou vacinas). Os resultados pré-clínicos devem ser acompanhados de uma discussão quanto à relevância dos achados em conexão com os efeitos terapêuticos esperados e possíveis efeitos indesejados em humanos."*	Core preclinical filing obligation

Item	Verbatim requirement (PT)	Amavita commentary
IV.1(d)	*"Os dados referentes à toxicologia pré-clínica compreendem o estudo da toxicidade aguda, sub-aguda a doses repetidas e toxicidade crônica (doses repetidas)."*	Toxicology scope
IV.1(e)	*"Os estudos de toxicidade deverão ser realizados pelo menos em 3 espécies animais, de ambos os sexos das quais uma deverá ser de mamíferos não roedores."*	Species requirement
IV.1(f)	*"No estudo da toxicidade aguda deverão ser utilizadas duas vias de administração..."*	Route requirement
IV.1(g)	*"...a duração do experimento deverá ser de no mínimo 24 semanas."*	Duration requirement
IV.1(h)	*"Na fase pré-clínica, os estudos da toxicidade deverão abranger também a análise dos efeitos sobre a fertilidade, embriotoxicidade, atividade mutagênica, potencial oncogênico (carcinogênico) e ainda outros estudos, de acordo com a natureza do fármaco e da proposta terapêutica."*	Repro / genotox / carcinogenicity

1. Waiver route. IV.1(i) permits the CEP to approve projects without all preclinical phases in urgent-need cases, but only *"neste caso deverá haver também aprovação da CONEP e da SVS/MS."* Under Decreto 12.651/2025, the CONEP consent becomes an INAEP consent once membership is seated; SVS/MS is now ANVISA.

2. Summarisation asymmetry. Item IV.1(k) expressly permits summarisation for the *clinical* prior-phase data. Item IV.1(c) requires *"Apresentação detalhada"* for the *preclinical* data plus a discussion of relevance. On the face of the text, summarisation is authorised for clinical and not authorised for preclinical.

3. Devices scope gap. Res. CNS 251/1997 items I.1 and II.1 limit the resolution to *"novos fármacos, medicamentos, vacinas e testes diagnósticos"*, and IV.1(c) is framed *"no caso de drogas, medicamentos ou vacinas."* The resolution therefore does not textually reach medical devices. Lei 14.874/2024, Arts. 37 and 62 close the gap by extension: *"Aplicar-se-ão aos produtos e dispositivos médicos e aos produtos de terapias avançadas experimentais as disposições desta Lei, no que couber."* No ISO 10993 or biocompatibility reference was found in any fetched Brazilian ethics instrument — this is an open regulatory question a device sponsor should raise on the record.

Res. CNS 466/2012 item III.3(a) adds the general prior-experimentation gate: biomedical experimental research on humans must *"estar fundamentadas na experimentação prévia, realizada em laboratórios, utilizando-se animais ou outros modelos experimentais e comprovação científica, quando pertinente."*

The modern-form obligation sits in Lei 14.874/2024, Art. 3º parágrafo único, I: a clinical trial requires *"disponibilidade de informação clínica e não clínica acerca do produto sob investigação, para respaldar a condução da pesquisa."*

Ethics-committee status: credenciamento and acreditação

Field	Value
Statutory conditions for a CEP	Interdisciplinary composition; must be credenciado com a instância nacional de ética em pesquisa (INAEP); regular functioning; adequate infrastructure; public member list; documented SOPs and written records; one research-participant representative (Lei 14.874/2024, Art. 9º I–VII)
Two-tier model	Low/moderate risk → CEP *credenciado* or *acreditado*; high risk → CEP *acreditado* only (Lei 14.874/2024, Art. 9º §1; Decreto 12.651/2025, Art. 25)
Credenciamento defined	Formal INAEP act authorising a CEP to conduct ethics review of low- or moderate-risk protocols (Decreto 12.651/2025, Art. 18)
Acreditação defined	Formal INAEP recognition that a CEP meets the higher requirements for high-risk protocols, preceded by an evaluation *"que poderá incluir inspeção presencial ou remota"* (Decreto 12.651/2025, Art. 19 §1)
Grandfathering	*"Até que seja feita nova avaliação pela Instância Nacional de Ética em Pesquisa, consideram-se credenciados e acreditados... os CEPs já credenciados e acreditados"* (Decreto 12.651/2025, Art. 37)
Risk classification drivers	Multidimensional analysis considering, among others, *"o estágio de desenvolvimento clínico do produto ou da tecnologia avaliada"* and international multicentre character (Decreto 12.651/2025, Art. 20 §1 VIII–IX)

First-in-human trials, which rely most heavily on preclinical data, are pushed toward CEP* acreditado *review under Art. 25 II.

Ethics-layer fees, timelines, and rejection triggers

Fees

No fee is established for ethics review in Lei 14.874/2024, Decreto 12.651/2025, or any CNS resolution. INAEP membership is expressly unremunerated (Decreto 12.651/2025, Art. 16). Local CEP practice varies and is not published.

Statutory timelines under Lei 14.874/2024

Step	Deadline
CEP acceptance of documentary completeness	up to 10 dias úteis from submission (Art. 14 caput)
CEP ethics opinion	up to 30 dias úteis from acceptance of complete documentation (Art. 14 caput)
Clock suspension when CEP requests further information	up to 20 dias úteis (Art. 14 §1)
Researcher response window	10 dias úteis, extendable once with justification; process may be cancelled for non-compliance (Art. 14 §2)
SUS-strategic / public-health-emergency research	opinion in no more than 15 dias úteis (Art. 15 parágrafo único)
Appeal, first instance (to the same CEP)	30 dias úteis to file (Art. 14 §5)
Appeal, second instance (national instance — CONEP transitional per Decreto 12.651/2025 Art. 40)	30 dias úteis to file (Art. 14 §5)
Decision on either appeal	up to 30 dias úteis (Art. 14 §6)

The 10-dias-úteis sponsor response window (Art. 14 §2) is the real translation-turnaround exposure. A CEP that treats an untranslated preclinical report as an incomplete filing can force the sponsor to produce a Portuguese version in ten working days or lose the review — even though translation itself is not a stated requirement.

On the sanitary side, ANVISA must resolve primary clinical-trial petitions within 90 dias úteis, and silence permits the sponsor to start clinical development provided ethics approvals are in place (Lei 14.874/2024, Art. 58 caput and §1).

Rejection triggers

The statutory outcome set is closed: *"I - aprovação da pesquisa; II - não aprovação da pesquisa; ou III - suspensão, quando a pesquisa aprovada, já em andamento, precisar ser interrompida por motivo de segurança"* (Lei 14.874/2024, Art. 14 §4). No translation-related rejection trigger exists in any fetched instrument.

Recent ethics-layer regulatory activity (2024–2026)

Date	Instrument	Relevance
28/05/2024 (DOU 29/05/2024)	Lei nº 14.874/2024	New statutory framework; creates SINEP; sets Art. 14 clocks; Art. 13 defers document list to future regulation; Art. 14 §8 limits what a CEP may demand; contains no language or translation provision
~28/08/2024	Lei 14.874/2024 entered into force	90 days after publication (Art. 65)
07/10/2025 (DOU 08/10/2025)	Decreto nº 12.651/2025	Creates INAEP; transfers norm-setting, *credenciamento* and *acreditação* (Arts. 10, 18, 19); risk classification keyed partly to development stage (Art. 20 §1 VIII); grandfathers existing CEPs (Art. 37); keeps CNS norms alive until INAEP legislates (Art. 39); reduces CONEP to appeals instance during transition (Art. 40); mandates a new integrated research platform (Arts. 8–9)
09/10/2025	CNS public statement on the new decree	Confirms INAEP substitutes the CNS/CONEP structure
2025	Nota Técnica nº 43/2025-DECIT/SCTIE/MS	Guidance on routing and risk classification within SINEP
2026	Nota Técnica nº 1/2026-DECIT/SCTIE/MS	Transition guidance: because Art. 40 leaves CONEP as appeals instance only, ethics review of Ministry-of-Health-proposed protocols moves to *credenciados*/*acreditados* CEPs of MoH-linked institutions

Date	Instrument	Relevance
02/04/2026	Resolução INAEP nº 01/2026 — Regimento Interno	First INAEP normative act
27/04/2026 (DOU 28/04/2026, in force 05/05/2026)	Despacho de Orientação nº 2/2026 do Colegiado da INAEP	Harmonises Art. 14 deadline counting; requires each *diligência* to be formally registered in the official routing system with the written basis, deadline, and communication date

Governance is still unsettled. CNS proposed on 29/07/2026 to re-create CONEP as a Comissão Intersetorial de Ética em Pesquisa; INAEP is still populating its full normative catalogue. Any translation demand made under transitional norms should be examined against Art. 14 §8's written-instrument requirement before compliance.

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

Sponsors almost always over-scope the preclinical stack. A full non-clinical package for a small molecule runs 2,000–8,000 pages of GLP toxicology, pharmacology, and ADME reports. Whether that stack has to be rendered into Portuguese — and if so, whether it needs desktop publishing (DTP) or only running text — is a three-question decision, not a single yes/no.

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

No. RDC 947/2024 carries the verbatim exemption that governs the whole question:

> *"Os documentos técnicos podem ser apresentados em língua inglesa ou espanhola, dispensada a tradução."*

Technical documents may be submitted in English or Spanish, with translation waived. That exemption reaches the non-clinical body of evidence directly: GLP study reports, pharmacology and toxicology reports, ADME and toxicokinetic data, certificates of GLP compliance, and the CTD Module 4 tabulated summaries. What it does not reach is the legal-administrative shell around the dossier — powers of attorney, corporate instruments, foreign authority certificates, apostilles — which remain in the sworn-translation tier described in Section C.

The second frequent misreading is the Guia CTD printing rule. ANVISA's CTD guidance specifies presentation and pagination conventions for the dossier; sponsors read the Portuguese-language

formatting instructions as a language mandate for the underlying study reports. It is a printing rule, not a language rule. The Module 4 study reports themselves stay in their source language under RDC 947/2024; only the navigational and index layer follows the Portuguese CTD conventions.

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

Where Portuguese is mandatory, ANVISA usually also cares about the visual object, not just the words. RDC 751/2022 Art. 10 §9 requires device labelling and instructions for use in Portuguese as they will appear to the Brazilian user — meaning the deliverable is a typeset artwork file, not a bilingual text table. That is DTP work: figure callouts, symbol legends, table headers, warning boxes, and pagination all have to be reconstructed in the target language at the same visual fidelity.

For the preclinical stack specifically, the DTP surface is narrow but real: any study report figure, seal, or signature page that is extracted into a Portuguese summary must reproduce the original layout, and every reproduced table must keep its numeric integrity against the source.

Deliverable	Language treatment	Production mode
GLP study reports (Module 4)	English or Spanish accepted — no translation	None
Non-clinical overview / summaries (Module 2.4, 2.6)	English or Spanish accepted; Portuguese recommended when the reviewer will read it end-to-end	Text-only
Legal instruments, apostilles, CPP	Sworn Portuguese translation mandatory	Text-only, certified
Device labels and IFU	Portuguese mandatory — RDC 751/2022 Art. 10 §9	Full DTP

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

Something always substitutes. In Brazil the substitutes are: a Portuguese non-clinical overview that maps each source study to the claim it supports; a cross-reference index in Portuguese so the reviewer can navigate an English body of evidence without guessing; and, for device dossiers, a Portuguese essential-principles justification citing the untranslated engineering and biocompatibility reports by study number. The substitute is navigation, not content.

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

- Clinical protocol and ICF in Portuguese.
- Investigator's Brochure accepted in source language with a Portuguese summary at CEP/CONEP discretion.
- Foreign health-authority letters (FDA IDE, GMP, CFS, CPP) as sworn Portuguese translation per RDC 200/2017 Art. 6.

Pathway 2 — market-access / sanitary registration

- Device application forms, IFU, and labelling in full Portuguese per RDC 751/2022 Art. 10 §9 (DTP required).
- Drug label and package insert in full Portuguese per RDC 71/2009.
- Other device documents in Portuguese, Spanish, or English per RDC 751/2022 Art. 10 §10.

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	Portuguese required?	Statutory basis	Certification tier	DTP?	Substitute deliverable
GLP toxicology and pharmacology reports	No	RDC 947/2024	—	No	Portuguese Module 2.4/2.6 overview
ADME / toxicokinetics	No	RDC 947/2024	—	No	Portuguese tabulated summary
GLP compliance certificates	No	RDC 947/2024	—	No	Cited in Portuguese index
Biocompatibility reports (devices)	No	RDC 947/2024	—	No	Essential-principles justification in Portuguese

Document class	Portuguese required?	Statutory basis	Certification tier	DTP?	Substitute deliverable
Powers of attorney, corporate instruments	Yes	Civil Code / ANVISA practice	Sworn (tradutor público)	No	None
Foreign authority certificates, apostilles	Yes	Section C tiering	Sworn	No	None
Device label and IFU artwork	Yes	RDC 751/2022 Art. 10 §9	Certified + regulatory review	Yes	None

Where the preclinical translation risk actually sits

Not in the toxicology binder. Sponsors lose money translating 4,000 pages ANVISA never asked for, and lose cycles by under-translating the twelve pages of legal instruments ANVISA will not accept in English. The second exposure is currency: an untranslated study report is fine, but a superseded one is an RFI regardless of language — which is why Document Currency is the seventh QC gate.

CATEGORY 1: DRUGS / PHARMACEUTICALS

D1. Drugs — Market Access

Governing body: CMED (Câmara de Regulação do Mercado de Medicamentos), created by Art. 5 of Lei nº 10.742/2003 as a body of the Conselho de Governo. Its stated objective is the adoption, implementation, and coordination of activities relating to the economic regulation of the medicines market, promoting pharmaceutical assistance through mechanisms that stimulate supply and sector competitiveness.

Pricing mechanism (Art. 4 Lei 10.742/2003):

- §1 — Price adjustment follows a price-cap model built on an index, a productivity factor, and an intra-sector/inter-sector relative-price adjustment factor.
- §2 — The index is the IPCA (Índice Nacional de Preços ao Consumidor Amplo) calculated by IBGE.
- §3 — The productivity factor passes projected productivity gains to consumers.

- §4(I) — Intra-sector relative-price factor calculated on market power (monopoly/oligopoly power, information asymmetry, entry barriers).
- §4(II) — Inter-sector factor on input-cost variation not already captured by the index.
- §7 — Adjustments occur annually.
- §9 — Permits exceptional positive or negative adjustments by the CMED Council of Ministers.

Enforcement: Art. 8, sole paragraph — refusal, omission, falsity, or unjustified delay in providing required information carries a daily fine of R$ 10,000, increasable up to 20×.

Translation requirements for CMED filings: The fetched CMED page carries only page metadata and no submission requirements or deadlines. Lei 10.742/2003 states no deadline in days (ANVISA, CMED). Sponsors should file in Portuguese and treat CMED submissions as high-consequence economic filings with a heavy penalty regime for defect.

Practical translation implications:

- Pricing dossier: Portuguese
- Cost-effectiveness / HTA supporting materials: Portuguese
- Supporting international pricing references: original language acceptable, Portuguese summary recommended
- Corporate/legal authorization documents: sworn Portuguese

D2. Drugs — Regulatory Submissions for Market Clearance

Drug registration in Brazil operates under a portfolio of ANVISA resolutions with the language and sworn-translation rules set out in Sections B and C above (ClinRegs Brazil; Amavita, Preclinical LATAM).

Verified pathway framework:

- RDC 947/2024 — general language rule (Portuguese; English and Spanish accepted; free translation absent a specific sworn requirement)
- RDC 25/2011 (as amended by RDC 50/2013) — English/Spanish sworn-translation exemption
- RDC 200/2017 Art. 6 — sworn translation for health-authority-issued documents
- RDC 403/2020 — sworn-translation waiver
- Guia CTD — Brazilian CTD format specifications

Verified language and sworn-translation position: Portuguese primary; English and Spanish accepted for supporting documents; sworn Portuguese for authority-issued documents, contracts, and corporate authorizations.

Per-pathway statutory clocks: Statutory day-counts for NME, generic, biosimilar, renewal, and variation registration pathways were not verified from a fetched primary source in this research pass. Sponsors should verify current review timelines directly against the specific RDC governing their pathway.

Empirical timelines: The verified Brazilian empirical figure applicable to drug market clearance is the clinical-dossier *exigência* RFI cycle — see Section F. Drug-registration empirical cycle times were not verified in this pass.

Priority review (carried from clinical-trial track for completeness): Priority review runs 45 calendar days for eligibility, 45 days for first response, and 60 days for final decision, extendable by 20 days, with 30 days for rare diseases (ClinRegs Brazil).

D3. Drugs — Clinical Research Trial Submissions

Authorizing agency: ANVISA, under RDC 945 of 29 November 2024 together with RDC 585/2021, with advanced therapies under RDC 506/2021 and the statutory frame of Law 14.874 of 28 May 2024 (ClinRegs Brazil).

Ethics framework — parallel and mandatory: Ethics review runs parallel to and independent of ANVISA. Site-level CEP review plus national CONEP escalation for substantive amendments and specified protocol categories. All ethics submissions flow through Plataforma Brasil.

Amavita characterizes the Brazilian TCLE → CEP → CONEP chain as the most complex amendment cascade in the region. Empirical data: 2% of Brazilian amendments incur ≥3 RFI rounds, equating to a ≥4.0× revision multiplier (Amavita, Amendment Cascade).

ANVISA-side timelines (ClinRegs Brazil):

Step	Deadline
DDCM/DEEC technical review	90 business days; deemed released if no ANVISA response
DEEC filing after DDCM	Within 15 business days
Technical requirement (*exigência*)	One permitted per review cycle; sponsor response within 30 business days
Continuous IMPD quality documents	30 calendar days
Priority pathway	45 cal. days eligibility → 45 days first response → 60 days final decision (extendable +20 days)
Rare disease	30 days
Documento de Importação (DI)	Issued within 30 business days
Import analysis	48 hours (5 days if for registration)

Critical operational point — the exigência resets the clock: When ANVISA issues a technical requirement, the review timer restarts once the sponsor responds. This is a fundamental Brazilian regulatory reality that vendors without ANVISA experience miss (Amavita, ANVISA guide).

Ethics-side timelines (ClinRegs Brazil; Amavita, Amendment Cascade):

Step	Deadline
CEP completeness check	10 working days
CEP opinion	30 days
CONEP escalation	+30–90 days

Translated documents required for a drug CTA:

- Protocol — Portuguese (via Plataforma Brasil for ethics; also part of ANVISA dossier)
- Investigator Brochure — Portuguese recommended
- IMPD Modules — technical content may be English; Portuguese summary
- TCLE — fully revised Portuguese, patient-comprehensible register
- Cover letters — Portuguese
- Investigational product labeling — Portuguese
- Imported human biological material labels — English AND Portuguese

PV report translation: The DSUR is forwarded to ANVISA in English upon request — the most English-friendly PV rule among the six LATAM regulators (ClinRegs Brazil).

Post-marketing pharmacovigilance framework: RDC 406/2020 establishes Good Pharmacovigilance Practices for medicine registration holders (Art. 1), requires responses to authority requests within the authority-set deadline with extension requests where needed (Art. 4 and §§1–3), mandates a Brazil-resident RFV (pharmacovigilance responsible person) plus substitute (Arts. 5–6, 16), locates the pharmacovigilance system in Brazil (Art. 12), permits outsourcing except of the RFV role (Art. 10 and §§1–7), and requires notification traceability retained for at least 20 years (Art. 25, sole paragraph). RDC 406/2020 as fetched sets no PBRER/DSUR day-count and no explicit language requirement.

CATEGORY 2: MEDICAL DEVICES

E1. Devices — Market Access

Brazil does not operate a centralized device pricing or reimbursement regulator equivalent to CMED for drugs. The CMED mandate in Lei 10.742/2003 addresses medicines, not devices.

No Brazilian device reimbursement or hospital-procurement framework was verified from a fetched primary source in this research pass. Device market access in Brazil operates primarily through:

- SUS (Sistema Único de Saúde) procurement — public sector hospital purchasing
- Private hospital procurement
- CONITEC (Comissão Nacional de Incorporação de Tecnologias no SUS) health technology assessment for SUS incorporation

Two commercially relevant device deadlines that affect market-access execution are fixed by RDC 751/2022:

Item	Deadline	Source
Publication of immediate-implementation alterations	Within 30 days of submission completion, regardless of documentary analysis	Art. 22 RDC 751/2022
Inventory depletion after alteration	120 days after alteration is published, except safety/performance-driven alterations	Art. 26, sole paragraph RDC 751/2022

Translation requirements for device market-access execution:

- SUS procurement tender documents: Portuguese
- CONITEC HTA submissions: Portuguese
- Hospital procurement documents: Portuguese
- International reference pricing / clinical evidence packages: original language acceptable; Portuguese summary and Portuguese-translated key claims recommended

E2. Devices — Regulatory Submissions for Market Clearance

Governing regulation: RDC 751/2022 — the current device baseline, in force since 2022.

DEVICE CLASSIFICATION — RDC 751/2022 ART. 5

Class	Risk level
Class I	Low risk
Class II	Medium risk
Class III	High risk
Class IV	Maximum risk

ANVISA decides classification in case of doubt.

TWO PATHWAY ARCHITECTURE — ARTS. 6–7

Class	Pathway
Class I, II	Notification (products exempt from marketing authorization under §1 of Art. 25 of Law No. 6,360/1976)
Class III, IV	Marketing authorization — ANVISA's exclusive act

Article 3 extends both pathways to families, systems, and kits. Article 60(1) bars industrialization, import, display, or delivery before publication of the notification or authorization number. Article 60(2) exempts export-only manufacture. Article 28 exempts notified products from revalidation — a Class I/II operational advantage.

CLASSIFICATION APPLICATION RULES — ARTS. 8–9 AND ANNEX I

- Intended purpose governs, except IVDs which follow specific rules (Art. 8)
- Combination-use devices classified separately (§1)
- Accessories classified separately (§2)
- Software controlling or influencing a device takes that device's class (§3)
- Independent Software as a Medical Device (SaMD) classified independently (§4)
- Non-body-part-specific devices classified on most critical use (§5)
- Most stringent applicable rule governs (§6)
- Continuous-use calculation disregards procedural interruptions and cleaning removals; accumulates same-type replacement use (§7)

Annex I rules:

- Rules 1–4: non-invasive devices

- Rules 5–8: invasive/implantable devices
- Rules 9–10: active devices
- Blood bags — Class III (Rule 2)
- Pre-implantation cell/tissue contact substances — Class IV (Rule 3)
- CNS and cardiac/central-circulatory contact escalations — Class IV (Rules 6–8)
- Breast implants, surgical meshes, joint prostheses, spinal implants — Class IV (Rule 8)
- Active-implantable control/monitoring devices — Class IV (Rule 9)

STATUTORY CLOCKS — RDC 751/2022

Item	Deadline
Notification processing	Routinely up to 30 days after submission (Art. 10 §6)
Marketing-authorization assessment	Within the legal deadlines of Brazilian health legislation (Art. 10 §2) — no day-count in the RDC itself
No technical analysis for notifications/notification alterations	Art. 10 §5
Incomplete/illegible/obsolete filings	Not subject to a technical requirement; lead to disapproval or rejection (Art. 10 §4)
Immediate-implementation alterations published	Up to 30 days (Art. 22)
Inventory depletion after alteration	120 days (Art. 26)
Use-instruction upload for new/altered products	Up to 30 days after DOU publication (Art. 33 §5)
Use-instruction upload for non-reportable alterations	Up to 180 days after implementation (Art. 33 §6)

Critical rejection rule: Under Art. 10 §4, incomplete or illegible device filings are rejected outright — no technical requirement (*exigência*) is issued. This is materially harsher than the drug clinical-trial track, where an *exigência* offers a 30-day response window. For devices, submission quality must be right on the first pass.

CONDITIONS ON GRANT

Marketing authorization requires:

- Publication of ANVISA's GMP certificate (Art. 10 §8)
- Maintenance bound to GMP, essential safety/performance requirements, and specific regulations (Art. 10 §7)
- Revalidation requires the fee, the Art. 27(I) manufacturer declaration, and a valid ANVISA GMP certificate (Art. 27(II))

- The Art. 27(I) declaration must name both companies, express representation authorization, and acknowledgement of RDC 665 of 30 March 2022 GMP requirements (Art. 27 §1)
- Filing within the period of RDC 250 of 20 October 2004 (Art. 27 §2)
- A GMP-certification application protocol is accepted to start revalidation analysis (Art. 27 §3)

PER-CLASS TRANSLATED DOCUMENTS

Document	Language required
Application forms	Portuguese (Art. 10 §9)
IFU (Instructions for Use / user or operator manuals)	Portuguese (Art. 10 §9)
Labeling models	Portuguese (Art. 10 §9)
All other documents	Portuguese, Spanish, or English (Art. 10 §10)
Art. 27(I) manufacturer declaration	Portuguese/English/Spanish OR with sworn translation

IFU PUBLICATION — DOCUMENTORY REPOSITORY

Use instructions are loaded into the Documentory Repository of Medical Devices and published exclusively on ANVISA's website immediately after protocol completion, independent of documentary analysis (Arts. 33–34). The holder attests content compliance (Art. 33 §4).

This means the IFU becomes public on ANVISA's website as soon as it's uploaded — before any technical review. IFU translation quality is therefore visible to competitors, distributors, and end users immediately. There is no "quiet phase" during which IFU translation defects can be corrected before public exposure.

E3. Devices — Clinical Research Trial Submissions

Governing instrument: RDC 837/2023, published 15 December 2023, effective 4 January 2024 (ANVISA news release).

RDC 837/2023 restructured Brazilian device clinical investigations with four key changes:

1. Single DICD process replaces per-investigation approvals. The *Anuência em Processo de Pesquisa Clínica* — previously mandatory for each investigation — is eliminated. All device and clinical-investigation-plan documentation now files in a single DICD (*Dossiê de Investigação Clínica de Dispositivos Médicos*) process.

2. ANVISA submission narrowed to Class III/IV registration-supporting investigations. From 4 January 2024, only investigations whose results could support Brazilian registration of Class III

and Class IV devices require ANVISA submission. Notifications for post-marketing studies and for Class I and II devices no longer need prior ANVISA approval.

This is a major operational simplification: post-market device studies and low-risk device studies are now outside the ANVISA authorization framework. Ethics review through CEP/CONEP still applies.

3. Terminology convergence with RDC 751/2022. RDC 837/2023 adopts the same device classification vocabulary as the market clearance regime under RDC 751/2022. This is a translation asset — the same terminology stack applies to both regulatory tracks.

4. CEP reasoned opinion removed from ANVISA's required document list. On the reasoning that CEP approval is an ethical rather than regulatory requirement, RDC 837/2023 removes the CEP opinion from ANVISA's filing requirements. This does not remove the ethics obligation — CEP/CONEP review continues under the framework described in D3 — but it separates ethics timing from ANVISA timing.

Practical impact: Sponsors can now begin ANVISA review without waiting for CEP approval. But ethics approval remains required before any subject enrollment.

5. Specific Resolutions replace Comunicados Especiais. Approved investigation decisions are now published as Specific Resolutions in the DOU (Diário Oficial da União), carrying the DICD and investigation data previously in the Comunicados.

Review timelines under RDC 837/2023: Not stated in the ANVISA news release — sponsors should verify current review clocks directly with ANVISA or against the RDC 837/2023 text itself.

First-in-human vs. pivotal vs. post-market: The release distinguishes post-marketing studies (no prior approval) from registration-supporting Class III/IV investigations (ANVISA submission required). A separate FIH regime is not stated in the fetched source.

Translated documents required for a device clinical investigation:

- Investigational plan — Portuguese
- Device IFU — Portuguese
- IB-equivalent (device dossier) — Portuguese
- TCLE — fully revised Portuguese, patient-comprehensible register
- Cover letters — Portuguese
- Labeling for investigational device — Portuguese

F. Common ANVISA RFI patterns

ANVISA and COFEPRIS (Mexico) show the highest translation-grounds RFI rates in Amavita's 24-month dataset (Amavita, RFI Anatomy).

The wrong-amendment-version RFI

A documented ANVISA case under RDC 945/2024 + IN 338/2024: a clinical dossier attached the wrong amendment version. Result: an *exigência* was issued. The sponsor responded on day 6 of the 30-calendar-day response window. Re-review took 21 days. Total delay: +27 days.

If the sponsor's response is unsatisfactory, the consequence is rejection plus full resubmission — not another *exigência*. ANVISA does not iterate infinitely on the same submission.

The seven-gate framework Amavita applies

Amavita's Regulatory Language Infrastructure™ applies seven QC gates to every ANVISA submission:

1. Structural inventory — every section of the CTD or DICD dossier present in the correct order
2. Numeric integrity — dose ranges, sample sizes, statistical parameters preserved verbatim
3. Unit consistency — SI units, decimal separators (comma vs. period), significant figures preserved
4. Negation preservation — every "no," "not," "sem," "não" preserved with meaning intact
5. Entity mapping — investigator institutions, sponsor legal entities, distributor entities correctly mapped
6. Adversarial back-translation — critical passages back-translated by a different translator to catch semantic drift
7. Document Currency *(new)* — every foreign-origin certificate, apostille, notarization, and issued regulatory document within its jurisdictional validity window at time of filing

Plus: Cryptographic audit ledger — release-layer commitment, SHA-256 signature on every version.

The *exigência* case above was preventable by Gate 1 (structural inventory) — a version-check control on the specific amendment file attached.

G. ANVISA timelines — consolidated

Sub-category	Item	Statutory	Empirical
D1	CMED price adjustment	Annual (Lei 10.742/2003 Art. 4 §7)	n.a.
D2	Drug registration pathways	n.a.	n.a.
D3	DDCM/DEEC review	90 business days, deemed released if no response (ClinRegs Brazil)	n.a.
D3	*Exigência* response	30 business days	+27 days total (Amavita, RFI Anatomy)
D3	Priority / rare disease	45+45+60 (+20) / 30 days	n.a.
D3	CEP / CONEP	10 wk days completeness, 30 days opinion	CONEP +30–90 days (Amavita, Amendment Cascade)
E2	Device notification	Up to 30 days (Art. 10 §6 RDC 751/2022)	n.a.
E2	Device marketing authorization	Legal deadlines of health legislation (Art. 10 §2)	n.a.
E2	Device alterations / IFU upload	30 days; 30/180 days (Arts. 22, 33)	n.a.
E3	Device investigations (RDC 837/2023)	n.a.	n.a.

H. Recent regulatory changes 2023–2026

- RDC 837/2023 (15 Dec 2023, effective 4 Jan 2024) — Single-DICD device investigation regime; Class III/IV-only ANVISA submission; CEP opinion removed from ANVISA document list; *Comunicados Especiais* replaced by DOU Specific Resolutions (ANVISA news release)
- RDC 945 of 29 November 2024 + IN 338/2024 — Current clinical trial dossier framework, alongside RDC 585/2021 (ClinRegs Brazil; Amavita, RFI Anatomy)
- RDC 947/2024 — Current general language rule (Portuguese; English and Spanish accepted; free translation absent a specific sworn requirement) (ClinRegs Brazil)
- Law 14.874 of 28 May 2024 — Statutory frame for research with human participants (ClinRegs Brazil)

- RDC 751/2022 — Device baseline, with RDC 665 of 30 March 2022 as the GMP reference cited in Art. 27 §1
- ICH status: E6(R2) adopted; E6(R3) not yet implemented — widening gap with Argentina's ANMAT, which adopted E6(R3) via Disposición 7516/2025

Amavita Sciences delivery model for Brazil sponsors

Preclinical dossier translation (device and drug programs)

Amavita Sciences produces Portuguese-language versions of preclinical study reports, Investigator's Brochures, and IND-equivalent packages that satisfy Res. CNS 251/1997 item IV.1(c)–(h) at the ethics layer and RDC 9/2015 at the sanitary layer, delivered in bilingual Layout A — English source verbatim, Portuguese on the facing page.

For device sponsors, we deliver against IEC 60601, ISO 14971, and ISO 10993 vocabularies simultaneously. The ISO 10993 gap in Brazil's ethics instruments is closed at the delivery level, not the regulatory level, and we produce a translator's declaration to that effect. See how we scope a Brazil program.

Sponsor-lever documentation

When a CEP requires Portuguese translation of a preclinical report without citing an instrument, Amavita Sciences prepares the written response invoking Lei 14.874/2024 Art. 14 §8 and Despacho INAEP 2/2026, formatted for filing back into Plataforma Brasil. The intent is not to refuse translation — it is to make the CEP's requirement fit within the *diligência*-registration duty so that later demands are bounded. Talk through a pending diligência.

First-Pass Acceptance program — Brazil scope

For Brazil, First-Pass Acceptance covers documentary-completeness pass at the CEP within the Art. 14 10-dias-úteis window and no substantive translation-related pendency in the Art. 14 §1 20-dias-úteis suspension window. Move a Brazil program through the workflow.

I. Cross-references in the Amavita library

Deeper Amavita content covering ANVISA-specific topics:

- ANVISA Regulatory Translation Requirements *(the original, now superseded by this guide)* — Brazilian Portuguese review, *tradutor público juramentado* via Junta Comercial, Vocabulário Controlado, MedDRA alignment, TCLE via CEP/CONEP, *exigência* clock reset.
- Preclinical Translation Requirements — 9 LATAM Regulators — RDC 25/2011 (as amended by RDC 50/2013), RDC 751/2022 Art. 10 §10, RDC 200/2017 Art. 6, RDC 403/2020, Guia CTD A4 rule.
- Which Regulators Accept English Dossiers — English technical + Portuguese summary; Portuguese sworn for legal tier.
- RFI Anatomy — Six LATAM Regulator Rejections — RDC 945/2024 + IN 338/2024 *exigência*, +27 days, rejection on unsatisfactory response.
- Amendment Cascade — 12-Country LATAM Translation Stack — RDC 9/2015 + RDC 945/2024, VisaDoc, TCLE→CEP→CONEP, CONEP +30–90 days, 2% of amendments with ≥3 RFI rounds (≥4.0× multiplier).
- The Three Bands of LATAM Regulatory Translation — Welocalize ANVISA batch-record case study.
- The INFLESZ Threshold — Resolution CNS 466/12, no Portuguese INFLESZ equivalent (Portuguese TCLE readability uses adapted Flesch).
- Sworn vs Certified Translation — the *tradutor público juramentado* Junta Comercial registration point.
- Translation QC for Regulatory Dossiers — the seven-gate QC framework applied to ANVISA submissions.
- Costly Translation Mistakes — case studies including ANVISA.
- Regulatory Language Infrastructure vs Traditional Translation — the platform architecture applied to ANVISA workflow.

Continue across the LATAM stack

Country	Guide
Argentina	ANMAT regulatory translation requirements
Colombia	INVIMA regulatory translation requirements
Dominican Republic	DIGEMAPS / CONABIOS regulatory translation requirements
Mexico	COFEPRIS regulatory translation requirements
Panama	DNFD regulatory translation requirements
Peru	DIGEMID regulatory translation requirements

FAQ

What language does ANVISA require for regulatory submissions?

Portuguese is primary. Under RDC 947/2024, English and Spanish are also accepted, with translation subject to ANVISA request. Sworn Portuguese translation is required only for health-authority-issued documents (RDC 200/2017 Art. 6) and for certain contracts and corporate authorizations.

Do medical device IFUs have to be in Portuguese?

Yes. RDC 751/2022 Art. 10 §9 requires application forms, IFUs, and labeling models to be in Portuguese. Other device documents may be in Portuguese, Spanish, or English (Art. 10 §10).

Who can produce sworn translations for Brazilian regulatory submissions?

Only a tradutor público juramentado registered with a state Junta Comercial. The translator must hold a valid matrícula number from the state's commercial registry. In-house or agency-certified translations do not qualify as sworn translations, regardless of what the delivery document claims.

What is the CEP/CONEP framework?

Brazil operates a two-tier ethics system parallel to ANVISA, but the top tier changed. Under Lei 14.874/2024 and Decreto 12.651/2025, the national instance is now INAEP (Instância Nacional de Ética em Pesquisa), which holds norm-setting, credenciamento and acreditação powers; CONEP functions as an appeals-only instance until INAEP members are seated (Decreto 12.651/2025, Art. 40). Local CEP review remains the operative first instance, filed through Plataforma Brasil: completeness check 10 dias úteis, opinion 30 dias úteis, sponsor response window 10 dias úteis (Art. 14) (ClinRegs Brazil; Amavita, Amendment Cascade).

What is the ANVISA clinical trial review timeline?

DDCM/DEEC technical review runs 90 business days; the dossier is deemed released if ANVISA does not respond. An exigência (technical requirement) may be issued once per review cycle, with a 30-business-day sponsor response window. Critically, the exigência resets the review clock — sponsors should assume total review can extend beyond the nominal 90-day timeline when defects are present.

What changed under RDC 837/2023 for device clinical investigations?

RDC 837/2023 (effective 4 January 2024) restructured device clinical investigations. Only investigations supporting Class III/IV registration now require ANVISA submission. Post-market studies and Class I/II investigations no longer need prior ANVISA approval. The CEP reasoned opinion was removed from ANVISA's required document list (though CEP review remains required). A single DICD process replaces the previous per-investigation authorization regime.

Has ANVISA adopted ICH E6(R3)?

Not as of August 2026. ANVISA has adopted E6(R2) but has not yet implemented E6(R3). Argentina's ANMAT became the first LATAM regulator to adopt E6(R3) via Disposición 7516/2025, effective 1 December 2025. Sponsors running trials across ANVISA and ANMAT should be aware of the framework asymmetry.

Does ANVISA accept the DSUR in English?

Yes. Under ClinRegs Brazil guidance, the DSUR is forwarded to ANVISA in English upon request. This is the most English-friendly PV rule among the six LATAM regulators covered in this guide series.

What is the most common ANVISA translation-grounds RFI?

In Amavita's 24-month dataset, ANVISA and COFEPRIS show the highest translation-grounds RFI rates among the six LATAM regulators. Common defect classes include wrong-amendment-version attachments, terminology drift from Vocabulário Controlado, and negation-preservation errors. See The RFI Anatomy for detailed case studies.

Where does Amavita Sciences sit in the ANVISA translation market?

Amavita Sciences is Regulatory Language Infrastructure™ — the multilingual clinical operations platform. We are not one of eleven Latin American translation vendors. Our platform combines automated readability scoring (adapted Flesch for Portuguese TCLE), the seven-gate QC framework, and a cryptographic release ledger. One workflow. The platform does the work. Humans certify the outcome. Every step logged. Every version signed. Every audit prepackaged.

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 **2.0.0**, last updated August 25, 2026. Every substantive change to the ANVISA requirements on this page is recorded below.

v2.0.0 August 25, 2026

- Rebuilt the Brazil ethics layer: institutional identity and legal basis for CONEP → INAEP under Lei 14.874/2024 and Decreto 12.651/2025.
- Established INAEP as norm-setter and CONEP as an appeals-only instance per Decreto 12.651/2025 Art. 40; removed the superseded description of CONEP as an active reviewer.
- Added the Res. CNS 251/1997 item IV.1(a)–(h) preclinical enumeration, the IV.1(i) waiver route, the clinical-vs-preclinical summarisation asymmetry, and the medical-device scope gap.
- Added credenciamento/acreditação status rules, ethics-layer fees, Art. 14 statutory clocks, rejection triggers, and 2024–2026 regulatory activity including Despacho INAEP 2/2026.
- Labelled the sworn-translation regime as sanitary-layer only and added the Amavita Sciences Brazil delivery model plus a six-country LATAM stack block.

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.