

ANVISA Submission Document Checklist

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Brazil requires the submission in Brazilian Portuguese. Foreign public documents additionally require an apostille on the original and a tradução juramentada issued by a sworn translator registered with a state Junta Comercial. Use this sheet to track each document before you file.

✓	Document	Language / certification requirement
☐	Clinical trial dossier (DDCM) and protocol amendments	Brazilian Portuguese, terminology locked against a project glossary
☐	Investigator brochure	Brazilian Portuguese; safety terminology consistent with the protocol
☐	TCLE (informed consent) and assent	Brazilian Portuguese, lay register, CEP/CONEP content elements present
☐	GMP certificate / certificate of free sale	Apostille on the original, then tradução juramentada
☐	Power of attorney and legal representation documents	Notarized, apostilled, tradução juramentada
☐	Labeling, bula, and IFU text	Brazilian Portuguese, aligned with approved product information
☐	CMC and quality sections	Brazilian Portuguese; units, nomenclature, and specifications carried over exactly
☐	Exigência responses and correspondence	Portuguese; reuse the terminology already filed in the dossier

Filing notes

Order of Operations & Rejection Triggers

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Order of operations

- 1 Confirm which documents are foreign public documents (these need apostille + sworn translation).
- 2 Obtain the apostille on the original document, from the authority in the issuing country.
- 3 Commission the tradução juramentada from a tradutor público registered with a state Junta Comercial.
- 4 Lock a project glossary before the dossier translation starts; reuse it for every later filing.
- 5 Translate the scientific dossier into Brazilian Portuguese with a certificate of accuracy.
- 6 Have the TCLE reviewed for lay register and CEP/CONEP content elements before submission.
- 7 File; answer any exigência using the terminology already on record in the dossier.

Common rejection triggers

- Sworn translation produced before the apostille — the translation must be redone.
- European Portuguese spelling and vocabulary in a Brazilian filing.
- Terminology drift between the protocol, the investigator brochure, and the TCLE.
- Agency certificate of accuracy used where a tradução juramentada is required.
- An untranslated annex or appendix attached to an otherwise complete dossier.
- TCLE written above lay reading level, returned by the CEP rather than ANVISA.

Need this run for a live filing?

Start a LATAM pilot: amavitasciences.com/start-your-latam-pilot

Full ANVISA guide: amavitasciences.com/guide/anvisa-regulatory-translation-requirements