LATAM REGULATORY GUIDES · PERU

DIGEMID Regulatory Translation Requirements: The Complete Guide for Drugs and Medical Devices in Peru

The Art. 28 two-year currency rule, the INS/DIIS/SUDEC versus DIGEMID/ANM split for trials, and why Document Currency is the seventh QC gate.

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INS/DIGEMID two-agency framework

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The direct answer

Peru's language regime is simultaneously the most permissive and the most unforgiving in LATAM's Big 6. Permissive because Art. 28 of Decreto Supremo N° 016-2011-SA accepts *traducción simple* — a plain, non-sworn Spanish translation — for every foreign-issued document in a registration dossier, and permits the ANM to designate by *comunicado* which documents can stay in English (DS 016-2011-SA). Unforgiving because the same article invalidates any foreign document older than two years regardless of translation quality: a perfectly translated but stale

Certificate of Pharmaceutical Product, Certificate of Free Sale, or GMP certificate fails on its face. Peru is also the only regulator of the six where a different agency authorizes clinical trials than the one that grants marketing authorization — the INS/DIIS/SUDEC approves trials while DIGEMID/ANM contributes a binding opinion on the investigational product (ClinRegs Peru). That structural split makes Peru the regulator where Amavita's 7th QC gate — Document Currency is most operationally consequential.

Section A. Regulator profile

Name: Dirección General de Medicamentos, Insumos y Drogas (General Directorate of Medicines, Supplies and Drugs), DIGEMID, which acts as the Autoridad Nacional de Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios (ANM) — the National Authority for Pharmaceutical Products, Medical Devices and Sanitary Products — within the Ministerio de Salud (ClinRegs Peru; DS 016-2011-SA).

Establishing statute: The operative regulation is Decreto Supremo N° 016-2011-SA, the *Reglamento para el Registro, Control y Vigilancia Sanitaria de Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios*, issued under Ley N° 29459 (*Ley de los Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios*). The decree entered into force 180 calendar days after publication in the Diario Oficial El Peruano (DS 016-2011-SA).

Scope: Registration (*inscripción* and *reinscripción*), sanitary control, and surveillance of pharmaceutical products, medical devices, and sanitary products — including labelling, importation, GMP certification, batch quality control, *farmacovigilancia* and *tecnovigilancia* (DS 016-2011-SA).

Website: https://www.digemid.minsa.gob.pe

Relevant HQ address: For clinical-trial matters, the operative address is the Instituto Nacional de Salud (INS) at Jirón Cápac Yupanqui 1400, Jesús María, Lima (ClinRegs Peru).

Adjacent bodies sharing responsibility. Peru is the only one of the Big 6 where a different agency authorizes clinical trials from the one that grants marketing authorization — a structural fact that reshapes the entire translation workflow.

Body	Role	Reference
Instituto Nacional de Salud (INS) — *Dirección de Investigación e Innovación en Salud (DIIS) / Subunidad de Ensayos Clínicos (SUDEC)*	Authorizes clinical trials. Constituted under Ley 27657 and DS 001-2003-SA; INS/DIIS receives and decides the trial application, with the INS President deciding appeals	ClinRegs Peru

Body	Role	Reference
DIGEMID / ANM	Issues the binding opinion on the investigational product inside the INS review; grants investigational-product import authorizations; grants and renews all marketing registrations	ClinRegs Peru; DS 016-2011-SA
Comités Institucionales de Ética en Investigación (CIEI)	Institutional ethics review; the Spanish protocol and Spanish ICF are the versions the CIEI approves	ClinRegs Peru
Ministerio de Relaciones Exteriores (MINREL Peru)	Authenticates the foreign sponsor's delegation of authority for trial filings	ClinRegs Peru
Órganos Desconcentrados / Autoridades Regionales de Salud	Under Art. 148 DS 016-2011-SA, promote and implement intensive *farmacovigilancia* and *tecnovigilancia* strategies at regional level	DS 016-2011-SA
Red Nacional de Laboratorios Oficiales de Control de Calidad	Official quality-control testing; a non-conforming result after a 180-calendar-day suspension leads to cancellation and a 3-year bar on re-registering the same product with the same IFA	DS 016-2011-SA

Section B. Official language requirements

Peru's rule is the most explicitly permissive of the six on translator qualification, and the most explicit on document age.

Statutory anchor — Art. 28 DS 016-2011-SA (verbatim):

> *"Los documentos expedidos en el extranjero deben tener una antigüedad no mayor de dos (2) años, contados desde la fecha de su emisión, salvo que el documento consigne una vigencia diferente, y estarán acompañados de su respectiva traducción simple al idioma español. La ANM, mediante comunicado, señala los documentos que pueden presentarse en idioma inglés."*

Foreign-issued documents must be no more than two years old unless they state a different validity, and must be accompanied by a simple Spanish translation; the ANM designates by comunicado which documents may be filed in English (DS 016-2011-SA).

Two rules embedded in one sentence. First, the translation standard: *traducción simple* — no sworn translator, no notarization of the translation, no consular authentication of the translation itself. Second, the currency standard: two-year expiry, from the issue date of the underlying foreign document. That second rule is where a technically correct dossier can fail regardless of translation quality.

Drug labelling — Art. 40 A numeral 9: The Categoría 1 dossier requires a *"Proyecto de rotulado en idioma español del envase mediato e inmediato"* — draft Spanish labelling for both outer and immediate packaging (DS 016-2011-SA).

Device labelling and IFU — Art. 137(a): Information on outer and immediate packaging and in the instructions for use must be expressed *"en idioma español con impresiones de caracteres indelebles, fácilmente legibles y visibles"*; other languages may be added in addition to Spanish provided the information matches what is in the sanitary registration (DS 016-2011-SA).

Art. 137(g): Where label information is in a language other than Spanish, a **traducción simple al español of at least the indications (*finalidad de uso*) and precautions** must be added. This is a partial-translation permission that is easy to under-execute (DS 016-2011-SA).

Device dossiers — Arts. 124 numeral 7, 125 numeral 8, 126 numeral 10, 127 numeral 10: The *manual de instrucciones de uso o inserto* must be traducido al idioma español for every class I–IV. Each of those four articles closes with the same sentence: *"Para productos importados, se requiere presentar la documentación en idioma original con su respectiva traducción simple al idioma español"* — imported-product documentation is filed in the original language with a simple Spanish translation (DS 016-2011-SA).

Clinical trials — language rules per ClinRegs Peru (ClinRegs Peru):

Document	Language
Trial application form	Spanish
Investigator's Brochure	Spanish
Protocol	Spanish and the original language
Informed consent form	Spanish and the original language; INFLESZ ≥ 55
Amendments	Tracked in both Spanish and original-language versions
Investigational-product labels	Spanish or English
DSUR summary	English and Spanish; form FOR-DIIS-048 in Spanish
CIOMS I	Spanish or English

Document	Language
Peru-only final study report	May be in English

Practical band. Amavita records DIGEMID as accepting English technical content with a Spanish summary, with Comunicado 008-2022-DIGEMID permitting English for CTD Modules 3, 4, and 5, and Decreto Legislativo 1272 underpinning the *traducción simple* standard (Amavita, Which Regulators Accept English Dossiers; Amavita, Preclinical LATAM).

Stock depletion for label errors. Where the holder detects an error in the approved labelling that does not affect safety, quality, or efficacy, it may request stock depletion for up to 12 months (DS 016-2011-SA).

Section C. Sworn vs certified vs simple translation

Peru is the only regulator of the Big 6 whose primary registration regulation names *traducción simple* as the default for all foreign documents, with English acceptance layered on top by *comunicado*. Argentina sits at the opposite pole, requiring a *traductor público matriculado* for any non-Spanish document from a foreign authority (Disposición 5755/1996, Art. 8).

Tier	Requirement	Statutory anchor
Any foreign-issued document in a registration dossier	*Traducción simple al idioma español*; document ≤ 2 years old unless it states its own validity	DS 016-2011-SA, Art. 28
Documents that may stay in English	Those the ANM designates by comunicado — English-acceptance perimeter is set administratively, not by statute	DS 016-2011-SA, Art. 28
CTD Modules 3/4/5	English permitted per Comunicado 008-2022-DIGEMID	Amavita, Preclinical LATAM
Imported-device documentation	Original language plus *traducción simple* into Spanish (all four classes)	DS 016-2011-SA, Arts. 124–127
Device IFU / insert	Translated into Spanish (mandatory, all classes)	DS 016-2011-SA, Arts. 124 no. 7, 125 no. 8, 126 no. 10, 127 no. 10
Foreign sponsor's delegation of authority (trials)	Authenticated by Peru's Ministry of Foreign Affairs; no sworn translator specified in the ClinRegs record	ClinRegs Peru
Statutory basis for the *traducción simple* standard	Decreto Legislativo 1272	Amavita, Preclinical LATAM

Tier	Requirement	Statutory anchor
Where sworn translation is used commercially	*Traductor público juramentado* — practice standard, not statutory	Amavita, Sworn vs Certified
Spanish variant	Peruvian Spanish within es-419	Amavita, Regulatory Language Infrastructure

Apostille and legalization sequencing

Peru has been an Apostille Convention signatory since 2010. Public documents from Convention signatories are validated with an apostille from the competent authority in the country of origin. Non-Convention documents require the legalization chain (foreign ministry + Peruvian consulate). Sponsor delegations of authority for clinical trials must be authenticated by Peru's Ministry of Foreign Affairs (ClinRegs Peru).

The 7th QC gate — Document Currency

Peru is where Amavita's seventh QC gate — Document Currency — carries the most operational weight in LATAM. Art. 28 DS 016-2011-SA invalidates any foreign document older than two years regardless of translation quality. That defect class does not appear in Amavita's six original defect classes (Amavita, Amendment Cascade), so it required a dedicated gate.

What the 7th gate verifies:

1. Every foreign-issued document in the dossier — CPP, CLC, GMP certificate, manufacturer letters, ISO 13485 certificate, FDA documentation — sits within its own jurisdictional validity window at the moment of filing.
2. The apostille or consular legalization is current under the origin country's rules.
3. Where the document states its own validity, that validity has not expired.
4. Colombia's parallel ≤ 1-year rule for pharmaceutical CPPs (Decreto 677/1995) is also verified in the same run.

See Blog corrections + seventh QC gate rollout for the full architecture.

Key contrast: In Argentina, translation must survive a *traductor público matriculado* register check. In Peru, translation survives a plain *traducción simple*, but the underlying document must survive a calendar check. Both are pass/fail. Neither is negotiable.

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

Peru has the most explicit English-acceptance rule of the seven and the least forgiving document-currency rule. Both facts change the preclinical scope.

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

No. Comunicado 008-2022-DIGEMID accepts English for CTD Modules 3, 4, and 5 outright. Module 4 is the entire non-clinical body of evidence: GLP toxicology, pharmacology, ADME, toxicokinetics. Module 3 covers quality and CMC; Module 5 the clinical study reports. In practice this removes the largest page volume in the dossier from the translation budget in a single line of guidance.

Spanish remains mandatory for the administrative layer, Module 1, labelling, and patient-facing content — and for the clinical-research documents that are not filed with DIGEMID at all.

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

Text-only for administrative and legal documents. DTP for labelling, inserts, and IFU. The trap in Peru is not format — it is currency. DS 016-2011-SA Art. 28 imposes a two-year validity limit on foreign documents: a certificate of pharmaceutical product, GMP certificate, or free-sale certificate older than two years at the time of filing is invalid, and the translation of an expired document is an expensive way to be rejected. Currency must be verified *before* translation is commissioned — which is exactly what Amavita's seventh QC gate, Document Currency, exists to enforce.

The second structural fact sponsors miss: clinical trials in Peru are authorized by INS through DIIS and SUDEC — not by DIGEMID and not by ANM. Protocol, ICF, and IB translation obligations run to the INS pathway, on a different timeline and a different reviewer population from the registration dossier.

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

For Modules 3/4/5, nothing needs to substitute — the English text is the accepted filing. What still adds value is a Spanish Module 2 overview and summary set so the evaluator can navigate, and a Spanish document-currency register listing every foreign document with its issue date, apostille date, and Art. 28 expiry date.

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

- INS/DIIS/SUDEC authorizes clinical trials — not DIGEMID/ANM.
- Protocol, IB, and ICF must be in Spanish; DIGEMID contributes a binding opinion on the investigational product that also requires Spanish.
- Foreign documents allowed as traducción simple under DS 016-2011-SA Art. 28, but the 2-year currency rule applies from filing date.

Pathway 2 — market-access / sanitary registration

- Device labelling and IFU in full Spanish per DS 016-2011-SA Art. 137(a) — indelible, legible, visible characters; other languages allowed in addition to Spanish provided the information matches the sanitary registration.
- Drug labelling in full Spanish.

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?	Basis	Certification tier	DTP?	Currency limit
CTD Module 4 — non-clinical study reports	No — English accepted	Comunicado 008-2022-DIGEMID	—	No	n/a
CTD Module 3 — quality / CMC	No — English accepted	Comunicado 008-2022-DIGEMID	—	No	n/a
CTD Module 5 — clinical study reports	No — English accepted	Comunicado 008-2022-DIGEMID	—	No	n/a
CTD Module 2 overviews and summaries	Recommended	DIGEMID practice	Certified	No	n/a
CPP, GMP and free-sale certificates	Yes	DS 016-2011-SA	Official translation + apostille	No	2 years — Art. 28
Powers of attorney, corporate instruments	Yes	DS 016-2011-SA	Official translation + apostille	No	2 years — Art. 28

Document class	Spanish required?	Basis	Certification tier	DTP?	Currency limit
Protocol, ICF, Investigator's Brochure	Yes	INS / DIIS / SUDEC pathway	Certified, MD-reviewed	No	n/a
Labelling, inserts, IFU	Yes	DIGEMID labelling rules	Regulatory review	Yes	n/a

Where the preclinical translation risk actually sits

Not in Module 4 — Peru already told you English is fine. It sits in Art. 28 currency on the twenty or so foreign legal documents, and in filing clinical-trial documents to the wrong authority. A perfectly translated CPP that was issued twenty-five months ago fails on date, not on language.

REGULATOR RESPONSE ON RECORD

Response received from SUDEC — Instituto Nacional de Salud (Perú)

Filed: 24 August 2026

Response received: 24 August 2026

Filed with: consultaensayos@ins.gob.pe

Question filed: Whether English CTD Modules 3, 4, and 5 accompanied by a Spanish Module 2 overview constitute a sufficient documentary scheme for clinical trial authorization before the INS (i.e., whether the market-access carve-out in Comunicado 008-2022-DIGEMID extends to trial-stage submissions).

> *En atención a su consulta respecto del idioma de presentación de la documentación técnica correspondiente a las solicitudes de autorización de ensayos clínicos, se precisa lo siguiente:*
>
> *El procedimiento de autorización de ensayos clínicos se rige por lo establecido en el Reglamento de Ensayos Clínicos, aprobado mediante Decreto Supremo N.° 021-2017-SA y sus modificatorias, así como por las disposiciones aplicables al referido procedimiento.*
>
> *Al respecto, el artículo 67 del citado Reglamento establece, entre los requisitos para solicitar la autorización de un ensayo clínico, la presentación del protocolo de investigación en versión en español y en idioma original, si este fuera diferente al español, así como del Manual del Investigador actualizado en versión en español y en idioma original, si fuera diferente al español. Asimismo, se requiere la presentación de la información relacionada con la calidad del producto en investigación, conforme al Anexo 5 del Reglamento.*
>
> *Respecto del Comunicado N.° 008-2022-DIGEMID establece disposiciones aplicables a los trámites de inscripción, reinscripción y cambios de importancia mayor en el Registro Sanitario, en consecuencia, su alcance no debe interpretarse de manera automática como una disposición que modifique los requisitos documentales establecidos específicamente para el procedimiento de autorización de ensayos clínicos ante el Instituto Nacional de Salud.*
>
> *En ese sentido, no corresponde confirmar, en los términos planteados en su comunicación, que la presentación de los Módulos 3, 4 y 5 del CTD en idioma inglés, acompañados únicamente de un overview en español (Módulo 2), constituye el esquema documental exigible o suficiente para la autorización de un ensayo clínico ante el INS.*
>
> *Para dicho procedimiento deberá observarse la documentación y los idiomas expresamente establecidos en el Reglamento de Ensayos Clínicos y demás disposiciones aplicables, considerando además que la evaluación de los aspectos relacionados con la calidad y seguridad del producto en investigación comprende la participación de la Autoridad Nacional de Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios – DIGEMID, en el marco de sus competencias.*
>
> *Finalmente, cabe señalar que las disposiciones correspondientes a procedimientos de registro sanitario no deben extrapolarse a los procedimientos de autorización de ensayos clínicos.*
>
> — Sub-Dirección de Ensayos Clínicos (SUDEC), Dirección de Investigación e Innovación en Salud (DIIS), Instituto Nacional de Salud (INS)

Read in English ↓

In response to your query regarding the language in which technical documentation must be filed for clinical trial authorization applications, the following is specified:

The clinical trial authorization procedure is governed by the Clinical Trials Regulation approved by Supreme Decree No. 021-2017-SA and its amendments, together with the provisions applicable to that procedure.

In that regard, Article 67 of the Regulation establishes, among the requirements for applying for authorization of a clinical trial, submission of the research protocol in Spanish and in the original language, where that differs from Spanish, as well as the updated Investigator's Brochure in Spanish and in the original language, where that differs from Spanish. Information relating to the quality of the investigational product must also be submitted in accordance with Annex 5 of the Regulation.

As to Communiqué No. 008-2022-DIGEMID, it establishes provisions applicable to registration, re-registration and major change procedures within the Sanitary Registry; consequently, its scope must not be automatically interpreted as a provision that modifies the documentary requirements established specifically for the clinical trial authorization procedure before the National Institute of Health.

Accordingly, it is not appropriate to confirm, on the terms set out in your communication, that submission of CTD Modules 3, 4 and 5 in English, accompanied only by a Spanish overview (Module 2), constitutes the documentary scheme required or sufficient for authorization of a clinical trial before the INS.

For that procedure, the documentation and languages expressly established in the Clinical Trials Regulation and other applicable provisions must be observed, bearing in mind that evaluation of matters relating to the quality and safety of the investigational product involves the participation of the National Authority for Pharmaceutical Products, Medical Devices and Sanitary Products — DIGEMID, within the scope of its competences.

Finally, provisions corresponding to sanitary registration procedures must not be extrapolated to clinical trial authorization procedures.

What this means for Perú CTA filings

1. **Comunicado 008-2022-DIGEMID governs market access, not clinical trial authorization.** Its scope is limited to *inscripción, reinscripción y cambios de importancia mayor en el Registro Sanitario*. The INS has confirmed in writing that its scope cannot be extrapolated to CTA procedures.
2. **CTA-stage translation scope is governed by DS 021-2017-SA Art. 67 and Anexo 5.** Protocol and Investigator's Brochure require Spanish plus source. Product quality and safety information falls under Anexo 5.
3. **DIGEMID retains competence over product quality and safety review inside the CTA process.** The INS explicitly named DIGEMID as a participating authority in CTA evaluation *“en el marco de sus competencias”*. Sponsors should assume DIGEMID's

registration-side vocabulary and format expectations may propagate into CTA quality review.

4. **The market-access position stated elsewhere in this guide is unchanged.** Sections D1 (Drugs — Market access), D2 (Drugs — Regulatory submissions for market clearance), E1 (Devices — Market access), and E2 (Devices — Regulatory submissions for market clearance) reflect the Registro Sanitario regime and are governed by COM 008-2022-DIGEMID and DS 016-2011-SA.
5. **Amavita Sciences™ scopes trial-stage preclinical translation on the strict reading.** For any CTA submission to the INS, we translate the preclinical stack in full (traducción simple, Spanish-target) unless the sponsor has documented instructions from the INS to the contrary. This is the same posture we apply in Panamá, Ecuador, and Costa Rica.

CATEGORY 1: DRUGS

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

The access instrument embedded in DS 016-2011-SA is the Petitorio Nacional Único de Medicamentos Esenciales (PNUME) — the single national essential-medicines list.

- Art. 40 A DS 016-2011-SA: A pharmaceutical whose active ingredient(s) or combinations are in the PNUME falls into Categoría 1, the fastest registration category. PNUME listing is therefore simultaneously an access instrument and a regulatory-clearance accelerator (DS 016-2011-SA).
- The same PNUME / high-surveillance-country split governs the review clock for agentes de diagnóstico, radiofármacos, and gases medicinales (60 / 90 days / 12 months) (DS 016-2011-SA).

Documents requiring translation for PNUME listing: The fetched regulation defines the PNUME's regulatory effect but not a listing dossier or its language rules.

A statutory price-control commission comparable to Brazil's CMED, Colombia's CNPMDM, or Mexico's CCNPMIS was not identified in Peruvian sources fetched for this guide. This category effectively exists in Peru only as the PNUME listing effect described above.

D2. Drugs — Regulatory submissions for market clearance

Pathways and statutory review clocks (Art. 43 and category-specific articles):

Pathway	Definition	Statutory review timeline
Categoría 1	IFA(s) or combinations in the PNUME (Art. 40 A)	45–60 calendar days
Categoría 2	IFA(s) not in PNUME but registered in *países de alta vigilancia sanitaria* (Art. 40 B)	45–90 calendar days
Categoría 3	IFA(s) in neither Cat. 1 nor 2 — genuine NMEs without high-surveillance precedent (Art. 40 C)	Up to 12 months
Vacunas e inmunológicos	Biological subset	Up to 180 calendar days
Other biological products	Art. 103 categories	Up to 12 months
Biosimilar (*vía de la similaridad*)	Files the Art. 104 biologic requirements, except numerals 13 and 14, which are replaced by pre-clinical and clinical comparability studies against the reference biologic	Same biologic clocks
Agentes de diagnóstico / radiofármacos / gases medicinales	PNUME / high-surveillance / neither	60 / 90 days / 12 months
Medicamentos herbarios de uso medicinal	High-surveillance-country registered / not	90 days / 12 months
Reinscripción (renewal)	Same article as inscription per class	Same clocks; Arts. 124–127 permit device-renewal *declaración jurada*
Variations (drugs) — major changes	—	Decided in 60 calendar days, with 6 months to implement
Orphan / rare disease	Biologics for rare/orphan diseases authorized in high-surveillance country with ≥ Phase II data	Registration granted subject to annual post-registration reporting; failure ⇒ suspension
Pediatric-specific pathway	—	Not identified as a separate pathway in the fetched text

Source: DS 016-2011-SA.

Categoría 1 dossier (Art. 40 A) — documents requiring translation. Representative of the drug set:

1. *Solicitud con carácter de declaración jurada*
2. Technical specifications and analytical technique for IFA(s), excipients, and finished product
3. Technical specifications for outer and immediate packaging and accessory descriptions
4. Validation of the finished-product analytical techniques

5. Manufacturing flow chart and process validation identifying critical control attributes and critical process parameters
6. Stability studies
7. Therapeutic-equivalence studies for interchangeability
8. Draft *ficha técnica* and *inserto*
9. Draft labelling in Spanish for outer and immediate packaging
10. Certificado de Producto Farmacéutico or Certificado de Libre Comercialización from the competent authority of the origin/export country, preferably on the WHO model, for imported products
11. GMP certificate, with certificates from high-surveillance or mutual-recognition countries accepted
12. Risk-management plan where the IFA has not previously been registered in Peru

Every foreign-issued item — CPP, CLC, GMP certificate — is caught by Art. 28 (≤ 2 years old + *traducción simple*).

Pharmacopoeial references — Art. 40. USP, British Pharmacopoeia, European Pharmacopoeia, and others; same pharmacopoeias apply to biologics under Art. 104. A pharmacopoeial monograph change gives holders 12 months to conform (DS 016-2011-SA).

RFI mechanics. Where observations are raised, the applicant must cure them within a maximum of 30 business days from notification, extendable where the observation's nature justifies it and the extension is substantiated — but never beyond the registration's validity period. Failure to cure is an express ground for denial (DS 016-2011-SA).

Suspension/cancellation on safety grounds. Follows where WHO information, information from high-surveillance regulators, or Peru's own control / *farmacovigilancia* / *tecnovigilancia* activity shows the product or device is unsafe or ineffective as authorized (DS 016-2011-SA).

Empirical RFI timeline: No Peru-specific empirical RFI delay figure appears in Amavita's RFI Anatomy case studies, whose worked examples cover INVIMA, ANVISA, COFEPRIS, ANMAT, and ISP.

D3. Drugs — Clinical research trial submissions

Authorizing agency: the INS, not DIGEMID. The *Instituto Nacional de Salud*, through the Dirección de Investigación e Innovación en Salud (DIIS) and its Subunidad de Ensayos Clínicos (SUDEC), is constituted under Ley 27657 and DS 001-2003-SA and is the authority that authorizes clinical trials. DIGEMID/ANM contributes a binding opinion on the investigational product inside that review and separately authorizes investigational-product imports (ClinRegs Peru).

This is unlike any other regulator in the Big 6. In Brazil, ANVISA runs both the marketing authorization and the CI pathway. In Argentina, ANMAT runs both — now under Disposición 7516/2025, which repealed the older Disposición 6677/2010 (Art. 7) and adopted ICH E6(R3)

effective 1 December 2025 (Boletín Oficial), making Argentina the first LATAM regulator to complete the E6(R3) transition. Peru remains on its two-agency architecture, and DS 016-2011-SA has no ICH-adoption change in the fetched record.

Documents requiring translation (see Section B table above; the ClinRegs Peru summary is the operative reference).

Ethics framework. Comités Institucionales de Ética en Investigación (CIEI) perform institutional review. The Spanish protocol and Spanish ICF are the versions the CIEI approves, so a Spanish text defect propagates to both the ethics track and the INS track (ClinRegs Peru). Both the INS authorization and the CIEI approval are required — neither substitutes for the other.

Substantive vs non-substantive amendments. Peru distinguishes amendments from modifications, per Decreto Supremo 028-2023 and Resolución 184-2023 (ClinRegs Peru). Operationally:

- Minor changes: decided within 30 business days; sponsor must give notice 10 business days before implementation.
- Extension of the authorization: requested 30 calendar days prior; authorization is valid 12 months.
- Expansion of the import list: decided within ≤ 10 business days.

Timelines

- INS review: ≤ 30 working days, a period that includes the ANM's 30-day investigational-product opinion.
- 2 business days to correct the file (unusually tight — sponsors need a Spanish-language rapid-response capability at Lima time).
- Appeals: 15 business days to file; the INS President decides within 30 business days.
- ANM investigational-product import authorization: 3 business days.

Pharmacovigilance report translation:

- Art. 149 DS 016-2011-SA — sponsors must file annual safety reports with the ANM covering all investigational products in use in Peru.
- Art. 112 — *informes periódicos de seguridad* (IPS) for biologics that filed a risk-management plan at registration are due every 6 months for the first 2 years from first marketing, then annually, then every 5 years (DS 016-2011-SA). This is a materially longer tail than Mexico's NOM-220 cadence (every 3 years) (DOF, NOM-220-SSA1-2016).
- Arts. 145–148 — the ANM operates the *Sistema Peruano de Farmacovigilancia y Tecnovigilancia* under Ley 29158, drawing on spontaneous individual-case notification of suspected adverse reactions and adverse incidents, post-authorization studies, clinical-trial information, safety databases, and scientific literature (Art. 150).
- Art. 151 — on new information indicating an important public-health risk, the ANM orders changes to the *ficha técnica* and *inserto* — a safety signal converts directly into a mandatory

Spanish labelling retranslation — and may require a risk-management plan during the registration's validity.

- Language of PV reports: DSUR summary in English and Spanish with FOR-DIIS-048 in Spanish; CIOMS I may be Spanish or English. DS 016-2011-SA states no separate language rule for *farmacovigilancia* filings beyond the general Art. 28 rule.

CATEGORY 2: MEDICAL DEVICES

E1. Devices — Market access

- Art. 121 DS 016-2011-SA places device definitions, classification, and essential conditions with the Health Authority, aligned to Peru's WTO and Comunidad Andina commitments (DS 016-2011-SA).
- The PNUME listing mechanism has a device analogue only for *agentes de diagnóstico*, whose review clock turns on PNUME inclusion (60 days).
- A device reimbursement list, HTA body, or hospital-procurement / tender translation requirement was not identified in Peruvian sources fetched for this guide. This sub-category is effectively absent from the operative device pathway.

E2. Devices — Regulatory submissions for market clearance

Classification (Art. 136 and Arts. 124–127 DS 016-2011-SA). Four risk classes, each with its own review clock:

Class	Statutory description	Review timeline
Clase I	*de bajo riesgo* (low risk)	Up to 30 calendar days
Clase II	*de moderado riesgo* (moderate risk)	Up to 60 calendar days
Clase III	*de alto riesgo* (high risk)	Up to 90 calendar days
Clase IV	*críticos en materia de riesgo* (critical risk)	Up to 90 calendar days

Source: DS 016-2011-SA, Art. 136.

Registration grant basis — Art. 122. The registro sanitario is granted by common name, risk classification, manufacturer, and manufacturer's country, and additionally by device group (kit, set, sistema, familia), manufacturing-site name and country, and commercial name/brand, taking into account IMDRF documents. All of that must be backed by the Certificado de Libre

Comercialización. Because the CLC is the anchoring document and is foreign-issued, the Art. 28 ≤ 2-year + *traducción simple* rule governs the entire naming chain — a nomenclature mismatch between the CLC translation and the dossier is precisely where a naming defect propagates (DS 016-2011-SA).

Per-class document lists (structural summary; see the full statutory text for verbatim requirements):

Clase I (Art. 124): (1) *solicitud con declaración jurada*; (2) CLC from origin/export country; (3) GMP certificate from ANM, or equivalent proof of conformity — expressly including EU CE certificate, current ISO 13485, or FDA documentation; (4) technical report per Art. 130 numerals 1–4; (5) technical / analytical verification (design V&V summary; declaration of conformity with international standards; certificate of analysis); (6) draft labelling; (7) IFU / insert translated into Spanish. Closing rule: imported products require original-language documentation plus simple Spanish translation. Renewals exempt from numerals 4–7 via *declaración jurada* of no variation.

Clase II (Art. 125): same structure; IFU/insert at numeral 8; same imported-product translation clause.

Clase III (Art. 126): adds full Art. 130 technical report and sterilization-process validation reports for sterile devices; IFU/insert at numeral 10.

Clase IV (Art. 127): Class III set plus risk-management report per the applicable current ISO standard and clinical evaluation report (*informe de evaluación clínica*); IFU/insert at numeral 10; renewals exempt from numerals 4–10 via *declaración jurada*.

Art. 130 technical-report content: (1) detailed device description including operating principles and action, content/composition, and integrated accessories; (2) indication, purpose, or intended use as stated by the manufacturer; (3) precautions, restrictions, warnings, special care, and clarifications on use, storage, and transport; (4) presentation form(s); (5) basic manufacturing flow chart with a summary description of each stage through to the finished device; (6) efficacy and safety description against essential safety and efficacy conditions (DS 016-2011-SA). Numerals 2 and 3 are the highest-risk translation surface — they must remain consistent with the Spanish IFU, the Spanish labelling, and the CLC-anchored intended use.

Changes to a device registration — Art. 123. Changes are classified as cambios de importancia menor and cambios de importancia mayor.

- Minor changes: a written communication from the holder suffices and takes effect automatically without any ANM pronouncement; the holder has 6 months from the day after the communication to implement. Minor-change list sits in an ANM Directiva.
- Purely administrative minor changes — commercial name or corporate name and address of the holder, technical director's name, or others the ANM defines — once authorized for the pharmaceutical establishment, take effect automatically across all labelling, inserts, and instruction manuals of every device the holder registers, with no separate filing. This is an unusually efficient cascade mechanism: one authorized corporate-name change flows into every Spanish artwork file without per-product submission.

- Major changes: applied for within the registration's validity, with (a) *solicitud con declaración jurada* and (b) supporting documents per the specific *directiva*; the ANM grants up to 6 months to adapt.

IVD / SaMD / combination-product extras — Art. 122:

- Combination producing a new intended use: classified per the new intended use — a new medical device in its own right.
- Combination for user convenience: takes the classification of the highest-risk device included.
- Standalone software (SaMD): classified per (1) intended use of the combination when driving/influencing a specific device; (2) taking IMDRF documents into account when independent of any other device; (3) treated as an active medical device when it standalone meets the device definition. This is functionally close to ANVISA RDC 751/2022 Art. 8 §3–§4 (RDC 751/2022).
- IVDs: the DS 016-2011-SA device definition expressly includes *"reactivo o calibrador in vitro"* and *"aplicativo informático"*, so IVDs and software fall inside the same four-class regime (DIGEMID, Dispositivos Médicos).
- Biomedical equipment of controlled technology: Art. 131 requires a post-registration report.

Administrative procedure references. DIGEMID's device page maps filings to TUPA procedures: *Inscripciones y reinscripciones de Dispositivos Médicos* = TUPA 79; *Cambios en el Registro Sanitario de Dispositivos Médicos* = TUPA 80; *Certificado de registro sanitario* = TUPA 119. Applicable normativity: DS 016-2013-SA, DS 001-2012-SA, DS 016-2011-SA, DS 029-2015-SA, DS 016-2017-SA, DS 010-97-SA, DS 020-2001-SA (DIGEMID, Dispositivos Médicos).

E3. Devices — Clinical research trial submissions

- The clinical-trial architecture described in D3 is agency-based, not product-based: the INS/DIIS/SUDEC authorizes clinical trials, with DIGEMID/ANM giving the investigational-product opinion. A device-specific clinical-investigation dossier equivalent to ANVISA's DICD under RDC 837/2023 was not identified in Peruvian sources fetched for this guide (ANVISA, RDC 837/2023 announcement).
- The one device-specific hook inside DS 016-2011-SA's surveillance title is tecnovigilancia: Arts. 145–150 place adverse incidents involving devices in the same national surveillance system as drug ADRs. Art. 127 numeral 9 requires an *informe de evaluación clínica* for Class IV registration — device clinical evidence enters Peru principally through the registration dossier rather than a distinct pre-market trial authorization pathway.
- FIH vs pivotal vs post-market device-study distinctions: not identified in the fetched text.
- Device-trial review timelines: not stated.
- Ethics framework: CIEI institutional ethics committees, mandatory alongside INS authorization.

Section F. Common RFI / rejection patterns

No Peru case study appears in Amavita's RFI Anatomy analysis. Mapping Amavita's six defect classes onto Peru's statutory surfaces gives the following exposure profile:

Structural inventory. Art. 122's registration-grant basis (common name, risk class, manufacturer, country, kit/set/system/family, site, brand) must be backed by the CLC; the CLC reaches the ANM only through an Art. 28 *traducción simple*. Any drift between the translated CLC nomenclature and the dossier naming is directly detectable.

Terminology inconsistency. Art. 130 numerals 2–3 (intended use; precautions, restrictions, warnings) must agree with the Spanish IFU (Arts. 124 no. 7 / 125 no. 8 / 126 no. 10 / 127 no. 10) and with the Spanish labelling (Art. 137(a)), while imported technical documentation lawfully remains in the original language — a three-way consistency requirement inside one file.

Jurisdictional adaptation. Art. 137(g) requires — where labelling is in another language — at minimum **indications (*finalidad de uso*) and precautions** in simple Spanish translation. A partial-translation rule that is easy to under-execute.

Numeric integrity. Drug labelling under Art. 44 requires IFA quantity per unit dose or concentration, and — for injectables, topicals, and ophthalmic solutions — all excipients listed. A decimal or unit error is a labelling defect on its face. This is the same defect class that produced Amavita's COFEPRIS infusion-pump *"999 ml/hr"* decimal-comma case.

Readability. The Spanish ICF is benchmarked to INFLESZ ≥ 55 (Amavita, INFLESZ Threshold).

Document age — the Peru-specific 7th defect class. Art. 28 invalidates any foreign document older than 2 years regardless of translation quality. A perfectly translated but stale CPP, CLC, or GMP certificate fails. This is the defect class that motivated Amavita's 7th QC gate — Document Currency. See Blog corrections + seventh QC gate rollout.

Cure window. Observations must be cured within 30 business days of notification, extendable only on substantiated grounds and never beyond the registration's validity; failure to cure is an express ground for denial (DS 016-2011-SA). For trials the correction window is far tighter: 2 business days to fix the file (ClinRegs Peru).

Section G. Consolidated timelines — DIGEMID / ANM Peru

Sub-category	Procedure	Statutory timeline	Empirical / added time	Source
D1 Drug market access	PNUME listing effect on review category	Not stated in fetched text	n.a.	DS 016-2011-SA, Art. 40
D2 Drug clearance	Categoría 1 (IFA in PNUME)	45–60 calendar days	n.a.	Art. 43
D2	Categoría 2 (high-surveillance-country registered)	45–90 calendar days	n.a.	Art. 43
D2	Categoría 3 (neither)	Up to 12 months	n.a.	Art. 43
D2	Vacunas e inmunológicos	Up to 180 calendar days	n.a.	DS 016-2011-SA
D2	Other biologicals (incl. biosimilars via *similaridad*)	Up to 12 months	n.a.	DS 016-2011-SA
D2	Agentes de diagnóstico / radiofármacos / gases medicinales	60 / 90 days / 12 months	n.a.	DS 016-2011-SA
D2	Medicamentos herbarios	90 days / 12 months	n.a.	DS 016-2011-SA
D2	Major drug change	60 calendar days to decide; 6 months to implement	n.a.	DS 016-2011-SA
D2	RFI cure window	30 business days (extendable)	n.a.	DS 016-2011-SA
D2	Orphan-biologics post-registration reporting	Annual; failure ⇒ suspension	n.a.	DS 016-2011-SA
D2	Label-error stock depletion	Up to 12 months	n.a.	DS 016-2011-SA
D3 Drug trials	INS authorization	≤ 30 working days (includes ANM's 30-day IP opinion)	n.a.	ClinRegs Peru
D3	File correction	2 business days	n.a.	ClinRegs Peru
D3	Minor amendment	30 business days; notice 10 business days pre-implementation	n.a.	ClinRegs Peru

Sub-category	Procedure	Statutory timeline	Empirical / added time	Source
D3	Extension of authorization	Request 30 calendar days prior; valid 12 months	n.a.	ClinRegs Peru
D3	Import-list expansion	≤ 10 business days	n.a.	ClinRegs Peru
D3	ANM investigational-product import	3 business days	n.a.	ClinRegs Peru
D3	Appeal	File in 15 business days; INS President decides in 30 business days	n.a.	ClinRegs Peru
D3	Clinical-trial annual safety report	Annual (Art. 149)	n.a.	DS 016-2011-SA
D3	Biologic IPS cadence	6-monthly for 2 years → annual → every 5 years (Art. 112)	n.a.	DS 016-2011-SA
E1 Device market access	—	Not identified	n.a.	DS 016-2011-SA, Art. 121
E2 Device clearance	Clase I	Up to 30 calendar days	n.a.	Art. 136
E2	Clase II	Up to 60 calendar days	n.a.	Art. 136
E2	Clase III	Up to 90 calendar days	n.a.	Art. 136
E2	Clase IV	Up to 90 calendar days	n.a.	Art. 136
E2	Device minor change	Written notice; automatic, 6 months to implement	n.a.	Art. 123
E2	Device major change	Application required; up to 6 months to adapt	n.a.	Art. 123
E3 Device trials	Device-specific pathway	Not identified	n.a.	DS 016-2011-SA

Sub-category	Procedure	Statutory timeline	Empirical / added time	Source
Cross-cutting	Foreign document age limit	≤ 2 years from issue (unless stated)	n.a.	Art. 28
Cross-cutting	Pharmacopoeial monograph change	12 months to conform	n.a.	DS 016-2011-SA
Cross-cutting	Quality-control suspension	180 calendar days; non-conforming re-test ⇒ cancellation + 3-year re-registration bar	n.a.	DS 016-2011-SA

Section H. Recent regulatory changes 2023–2026

- Decreto Supremo 028-2023 and Resolución 184-2023 — established the operative distinction between clinical-trial amendments and modifications, with the associated notice and decision windows (ClinRegs Peru).
- Comunicado 008-2022-DIGEMID — permits English for CTD Modules 3, 4, and 5, materially narrowing the translated preclinical/quality surface. It is a *comunicado*, not a decree, exactly the administrative instrument Art. 28 designates for this purpose (Amavita, Preclinical LATAM).
- DS 016-2011-SA remains the operative registration regulation. DIGEMID's device page lists the amending/related decrees in force: DS 016-2013-SA, DS 001-2012-SA, DS 029-2015-SA, DS 016-2017-SA, DS 010-97-SA, DS 020-2001-SA (DIGEMID, Dispositivos Médicos). Several DS 016-2011-SA articles carry an *"Artículo(s) modificado(s) o derogado(s)"* marker — including Arts. 28, 122, 123, 130, 136 — confirming they are consolidated rather than original text.
- Regional ICH context. Unlike Argentina — which adopted ICH E6(R3) via Disposición 7516/2025, repealing the older Disposición 6677/2010 (Art. 7) effective 1 December 2025 (Boletín Oficial), and becoming the first LATAM regulator to complete the E6(R3) transition — and Brazil (E6(R2) adopted, E6(R3) pending) (ClinRegs Brazil), no ICH-adoption change for Peru appears in the fetched record.

Section I. Amavita library cross-references

- Preclinical Translation Requirements — 9 LATAM Regulators — DIGEMID tier, DS 016-2011-SA Arts. 124–127, Comunicado 008-2022-DIGEMID (English for CTD Modules 3/4/5), Decreto

Legislativo 1272 as *traducción simple* basis.

- Which Regulators Accept English Dossiers — DIGEMID band: English technical content with Spanish summary.
- Sworn vs Certified Translation for Regulatory Submissions — Peru's *traductor público juramentado* where sworn is used commercially, against the statutory *traducción simple* default.
- INFLESZ Threshold — Spanish ICF Readability Compliance — INFLESZ ≥ 55 for Spanish ICF.
- RFI Anatomy — Six LATAM Regulator Rejections Deconstructed — no Peru case study; the six defect classes map onto Arts. 28 / 122 / 130 / 137 as set out in Section F.
- Amendment Cascade — One Protocol Change × 12-Country LATAM Stack.
- Three Bands of LATAM Regulatory Translation.
- Translation QC for Regulatory Dossiers.
- Costly Translation Mistakes in Regulatory Submissions.
- Regulatory Language Infrastructure vs Traditional Translation.
- Blog corrections + seventh QC gate rollout — the operative account of Document Currency, of which Peru is the paradigm case.

FAQ

Does DIGEMID require a sworn translator?

No. Art. 28 DS 016-2011-SA requires only traducción simple al idioma español for foreign-issued documents. The ANM designates by comunicado which documents may be filed in English (DS 016-2011-SA).

How old can a foreign document be when filed with DIGEMID?

No more than two years old from its issue date, unless the document itself states a different validity period. This applies to CPPs, CLCs, GMP certificates, and any other foreign-issued document in the dossier (DS 016-2011-SA Art. 28).

Who authorizes clinical trials in Peru — DIGEMID or the INS?

The INS authorizes clinical trials, through its DIIS and SUDEC units, under Ley 27657 and DS 001-2003-SA. DIGEMID/ANM contributes a binding opinion on the investigational product and separately authorizes investigational-product imports (ClinRegs Peru).

Which CTD modules can be filed in English in Peru?

CTD Modules 3, 4, and 5, per Comunicado 008-2022-DIGEMID (Amavita, Preclinical LATAM). This is the administrative instrument Art. 28 designates for setting the English-acceptance perimeter.

How fast is the INS trial-review clock?

≤ 30 working days, and that period includes the ANM's 30-day investigational-product opinion — so the two agencies do not add sequentially. The file-correction window is only 2 business days (ClinRegs Peru).

What is the fastest drug registration pathway in Peru?

Categoría 1 for products whose IFA is in the PNUME: statutory review 45–60 calendar days under Art. 43 DS 016-2011-SA (DS 016-2011-SA).

Can device labelling stay in a language other than Spanish?

Only if it also carries at minimum *indications (finalidad de uso) and precautions in simple Spanish translation under Art. 137(g). Other languages may be added in addition to* Spanish, provided the information matches what is in the sanitary registration (Art. 137(a)) (DS 016-2011-SA).

How do minor changes to a Peruvian device registration take effect?

By written communication to the ANM, taking effect automatically without ANM pronouncement; the holder has 6 months to implement. Purely administrative minor changes — corporate name, technical director name — cascade automatically across all products the holder registers, with no per-product filing (Art. 123) (DS 016-2011-SA).

What is the pharmacovigilance reporting cadence for biologics in Peru?

Every 6 months for the first 2 years from first marketing, then annually, then every 5 years — under Art. 112 DS 016-2011-SA. This is materially longer than Mexico's NOM-220 cadence (every 3 years) (DS 016-2011-SA).

What happens if a Peruvian registration fails quality-control testing?

A non-conforming quality-control result after a 180-calendar-day suspension leads to cancellation of the registration and a 3-year bar on re-registering the same product with the same IFA (DS 016-2011-SA).

About the author

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Version history

This guide is version **1.4.0**, last updated August 24, 2026. Every substantive change to the DIGEMID requirements on this page is recorded below.

v1.4.0 August 24, 2026

- Added SUDEC response block at end of Section D. SUDEC clarified in writing that Comunicado 008-2022-DIGEMID does not extend to clinical trial authorization filings before the INS.
- Sections D1, D2, E1, E2 (market access) are unchanged. Sections D3 and E3 (clinical trials) now reflect the strict reading confirmed by SUDEC.

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 August 4, 2026

- Initial publication of the regulator translation requirements guide.