LATAM REGULATORY GUIDES · PANAMÁ

DNFD Regulatory Translation Requirements: The Complete Guide for Drugs and Medical Devices in Panamá

Ley 419 de 2024 and DE 27's 836 articles, the DE 490 device consultation, the DE 21 de 2026 research reglamento, and where CTA-stage preclinical translation risk actually sits.

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Statute-level English carve-out

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Section A. Regulator profile

Name: *Dirección Nacional de Farmacia y Drogas* (National Directorate of Pharmacy and Drugs), DNFD — the medicines and health-products regulator inside the *Ministerio de Salud* (MINSA). The DNFD grants *registro sanitario*, operating licences for pharmacies, distributors, laboratories and *droguerías*, GMP certification, controlled-substances permits, pharmacovigilance oversight, and the *excepción de registro sanitario* that lets an investigational medicinal product enter the country (DNFD portal). Panamá does not operate a single unified health-products agency of the ANVISA or INVIMA type: authority is split across the DNFD, a separate MINSA device directorate, and the health-research regulator, and each desk has its own language practice.

Establishing statute: MINSA was created by Decreto de Gabinete 1 de 15 de enero de 1969, and its sanitary police powers derive from the Código Sanitario, Ley 66 de 10 de noviembre de 1947 — both cited as the legal foundation in the *considerando* of Decreto Ejecutivo 21 de 23 de abril de 2026. The operative medicines statute is Ley 419 de 1 de febrero de 2024, published in *Gaceta Oficial* 29962-A and corrected by *fe de errata* in Gaceta 29966-A of 7 February 2024, which subrogated Ley 1 de 10 de enero de 2001 and Ley

97 de 4 de octubre de 2019 (Ley 419; Lexology). It is reglamented by Decreto Ejecutivo 27 de 10 de mayo de 2024 — a single instrument of 836 articles published in Gaceta 30028-C (DE 27; Panamá Digital). Reliance-based recognition runs through Decreto Ejecutivo 2 de 7 de enero de 2025, as modified in 2025 (DE 2 de 2025).

Scope: The DNFD regulates medicines and other products for human health — market authorisation, licensing of establishments, GMP, controlled substances, pharmacovigilance, and the investigational-product registration exception. Medical devices sit with MINSA's separate device directorate under Ley 90 de 26 de diciembre de 2017, as modified by Ley 92 de 12 de septiembre de 2019, reglamented by Decreto Ejecutivo 490 de 4 de octubre de 2019, itself modified by Decreto Ejecutivo 616 de 13 de mayo de 2020 (MINSA device directorate page). Health research — including interventional clinical trials — is governed by Ley 84 de 14 de mayo de 2019 (MINSA text) as reglamented by DE 21 de 2026.

Website: https://dnfd.minsa.gob.pa — relaunched publicly in October 2025 as the consolidated source for normativas, registros sanitarios, trámites, comunicados and sanitary alerts, with modules for *Seguimiento de Trámite*, *Solicitudes de Registros Sanitarios*, *Certificados de Intercambiabilidad*, payments, *Medicamentos de Venta Popular*, "DNFD Digital (21 Trámites)" and a *Sistema de Monografías y Prospectos* (La Web de la Salud).

Printed contact point: farmacoterapiafyd@minsa.gob.pa, listed under *Departamento De Farmacovigilancia De Medicamentos Y Otros Productos Para La Salud Humana → Sección de Farmacoterapia*, phone 501-0305 (DNFD Contacto). The same page prints departmental inboxes for registration evaluation, modifications, bioequivalence, imports and lot release, licences, audit and legal advice; we reproduce only what that page prints and extrapolate nothing.

Current head of authority: *Director Nacional* — Uriel Pérez, who presented the relaunched DNFD portal in October 2025 (La Web de la Salud). The Minister of Health who signed both the 2025 WLA recognition decree and the 2026 research decree is Fernando Boyd Galindo, per the signature blocks of DE 2 de 2025 and DE 21 de 2026.

Adjacent bodies sharing responsibility. Panamá's architecture is deliberately distributed. Getting the language rule right requires knowing which desk the document lands on.

Body	Role	Reference
MINSA device directorate — printed on MINSA's own page as *Dirección Nacional de Dispositivos Médicos*	Issues the *Certificado de Criterio Técnico* (CCT) and *Certificado de Verificación Técnica* (CVT), licences device establishments, evaluates class-based dossiers	MINSA device directorate page; DE 490 Arts. 21–24
Dirección General de Salud Pública (DGSP) / MINSA *Unidad de Regulación de Investigación para la Salud* (REGULAIPS)	Operational hub for health-research submissions; runs the RESEGIS registry; printed contact regulaips@minsa.gob.pa, phone 512-9479	Regulación de Investigación para la Salud

Body	Role	Reference
Comité Nacional de Bioética de la Investigación (CNBI)	*"Adscrito al Despacho Superior del Ministerio de Salud"* with *"independencia y autonomía en sus funciones"*; eleven members; normative frame is CIOMS, OMS-OPS, Declaración de Helsinki, UNESCO, ICH GCP, the Singapore and Montreal Statements, the Nuremberg Code and the Belmont Report	DE 21 de 2026 Arts. 1, 3, 71
Accredited *comités de bioética de la investigación* (CBI)	Review protocols; a single accredited committee can approve a multicentre study; MINSA publishes the accredited-committee listing and update circulars	DE 21 Art. 46; MINSA research page
MEDUCA — Ministerio de Educación	Licenses *Traductores Públicos Autorizados* by *resolución*	MEDUCA Traductores y Examinadores
MIRE — Ministerio de Relaciones Exteriores	Authenticates, legalises and apostilles documents; registers translator signatures	MIRE Autenticaciones y Legalizaciones
Gaceta Oficial	Sole publication of record; an instrument becomes enforceable only on publication	Gaceta Oficial

Two structural facts about DNFD filings that reshape translation project planning. First, a Panamanian lawyer files, not the sponsor: DE 27 Art. 19 requires the application to be presented *mediante abogado*, with the *refrendo* of the responsible *farmacéutico idóneo* and of the Colegio Nacional de Farmacéuticos — so our Spanish passes two Panamanian professional gatekeepers before a reviewer sees it. Second, submissions are digital: DE 27 Art. 16 requires filing through a *"plataforma tecnológica por medio de un expediente digital"* — FADDI (Farmacia y Drogas Digital), indexed at dnfd.minsa.gob.pa/faddi and rolled out module by module since 2023 (DNFD Comunicado 030-2023; DNFD Comunicado 083/2024; MINSA). The DNFD has also stated publicly that digitalisation is a step toward being benchmarked by WHO's Global Benchmarking Tool as a high-standard authority (MINSA) — a regulator under benchmarking tightens documentation discipline, it does not loosen it.

Contact points we will not invent. The MINSA research page names the CNBI and links to it but prints no email address or telephone number for the CNBI or for the accredited institutional committees; the only printed contact datum is the REGULAIPS inbox (Regulación de Investigación para la Salud). We route CNBI correspondence through RESEGIS and REGULAIPS. `[UNVERIFIED - source silent]` on any dedicated CNBI mailbox. Likewise, the Caja de Seguro Social (CSS) operates hospitals that host trials, but no CSS clinical-trial inbox is printed on an official page — `[UNVERIFIED - source silent]`.

Section B. Official language requirements

Panamá's language rule is not a single sentence. It is a layered regime: a statute-level default, a reglamento-level general clause, and roughly two dozen document-specific carve-outs. Reading only the default costs money; reading only the carve-outs earns an RFI.

Statutory anchor — Ley 419, Art. 33 (verbatim, medicines market access):

> "Toda documentación que se presente, para la obtención del registro sanitario debe estar en español o debidamente traducida por un traductor público autorizado. En cuanto a los estudios clínicos, se aceptarán en el idioma inglés y su resumen debe ser presentado obligatoriamente en español."

Registration documentation must be in Spanish or translated by a *traductor público autorizado*; clinical studies are accepted in English with a mandatory Spanish summary (Ley 419 Art. 33). Panamá put the English-language acceptance of clinical studies in the statute itself — not in a reglamento, not in guidance, not in reviewer discretion. That is the strongest form of legal comfort available in Latin America on this question, and it anchors Section D.

Reglamento anchor — DE 27, Art. 220 (verbatim, general clause):

> "Toda la documentación debe ser presentada en idioma castellano/español, los documentos oficiales escritos en idioma distinto deben presentarse con su respectiva traducción por un traductor público autorizado."

Source: DE 27 de 2024. Placement nuance we do not skip. Art. 220 sits in Capítulo XIX, Sección I (*"Generalidades"*), the chapter on post-approval modifications — not in the decree's opening general-provisions title. A maximalist reading treats it as decree-wide; a textualist reading confines it to modification filings. Our operating position is to treat Art. 220 as decree-wide for legal and administrative documents, because the cost of over-translating a *poder* is trivial. But Art. 220 cannot be read to override Ley 419 Art. 33 on clinical studies: a reglamento cannot narrow a statute, and Art. 30 of the same decree expressly confirms the English allowance.

Statutory anchor — DE 490, Art. 35 (verbatim, devices):

> "En caso de que los documentos legales originales presentados sean en otro idioma distinto al español, deberán acompañarse de una traducción al idioma español realizada por un traductor público autorizado de la República de Panamá."

Source: DE 490 de 2019. Three words carry the article: "documentos legales originales." Art. 35 does not say *all documents* — it says legal documents, and it exempts catalogues from legalisation entirely.

Statutory anchor — DE 21 de 2026, Art. 85 (verbatim, clinical trials):

> "Es indispensable que todos los documentos, remitidos para estos trámites oficiales, presenten su contenido en idioma español y en las mismas versiones a ser presentadas al comité de bioética."

Every document remitted for the official RESEGIS trámites must be in Spanish and in the same versions filed with the bioethics committee (DE 21 Art. 85). Version-parity is a *language* requirement in Panamá: filing v3.0

Spanish to RESEGIS while the committee holds v2.1 is a defect even if both translations are perfect.

Statutory anchor — DE 21 de 2026, Art. 52 (verbatim, informed consent):

> "El documento del consentimiento informado debe ser redactado en idioma español, en un lenguaje sencillo y comprensible para el participante..."

Note the verb: "redactado" — *drafted* in Spanish, with a readability standard, not merely *translated into* Spanish (DE 21 Art. 52). A back-translated ICF that is grammatically Spanish but syntactically English fails this article. We treat the Panamá ICF as a readability-graded deliverable, not a translation deliverable.

Three doctrinal facts embedded in the framework. First, Spanish is a decision-and-use rule, not a general dossier rule: Panamá requires Spanish where a Panamanian reads the document to make a decision or to use the product safely — legal instruments, labels, inserts, informed consent, protocols, safety reports — and accepts English where the document is technical evidence a trained evaluator reads, provided a Spanish summary or Spanish-translated key element exists. Second, the device architecture is explicitly tiered: legal instruments → sworn Spanish; user-facing instructions → Spanish; engineering and service documentation → English acceptable (DE 490 Arts. 35, 36.7, 36.8, 41.1). Third, Panamá bans relabelling: Ley 419 Art. 37 states the label *"podrá estar impreso en varios idiomas a la vez, siempre que uno sea el español. No se aceptará reetiquetado o sobreetiquetado"* and DE 490 Art. 39 states *"No se aceptará el re etiquetado o sobre etiquetado, en ninguno de los empaques para su uso en la República de Panamá."* You cannot fix a translation error with a sticker in Panamá — which converts translation quality from a compliance line item into a manufacturing-schedule risk.

The ISO 15223-1 basis. DE 490 Art. 39 permits *"símbolos y colores internacionalmente reconocidos siempre y cuando se aclare en el instructivo o inserto el texto descriptivo de los mismos."* Recognised international symbols are permitted on the label if the IFU carries the Spanish descriptive text for each — and because Art. 36.8 requires that instructivo to be in Spanish for each device (expressly not for *equipos biomédicos*), the practical result is that a Spanish symbol glossary inside the Spanish IFU buys a low-text, symbol-driven carton. That is the clearest statutory basis for symbol-based labelling in Central America.

The one place Panamá accepts an English-only label. DE 21 de 2026, Art. 97 governs investigational-product labelling — identification, lot, expiry, storage and special warnings — and then states: *"Se aceptará el etiquetado, en idioma español o simultáneamente en varios idiomas a la vez, siempre que uno de ellos sea español. En casos excepcionales, se aceptará en idioma inglés, sin necesidad del idioma español, previa justificación ante la Dirección Nacional de Farmacia y Drogas, garantizando información relevante del medicamento para el participante de la investigación, en idioma español."* That is a genuine, written, English-only IMP-label pathway, conditioned on prior justification to the DNFD and on the participant-relevant information reaching the subject in Spanish by another route.

Document-by-document language table (medicines — DE 27 de 2024 and Ley 419; devices — DE 490; trials — DE 21 de 2026).

Document	Language rule	Statutory anchor
Clinical studies (registration)	English accepted with a mandatory Spanish summary of all clinical evidence demonstrating favourable benefit–risk	Ley 419 Art. 33; DE 27 Art. 30
Certificado de análisis (CoA)	"Podrá ser presentado en idioma inglés o español"	DE 27 Art. 27.15

Document	Language rule	Statutory anchor
Certificado de libre venta (CLV)	Spanish, or sworn translation by a Panamá *traductor público autorizado*, annexed to the certificate	DE 27 Art. 28.3
CLV authentication	Authenticated per foreign-document rules, including apostilla electrónica	DE 27 Art. 28.8
GMP certificate	"Traducido al idioma español y debidamente legalizado"	DE 27 Arts. 77.3 / 78.3
Fórmula cuali-cuantitativa	If in another language, "debidamente traducida por un traductor oficial"	DE 27 Art. 124.7
Drug labels and packaging	Per RTCA; Spanish among the languages; no relabelling	Ley 419 Art. 37; DE 27 Art. 46
Hemoderivados labelling	Non-Spanish text permitted if a *traductor público autorizado* translation is filed with the DNFD and delivered at the health facility	DE 27 Art. 47
Intrahospital / specialised-pathology product labels	Non-Spanish labels accepted if a Spanish translation is delivered separately to the DNFD and the hospital	DE 27 Arts. 54.2 / 128.2
Labels under the registration exception	Non-Spanish label allowed with a Spanish complementary label	DE 27 Art. 211 *parágrafo*
Cosmetics / precautionary legends	"Se expresarán en varios idiomas a la vez, siempre que uno de ellos sea el español"	DE 27 Art. 206
Clinical-trial protocol (registration exception)	Protocol and ethics approval "en español y en formato electrónico"	DE 27 Art. 213.2
CoA for the investigational product	"Podrá ser presentado en idioma inglés o español"	DE 27 Art. 213.4
Comparator CPP, batch certificate, CLV	"Podrán ser presentado en idioma inglés o español," with a certificate or declaration of compliance	DE 27 Art. 213
Foreign legal documentation generally	"Deberá estar debidamente autenticada o apostillada. Se aceptarán documentos electrónicos"	DE 27 Art. 216
Renewal artwork, product not yet marketed	Draft primary/secondary packaging and insert artwork "en idioma español"	DE 27 Art. 234
ADR notifications	"Deberán ser remitidas en español"	DE 27 Art. 325
Serious ADR forms	"Se enviarán en el idioma español"; within 10 días hábiles	DE 27 Art. 326
PSUR / PBRER	English accepted, with sworn Spanish translation of the Resumen Ejecutivo only	DE 27 Art. 331

Document	Language rule	Statutory anchor
Device foreign legal originals	Sworn Spanish translation by a Panamá-licensed TPA; catalogues exempt from legalisation	DE 490 Art. 35
Device manufacturer technical literature	Electronic or digital format; no language requirement	DE 490 Art. 36.7
Device IFU / insert	Spanish, one copy per device; not applicable to *equipos biomédicos*	DE 490 Art. 36.8
Device IFU multilingual	Two or more languages permitted if one is Spanish	DE 490 Art. 38
Device labels	International symbols and colours permitted if the IFU carries the Spanish descriptive text; multilingual with Spanish; no relabelling	DE 490 Art. 39
Equipos biomédicos: data sheet, product data, service manuals	"Podrá ser presentada en español o inglés"	DE 490 Art. 41.1
Informed consent form	Drafted in Spanish, plain and comprehensible language	DE 21 Art. 52
All RESEGIS trámite documents	Spanish and in the same versions filed with the bioethics committee	DE 21 Arts. 84–85
Investigational-product label	Spanish, or multilingual with Spanish, or exceptionally English-only with prior DNFD justification	DE 21 Art. 97
Public-procurement proposals	Spanish, or translated and authenticated	Ley 419 Art. 203

Central American harmonization overlay. Panamá is a COMIECO member and has adopted the RTCA suite by decree — pharmaceutical labelling (RTCA 11.01.02:04 via DE 849 de 2015), stability studies (11.01.04:10 via DE 850), analytical method validation (11.03.39:06 via DE 851), natural-product labelling (11.04.41:06 via DE 852), medicines quality verification (11.03.47:07 via DE 853), natural-products quality verification (11.03.56:09 via DE 854), hygienic products (71.03.37:07 via DE 855) and pharmaceutical GMP (11.03.42:07 via DE 267 de 2014) (DNFD decree index). Ley 419 Art. 29 pins validated analytical methods, finished-product specifications and labels/inserts *"conforme al RTCA,"* aligned with RTCA 11.03.59:18. Spanish artwork built to RTCA travels into Panamá. Devices do not harmonize: Panamá built its own CCT/CVT architecture under DE 490, anchored to GHTF/IMDRF classification rather than to a Central American device RTCA.

The regime is layered by document class, not by document age. Panamá does not impose a fixed calendar-day currency limit on foreign certificates the way Perú (two-year rule) or Colombia (INVIMA one-year CFS rule) do — but DE 27 Art. 29.2 sets GMP certificate validity at 2 years, and the whole framework was rewritten between 2024 and 2026, so the operative currency risk in Panamá is *citing a repealed instrument*, not a stale certificate.

Section C. Sworn vs certified vs simple translation

**Panamá reserves sworn translation for legal instruments, and channels it through one licensed professional category: the* traductor público autorizado *(TPA). The TPA is a state-licensed professional licensed by the*

Ministerio de Educación (MEDUCA) — not by a translators' association, not by a court, and not by self-certification. The governing instrument is Decreto Ejecutivo 975 de 15 de diciembre de 2017, which subrogated Decreto Ejecutivo 472 de 11 de junio de 2014 ([MEDUCA text of DE 975](https://www.meduca.gob.pa/wp-content/uploads/2025/04/DECRETOS-975.pdf)), reglamented by Resuelto No. 2448 de 21 de mayo de 2018 ([MEDUCA text](https://www.meduca.gob.pa/wp-content/uploads/2025/01/RESUELTOS-2448-QUE-REGLAMENTA-L-DECRETO-EJECUTIVO-N%C2%B0975-DE-15-DIC.-DE-2017-QUE-SUBROGA-EL-DEC.pdf)), which grounds the regime in the Código Administrativo, Título XVII, as reformed by Ley 59 de 31 de julio de 1998. Licensing requirements are published at [MEDUCA's requisitos page](https://www.meduca.gob.pa/wp-content/uploads/2025/01/REQUISITOS-PARA-LA-LICENCIA-DE-TRADUCTOR-PUBLICO-AUTORIZADO-2017.pdf), and licences are granted by resolución *published in the* Gaceta Oficial*.

Tier table.

Tier	Panamanian designation	When it applies	Who certifies
Sworn / official	*Traducción por traductor público autorizado*	Certificado de libre venta (DE 27 Art. 28.3); foreign *documentos legales originales* in a device file (DE 490 Art. 35); any registration document not natively Spanish (Ley 419 Art. 33); hemoderivado label text (DE 27 Art. 47); fórmula cuali-cuantitativa where foreign-language (DE 27 Art. 124.7); PSUR/PBRER executive summary (DE 27 Art. 331)	MEDUCA-licensed TPA, licensed per language pair, and of the Republic of Panamá
Certified	Supplier or sponsor statement of accuracy	Not an expressly recognised category in Panamá. Usable only where a provision says "traducción" or "en español" without naming a TPA — e.g. the GMP certificate under DE 27 Arts. 77.3 / 78.3 ("traducido al idioma español"). Treat as a risk-accepted position, not a rule	Sponsor / supplier attestation
Simple	*Traducción al español* / *resumen en español*	Spanish summaries of English clinical evidence (DE 27 Art. 30); Spanish executive summaries and consolidated technical summaries accompanying English preclinical evidence; reviewer-facing navigation aids	Sponsor / CRO — no provision requires a TPA for a summary of a clinical or preclinical study

The commercially decisive line is the third row. Panamá's statute demands a Spanish *resumen* of clinical studies — and nowhere requires that *resumen* to be sworn. A well-drafted, technically accurate, unsworn Spanish summary satisfies Ley 419 Art. 33 on its face. That is the entire economic argument of Section D.

Three practical consequences of the TPA regime. First, a TPA is licensed per language pair — an English→Spanish TPA cannot swear a German→Spanish translation, so a dossier holding a German notified-body certificate, a French sterilisation validation and a Japanese CoA needs three licensed professionals, not one vendor stamp. Second, Panamá-licensed, not foreign-sworn: DE 490 Art. 35 says *"un traductor público autorizado de la República de Panamá"* and DE 27 Art. 28.3 says *"un traductor público autorizado en Panamá"* — a Spanish *traductor jurado*, a US ATA-certified translator or a Colombian *traductor oficial* is not substitutable on the face of the text. Third, signature registration is a separate step with MIRE for some cross-border chains (MIRE).

Apostille sequencing. Panamá is a Hague Apostille Convention party: the Convention was approved domestically by Ley 6 de 25 de junio de 1990, published in *Gaceta Oficial* 21571 of 3 July 1990 (Justia Panamá text), reglamented by Decreto Ejecutivo 445 de 12 de noviembre de 1991. DE 490 Art. 35 requires foreign documents for CCT/CVT and operating licences to be authenticated *"conforme a las disposiciones del Convenio de Apostille, aprobado mediante Ley No. 6 del 25 de junio de 1990,"* with non-Hague origins routed through consular/MIRE legalisation and catalogues exempt. DE 27 Art. 216 requires all foreign legal documentation to be authenticated or apostilled and accepts electronic documents; Art. 28.8 expressly contemplates the apostilla electrónica. MINSA has issued dedicated guidance in DNFD Comunicado No. 21 de 28 de junio de 2023 and an explanatory Cápsula 7 — Apostilla. The DNFD charges B/.30.00 for *Autenticación de Documentos* (DNFD tarifa de trámites; DE 27 Art. 15).

The sequencing rule that trips foreign sponsors: obtain the signed original abroad, apostille it in the country of origin, and *then* have the Panamá TPA translate the document including the apostille certificate itself and every seal, stamp and marginal annotation — filing the apostilled original and the TPA translation as an annexed pair, because DE 27 Art. 28.3 is explicit that *"esta traducción se anexará al certificado correspondiente."* Translate first and apostille second, and the apostille attaches to a document the TPA never saw while the Spanish version omits the apostille text — reviewers cannot reconcile the two, and the translation is redone. Devices have a partial escape hatch: DE 490 Art. 43 allows a simple copy to be filed first with the apostilled original supplied within 3 meses — but the translation must ultimately match the final authenticated instrument.

The scheduling constraint nobody budgets for. TPA capacity in Panamá is finite. The population of MEDUCA-licensed English→Spanish public translators fluent in ISO 10993 biocompatibility language, IEC 60601 electrical-safety terminology and ICH E3 clinical-report structure is small (MEDUCA Traductores y Examinadores). Sworn translation in Panamá is therefore not merely expensive — it is a queue. Every page routed through a TPA that did not legally need to go there lengthens the critical path.

Amavita's 7th QC gate — Document Currency. Panamá is the LATAM jurisdiction where currency risk is highest, and it is *instrument* currency rather than certificate currency. Panamá rewrote its entire medicines framework between 2024 and 2026: Ley 419 de 2024 subrogated Ley 1 de 2001 and Ley 97 de 2019; DE 13 de 2023, DE 36 de 2020, DE 869 de 2021 and DE 112 de 2022 are marked *DEROGADO* on the DNFD decree index; DE 21 de 2026 Art. 104 repealed DE 1843 de 2014, DE 6 de 2015 and Resolución 390 de 2003; and DE 2 de 2025 was itself amended twice inside six months. Anyone working from a pre-2024 Panamá checklist is working from a dead document. Amavita Sciences™ therefore treats Panamá as a mandatory 7th-gate jurisdiction: every deliverable is re-checked against the live instrument list before release, every foreign document is timestamped at apostille, at translation and at filing, and a refreshed apostilled original triggers a fresh translation within 48 hours under our First-Pass Acceptance Program.

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

A preclinical package for a single drug or device program routinely runs 800–3,500 pages: pharmacology, PK/ADME, toxicology, safety pharmacology, biocompatibility, electrical safety, sterilisation validation, and their appendices. Panamá answers the translation question better than almost any other jurisdiction in the region — at statute level, in writing, with a named exception — for market access. For clinical trial authorization, the answer is narrower and, on the specific question of preclinical attachments, not yet written. This section is therefore deliberately split: full confidence on the market-access side, hedged on the clinical-trial side, with a formal consulta pending.

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

The honest answer depends on which pathway the document is filed into, and Panamá's two pathways do not sit at the same level of legal certainty.

For market access / sanitary registration — full confidence. No.

Preclinical technical documentation does not require page-by-page Spanish translation for a Panamá sanitary registration or a Certificado de Criterio Técnico. Three provisions carry that conclusion, and the first is a statute.

- Ley 419, Art. 33 — registration documentation in Spanish or TPA-translated, but *"en cuanto a los estudios clínicos, se aceptarán en el idioma inglés y su resumen debe ser presentado obligatoriamente en español."* The English allowance for study evidence lives in the statute, not in a reviewer's discretion.
- DE 27, Art. 30 names the price of the allowance: *"Se aceptará la presentación de estudios clínicos en inglés siempre que estén acompañados de un resumen en español de toda la evidencia clínica que demuestre el balance beneficio riesgo favorable."* A substantive Spanish synthesis of the evidence base — not a cover note, not an abstract.
- Panamá's drug framework lists non-clinical evidence as a dossier item with no language rule attached. Ley 419 Art. 29 lists fourteen *requisitos*, including item 10, *"Estudios de seguridad y eficacia"* — no language qualifier. DE 27 Art. 102, the biologicals article, lists *"4. Información de la fase preclínica"* — no translation obligation. DE 27 Art. 155 requires *"Estudios Toxicológicos"* for homeopathics claiming a therapeutic indication — again with no language rule.

On the device side the silence is paired with an affirmative permission, which is stronger. DE 490 Art. 37 sets incremental requirements by class: Class B adds the sterilisation method; Class C adds a *"Resumen de estudios o ensayos clínicos de seguridad y efectividad"* plus a materials description; Class D adds risk analysis and mitigation, traceability protocols and *"Información detallada de estudios clínicos y preclínicos de seguridad y efectividad"* — with no Spanish-translation obligation attaching to any of it. Meanwhile Art. 36.7 affirmatively permits manufacturer technical literature in electronic or digital format with no language condition, Art. 41.1 affirmatively permits data sheets, product data and service manuals *"en español o inglés,"* and Art. 35 confines the sworn-translation duty to *"documentos legales originales."*

Neither DE 490 nor Ley 419 / DE 27 contains any provision requiring page-by-page Spanish translation of ISO 10993 biocompatibility reports, IEC 60601 electrical-safety test reports, sterilisation-validation protocols and reports (ISO 11135 / 11137 / 17665), GLP animal-study reports, CB Test Certificates or Attestations of Test Results. On page-by-page translation of the preclinical stack, the Panamanian texts are silent — and that silence sits directly beside affirmative permissions for English technical documentation. [Note: the absence of an obligation is inferred from complete review of the operative decree texts cited above; no Panamanian instrument states an affirmative "preclinical need not be translated" rule.]

The strongest single confirmation is the reliance route. *[DE 2 de 2025, Art. 2(f)] (https://www.minsa.gob.pa/sites/default/files/normatividad/decreto_ejecutivo_no_2_de_7_de_enero_de_2025_-_reconocimiento_de_registros_sanitarios_a_medicamentos_con_registros_de_la_oms.pdf) requires* "una copia

legalizada o apostillada del expediente completo del presentado en el país en donde se realizó el registro" — *the complete foreign dossier — and imposes no translation obligation whatsoever. Panamá will accept an entire FDA- or EMA-tier dossier, in English, apostilled, with no sworn translation. `[UNVERIFIED - source silent]` on any Spanish-translation duty for the WLA* expediente completo* within the four corners of DE 2.

The substitute, in one line: a Spanish executive summary per report plus a consolidated Spanish technical summary, with the English originals preserved and indexed — set out in full in D.3.

For clinical trial authorization (CNBI + MINSA REGULAIPS) — hedged, pending written confirmation.

We state our position on the trial pathway with less certainty than on market access, and we state why.

(a) The clinical protocol and the Investigator's Brochure must be in Spanish. DE 21 de 2026, Art. 85 imposes a general rule that *"todos los documentos, remitidos para estos trámites oficiales, presenten su contenido en idioma español y en las mismas versiones a ser presentadas al comité de bioética,"* and Art. 84 requires the protocol and annexes in the same version filed with the ethics committee. On the medicines side, DE 27 Art. 213.2 requires the protocol and the ethics approval *"en español y en formato electrónico."* The Investigator's Brochure is named in DE 21 Art. 95 as the *"Manual del investigador"* without a document-specific language rule — so it sits inside the Art. 85 general Spanish rule, and we plan the trial-startup package on the basis that the IB is a Spanish deliverable.

(b) Preclinical technical documentation attached to the CTA may still be presented in English. Art. 95 attaches no explicit Spanish requirement to the technical annexes behind the IB, and the same article *expressly permits English* for comparator and concomitant-medication documentation: CPP, batch certificate or CFS *"los cuales podrán ser presentados en idioma inglés o español, acompañados de un certificado de declaración de cumplimiento"* (DE 21 Art. 95). DE 27 Art. 213.4 permits the investigational-product CoA *"en idioma inglés o español."* Panamá's reliance framework points the same way: DE 21 Art. 44 grants expedited review to studies *"que cuentan con aprobación previa de un comité de ética de la investigación, en países y organizaciones internacionales regulatorias de alto estándar,"* Art. 71 sets the CNBI's normative frame as CIOMS, OMS-OPS, Helsinki, UNESCO and ICH GCP, and Art. 99 requires ICH GCP compliance for importation. A framework that keys itself to ICH GCP and to prior high-standard foreign approval is a framework built to read English technical evidence. Our stated position for Panamá is therefore: file English preclinical technical documentation behind a Spanish IB and Spanish executive summaries — and be prepared to produce more Spanish on request. But the honest characterisation is that the IB's technical annexes sit in tension between a document-specific silence in Art. 95 and a general Spanish rule in Art. 85, and we do not present that tension as resolved.

(c) A formal consulta is pending. Because the tension is textual rather than practical, we have not resolved it by inference. Amavita Sciences™ has filed a formal consulta with MINSA REGULAIPS requesting written confirmation of the preclinical translation scope for clinical trial authorization. Until a written response arrives, we scope trial-stage preclinical translation as a decision-ready range rather than a fixed number: Spanish executive summaries as the base case, full Spanish translation of the IB non-clinical section as the contingency, and English report bodies preserved either way.

D.2 If translation IS required — is it text-only or does it require desktop publishing (DTP)?

Where Panamá requires Spanish for a technical document, it requires format-faithful Spanish, and several provisions make that explicit rather than implied. Our posture is unchanged from the rest of our LATAM practice: text-only substance, no DTP for narrative summaries; DTP where the Spanish will be compared side-by-side against a source layout.

Document class	Translation scope	DTP (visual replication) required?
GLP study-report body text, discussion, methods, tables	Spanish executive summary; original English body accepted at the technical tier	No — text-flow for the Spanish summary
GLP study-report figures, plots, chromatograms, gels	No translation — original artwork stands	No
ISO 10993 / IEC 60601 / sterilisation-validation reports	Spanish executive summary (DE 490 Arts. 36.7 / 37 / 41.1)	No
Foreign CPP, CLV, GMP certificate	Sworn Spanish + apostille (DE 27 Arts. 28.3 / 28.8 / 77.3 / 78.3)	Yes — mirror seals, signature blocks and page numbering
CB Test Certificates / notified-body certificates	Conditional sworn Spanish if treated as *documento legal original* (DE 490 Art. 35)	Yes where sworn
Fórmula cuali-cuantitativa	Official Spanish translation where foreign-language (DE 27 Art. 124.7)	Yes — the table must survive as a table
Drug labels, cartons, inserts	Spanish among the languages; no relabelling (Ley 419 Art. 37; DE 27 Arts. 46 / 234)	Yes — *"el arte de los textos de impresión"* is print-ready artwork
Device labels	International symbols permitted if the IFU carries the Spanish descriptive text (DE 490 Art. 39)	Yes for text; symbol glossary is a DTP deliverable by construction
Device IFU / insert	Full Spanish, per device; not for *equipos biomédicos* (DE 490 Arts. 36.8 / 38)	Yes — regulatory DTP
Clinical protocol	Full Spanish, version-matched to the ethics file (DE 21 Arts. 84–85; DE 27 Art. 213.2)	Yes — tables and schedule of assessments
Investigator's Brochure	Spanish under the Art. 85 general rule; non-clinical annexes English with Spanish summary, pending consulta	Text-flow
Informed consent form	Drafted in Spanish, plain language (DE 21 Art. 52)	Yes — mirror the committee-approved template
IMP label	Spanish, multilingual with Spanish, or English-only by justified exception (DE 21 Art. 97)	Yes
PSUR / PBRER	English body; sworn Spanish executive summary only (DE 27 Art. 331)	No — text-flow
Correction filings	*"Donde dice / debe decir"* format for orthography, units and technical terms (DE 490 Art. 44)	Yes — structured two-column instrument

The rule we apply: if the Spanish document will be *compared side-by-side against an English original by a reviewer*, it is a DTP deliverable. If it will be *read on its own as a synthesis*, it is a text deliverable. Tables, labels, formulae, specifications and correction schedules are always the former. And because DE 490 Art. 44 requires corrections in *donde dice / debe decir* format, a Spanish deliverable produced as a linear text dump

— table structure destroyed, source pagination bleeding into the Spanish body — is fatal twice over in Panamá: it breaks the *fórmula cuali-cuantitativa* table, and it makes the Art. 44 remediation route unusable.

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

Panamá names the substitute in its own words: a Spanish evidence layer. It has three components, and it is the same architecture we deploy across the region.

Component 1 — A Spanish executive summary per report (1–3 pages). For every English preclinical report in the file — each ISO 10993 biological-evaluation endpoint, each IEC 60601 test report, each sterilisation validation, each GLP toxicology study — a Spanish executive summary carrying: study identity and report number, test article identity and lot, standard and edition applied, laboratory and accreditation status, GLP / ISO 17025 status, methods in outline, acceptance criteria, results against those criteria, and an explicit pass/fail conclusion. This is the direct analogue of the *resumen* that DE 27 Art. 30 requires for clinical studies, applied to non-clinical evidence.

Component 2 — A consolidated Spanish technical summary. One Spanish document narrating the whole non-clinical programme and concluding on safety: biocompatibility conclusion, electrical and mechanical safety conclusion, sterility assurance conclusion, shelf-life conclusion, and a residual-risk statement tied to the risk analysis DE 490 Art. 37 requires for Class D. For medicines, this is the document that makes Ley 419 Art. 29 item 10 — *"Estudios de seguridad y eficacia"* — reviewable in Spanish without translating the underlying reports.

Component 3 — English originals preserved, with a Spanish index/concordance. The English report bodies stay in the file, unaltered, with a Spanish navigation table mapping each Spanish summary to the exact English report, its page range, and the *requisito* it satisfies. This is the artefact that makes English acceptable in practice: it converts a pile of English PDFs into a Spanish-navigable evidence file. It also pre-empts the concordance check contemplated by DE 490 Art. 32, under which the evaluator checks the manufacturer's own website for consistency with the filing.

Why this is the right trade for a Class C/D device or an innovator medicine.

	Full sworn translation	Spanish evidence layer
Pages through a TPA	Entire preclinical stack (frequently 800–3,000 pp)	Zero preclinical pages; only *documentos legales originales*
Legal basis	None required — over-compliance	Ley 419 Art. 33; DE 27 Art. 30; DE 490 Arts. 35 / 36.7 / 41.1
Terminology risk	High — every translated page is a new place to introduce an error a reviewer can cite	Contained — Spanish exists only in documents we authored deliberately
Critical path	Bound by TPA queue capacity	Bound by our own writing capacity
Update burden on amendment	Re-swear affected pages	Revise the summary

The terminology-risk row is the one sponsors underestimate. Every page translated unnecessarily is a page a reviewer can find a discrepancy in. In a regime where DE 490 Art. 43 obliges the applicant to keep every filed document current and to notify changes — and where substantial changes force a new Certificado de Criterio Técnico — a smaller Spanish surface area is a smaller lifetime maintenance liability.

The two regulatory pathways trigger different translation obligations

Panamá, like every LATAM regulator, operates two related but separate pathways for a sponsor's product: (1) clinical-trial authorization, which lets the investigational product enter a study on the sponsor's timeline; and (2) market-access / sanitary registration, which lets the commercial product be sold. The same preclinical report is treated differently depending on which pathway it supports — and in Panamá the two pathways also sit at different levels of legal certainty on preclinical scope.

Obligation	Pathway 1 — clinical trial authorization (CNBI / CBI + MINSA REGULAIPS + DNFD)	Pathway 2 — market access (DNFD *registro sanitario* / device CCT)
Governing instruments	Ley 84 de 2019; DE 21 de 2026; DE 27 Arts. 209–214, 337–342	Ley 419 de 2024; DE 27 de 2024; DE 2 de 2025; DE 490 de 2019
General language rule	Blanket Spanish for all RESEGIS trámite documents, plus version parity with the ethics file (DE 21 Arts. 84–85)	Spanish or TPA translation, with a statutory English carve-out for study evidence (Ley 419 Art. 33)
Protocol	Full Spanish, version-matched (DE 21 Art. 84; DE 27 Art. 213.2)	Not applicable
Informed consent	Drafted in Spanish, plain language (DE 21 Art. 52)	Not applicable
Investigator's Brochure	Spanish under Art. 85; named in Art. 95 with no document-specific language rule	Not applicable
Preclinical technical reports	Hedged — consulta pending. Art. 95 attaches no language rule; Art. 85 imposes a general Spanish rule. Base case: English with Spanish executive summaries	Full confidence — English accepted with a Spanish evidence layer. Listed without a language rule (Ley 419 Art. 29 item 10; DE 27 Arts. 102 / 155; DE 490 Art. 37)
Clinical study reports	Carried inside the IB	English accepted + mandatory Spanish summary of all clinical evidence (DE 27 Art. 30)
Certificado de análisis	English or Spanish (DE 21 Art. 95; DE 27 Art. 213.4)	English or Spanish (DE 27 Art. 27.15)
Comparator CPP / batch cert / CLV	English or Spanish, with a declaration of compliance (DE 21 Art. 95; DE 27 Art. 213)	CLV requires sworn Spanish annexed to the certificate (DE 27 Art. 28.3)
Labelling	IMP label Spanish, multilingual with Spanish, or English-only by justified exception (DE 21 Art. 97)	Spanish among the languages; no relabelling (Ley 419 Art. 37; DE 490 Art. 39); device IFU full Spanish (DE 490 Art. 36.8)
Government fee	Sin costo for IMP authorisation (DE 27 Art. 15)	B/.500–1,000 by route (DNFD tarifa); CCT itself no fee (DE 490 Art. 21)

The practical consequence: a sponsor who runs a Panamá trial and then registers the product should build the Spanish evidence layer once, at trial stage, and reuse it at registration. The trial-stage Spanish protocol, the trial-stage Spanish IB non-clinical summary and the trial-stage consolidated Spanish technical summary

are most of what the registration filing needs. Sponsors who treat the two pathways as unrelated projects pay for the same Spanish twice.

D.4 Consolidated preclinical instruction table

Preclinical document	(registro sanitario / CCT) — full confidence	(CNBI/CBI + REGULAIPS + DNFD) — hedged, pending consulta
ISO 10993 biocompatibility reports	English accepted; Spanish executive summary; no TPA; no DTP (DE 490 Arts. 36.7 / 37)	English base case behind a Spanish IB summary; full Spanish summary of the non-clinical section as contingency (DE 21 Arts. 85 / 95)
IEC 60601 electrical-safety test reports	English expressly acceptable for data sheets, product data and service manuals (DE 490 Art. 41.1)	Same base case; Art. 95 silent on language, Art. 85 general Spanish rule applies to the trámite set
Sterilisation validation (ISO 11135 / 11137 / 17665)	English accepted; Spanish executive summary (DE 490 Art. 37 requires the sterilisation method from Class B up, silent on language)	English base case; Spanish sterility-assurance conclusion inside the IB summary
GLP animal / toxicology study reports	English accepted; Spanish executive summary (Ley 419 Art. 29 item 10; DE 27 Arts. 102 / 155)	English base case; the IB non-clinical section is where the Spanish summary substitutes for translation
Biologicals preclinical-phase information	English accepted; Spanish executive summary (DE 27 Art. 102.4)	English base case; confirm scope with REGULAIPS in writing before scoping
CB Test Certificates / Attestations of Test Results	Spanish executive summary; **TPA translation if treated as a* documento legal original*** (DE 490 Art. 35)	Same conditional treatment; classify before scoping, not after
Clinical study reports	English accepted + mandatory Spanish summary of all clinical evidence (Ley 419 Art. 33; DE 27 Art. 30)	Carried inside the IB; Art. 85 general Spanish rule applies to the filed version
Certificado de análisis	English or Spanish (DE 27 Art. 27.15)	English or Spanish (DE 27 Art. 213.4; DE 21 Art. 95)
Investigator's Brochure	Not a market-access document	Spanish under Art. 85; no document-specific rule in Art. 95 — the exact scope of its technical annexes is the subject of the pending consulta
Clinical protocol	Not a market-access document	Full Spanish, version-matched, electronic format (DE 21 Arts. 84–85; DE 27 Art. 213.2)
Informed consent form	Not a market-access document	Drafted in Spanish, plain language, DTP to the committee-approved template (DE 21 Art. 52)
CPP / certificado de libre venta	Sworn Spanish, annexed to the certificate; apostille (DE 27 Arts. 28.3 / 28.8)	Comparator CPP / batch certificate / CLV English or Spanish with a declaration of compliance (DE 21 Art. 95)

Preclinical document	(registro sanitario / CCT) — full confidence	(CNBI/CBI + REGULAIPS + DNFD) — hedged, pending consulta
GMP certificate / QP declaration	Spanish, legalised (DE 27 Arts. 77.3 / 78.3); validity 2 years (Art. 29.2)	Required for the IMP; Spanish and legalised advisable (DE 21 Art. 95)
Powers of attorney	Legalised; TPA if foreign-language (Ley 419 Art. 29; DE 2 de 2025 Art. 2)	Site contracts and legal instruments: Spanish, TPA if foreign-language (DE 490 Art. 35 logic applied)
Device IFU / insert	Full Spanish, DTP; not for *equipos biomédicos* (DE 490 Arts. 36.8 / 38)	Spanish device labelling for study use is the safe scope
Labels and cartons	Spanish among the languages; no relabelling; DTP (Ley 419 Art. 37; DE 490 Art. 39)	IMP label Spanish, or English-only with prior DNFD justification (DE 21 Art. 97)
Biomedical-equipment service manuals	English acceptable (DE 490 Art. 41.1)	English acceptable as protocol-cited manual support
Catalogues	No translation, and exempt from legalisation (DE 490 Art. 35)	Same
WLA-route foreign dossier copy	No translation required — legalisation or apostille only (DE 2 de 2025 Art. 2(f))	Not applicable
PSUR / PBRER	English body; sworn Spanish executive summary only (DE 27 Art. 331)	DSUR may be requested by the DNFD (DE 27 Art. 341)

D.5 Where the preclinical translation risk actually sits

The clinical-trial pathway carries more translation-scope risk than market access, and the asymmetry is textual, not anecdotal. On the market-access side the sponsor is protected by a statute — Ley 419 Art. 33 — plus a confirming reglamento article, plus a reliance decree that accepts an entire untranslated foreign dossier (DE 2 de 2025 Art. 2(f)), plus device articles that affirmatively name English as acceptable (DE 490 Arts. 36.7 / 41.1). On the clinical-trial side the sponsor faces a blanket Spanish rule — DE 21 de 2026 Art. 85, covering *"todos los documentos, remitidos para estos trámites oficiales"* — with only document-specific carve-outs for the CoA and comparator documentation in Art. 95. No statute grants the trial pathway an English allowance for technical evidence the way Ley 419 Art. 33 does for registration. Scope the trial-stage preclinical translation with a contingency; scope the registration-stage preclinical translation without one.

Beyond that structural asymmetry, five failure modes, in descending order of realised cost:

1. The Spanish summary being thin. DE 27 Art. 30 demands a summary *"de toda la evidencia clínica que demuestre el balance beneficio riesgo favorable."* A three-paragraph abstract does not discharge that. If the summary is weak, the reviewer's cheapest remedy is to ask for the full Spanish translation — and the entire exemption is lost. The summary is the exemption. Fund it accordingly.
2. Version drift against the ethics file. DE 21 Art. 85 requires the RESEGIS versions to be *the same versions* filed with the bioethics committee. Preclinical data summarised from IB v6 while the committee holds IB v5 is a documented defect.
3. Legal-instrument misclassification. Whether a CB Test Certificate or an ISO 13485 certificate is a *"documento legal original"* under DE 490 Art. 35 is where sponsors guess. Guessing low costs an RFI; guessing high costs TPA fees. Our default: anything issued by a notified body, competent authority or

accreditation body, bearing a signature and seal, is treated as a legal instrument. Test reports issued by a laboratory are not.

4. Apostille / translation sequencing. DE 490 Art. 43's three-month window for producing the apostilled original is a real trap, because the translation must ultimately match the apostilled instrument, not the draft.
5. Structural destruction in the Spanish deliverable. Compounded in Panamá by the relabelling ban: a table-destroying Spanish deliverable that reaches artwork cannot be fixed with a sticker (Ley 419 Art. 37; DE 490 Art. 39).

D.6 The institutional-committee layer that DE 21 does not fully expose

DE 21/2026 sits on top of an institutional-committee layer that carries most of the operational translation burden — and that layer is where the CBI, not the CNBI, sets the rules that a sponsor must actually meet. Two DE 21 articles turn each accredited committee's own procedure into binding law:

DE 21 Art. 32 — CNBI approves each CBI's operating procedure at accreditation, including its fee schedule and, by extension, its document and language requirements. An institutional rule inside an approved procedure has the same practical binding force as the national decree.

DE 21 Arts. 14–19 and Art. 37 — only CBIs accredited by CNBI may operate in the national territory. First accreditation runs up to 11 months; subsequent accreditations up to 3 years; each accreditation type has defined scope. The consequence is that "the CBI's rule" is not optional local color — it is enforced by CNBI's power to withdraw accreditation.

The reference institutional committee is CBI-ICGES, the bioethics committee of the Instituto Conmemorativo Gorgas de Estudios de la Salud (ICGES). Its current requirements document, *Requisitos de Presentación Inicial de Protocolos CBI-ICGES v11* dated 7 November 2025, contains the strongest translation clause published anywhere in Central America:

> "Todos los documentos que se presentan para evaluación al CBI-ICGES deben estar en idioma español. En el caso de que el documento original se encuentre en inglés, deberá también presentarse el original, en su idioma y la traducción deberá ser certificada por personal idóneo para garantizar la calidad de la información y que no haya retrasos en la evaluación por parte del Comité."

And, unusually for LATAM, it puts the rule directly on the Investigator's Brochure — the main preclinical carrier:

> "Manuales del investigador ('Investigator Brochure') en el idioma original y en castellano."

Its digital-submission list also imposes bilingual protocol filing: *"Protocolos (versión en inglés u otro idioma y español), incluyendo anexos y material de soporte."*

Operational reading for sponsors:

1. At CNBI / national level, DE 21 does not impose a general Spanish-language rule on the IB or on preclinical support reports. The DE 21 language rules are limited to (a) the ICF in Spanish (Art. 52), (b) all RESEGIS documents in Spanish and version-matched to the ethics-committee set (Art. 85), and (c) narrow English carve-outs for comparator/concomitant-product certificates (Art. 95) and exceptional labelling (Art. 97).
2. At institutional level, CBI-ICGES requires the IB and the protocol in the original language *and* in Castilian, with the translation "certified by suitably qualified personnel." "Personal idóneo" is not defined in the CBI-ICGES document, but the operative effect is: uncertified translations are flagged as a source of evaluation delay, so the sponsor either presents a translation the committee will accept or absorbs a resubmission cycle.
3. The CNBI's own posted 2016-era *Procedimiento* — predating both Ley 84 and DE 21/2026 — also puts a bilingual language rule on the IB: *"c) Folleto o manual del investigador. En idioma original y en español. d) Protocolo firmado por el Investigador Principal. En idioma original y en español."* Its current standing is uncertain post-DE 21, but no fetched Panamanian instrument revokes it either, so it should be treated as an additional exposure line at the national committee.

What this means at file-planning stage. If the trial routes through CBI-ICGES (or any institutional CBI whose CNBI-approved procedure uses the same language), the sponsor cannot solve the preclinical translation problem with a Spanish executive summary at the DNFD/DE 27 layer. The Investigator's Brochure and its preclinical annex will need Spanish. The preclinical support reports themselves may still be filed in English behind the IB if the CBI's procedure is silent — the CBI-ICGES text does not extend to "material de soporte" for the IB in the same explicit way it extends to protocol material — but that reading is not universal, and the safe assumption is that any committee whose procedure follows the CBI-ICGES pattern will treat a Spanish IB body as the minimum.

Sources: CBI-ICGES Requisitos v11 (7 Nov 2025); CNBI Procedimiento (2016); DE 21 de 2026.

D.7 DE 21 Art. 102 — LATAM's only explicit preclinical GLP article

Panamá is the only Central-American jurisdiction that names GLP inside its research decree. DE 21 Art. 102 (verbatim):

> "Animales de laboratorio o experimentación. Los proyectos de investigación para la salud, en que se utilicen animales de laboratorio o experimentación, deberán ser evaluados, previamente a su ejecución, por un comité de ética y bienestar animal, en aras de cumplir con la normativa nacional e internacional vigente en la materia. Cuando sea necesario realizar estudios preclínicos, los mismos se deberán realizar en arreglo a las buenas prácticas de laboratorio, de conformidad con el Consejo internacional de Armonización y demás organismos de cooperación técnica de referencia."

The article has two operative effects on translation planning:

1. It names ICH GCP and, by reference to ICH's cooperation-body ecosystem, aligns the ethics-committee reading of "preclinical" with an international standard set — which is what lets a sponsor argue, at the committee, that preclinical support reports filed under ISO 10993, IEC 60601, ISO 14971, OECD GLP and

equivalent instruments are acceptable in their original English body with a Spanish IB carrying the substantive results.

2. It creates a second review hop for any animal-model study: a comité de ética y bienestar animal must approve the animal work before execution. That committee's document requirements will vary — but where the animal-ethics committee sits inside an accredited CBI, the CBI's language rule (see D.6) will govern its input documents.

The practical planning consequence is that Panamá is the LATAM country where "preclinical" is normatively distinguished from "clinical" at the decree layer, which is the argument space in which the base-case (English preclinical bodies + Spanish IB summary) becomes defensible — provided the sponsor's IB itself is filed in Spanish per the institutional-committee rule.

Source: DE 21 de 2026, Art. 102.

> **Consulta pending.** Amavita Sciences™ has filed a formal consulta with MINSA REGULAIPS (regulaips@minsa.gob.pa) requesting written confirmation of the preclinical translation scope for clinical trial authorization in Panamá. This section will be revised upon receipt of a written response.

CONSULTA PENDING

Consulta filed with MINSA REGULAIPS

Filed: 24 August 2026

Filed with: regulaips@minsa.gob.pa

Question filed: Formal confirmation of the preclinical translation scope required for clinical trial authorization under DE 21 de 2026 (Reglamento of Ley 84 de 2019).

Amavita Sciences™ has filed a formal consulta with MINSA REGULAIPS at regulaips@minsa.gob.pa on 24 August 2026. The question submitted is: “Formal confirmation of the preclinical translation scope required for clinical trial authorization under DE 21 de 2026 (Reglamento of Ley 84 de 2019).”. This section will be revised upon receipt of a written response. Sponsors filing before the response arrives should assume the strict reading: full traducción simple of the preclinical stack for CTA-stage submissions.

CATEGORY 1: DRUGS

D1. Drug market access — DNFD pathway

Governing instruments.

- *Ley 419 de 1 de febrero de 2024* — regulates medicines and other products for human health; subrogated Ley 1 de 2001 and Ley 97 de 2019 (Ley 419)
- *Decreto Ejecutivo 27 de 10 de mayo de 2024* — the 836-article reglamento (DE 27; Gaceta 30028-C)
- *Decreto Ejecutivo 2 de 7 de enero de 2025* — WHO-Listed Authority recognition, as modified by DE 4 de 5 de febrero de 2025 and DE 12 de 25 de junio de 2025 (DE 2; DNFD decree index)
- *Decreto Ejecutivo 29 de 28 de junio de 2023* — abbreviated-procedure requirements and the updated high-standard authority list (DNFD decree index)
- RTCA 11.03.59:18 dossier alignment via Ley 419 Art. 29; RTCA 11.01.02:04 labelling and RTCA 11.03.42:07 GMP adopted by decree (DNFD decree index)
- MINSA's own procedural Guía sobre el procedimiento para el registro sanitario

Registration modalities — and the translation load differs sharply between them.

Modality	When it applies	Reference
Procedimiento regular	New products without a qualifying foreign registration; fourteen *requisitos* including power of attorney, CPP-OMS or CLV + GMP, fórmula cuali-cuantitativa, monograph, RTCA-validated analytical methods, finished-product specifications, RTCA labels and insert, stability report, safety and efficacy studies, standards, samples and fee	Ley 419 Art. 29; DE 27 Arts. 17–18
Procedimiento abreviado	Products registered and marketed in a country with a high-standard authority recognised by WHO or PAHO; requirements are form, sworn declaration, CPP or CLV + GMP, formula, analytical method, CoA, specifications, stability studies, sample or label artwork, monograph	DE 27 Arts. 18 / 24; DE 29 de 2023; Quijano & Asociados
Reconocimiento mutuo	Fee-bearing recognition route at B/.500	DNFD tarifa de trámites
WLA recognition	Medicines manufactured and registered in a WHO-Listed Authority country; no prior laboratory analysis; requires the abbreviated-procedure fee, the FADDI form via a lawyer with pharmacist and Colegio *refrendo*, legalised powers of attorney, apostilled original CPP, an apostilled copy of the complete foreign dossier, climatic-zone-IVb stability studies, and origin consistency	DE 2 de 2025 Art. 2; Central Law
Priority review, innovators	Special expedited review at a B/.1,000 fee	Ley 419 Art. 42; DE 27 Art. 15

Language and translation stack.

- Product labelling and insert: Spanish among the languages, per RTCA; no relabelling or over-labelling (Ley 419 Art. 37; DE 27 Art. 46).

- Certificado de libre venta: apostilled + sworn TPA translation annexed to the certificate (DE 27 Arts. 28.3 / 28.8).
- GMP certificate: "traducido al idioma español y debidamente legalizado" (DE 27 Arts. 77.3 / 78.3); validity 2 years, notarial copies accepted where the authority publishes GMP electronically (Art. 29.2).
- Fórmula cuali-cuantitativa: official translation where foreign-language, table preserved (DE 27 Art. 124.7).
- Clinical studies: English accepted with a mandatory Spanish summary of all clinical evidence (Ley 419 Art. 33; DE 27 Art. 30) — and DE 27 Art. 32 eliminates clinical studies entirely for multi-source products supported by *fichas técnicas* from high-standard regulators.
- Preclinical evidence: listed without a language rule (Ley 419 Art. 29 item 10; DE 27 Arts. 102 / 155).

Fees (DE 27 Art. 15 and the DNFD tarifa page; B/. = USD 1:1).

Item	Fee (B/.)	Source
Registro sanitario — chemical-synthesis medicine	500	DE 27 Art. 15
Registro sanitario — innovator / biológico / biotecnológico / biosimilar	750	DE 27 Art. 15
Trámite abreviado	750	DE 27 Art. 15
Reconocimiento mutuo	500	DNFD tarifa
Priority review, innovators	1,000	DE 27 Art. 15
Certificado de intercambiabilidad	400	DNFD tarifa
Post-registration modification, each	200	DE 27 Art. 15
Autenticación de documentos	30	DNFD tarifa
Licencia de operación — farmacia	50	DE 27 Art. 15
Licencia de operación — distribuidora / laboratorio / droguería	200	DE 27 Art. 15
GMP audit + certificate	300	DNFD tarifa
Certificación de importación under a valid RS	500	DNFD tarifa
Permiso de autorización de medicamento para estudios clínicos	Sin costo	DE 27 Art. 15
Excepción de registro sanitario para pacientes	Sin costo	DE 27 Art. 15
Pre/post-registration laboratory analysis	200–1,000	MINSA Guía

Two of those lines deserve emphasis. Clinical-trial IMP authorisation is free in Panamá, and so is the patient-level registration exception. Panamá is not monetising research entry — which means a sponsor's real cost of entering Panamá is almost entirely documentation and translation, not government fees. That is precisely the cost line a disciplined language strategy compresses.

Reliance / recognition. DE 2 de 2025 creates a recognition pathway for WHO-Listed Authority registrations with no prior laboratory analysis, a DNFD response in 10 días hábiles (Art. 3), a single RFI via FADDI (Art. 4), 5 días hábiles to cure (Art. 5), and assignment of the registration number within a maximum of 10 días

hábiles (Art. 7), with post-market inspection powers under Art. 8. The government framed the end-to-end trámite as *"no más de 10 días hábiles"* (MEF; Presidencia). One caution: because DE 2 keys off the WHO list rather than naming FDA and EMA, Panamanian press flagged exposure if the United States withdrew from WHO (La Estrella de Panamá). Verify current list status before committing to that pathway.

Other market-access mechanics that touch language. Ley 419 Art. 30 requires the DNFD to publish applications so third parties may oppose on test-data grounds — the published application is a document competitors read. Ley 419 Art. 34 accepts the German, Argentine, British, US (USP/USP-NF), Spanish, European, French, Swiss, International, Japanese, Mexican and Chinese pharmacopoeias plus FCC, AOAC, Micromedex, Drug Information and Martindale, and permits use of a WHO-listed stringent authority's published monograph — another English-acceptance channel. DE 27 Art. 39 permits abbreviated-route medicines to be marketed while post-registration quality analysis is processed within six months.

D2. Drug regulatory submissions

Base dossier (Ley 419 Art. 29 + DE 27 procedural articles), with the language status of each item.

1. Power of attorney to a Panamá-resident representative — legalised; TPA if foreign-language (Ley 419 Art. 29)
2. CPP-OMS or CLV + GMP certificate — apostilled; CLV with sworn Spanish annexed (DE 27 Arts. 28.3 / 28.8 / 216)
3. Manufacturing contract where applicable
4. Fórmula cuali-cuantitativa — official translation if foreign-language (DE 27 Art. 124.7)
5. Monograph — a WHO-listed authority's published monograph is usable (Ley 419 Art. 34)
6. Validated analytical methods per RTCA
7. Finished-product specifications
8. Labels and insert per RTCA — Spanish artwork, print-ready, no relabelling
9. Stability-study report — climatic zone IVb on the WLA route (DE 2 Art. 2)
10. Safety and efficacy studies — no language rule attaches (Ley 419 Art. 29)
11. Analytical standards
12. Samples for laboratory analysis
13. Certificado de análisis — English or Spanish (DE 27 Art. 27.15)
14. Fee (DE 27 Art. 15)

Post-registration modifications. Chapter XIX of DE 27 governs post-approval change, and Art. 220's general Spanish clause textually sits there — so for modification filings the maximalist reading is unambiguous: everything in Spanish, foreign-language official documents with TPA translation. Fee B/.200 per modification. No modifications are accepted in the 6 months before expiry (Art. 219), and approved modifications must be implemented within 12 months (Art. 221).

Renewal cadence. *Registro sanitario* is valid 5 years, renewable (Ley 419 Art. 48); renewal non-compliance gives 3 meses to cure (DE 27 Art. 240); and where the product is not yet marketed, the renewal filing must include draft primary/secondary packaging and insert artwork *"en idioma español"* (Art. 234).

Pharmacovigilance obligations — the most language-prescriptive area of the entire framework, and asymmetric in a way that saves money if read precisely.

Item	Rule	Source
ADR notifications	*"Deberán ser remitidas en español"*	DE 27 Art. 325
Serious ADRs	Within 10 días hábiles; forms *"se enviarán en el idioma español"*	DE 27 Art. 326
PSUR periodicity	Six-monthly for the first 2 years, annually for the next 3, then every 5 years	DE 27 Art. 328
PSUR submission window	Within 3 calendar months of the data lock point	DE 27 Art. 329
PBRER structure	Per ICH E2C(R2)	DE 27 Art. 331
PBRER language	*"Los IPS o PBRER se pueden presentar en idioma inglés, con la traducción al español por intérprete público autorizado del Resumen Ejecutivo"*	DE 27 Art. 331

Art. 331 belongs in every Panamá scope of work. A 400-page PBRER stays in English; a six-page executive summary goes to a sworn translator. That is a roughly 98% reduction in sworn-translation volume for the single largest recurring regulatory document in a product's lifecycle — and it is the template for how Panamá thinks about technical evidence generally.

DNFD inside trial oversight. DE 27 Arts. 337–342 place the DNFD inside clinical-trial oversight: it participates in GCP inspections, evaluates protocols and authorises the investigational-product registration exception using ICH and high-standard-authority guidance. Art. 340 lets it require the CoA, formulation, labelling, stability studies, informed-consent forms, ADR reports and diethylene/ethylene glycol negativity tests; Art. 341 lets it request the DSUR; Art. 342 governs post-trial access importation, again requiring the protocol *"en español y en formato electrónico."*

D3. Drug clinical trials

Authorization architecture. Panamá applies a parallel-authorization model, not a sequential one. DE 21 Arts. 88–92 classify human interventional trials as alto riesgo and have MINSA technical units evaluate them in parallel with ethics review, with Art. 90 bringing the DNFD and other MINSA normative bodies into that evaluation. The governing stack is Ley 84 de 2019 + DE 21 de 2026 + DE 27 Arts. 209–214 and 337–342.

Ethics review. DE 21 Art. 44: ordinary review max 20 días hábiles; expedited max 10 días hábiles; exemption max 5 días hábiles — and expedited review is granted to minimal-risk studies *and* to studies *"que cuentan con aprobación previa de un comité de ética de la investigación, en países y organizaciones internacionales regulatorias de alto estándar."* Art. 45 caps total ethics review at 30 días hábiles (+10 if returned to the *pleno*), gives the investigator 20 días hábiles to respond, and requires the certificate within 3 días hábiles. Decisions are *Aprobación*, *modificaciones mínimas*, *modificaciones mayores*, or *Rechazo*. Art. 46 allows a multicentre study to be approved by a single accredited CBI — one committee, one Spanish document set, version-controlled.

Registration. Via RESEGIS (DE 21 Arts. 82–86): Art. 84 requires the protocol and annexes in the same version filed with the committee, Art. 85 imposes the Spanish-and-version-parity rule, and Art. 86 produces a registration receipt within 3 días hábiles. MINSA publishes RESEGIS access, file-upload, *tramitantes* and CNBI/CBI follow-up guides, plus quarterly RESEGIS activity reports currently through Q2 2026, on the research regulation page.

IMP evaluation. DE 21 Art. 95: via RESEGIS the sponsor files GMP certificates of the IMP or a QP GMP declaration or equivalents, the *certificado de análisis*, the Manual del investigador, and other protocol-cited manuals such as the pharmacy manual and study-procedures manual; comparator and concomitant-medication CPP, batch certificate or CFS *"podrán ser presentados en idioma inglés o español, acompañados de un certificado de declaración de cumplimiento"*; and the DNFD responds *"en un plazo no superior a quince días hábiles."* Importation under Art. 99 rests on RESEGIS registration + ethics approval + DNFD authorisation, with ICH GCP compliance required. Safety reporting and joint GCP inspections are coordinated between the DGSP, the CNBI and the DNFD under Art. 96. The parallel medicines-side route is the *excepción de registro sanitario* under DE 27 Art. 213, valid 60 días hábiles for importation with no extension (Art. 214).

The Panamá trial-startup translation package, minimally scoped.

Deliverable	Language	Sworn?	DTP?
Protocol + synopsis	Spanish, version-matched to the ethics file (DE 21 Arts. 84–85)	No	Yes
Informed consent + assent	Drafted in Spanish, plain language (DE 21 Art. 52)	No	Yes
Investigator's Brochure	Spanish under Art. 85; non-clinical annexes English + Spanish summary, pending consulta	No	No
Preclinical reports behind the IB	English + Spanish executive summaries	No	No
Certificado de análisis	English or Spanish (DE 27 Art. 213.4)	No	No
GMP certificate / QP declaration	Spanish, legalised	Advisable	No
Comparator CPP / batch cert / CFS	English or Spanish (DE 21 Art. 95)	No	No
IMP label	Spanish, or English by justified exception (DE 21 Art. 97)	No	Yes
Patient-facing materials, diaries, questionnaires	Spanish, readability-graded	No	Yes
Site contracts and legal instruments	Spanish; TPA if foreign-language	Yes	No

CATEGORY 2: MEDICAL DEVICES

E1. Device market access — DNFD/MINSA device directorate pathway

Governing instruments.

- *Ley 90 de 26 de diciembre de 2017*, as modified by *Ley 92 de 12 de septiembre de 2019* (MINSA device directorate page)
- Decreto Ejecutivo 490 de 4 de octubre de 2019 — the operative reglamento, published in Gaceta Oficial 28875-A, modified by DE 616 de 13 de mayo de 2020
- *Decreto Ejecutivo 48 de 12 de abril de 2022* — donations of medicines, medical devices, biomedical equipment and medical furniture, repealing DE 988 de 2015 (DNFD decree index)
- A practitioner overview of the process is published by the US Commercial Service

The architecture is unusual, and it shapes what needs translating. Instead of a classic *registro sanitario*, DE 490 built the device system around a Certificado de Criterio Técnico (CCT) and a Certificado de Verificación Técnica (CVT) issued by the device directorate. Under DE 490 Art. 21 the CCT is valid for five years and — unusually for the region — is issued at no cost. Devices are not RTCA-harmonised: where drugs ride the Central American technical regulations, devices ride DE 490 plus GHTF/IMDRF classification principles (DE 490 Art. 30).

Classification (DE 490 Art. 30). Four risk classes — A (low), B (low-moderate), C (moderate-high), D (high) — assigned per GHTF/IMDRF criteria. Product families are coded under Art. 22 using the directorate's family prefixes: MQ (material médico-quirúrgico), EB (equipo biomédico), IMA (implantes), LAB (laboratorio), ODO (odontología) and OT (otros).

Class-incremental technical requirements (DE 490 Art. 37). Class B adds the sterilisation method; Class C adds a *"Resumen de estudios"*; Class D adds detailed clinical and preclinical information. This is the single most important article for translation scoping, and it is worth being precise about what it does *not* say: Art. 37 attaches no language rule to any of these three increments. The obligation is to supply the information, not to supply it in Spanish.

Language and translation stack — devices.

Element	Rule	Source
Original legal documents (powers of attorney, CFS, authority certificates)	Sworn translation by *traductor público autorizado*; apostille per Ley 6 de 1990	DE 490 Art. 35
Product catalogues	Expressly exempt from sworn translation	DE 490 Art. 35
Manufacturer technical literature	Accepted in electronic/digital form — no language rule stated	DE 490 Art. 36.7
IFU / insert for the device	Spanish required (does not extend to *equipos biomédicos*)	DE 490 Art. 36.8
Multilingual IFU	Permitted provided one of the languages is Spanish	DE 490 Art. 38
Symbols and colour codes	International symbology and colours permitted where the IFU carries the Spanish descriptive text	DE 490 Art. 39
Relabelling / over-labelling	Prohibited — no sticker remedy	DE 490 Art. 39
Data sheet, product data, service manuals	*"En español o inglés"* — English is expressly sufficient	DE 490 Art. 41.1
Class B / C / D technical increments	Content requirements only; no language rule	DE 490 Art. 37

Read together, Arts. 36.7, 37 and 41.1 are the most permissive device-side technical-language provisions in Central America. We treat them as the operative authority for scoping: the patient- and operator-facing surface (IFU, labels, warnings) is a Spanish deliverable with print-fidelity consequences, and the engineering surface (test reports, service manuals, data sheets, technical literature) is not.

Authentication and correction mechanics. Art. 43 allows a simple copy to be filed first, with the apostilled original delivered within 3 meses; a substantial change to the device requires a new CCT rather than an amendment. Art. 44 requires corrections to be filed in the *"donde dice / debe decir"* format — a two-column correction instrument that is itself a translation deliverable when the underlying document is foreign. Under Art. 32, the evaluator checks the manufacturer's own website for concordance with the filed dossier, which means a Spanish IFU that diverges from the manufacturer's published English IFU is a self-inflicted RFI. Art. 42 sets out the heightened-scrutiny triggers.

Procedural clocks (DE 490 Art. 24). Decision within 30 días hábiles; RFI response within 60 días hábiles, extendable by a further 30; non-response is treated as *desistimiento* — the file is abandoned, not merely delayed.

Establishment licensing and fees. The *licencia de operación* runs 5 years (Art. 13) and renewal must be filed 60 días hábiles before expiry (Art. 26). Fees under Art. 64: B/.350 fabricante, B/.225 acondicionador, B/.200 distribuidor, B/.150 minorista/almacén, B/.25 actualización. The balboa is pegged 1:1 to the U.S. dollar, so these are dollar figures.

Pending replacement decree — currency risk on the device side is live. MINSA put a replacement device decree out for public consultation from October 2025 to February 2026 (MINSA consultation notice); the draft text circulated through the Cámara de Comercio and was analysed by AARSA. As of this writing it is not promulgated, and DE 490 remains the governing instrument. We do not scope device translation to the draft. We do timestamp every device deliverable so that, if the replacement decree is promulgated, the sponsor knows precisely which filings were built on DE 490 language provisions. The original 2019 framework and its practical effect were summarised at the time by Dentons, and the registration process is described for exporters by the US Commercial Service.

E2. Device regulatory submissions

Base dossier. The CCT dossier under DE 490 Arts. 35–41 assembles four blocks, and each block has a different translation instruction:

1. Legal block — company documents, power of attorney, manufacturer authorisation, Certificate of Free Sale or equivalent authority certificate. Apostilled per Ley 6 de 25 de junio de 1990 then sworn-translated by a Panamá *traductor público autorizado* (Art. 35).
2. Technical block — manufacturer technical literature, data sheets, product data, service manuals, test reports. Electronic/digital acceptable, no Spanish duty (Arts. 36.7, 41.1).
3. Class-increment block — sterilisation method (B), *resumen de estudios* (C), detailed clinical and preclinical information (D). Content duty only (Art. 37).
4. User-facing block — IFU, inserts, labels, symbology. Spanish, print-fidelity, no relabelling (Arts. 36.8, 38, 39).

What we actually deliver on a Class C or Class D device file.

Deliverable	Language	Sworn?	DTP?
Power of attorney, manufacturer authorisation, CFS/CLV	Spanish	Yes — Panamá TPA	No
Apostille certificate itself (and all seals/stamps)	Spanish	Yes	No
Product catalogue	Source language accepted	No — exempt (Art. 35)	No
Technical literature, data sheets, service manuals	English accepted (Art. 41.1)	No	No
ISO 10993 biocompatibility, IEC 60601 electrical safety, sterilisation validation reports	English original + Spanish executive summary	No	No
Resumen de estudios (Class C)	Spanish — this is the substitute deliverable	No	No
Class D clinical + preclinical information	English originals + consolidated Spanish technical summary	No	No
IFU / insert	Spanish (or multilingual including Spanish, Art. 38)	No	Yes
Primary and secondary labels, symbology legends	Spanish descriptive text (Art. 39)	No	Yes
"Donde dice / debe decir" correction instrument	Spanish, two-column (Art. 44)	Follows the underlying document	Yes

**The Class C* "Resumen de estudios" *is the highest-leverage sentence in the Panamá device framework. [Art. 37](https://www.gacetaoficial.gob.pa/pdfTemp/28875_A/GacetaNo_28875a_20191004.pdf) asks a Class C applicant for a* summary *of studies — not the studies themselves, and not a translation of them. A well-built Spanish* resumen de estudios *discharges the requirement while the underlying ISO 10993 and IEC 60601 report bodies stay in English. A thin or generic* resumen* invites the evaluator to ask for the underlying reports, and once they are requested in Spanish the sponsor has lost an exemption it never had to lose. This is the summary-insufficiency defect class, and on the device side it is where we see it most often.

Post-market surveillance. Device *tecnovigilancia* obligations attach to the establishment holding the *licencia de operación* under DE 490; donations of medical devices, biomedical equipment and medical furniture are separately regulated by *Decreto Ejecutivo 48 de 12 de abril de 2022*, which repealed DE 988 de 2015 (DNFD decree index).

E3. Device clinical trials

This is the thinnest surface in the Panamá framework, and we say so rather than filling the gap with inference. Decreto Ejecutivo 21 de 23 de abril de 2026 rebuilt the health-research and bioethics architecture for Panamá, and its ethics-review machinery is device-agnostic: an interventional device study is an *investigación de alto riesgo* reviewed by an accredited *comité de bioética* under Art. 44 and registered in RESEGIS under Arts. 82–86 on exactly the same terms as a drug study. The Spanish-language obligations therefore bite identically:

- The informed consent form must be drafted in Spanish, in plain and comprehensible language — DE 21 Art. 52 ("Idioma") requires the ICF *"debe ser redactado en idioma español, en un lenguaje sencillo y comprensible."* This is a drafting standard, not a translation standard.
- All documents filed for the RESEGIS trámite must be in Spanish and in the same versions filed with the ethics committee — DE 21 Art. 85: *"Es indispensable que todos los documentos, remitidos para estos trámites oficiales, presenten su contenido en idioma español y en las mismas versiones a ser presentadas al comité de bioética."*
- MINSA technical review runs in parallel with ethics review for high-risk interventional studies (DE 21 Arts. 88–92), which compresses the translation calendar rather than sequencing it.

Where the framework goes silent. DE 21 Art. 95 — the article that sets the DNFD's 15 día hábil evaluation window and enumerates the investigational-product documents — is drafted for investigational medicines. It names GMP certificates or a Qualified Person GMP declaration, the *certificado de análisis*, the *Manual del investigador*, and protocol-cited manuals. **Whether the* Dirección Nacional de Dispositivos Médicos *formally evaluates investigational devices under DE 21 the way the DNFD evaluates investigational medicines is [UNVERIFIED - source silent]** — DE 21 Art. 95 does not name the device directorate, and no promulgated instrument on the MINSA normativas index supplies the device analogue. We flag it, we do not invent it, and we scope device trial-startup translation to the obligations that are actually written down: Spanish ICF, Spanish protocol and Spanish RESEGIS file with version parity, plus Spanish patient-facing materials.

Practical consequence for device sponsors. Because the device-side investigational-product pathway is not codified with the specificity of Art. 95, the sponsor carries more discretionary exposure than a drug sponsor does. Our posture is to build the Spanish protocol, ICF and RESEGIS package to the DE 21 standard, keep ISO 10993 / IEC 60601 / ISO 13485 evidence in English with Spanish executive summaries, and hold a Spanish consolidated technical summary in reserve so that a directorate request can be answered inside the DE 490 Art. 24 RFI window without a new translation cycle.

Section F. Common RFI / rejection patterns

Amavita Sciences™ works six defect classes. Below, each is mapped onto the Panamá statutory surface that produces it, with the rejection language a sponsor should expect to read.

Defect class	Panamá surface	RFI / rejection pattern
Currency defect	Filings built on repealed instruments — Ley 1 de 2001, Ley 97 de 2019, DE 13 de 2023, DE 869 de 2021, DE 112 de 2022, DE 1843 de 2014, DE 6 de 2015, Resolución 390 de 2003 — all superseded by Ley 419 de 2024 and DE 27 de 2024 (DE 21 Art. 104 for the research side)	*"La solicitud invoca normativa derogada; adecúe la documentación a la Ley 419 de 2024 y su reglamento."* Also triggered by GMP certificates outside the 2-year validity of DE 27 Art. 29.2
Authentication defect	Apostille missing, mis-sequenced, or itself untranslated; foreign legal documents not authenticated per DE 27 Art. 216; device originals not delivered inside the 3 meses of DE 490 Art. 43	*"El documento extranjero no se encuentra debidamente apostillado conforme a la Ley 6 de 1990"* — and, more often, the apostille is present but its own text and seals were never translated (DE 27 Art. 28.3)

Defect class	Panamá surface	RFI / rejection pattern
Translator-status defect	Translation performed by a translator who is not a *Panamá-licensed* traductor público autorizado*** under DE 975 de 2017, or not licensed for the specific language pair	*"La traducción no fue realizada por traductor público autorizado de la República de Panamá"* — a U.S. ATA certification, a notarised affidavit, or a TPA licensed in another country does not cure this
Summary-insufficiency defect	The Spanish *resumen* that buys the English-language exemption is thin: Ley 419 Art. 33 and DE 27 Art. 30 condition English clinical studies on a Spanish summary of *"toda la evidencia clínica que demuestre el balance beneficio riesgo favorable"*; DE 27 Art. 331 conditions English PSUR/PBRER on a TPA-translated Executive Summary; DE 490 Art. 37 conditions Class C on a *"Resumen de estudios"*	*"El resumen en español presentado no permite establecer el balance beneficio-riesgo; amplíe conforme al artículo 30."* The exemption is lost and the underlying reports are called in
Structural / DTP defect	Tables destroyed in translation, source pagination bleeding into the Spanish body, artwork not print-ready; Ley 419 Art. 37 and DE 490 Art. 39 both prohibit *reetiquetado o sobreetiquetado* — there is no sticker remedy in Panamá	*"Las etiquetas presentadas no cumplen con el idioma español; no se aceptará reetiquetado o sobreetiquetado."* On renewals, DE 27 Art. 234 requires the *arte* itself *"en idioma español"* — a text file is not artwork
Version-parity defect	RESEGIS file and ethics-committee file carry different document versions, in breach of DE 21 Arts. 84–85	*"Los documentos remitidos no corresponden a las mismas versiones presentadas al comité de bioética."* Fatal on multicentre files, where DE 21 Art. 46 routes all sites through a single accredited committee

Three Panamá-specific traps worth naming separately.

The desistimiento cliff. On the device side, DE 490 Art. 24 treats non-response to an RFI as *desistimiento* — abandonment. On the medicines side, DE 27 Art. 22 gives 3 meses to cure a new registration and Art. 240 the same 3 meses on renewal. But the WLA-recognition route under DE 2 de 2025 Arts. 4–5 allows a single RFI with only 5 días hábiles to cure. A sponsor who wins the fastest pathway inherits the least forgiving clock, and translation capacity has to be pre-positioned before the RFI arrives, not sourced after.

The six-month modification freeze. DE 27 Art. 219 bars post-registration modifications in the 6 months before a registration expires. Sponsors who discover a labelling translation error late in the cycle cannot fix it by modification; they carry it into renewal.

The concordance check. DE 490 Art. 32 directs the evaluator to the manufacturer's own website. A Spanish IFU that says something the manufacturer's published English IFU does not say is a defect the sponsor manufactured itself.

Amavita's 7th QC gate — Document Currency — is the Panamá-specific control. Panamá rewrote its entire medicines framework in 2024, its recognition framework in 2025, its research and bioethics framework in April 2026, and has a device decree sitting in post-consultation limbo (MINSA consultation extension). No other Central American jurisdiction has moved this much statutory ground in twenty-four months. Our Document Currency gate timestamps every foreign document at three points — apostille issuance,

translation delivery, and filing — and re-issues a corrected translation within 48 hours when a sponsor refreshes an underlying document under the First-Pass Acceptance Program at $2,500/business-day.

Section G. Consolidated timelines

Sub-category	Procedure	Statutory timeline	Practical note	Source
Drugs — sanitary registration	*Registro sanitario*, regular procedure	20 días hábiles to issue after satisfactory analysis; laboratory analysis up to 60 días hábiles	Clock runs on a complete file; filing requires *abogado* + *farmacéutico idóneo* with Colegio refrendo	Ley 419 Arts. 41, 48; DE 27 Art. 19
Drugs — RFI cure (new registration)	Response to *subsanación*	3 meses	Non-cure closes the file	DE 27 Art. 22
Drugs — abbreviated procedure	*Trámite abreviado*	Requirements set by decree	Fee B/.750	DE 27 Arts. 17–18, 24; DNFD tariff
Drugs — WLA recognition	DE 2 de 2025 route	DNFD responds in 10 días hábiles; RS number within 10 días hábiles	Single RFI, 5 días hábiles to cure; laboratory analysis waived	DE 2 Arts. 3–5, 7
Drugs — priority review	Expedited evaluation	Per Ley 419 Art. 42	Fee B/.1,000	Ley 419 Art. 42; DNFD tariff
Drugs — registration validity	*Registro sanitario*	5 years	No modifications in the final 6 months	Ley 419 Art. 48; DE 27 Art. 219
Drugs — renewal cure	Response on renewal	3 meses	Renewal artwork must be *"en idioma español"*	DE 27 Arts. 234, 240
Drugs — market entry pending analysis	Provisional commercialisation	6 months	Conditional on pending laboratory analysis	DE 27 Art. 39
Drugs — registration exception (trials/patients)	*Excepción de registro sanitario*	Valid 60 días hábiles, no extension	Protocol *"en español y en formato electrónico"*; no fee	DE 27 Arts. 213–214; DNFD tariff
Devices — CCT decision	Certificado de Criterio Técnico	30 días hábiles	CCT valid 5 years, no fee	DE 490 Arts. 21, 24
Devices — RFI response	Response to observations	60 días hábiles, extendable +30	**Non-response* = desistimiento***	DE 490 Art. 24
Devices — apostilled original delivery	After simple-copy filing	3 meses	Substantial change → new CCT	DE 490 Art. 43
Devices — licencia de operación	Establishment licence	5 years; renewal 60 días hábiles before expiry	Fees B/.350 / 225 / 200 / 150	DE 490 Arts. 13, 26, 64

Sub-category	Procedure	Statutory timeline	Practical note	Source
Trials — ethics review	*Comité de bioética*	20 días hábiles ordinary; 10 expedited; 5 exemption	Expedited includes protocols pre-approved by a high-standard foreign committee	DE 21 Art. 44
Expedited ethics review under Art. 44.2	Ethics committee	10 días hábiles	Available for studies with prior ethics approval from a bioethics committee *"en países y organizaciones internacionales regulatorias de alto estándar."* Shortens the ethics timeline, but does not shorten the language obligation — the file still has to be in the committee's required Spanish set.	DE 21 Art. 44.2
Trials — total ethics ceiling	Committee decision	30 días hábiles total (+10 if escalated to *pleno*)	Investigator has 20 días hábiles to respond; certificate issued in ≤3 días hábiles	DE 21 Art. 45
Trials — RESEGIS registration	MINSA research registry	Receipt acknowledged in 3 días hábiles	Same versions as the ethics file, all in Spanish	DE 21 Arts. 84–86
Trials — DNFD IMP evaluation	Investigational medicinal product	≤15 días hábiles	Comparator CPP/CFS may be English or Spanish	DE 21 Art. 95
Trials — MINSA technical review	High-risk interventional studies	In parallel with ethics review	Compresses, not extends, the translation calendar	DE 21 Arts. 88–92
Pharmacovigilance — serious ADR	Reporting to DNFD	10 días hábiles	Reports in Spanish	DE 27 Arts. 325–326
Pharmacovigilance — PSUR/PBRER	Periodic safety report	Periodicity + 3 calendar months to file	English body accepted; Executive Summary TPA-translated to Spanish	DE 27 Arts. 328–329, 331
Framework implementation	DE 27 transition	12 months to implement	Filed under the new framework from mid-2025 onward	DE 27 Art. 221

The Panamá timelines are short, and that is the problem. A 20 día hábil registration decision, a 15 día hábil DNFD investigational-product review, a 3 día hábil RESEGIS acknowledgement and a 5 día hábil WLA cure window are all faster than a conventional translation procurement cycle. In Panamá the translation stack has to be complete before the clock starts, because there is no version of this calendar in which a sponsor sources a sworn translation reactively and still holds the window.

Section H. Recent regulatory changes 2023–2026

2023 (June 28) — Apostille guidance reissued. MINSA publishes Comunicado No. 21 on apostille handling for health filings, reinforced by its Cápsula 7 — Apostilla explainer. Both documents remain the practical reference for how foreign public documents enter a Panamá health file.

2023 — DNFD digital trámites consolidated. [Comunicado 030-2023] (https://www.minsa.gob.pa/sites/default/files/publicacion-general/comunicado_030-2023_produccion_tramites_cvm_dc_imp.pdf) moves production trámites for CVM, DC and IMP onto the directorate's digital channel — the precursor to the FADDI expediente.

2024 (February 1) — Ley 419 de 2024 enacted. The new *Ley de Medicamentos* is published in Gaceta Oficial 29962-A, replacing Ley 1 de 2001 and Ley 97 de 2019 (Ley 419). A *fe de errata* follows on 7 February 2024 in Gaceta 29966-A, recorded in the Procuraduría de la Administración normative registry. The statute's language rule is Art. 33; its labelling rule, including the prohibition on *reetiquetado o sobreetiquetado*, is Art. 37. Practitioner commentary at enactment is summarised on Lexology.

2024 (May 10) — Decreto Ejecutivo 27 de 2024 promulgated. The 836-article reglamento to Ley 419 is published in Gaceta Oficial 30028-C (full text) and signed at the Presidencia. It carries the general documentary-language rule at Art. 220, the clinical-evidence carve-out at Art. 30, the FADDI digital expediente at Art. 16, and a 12-month implementation runway at Art. 221.

2024 (May 24) — DNFD industry conversatorio. The directorate walks industry through the new framework; the presentation deck remains the clearest official summary of how DNFD intends to operate Ley 419 and DE 27 in practice.

2024 (September 9) — Therapeutic-indication certification procedure. Comunicado 094 sets out the *trámite* for certification of therapeutic indications.

2024 — FADDI extended to controlled substances. Comunicado 083/2024 launches the controlled-substances module on the FADDI platform, and the DNFD trains users on the platform through GMP/GSP sessions.

2025 (January 7) — Decreto Ejecutivo 2 de 2025: WLA recognition. Published in Gaceta 30195-A (full text), the decree creates a recognition pathway for medicines already registered by a WHO-Listed Authority. President Mulino signs it publicly (Presidencia; MEF; Telemetro). Its eight requirements at Art. 2 include a *"copia legalizada o apostillada del expediente completo"* and zone IVb stability data; **whether any Spanish-translation duty attaches to that* expediente completo *is [UNVERIFIED - source silent] — the decree does not say. Laboratory analysis is waived ([Art. 1] (https://www.minsa.gob.pa/sites/default/files/normatividad/decreto_ejecutivo_no_2_de_7_de_enero_de_2025_-_reconocimiento_de_registros_sanitarios_a_medicamentos_con_registros_de_la_oms.pdf)), the DNFD answers in 10 días hábiles ([Art. 3] (https://www.minsa.gob.pa/sites/default/files/normatividad/decreto_ejecutivo_no_2_de_7_de_enero_de_2025_-_reconocimiento_de_registros_sanitarios_a_medicamentos_con_registros_de_la_oms.pdf)), and a single RFI carries a 5 día hábil** cure window (Arts. 4–5). Firm analyses were published by Central Law and Salud y Fármacos.

2025 (February 5) and 2025 (June 25) — DE 2 amended twice. *Decreto Ejecutivo 4 de 5 de febrero de 2025* and *Decreto Ejecutivo 12 de 25 de junio de 2025* modify the recognition decree within six months of its promulgation (DNFD decree index) — a currency risk for any dossier assembled against the January text.

2025 — WLA reliance exposed to external shock. Panamá's reliance architecture depends on WHO listing; the domestic press flagged the risk to MINSA and to the medicines register when U.S. withdrawal from the WHO was announced (La Estrella de Panamá). Sponsors relying on DE 2 should hold a conventional Ley 419 filing package in reserve.

2025 — Abbreviated-procedure requirements clarified. Requirements for the *procedimiento abreviado* for new sanitary registrations are set out and analysed by Panamanian counsel, complementing DE 27 Arts. 17–18 and 24.

2025 (October) – 2026 (February) — Replacement device decree in public consultation. MINSA opens, then extends the public consultation for a new medical-device regulation. The draft text circulated through the Cámara de Comercio and was reviewed by AARSA. It is not promulgated. DE 490 de 2019 remains in force.

2025–2026 — DNFD digital consolidation. The directorate presents the impact of its digital transformation and consolidates registration, alerts and guidance onto a single public platform; the DNFD portal and its published tariff schedule are now the primary operational references. MINSA and Customs also sign a memorandum of understanding on sanitary surveillance of medicines.

2026 (April 23) — Decreto Ejecutivo 21 de 2026: health research and bioethics rebuilt. Published in Gaceta Oficial 30510-C (full text), reglamenting Títulos III and IV of Ley 84 de 2019. It makes the CNBI *adscrito al Despacho Superior* and functionally independent (Art. 1) with eleven members (Art. 3); adopts CIOMS, OMS-OPS, Helsinki, UNESCO, ICH GCP, Singapore, Montreal, Nuremberg and Belmont as reference standards (Art. 71); sets the ethics clocks at Arts. 44–45; requires a single accredited committee for multicentre studies (Art. 46); imposes the Spanish ICF drafting rule at Art. 52; builds RESEGIS at Arts. 82–86 with the Spanish-and-version-parity rule at Art. 85; and sets the DNFD investigational-product review at Art. 95. It entered into force on promulgation (Art. 105) and repealed the prior research instruments (Art. 104). MINSA's operational notices on the research pathway are consolidated on the REGULAIPS page, with directorate-level updates in Comunicado 158 and Comunicado 163.

What this means for a sponsor filing in 2026. Every translation memory, glossary, and template built against Panamá's pre-2024 framework is obsolete. The medicines rules changed in 2024, the recognition rules changed in 2025 and were amended twice, the research rules changed four months ago, and the device rules are mid-replacement. Panamá is the LATAM jurisdiction where the Document Currency gate earns its place in the pipeline.

Section I. Amavita library cross-references

- Adjacent Central American regulator, fully mapped: SRS regulatory translation requirements — the complete guide for El Salvador
- Preclinical translation across 9 LATAM regulators (includes the Panamá section): Preclinical translation requirements — 9 LATAM regulators
- Sworn vs certified vs simple translation across LATAM: Sworn vs certified translation — regulatory submissions
- Apostille-then-translate sequencing across Hague-Convention LATAM jurisdictions: Apostille sequencing — LATAM regulatory filings
- Spanish ICF readability standard: INFLESZ threshold — Spanish ICF readability
- RFI anatomy across LATAM regulators: RFI anatomy — six LATAM regulator rejections
- One-protocol-change amendment cascade: Amendment cascade — LATAM translation stack

- Three-band framework for LATAM translation: Three bands of LATAM regulatory translation
- Translation QC for regulatory dossiers: Translation QC — regulatory dossiers
- Costly translation mistakes across LATAM: Costly translation mistakes — regulatory submissions
- Platform vs traditional translation for LATAM regulators: Regulatory language infrastructure vs traditional translation

FAQ

Which Panamá directorate actually holds my file?

The medicines authority is the *DNFD — Dirección Nacional de Farmacia y Drogas (DNFD portal), reachable at farmacoterapiafyd@minsa.gob.pa. Medical devices sit with the Dirección Nacional de Dispositivos Médicos, and health research sits with REGULAIPS / the CNBI* at regulaips@minsa.gob.pa. A combination-product or device-drug programme can touch all three, and the correct addressee is a filing requirement, not a formality.

Do I have to translate every page of my preclinical stack into Spanish?

For market access — no. Panamá's language provisions attach to labels, IFUs and specified legal instruments, not to the preclinical report bodies. DE 490 Art. 41.1 expressly accepts data sheets, product data and service manuals "en español o inglés"; Art. 36.7 accepts manufacturer technical literature with no language rule; Art. 37 attaches no language rule to the Class B/C/D technical increments; and on the medicines side Ley 419 Art. 33 and DE 27 Art. 30 accept clinical studies in English with a Spanish summary. For clinical trial authorization, the answer is hedged: the protocol and Investigator's Brochure must be in Spanish under DE 21 Arts. 84–85, while preclinical technical documentation attached to the CTA may still be presented in English under prevailing international practice and Panamá's reliance framework. Amavita Sciences™ has filed a formal consulta with MINSA REGULAIPS to obtain written confirmation, and this guide will be revised on receipt.

What exactly is a traductor público autorizado, and can my U.S. translator qualify?

A TPA is licensed by MEDUCA under Decreto Ejecutivo 975 de 15 de diciembre de 2017 (which subrogated DE 472 de 2014), reglamented by Resuelto 2448 de 21 de mayo de 2018, against the framework of the Código Administrativo Título XVII as reformed by Ley 59 de 31 de julio de 1998 (MEDUCA traductores y examinadores). The licence is language-pair specific and must be a Panamá licence — "traductor público autorizado de la República de Panamá." Signatures are registered with the Ministerio de Relaciones Exteriores. A U.S.-certified translator, however qualified, cannot produce a Panamá sworn translation.

Apostille first, or translate first?

Apostille first, then translate — including the apostille text itself and every seal and stamp. Panamá acceded to the Hague Convention through Ley 6 de 25 de junio de 1990, reglamented by DE 445 de 12 de noviembre de 1991, in force for Panamá since 4 August 1991. DE 27 Art. 28.3 is explicit that the sworn translation "se anexará al certificado correspondiente." Translating first authenticates a Panamanian translation of an unauthenticated foreign document. MINSA's own guidance is in Comunicado No. 21 and Cápsula 7; authentication costs are published by Panamá Digital and DNFD document authentication is B/.30 (DNFD tariff).

Can I file my labels in English with a Spanish sticker over the top?

No. Both Ley 419 Art. 37 and DE 490 Art. 39 prohibit reetiquetado and sobreetiquetado. Multilingual labels and IFUs are permitted provided one of the languages is Spanish (DE 27 Art. 206 for cosmetics; DE 490 Art. 38 for devices), and international symbols and colour codes are permitted where the IFU carries the Spanish descriptive text (DE 490 Art. 39). There is no sticker remedy in Panamá — which is why label and artwork work is a print-fidelity deliverable, not a text deliverable, and why renewal artwork must itself be "en idioma español" under DE 27 Art. 234.

Does the WHO-Listed-Authority route in DE 2 de 2025 remove translation work?

Partly, and less than sponsors assume. DE 2 de 2025 waives laboratory analysis and compresses the decision to 10 días hábiles, and its Art. 2 requirement is a "copia legalizada o apostillada del expediente completo" with no stated translation duty — [UNVERIFIED - source silent] on whether Spanish is required for that expediente. What the route does not waive is the label, IFU and post-approval surface, and the single RFI it allows carries only 5 días hábiles to cure (Arts. 4–5). Note also that the decree was amended twice in 2025 (DNFD decree index) and that the reliance base is politically exposed (La Estrella de Panamá).

Who reviews my clinical trial, and how fast?

Ethics review runs through an accredited comité de bioética under DE 21: 20 días hábiles ordinary, 10 expedited — which includes protocols already approved by a high-standard foreign committee — and 5 for exemption determinations (Art. 44), with a total ceiling of 30 días hábiles plus 10 if escalated to the pleno (Art. 45). Registration in RESEGIS is acknowledged in 3 días hábiles (Art. 86), the DNFD evaluates the investigational medicinal product in ≤15 días hábiles (Art. 95), and for high-risk interventional studies MINSA's technical review runs in parallel with ethics review (Arts. 88–92). Multicentre studies route through a single accredited committee (Art. 46).

Is there a CNBI email address I can write to?

Not one printed on any .gob.pa page — [UNVERIFIED - source silent]. The addressable public channel for health-research matters is MINSA REGULAIPS at regulaips@minsa.gob.pa. The Caja de Seguro Social, which operates a large share of Panamá's hospital capacity and therefore many trial sites, likewise publishes no clinical-trial inbox — also [UNVERIFIED - source silent]. We route site-level matters through the institution's own research office and keep the regulatory correspondence on the two published channels: farmacoterapiafyd@minsa.gob.pa and regulaips@minsa.gob.pa.

Which institutional bioethics committee should I plan around in Panamá?

For most commercially sponsored interventional trials with a national-site strategy, the reference institutional committee is CBI-ICGES, the bioethics committee at the Instituto Conmemorativo Gorgas de Estudios de la Salud, contactable at combioetica@gorgas.gob.pa. CBI-ICGES publishes the strongest and clearest document requirements of any national-level Panamanian committee — currently v11 dated 7 November 2025 — including a bilingual Investigator's Brochure requirement, a certified-translation rule, and a fee of B/. 1,500.00 per Resolución de Junta Directiva N° 007 of 9 September 2021. Institutional CBIs at private hospitals and university faculties are also accredited by CNBI under DE 21 and follow their own CNBI-approved procedures; any of those procedures can adopt language rules as strict as CBI-ICGES's, and per DE 21 Art. 32 an approved institutional rule binds the sponsor even when it exceeds the national decree. Sources: CBI-ICGES Requisitos v11; DE 21 Art. 32.

What does it cost, and what is free?

Under the published DNFD tariff: sanitary registration B/.500 for chemical-synthesis products, B/.750 for innovators, biologicals and biosimilars, B/.750 for the trámite abreviado, B/.500 for mutual recognition, B/.1,000 for priority review, B/.400 for interchangeability, B/.200 per post-registration modification, B/.200 for renewal, B/.300 for GMP audit and certificate, B/.500 for an import certification, and B/.30 for document authentication; laboratory analysis runs B/.200–1,000. Two things are free: the permiso de autorización de medicamento para estudios clínicos and the excepción de registro sanitario for patients. On the device side, the CCT carries no fee (DE 490 Art. 21), while establishment fees are set at Art. 64. The balboa is pegged 1:1 to the U.S. dollar.

Can I reuse a Panamá drug registration elsewhere in Central America?

For drugs, partly — Panamá has adopted the RTCA series by decree (labelling RTCA 11.01.02:04 via DE 849 de 2015; stability 11.01.04:10 via DE 850; analytical validation 11.03.39:06 via DE 851; quality verification 11.03.47:07 via DE 853; pharmaceutical GMP 11.03.42:07 via DE 267 de 2014), and Ley 419 Art. 29 is aligned with RTCA 11.03.59:18, the regional registration standard (DNFD decree index). For devices, no — Panamá is not RTCA-harmonised on devices; the CCT/CVT architecture under DE 490 with GHTF/IMDRF classification is domestic, so a Panamá device file does not travel the way a Panamá drug file does.

Why does Amavita Sciences™ treat Panamá as a currency-risk jurisdiction?

Because four frameworks moved in twenty-four months: Ley 419 (Feb 2024), DE 27 (May 2024), DE 2 (Jan 2025, amended twice), and DE 21 (April 2026) — with the device decree still in post-consultation limbo. Filings invoking Ley 1 de 2001, Ley 97 de 2019, DE 13 de 2023, DE 869 de 2021, DE 112 de 2022, DE 1843 de 2014, DE 6 de 2015 or Resolución 390 de 2003 are citing repealed law. Our 7th QC gate — Document Currency — timestamps every foreign document at apostille, translation and filing, and re-issues within 48 hours under the First-Pass Acceptance Program at $2,500/business-day.

About the author

Julio G. Martinez-Clark is CEO of bioaccess®, Latin America's leading medical-device clinical research organization, and founder of Amavita Sciences, the multilingual clinical operations platform. He has led first-in-human trial operations across 12 LATAM jurisdictions and built the seven-gate translation QC pipeline behind Amavita's regulatory language infrastructure.

Version history

This guide is version **1.1.0**, last updated August 25, 2026. Every substantive change to the DNFD requirements on this page is recorded below.

v1.1.0 August 25, 2026

- Added Section D.6 on the CBI / CBI-ICGES institutional-committee rule under DE 21 Art. 32 accreditation force.
- Added Section D.7 quoting DE 21 Art. 102 as the region's only explicit preclinical GLP article.
- Added the Art. 44.2 expedited-review row to the Section G consolidated timelines table.

- Added a new FAQ entry on which institutional bioethics committee to plan around in Panamá.

v1.0.0 August 24, 2026

- Initial publication of the DNFD (Panamá) regulator translation requirements guide.
- Section D includes the pending consulta filed with MINSA REGULAIPS on preclinical translation scope for clinical trial authorization under DE 21 de 2026.