DEFI®
LATINA HEALTHCARE

COFEPRIS CERTIFIED PROFESSIONALS IN REGULATORY AFFAIRS

Your control, our execution: DEFI as the operational holder

YOUR DIRECT ACCESS TO THE MEXICO MARKET (TURN-KEY)

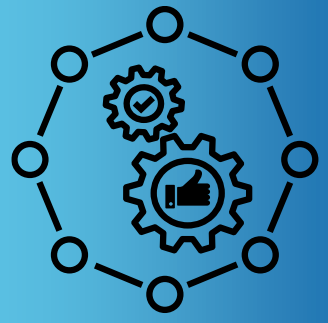
- COMPLETE REGULATORY MANAGEMENT
- PRIVATE MARKET AUTHORIZATION
- INSTITUTIONAL FORMULARY ACCESS
- STRATEGIC COMMERCIAL ALLIANCES

FIRST STAGE:
MARKETING AUTHORIZATION – PRIVATE MARKET

APPROX. USD$20 BILLION MARKET

SUCCESSFULLY MANAGED
1,700+ REGULATORY DOSSIERS

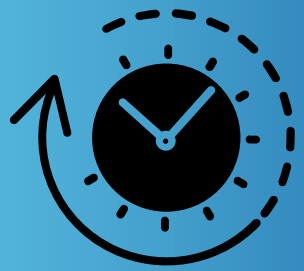
- New Marketing Authorizations (MAs)
- MA Renewals
- Amendments to Registration Conditions
- Orphan Drugs
- Medical Devices
- New Chemical Entities
- Nutritional Supplements



We manage the entire submission process and work alongside you to fulfill all regulatory requirements and studies.

SECOND STAGE (OPTIONAL): INSTITUTIONAL ACCESS

APPROX. USD$10 BILLION PROCUREMENT MARKET



Can be executed in parallel with the private market MA process, potentially saving up to two years in procurement access.

DEFI® LATINA HEALTHCARE

DEFI ADVANTAGE

The holder retains full control — DEFI facilitates and operates according to your instructions.

In-house team of 15 Mexican Health Authority-certified professionals

Specialized in:

- New Marketing Authorizations
- Registration Amendments
- Registration Renewals
- Class I, II & III Medical Devices
- Pharmaceuticals

Regulatory expertise + strategic execution

- Full compliance with current regulations
- Proven ability to resolve complex regulatory challenges
- Rigorous cybersecurity protocols protecting client data
- Direct and immediate-response communication with authorities

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ANVISA Agência Nacional de Vigilância Sanitária

invima Instituto Nacional de Vigilancia de Medicamentos y Alimentos.

AGEMED AGENCIA ESTATAL DE MEDICAMENTOS Y TECNOLOGÍAS EN SALUD

OUR SERVICES

- New MAs: Allopathic and Biotechnology Medicines, Medical Devices (Class I, II, III), Nutritional Supplements
- Registration Amendments: Administrative and technical modifications for medicines (allopathic, biotechnological, vitamin-based, herbal) and medical devices
- Registration Renewals: Medicines and medical devices across all categories
- Regulatory Documentation: Labeling projects, inserts, prescribing information
- Translation Services as necessary
- New Molecule Committee applications: Organization and submission for Regulatory Committee Filings when necessary
- Other LATAM Regional Expertise: Advisory and management of regulatory procedures across LATAM
- Risk and Safety: Risk Management Plans, Periodic Safety Reports, Pharmacovigilance and Technovigilance reports
- Formulary access to procurement (tenders)

DEFI® LATINA HEALTHCARE

WHY CHOOSE US?

- Secure & transparent communication
- Proven track record in complex regulatory pathways
- Immediate, personalized support
- Compliance-driven with strategic insight

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GETTING STARTED

1. Initial meeting to align objectives and priorities
2. Market assessment discussion
3. Budget alignment
4. Regulatory timeline: up to 18 months for Private Market Authorization
5. Institutional formulary access: additional 1–2 years (or parallel strategy available)

DEFI® LATINA HEALTHCARE

MEET OUR TEAM

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THANK YOU

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Your Direct access to
the Mexico Market