MEDICAL DEVICES

LATAM Market Entry for Medical Devices

Regulatory-commercial strategy, local partner mapping and LATAM project coordination.

Brazil-based. LATAM-connected. The right way.

lifescience@linkscomex.com

Brazil & LATAM market entry specialists

A strategic coordination hub for regulated healthcare products entering Brazil and selected Latin American markets.

Cristina V. Wolowski

Managing Partner — Medical Devices & Healthtech
Brazil & LATAM Market Entry

With over 20 years in international markets and hands-on experience in medical device registration, distribution structures and channel development across 50+ countries.

01 Medical Devices & Healthtech

Regulatory-commercial strategy, ANVISA pathway, distributor route and LATAM partner coordination.

02 LATAM execution model

Centralized strategy from Brazil supported by qualified in-country regulatory and commercial partners.

03 Customized, not templated

Each roadmap is built around product classification, target countries, approvals and business model.

04 Commercial + regulatory view

We connect registration feasibility, partner structure and market access decisions before commitments are made.

Supported by a life sciences and business development network when the project requires broader commercial, regulatory or alliance expertise.

Strategic LATAM route before partner selection

For orthopaedic devices, registration ownership and commercial structure can determine the manufacturer’s long-term control over the market.

01

Registration ownership

Who holds the registration may control market continuity if the relationship with the distributor ends.

02

Local representative / hosting

Some countries may require a local holder, representative or importer structure before commercialization.

03

Importer and distributor model

The distributor, importer of record and registration holder are not always the same party.

04

Technical and after-sales support

Medical devices may require qualified local technical, clinical or post-market support.

05

Exclusivity and performance clauses

Broad exclusivity without milestones can block market development for years.

06

Country-by-country variation

Regulatory authority, documents, timelines and commercialization route vary significantly across LATAM.

Core support for medical device projects

A modular scope can be structured according to the target countries, product portfolio and level of market control required by the manufacturer.

01

Regulatory Pathway & Roadmap

Country-by-country regulatory route, registration model, documents, timelines, key risks and sequence.

02

Market Entry Model Assessment

Recommended structure per country: distributor, importer, representative, hosting, own entity or phased model.

03

Local Partner Mapping

Identification and qualification of regulatory consultants, registration holders, importers and distributors.

04

Initial Engagement & Shortlist

Approach selected stakeholders, validate interest, align requirements and prepare a shortlist.

05

LATAM Project Coordination

Centralized communication, strategic alignment and partner coordination across selected markets.

06

Brazil Market Entry Support

ANVISA strategy, Brazilian registration-holder implications and commercial entry route assessment.

Country-by-country assessment before commitment

The roadmap connects regulatory feasibility with the commercial route and local execution requirements.

Regulatory questions

- Authority and pathway
- Device classification
- Registration / notification regime
- Required certificates and technical files
- Estimated sequence and dependencies

Commercial-structural questions

- Who can import?
- Who should hold the registration?
- Distributor vs independent holder
- Hosting / representation feasibility
- Local service and post-market requirements

Strategic outputs

- Recommended route per country
- Risk map and critical decisions
- Priority sequence
- Partner profile to be searched
- Next-step action plan

Choosing the right structure is a strategic decision

The safest model may vary by country depending on registration rules, partner maturity, commercial objectives and desired control.

1	**Distributor as registration holder**	Faster alignment with local sales partner, but may create dependence and transfer market control.
2	**Independent regulatory hosting**	Can separate registration ownership from commercial distribution, when legally and operationally feasible.
3	**Importer / local representative**	May be required for customs, regulatory or post-market responsibilities depending on the country.
4	**Own local entity**	Higher control, but greater setup cost, tax/accounting obligations and operational complexity.
5	**Phased market entry**	Useful when the manufacturer wants to validate demand before committing to a permanent structure.

Key principle: do not assign registration ownership before understanding the country-specific commercial and regulatory consequences.

Types of partners we can identify and qualify

The project may require different partner profiles in each market — regulatory, commercial, operational or technical.

Regulatory consultants

Country-specific pathway validation, document review and submission support.

Registration holders / hosting structures

Local legal structures able to hold or support product registration when applicable.

Importers of record

Companies able to manage importation, customs and local regulatory responsibilities.

Distributors

Commercial partners with portfolio fit, channel access and orthopaedic market coverage.

Commercial representatives

Local relationship builders to support early market access and stakeholder engagement.

Technical / service partners

Clinical, training, technical support or after-sales partners, when applicable.

Brazil-based strategic hub with local execution

LinksComex coordinates the strategic route and activates local partners according to the target countries and required scope.

Manufacturer / Global consultant

Project objectives, portfolio, target countries and preferred business model.

LinksComex coordination hub

Regulatory-commercial strategy, roadmap, partner mapping, communication and project alignment.

Qualified local partners

In-country regulatory, representation, importation, distribution and service support.

Our role is to connect regulatory feasibility, commercial strategy and local execution before market commitments are made.

This allows the client to compare routes, reduce partner-dependency risks and prioritize countries with a clearer view of regulatory and commercial implications.

PROJECT FLOW

From scope diagnosis to qualified partner shortlist

The sequence can be adapted depending on whether the project starts with country prioritization, regulatory feasibility or partner search.

01

Scope diagnosis

Understand portfolio, countries, approvals, business model and urgency.

02

Country prioritization

Define target markets and sequence based on opportunity, feasibility and risk.

03

Roadmap

Build regulatory-commercial route per country.

04

Partner mapping

Identify local structures and distributors aligned with the route.

05

Initial engagement

Approach and validate interest, requirements and fit.

06

Shortlist & recommendation

Recommend next steps, partner options and risk points.

Initial information for a focused scope discussion

These inputs allow us to understand the potential route before defining the scope, partner search and timeline.

01

Product information

Product family, intended use, risk classification and whether implants/instruments/software are involved.

02

Existing approvals

CE, FDA, ISO 13485, MDSAP, Free Sale Certificates and current technical documentation status.

03

Target countries

Priority countries, secondary countries and any existing leads or pending opportunities.

04

Current registrations

Existing registrations in LATAM or other reference markets, including holders and expiration status.

05

Preferred business model

Distributor-led, independent hosting, importer model, direct presence or phased approach.

06

Timeline and control level

Urgency, desired control over registration ownership, exclusivity tolerance and partner profile.

Let’s assess the LATAM route before committing to local partners.

Introductory call to understand target countries, product portfolio, desired business model and potential collaboration structure.

Cristina V. Wolowski

Market-Entry Strategist | LinksComex

cristina@linkscomex.com | +55 48 99962-6272

LinksComex

Brazil & Latin America Market Entry for Medical Devices

Florianópolis – SC | São Paulo – SP | Brazil