Emerging Markets Regulatory Challenges and Considerations in Latin America

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Emerging Markets
Regulatory Challenges and Considerations in Latin America

AGENDA

LATIN AMERICA OVERVIEW
REGULATORY CONSIDERATIONS
COUNTRIES: BRAZIL & MEXICO
- REGULATIONS
- SITE/ESTABLISHMENT LICENSES
- REGULATORY PROCESS
- REGULATORY ENVIRONMENT
CLOSING COMMENTS
Latin American markets have some unique characteristics that need to be taken into account.

If your company intends to make a global submission that includes Latin American countries, it is important to perform short and long-term planning that factor in all related investments:

- Product strategy
- Language/Translations
- Regulatory requirements for product approval
- Others ...
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**Regulatory Considerations:**

- **Company technical readiness**
  - Personnel & infrastructure must meet requirements

- **Intellectual property (patents)**
  - Is there a patent law in place?

- **Local vs. international regulatory environments**
  - What are the main differences?

- **Timeline and expected Return On Investment**
  - How long does it take for approval and launch?

- **Partners in target countries**
  - Usually Required
Argentina, Brazil, Paraguay and Uruguay have formed “Mercosul” or “Mercosur”, an economic and commercial trading bloc loosely similar to NAFTA. Bolivia, Chile, Ecuador, Peru and Venezuela participate as associate members with Venezuela awaiting full membership pending ratification by Brazil and Paraguay. Mexico participates as an observer.

Mercosul/Mercosur's harmonized regulations must be enforced by its full members.
Medical Devices

- Most Latin American countries are not yet regulated in this area

- Markets with mature regulations in Argentina, Brazil, and Mexico

- Non-regulated Latin American countries are adopting the Brazilian regulations for medical devices always adapting them to their own environments (i.e. Colombia)

- Specific country-by-country Product Market Authorization Approvals
Common Requirements

- Language is primarily Spanish → Portuguese in Brazil → Notarized translation and consularization is always required.
- Inspections are not yet in place except for recall situations.
- International clinical studies and data are accepted. Clinical studies/data are mandatory for implantables.
Must have physical presence in the country

Legal representative

Technical representative

Subsidiary

Partner

Distributor/Importer

Established Producer
Argentina, Brazil, Colombia and Mexico enforce their own GMP certification regimes (including international inspection policies). To date, no Latin American country inspects medical device manufacturing facilities for product registration approval, unless the product is offered in combination with a pharmaceutical. GMP certification granted by country of origin is accepted.
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Focus on 2 countries:
Brazil

Regulatory Agency: ANVISA

- Regulations
  - Law 6360/76 and Decree 79094/77
  - RDC 59/00 (GMP)
  - RDC 185/01
  - RDC 260/02
  - RDC 207/06
  - Portarias
  - Specific regulations (i.e Condoms, Rubber Gloves, etc.)
  - Technical Internal Rules
  - List of Non Medical Device Products
SITE/ESTABLISHMENT LICENSES (Brazil)

For medical devices, in addition to obtaining a business license, a company must also be licensed by the health authorities.

- Municipal – Licença de Funcionamento
  - must be renewed every year

- Federal – Autorização de Funcionamento
  - approval is published in the “Diário Oficial da União”
ANVISA does not yet accept electronic submissions. However, application and fee forms can be completed on, and printed from, ANVISA's website.
**REGULATORY PROCESS (Brazil)**

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<tr>
<th>Apólice Nacional de Vigilância Sanitária</th>
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<tr>
<td>Nome ou Razão Social/Endereço/Fone</td>
<td>Número da Guia</td>
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<td>CNPJ/CPF:</td>
<td>Nº Guia Referência</td>
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<tr>
<td>Tipo da Guia: Normal</td>
<td>Valor da Taxa</td>
</tr>
</tbody>
</table>

**Guia de Recolhimento (Fee/Payment Form)**

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-Valido somente com autenticação bancária.

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**Regulatory Challenges and Considerations in Latin America - BRAZIL**
As per ANVISA: **Definitions of Medical Devices**

- **Diagnostic equipment**: Medical, odontologic or laboratory appliance, apparatus or instrument used for detecting information from the human body for the purpose of assisting clinical procedures.

- **Therapy equipment**: Medical or odontologic appliance, apparatus or instrument used for treatment of pathologies, including substitution or modification of the anatomy or physiological process of the human body.

- **Medical-hospital support equipment**: Medical, odontologic or laboratory appliance, apparatus or instrument used to provide support to diagnostic, therapeutic or surgical procedures.

- **Disposable materials and devices**: Medical, odontologic or laboratory materials and devices intended to be used only once, temporarily or for a short time.
REGULATORY ENVIRONMENT (Brazil)

- **Implantable materials or devices:** Medical or odontologic materials and devices, intended to be introduced totally or partially, through medical procedure, into the human body or natural orifice of the human body, or intended to replace an epithelial surface or eye surface, remaining for a long time inside the body after the procedure, and removable only through surgical procedure.

- **Medical-hospital support materials and devices:** Medical, odontologic or laboratory materials and devices intended to provide support to diagnostic, therapeutic or surgical procedures.

- **"In-vitro" diagnostic products:** Reagents, instruments and systems that, together with their instructions for use, contribute to the undertaking of a qualitative, quantitative or semi-quantitative assessment of a biological specimen, and that are not intended to fulfill any anatomical, physical or therapeutic function and are used exclusively to provide information about specimens collected from the human body.
REGULATORY ENVIRONMENT (Brazil)

- Classification: Class 1, 2, 3 (according to product risk)
- Registration is valid for 5 years and must be renewed 6 months before expiration
- Documents need to be translated, notarized and consularized
- Clinical data required – in particular for new products
- Consumer Protection Law is very strict
- Risk management mandatory for implantables (ISO 14971)
- Mandatory post-market surveillance (adverse events reported by an electronic reporting system)
- Timeline for review and approval: from 6 to 18 months
Mexico

Regulatory Authority: Secretaría de Salud - 
**COFEPRIS** is the section responsible for product registration

- **Regulations**
  - Ley General de Salud
  - Normas Oficiales Mexicanas (NOM)
  - Reglamento de Insumos para la Salud (refer to medical devices)
  - Lineamientos para Tramite
  - Specific regulations (i.e. Condoms, Rubber Gloves, etc.)
  - List of Medical Device Products and Classification
SITE/ESTABLISHMENT LICENSES (Mexico)

Similar to the practice in Brazil, a medical device company operating in Mexico must also be licensed by the health authorities.

- **Licencia Sanitaria del Establecimiento**

- Approval is published in the D.O.F.
Mexico accepts electronic submissions. Only local companies are permitted to access the electronic SSA system by first creating their own login credentials (id and password).

Fees are subject to specific regulations - “Pagos de Derechos”.

“Formato de Solicitudes” is the form required for the submission of medical device registrations.

“Formato de Avisos” is the form required for any changes to the medical device and/or company file(s).
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REGULATORY PROCESS (Mexico)

<table>
<thead>
<tr>
<th>COMISIÓN FEDERAL PARA LA PROTECCION CONTRA RIESGOS SANITARIOS</th>
<th>FORMATO DE SOLICITUDES</th>
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</thead>
<tbody>
<tr>
<td>No. RUFA</td>
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1.- SOLICITUD DE:
- LICENCIA
- PERMISO
- CERTIFICADO
- MODIFICACIÓN
- PRIMERA VEZ
- TEMPORAL
- SUBSECUENTE
- DEFINITIVA
- UNITARIA
- NACIONAL
- PROPIETARIO
- RESPONSABLE
- ASOCIADO

NOMBRE DEL TRAMITE:

2.- MODIFICACIÓN DE: (Sólo en caso de habér seleccionado este campo en la sección 1)
- NÚMERO DE DOCUMENTO A MODIFICAR
- DESCRIP. DE LICENCIA/SOLICITUD

3.- DATOS DEL ESTABLECIMIENTO
- CLAVE: CNMP
- DESCRIP. DE CNMP:

NOMBRE DEL PROPRIETARIO (PERSONA FÍSICA) O RAZÓN SOCIAL (PERSONA MORAL):

<table>
<thead>
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<th>COMISIÓN FEDERAL PARA LA PROTECCION CONTRA RIESGOS SANITARIOS</th>
<th>FORMATO DE AVISOS</th>
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</thead>
<tbody>
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<td>No. RUFA</td>
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</table>

1.- AVISO DE:
- LICENCIA
- RESPONSABLE
- MODIFICACION
- SANCION
- TEMPORAL DE ACTIVIDADES
- RESTRICCION DE ACTIVIDADES
- PROPIETARIO
- RESPONSABLE
- PERSONAS AUTORIZADAS
- CLAVES CNMP

NOMBRE DEL TRAMITE:

2.- MODIFICACION:
- RAZÓN SOCIAL O DENOMINACIÓN
- RIF
- DOMICILIO
- CLAVE CNMP
- PERSONAS AUTORIZADAS
- CLAVES CNMP

3.- DATOS DEL ESTABLECIMIENTO / PROPRIETARIO
- CLAVE: CNMP
- DESCRIPTIV. DE CNMP:

Formato de Solicitud
Formato de Avisos
REGULATORY ENVIRONMENT (Mexico)

Products subject to registration as medical devices:

- Diagnostic agents
- Surgical equipment and instruments
- Implantables (i.e. prostheses, bone screws, teeth, etc.)
- Hygienic products (including dental products)
- Ingredients in dental use
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REGULATORY ENVIRONMENT (Mexico)

- Classification: Class I, II, III (according to product risk)
- Registration is valid for 5 years must be renewed before expiration
- Import permission prior to import of any product, part or ingredient
- Documents need to be notarized, translated and consularized
- Clinical data required In particular for Class II & III implantables

Refer to list of product classifications
Appropriate procedures must be followed
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REGULATORY ENVIRONMENT (Mexico)

- Stability data
  Required in particular for Class II & III implantables
- Consumer Protection Law requires toll free number
- Mandatory Quality and Risk management systems
- Mandatory post market surveillance
- Estudios de Tecnovigilancia
- Timeline for review:
  from 30 days to 60 days
  if no answer submission denied
  If more information is required, a letter is sent and review is delayed
Health authorities throughout Latin America, like those of sovereign nations the world over, have developed internal regulations which they enforce predominantly for the benefit of their own populations and environments.

Although regulations in any given country may be similar to those of other countries, many times they are not. And even though international standards form the basis for countless regulations in Latin America and elsewhere, these building blocks are frequently structured to each country's specific reality. The situation for medical devices is no different.

As regulatory affairs professionals, it is our responsibility to do our homework. We must constantly research and continue to learn about each country's unique regulatory framework and, if necessary, we must not be afraid to seek specialized advice.

No magic recipe for successful approval in Latin America and in other regions is to be found. It is simply a matter of combining due diligence with accumulated knowledge and hard-won experience.
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Attractive opportunities exist in Latin America.

As a whole, Latin America is a growing market where, due to considerable unfulfilled demand, public health expenditures continue to rise.

However, challenges are present in every market. Understanding the regulatory differences within Latin America will help you to navigate them.
Thank you!

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