THE SECOND ANNUAL MEDICAL DEVICE REGULATORY, REIMBURSEMENT AND COMPLIANCE CONGRESS ON THE CAMPUS OF HARVAD UNIVERSITY

OPPORTUNITIES IN SOUTH AMERICA

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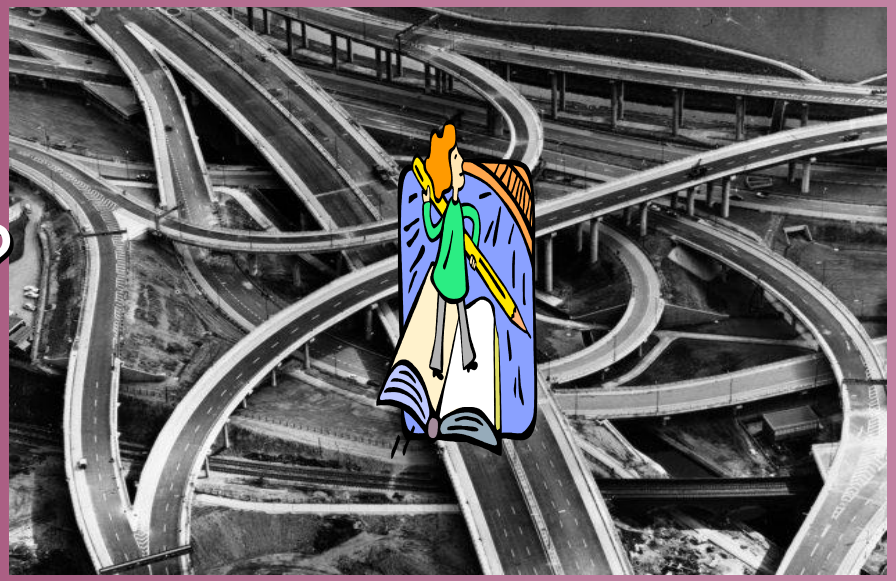
Marketing a Medical Device in Latin America Countries: – Routes to Market -

- Understanding the Latin America RA Legislation;
- Learning how to improve the RA environment in Latin America Countries;
- Cross Culture;
- Definition of a Medical Device
- General Principles (Reasonable Safety and Effectiveness)

Understandanding Latin America Regulatory System

- What should you know?

What is the right route?



DO YOU KNOW WHERE YOU ARE??!!!

HOW CAN YOU DEVELOP SUCESSFUL STRATEGIES FOR THE LATIN AMERICA MARKET?

Cross culture...

- **Language;**
- **Popular culture**;
- **Timing;**
- **Interests;**
- **Local Government**

OFFICIAL LANGUAGE – PORTUGUESE AND SPANISH

LATIN AMERICA

21 COUNTRIES

Argentina; Bolívia; Brazil, Belize; Caribe; Chile; Colômbia; Costa Rica; Cuba; El Salvador; Equador; Guiana Francesa; Guiana; Guatemala; Honduras; Mexico; Nicaragua; Panama; Peru; Paraguay; Suriname; Urugauy; Venezulea

How to Identify the right...

- Partner...
- Consultant...
- Market...
- Distributor...
- Model...
- Strategy...

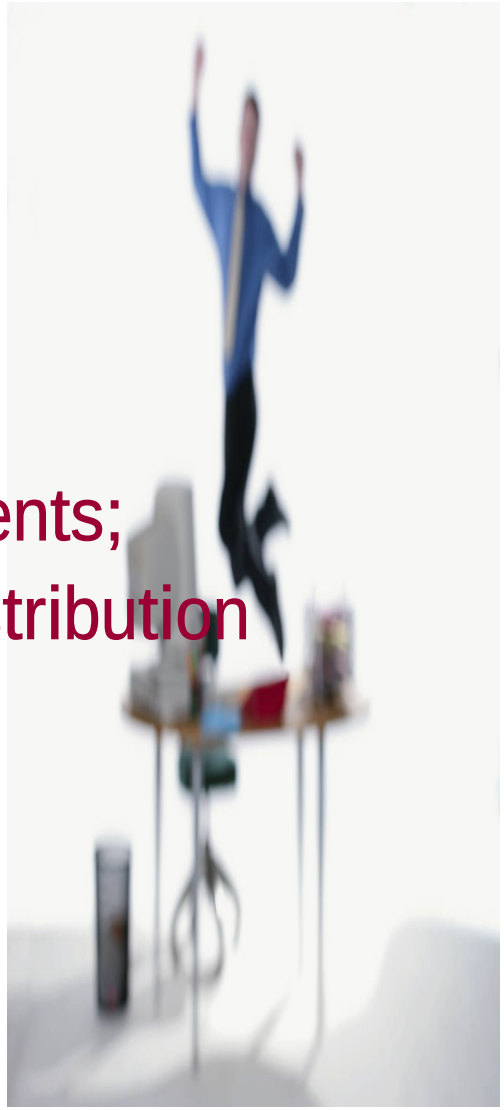
And Control your business staff!

Ask: what is the...

- **Legal System;**
- **Government Structure;**
- **Administrative Law System;**
- **Administrative Procedures;**
- **Legal Requirements;**
- **International Agreements**

To facilitate the RA process...

- Understand the legal requirements;
- Identify comum documents;
- Identify the main local laws;
- Identify the main international agreements;
- Identify the “distributor” and/or the distribution system””;
- Identify the local consultant;
- Control local staff’;



TO DO BUSINESS OUTSIDE OF YOUR COUNTRY...

Do not wear wrong sizes.....

General Principals of Market Clearance...

- **PREVENCION OF HARM**

- **PROMOTION OF BENEFIT**

Protect the public from products that are unsafe or ineffective

(Reasonable Safety and Effectiveness)

LEGAL CONCEPTS

BRAZIL

Healthcare product such as equipment, device, material, article or system for medical, dental or laboratory use or application, intended for the purposes of prevention, diagnosis, treatment, rehabilitation or anticonception and that does not make use of any pharmacological, immunological or metabolic means to perform its main function in human beings, although it may be assisted in its functions through such means.

ARGENTINA

- Any healthcare product such as equipment, device, material, article or system for medical, dental or laboratory use or application intended for prevention, diagnosis, treatment, rehabilitation or anticonception and that does not make use of any pharmacological, immunological or metabolic means to perform its main function in human beings, although it may be assisted in its functions through such means.

LEGAL DEFINITIONS

URUGUAY

"Therapeutic device": any article, instrument, device or artifact including the components, parts or accessories thereof for use in:

- a) Diagnosis, treatment, attenuation or prevention of a disease, disorder or anomalous physical state and the symptoms thereof.
- b) Restoring, correcting or modifying a physiological or bodily structure function.
- c) Avoiding pregnancy.
- d) Caring for human beings during pregnancy or birth, or immediately thereafter.

MEXICO

Devices, accessories and instruments for a specific purposes, intended to provide medical care, surgery or exploratory diagnostic, treatment and rehabilitation procedures in patients, as well as those intended for biomedical research purposes.

What does the LAW require...

Brazil, Mexico, Colombia, Venezuela, Uruguai, Chile...

- ✓Presence in the countrie (through distributor / company);
- ✓Product registration / Certification of free sale;
- ✓Device Classification – Three levels: Class I, II and III
- ✓GMP (not for Chile*);
- ✓Technical Report;
- ✓Compliance with label requirements (local rules – people culture)
- ✓Instruction of use;
- ✓Clinical studies of significant risk,

Regulatory Process

- Application Forms.
- Deed of Entitlement of the Company.
- User Fees
- Valid State/Municipal License.
- Valid Technical Liability Certification.
- Trade Mark.
- Operating Instructions.
- Document showing the technical responsibility - issued by the respective entity
- Product Registration in the Country of Origin / BPF Certification.
- Conformity Certificate (if necessary).
- Deed of Liability.
- **Technical Report (!)**

Contractual Aspects

- Guarantee of Replacement Parts
- Guarantee that Technical Manuals are supplied
- Technical Competence of the Bidder
- Liability in the case of Technical Failure of the Equipment
- Training
- Guarantee Conditions

- **Guarantee of Replacement Parts**
- Form of Maintenance
- Purchase process with commitment from the supplier/manufacturer to furnish replacement parts/material consumed, for a minimum period of 10 years, guarantee of the utility of the equipment, regardless of any possible manufacture discontinuity.
- Imported Equipment
- Maintenance with a greater or lesser agility
- Negotiation with the manufacturer and/or supplier of the minimum stock levels of the parts considered critical

Registration of Medical Devices with the Public Health Authorities in Latin América

	Brazil	Mexico	Argentina	Colombia	Uruguay	Chile[2]	Venezuela
	Yes	Yes	Yes	Yes	Yes	No	Yes
Copy of notification or authorization issued by the public health authorities	Yes	Yes	Yes	No	No	No	Yes
Technical and scientific information	Yes	Yes	Yes	Yes	Yes	No	Yes
Technical and scientific information	Yes	Yes	Yes	Yes	Yes	No	Yes
Instructions for use or operating manual written in Spanish	Yes	Yes	Yes	Yes	Yes	No	No
Description of fabrication process	Yes	Yes	Yes	Yes	Yes	No	No
Description of structure, materials, parts and functions	Yes	Yes	Yes	Yes	Yes	Yes	No
Declaration of good fabrication practices	Yes	Yes	Yes	No	No	No	No
Bibliographic references	Yes	Yes	No	No	No	No	No
Restriction-free sale certificate or equivalent issued by the public health authority in the cou	Yes	Yes	Yes	Yes	Yes	No	Yes
Power of Attorney issued by the manufacturer	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Certificate of good fabrication practices issued by the public health authority in the country	Yes	Yes	Yes	No	No	Yes	Yes
Original analysis certificate issued by the company manufacturing the product, giving its registered corporate name and signed by the chemists representing the foreign company	Yes	Yes	No	No	No	No	No
Proof of quality control	No	No	Yes	Yes	No	No	No
Certificate issued by the Superintendency for Industry and Trade, stating whether or not the product brand name is registered and whether or not it is available for registration	Yes	No	No	Yes	No	No	No
Copy of registration document of the technical representative with the respective Professional Board	Yes	No	Yes	No	No	No	No
Importer certificate issued by the Chamber of Commerce	No	No	No	Yes	No	No	No
Written authorization issued by to the importer by the proprietor of the product covering the application for registration with the public health authorities and permission to sell the product	Yes	No	No	Yes	No	No	Yes
Documentary evidence of corporate registration and site licenses issued by the Ministry for Public Health	Yes	No	No	No	Yes	No	No
Copy of documentation appended to the product at the time of sale (leaflets, instructions, warranties, etc.)	Yes	No	No	No	Yes	No	No
Certification of analytical and / or clínical evidence proving the quality and efficacy of the product characteristics as described, undertaken in the country of origin and appending quality, stability and / or activity protocols that guarantee prod	Yes	No	No	No	No	Yes	Yes
Quality certificate and analysis protocol providing satisfactory documentary proof of the product characteristics, issued by the Ministry of Public Health	No	No	No	No	No	Yes	Yes

1. Notarized through the legal procedure stipulated in the country of origin, in Spanish or another language with the respective translation into Spanish by a qualified expert translator, if the product is not manufactured by head offices by head offic
2. No registrations required for medical deviced.

The Source of Enforcement and Harmonization Process...

INTERNATIONAL AGREEMENTS

- Mercosur
- WTO – GATT
- NAFTA
- PARIS AGREEMENT...

Frequentely asked questions...

What are the time frame for medical equipment registration?

Is there a premarket notification process?

Can we market the used or recycled products?

How is the clinical trial process for medical device?

How many distributor can market my product and register it?

What is the confidential protection system?

Can we launch the product in the market without registration?

GOVERNMENT OFFICES

- BRAZIL – ANVISA (www.anvisa.org.br)
- ARGENTINA – ANMAT (www.anmat.org.ar)
- BOLÍVIA – DINAMED (www.sns.gov.bo/dinamed)
- México – Cofepris (www.cofepris.gov.mx)
- URUGUAY – (www.msp.gub.uy)
- CHILE – Instituto de Salud Pública (www.ispch.cl) *
- VENEZUELA – (www.msds.gov.ve/msds)

Thank You!

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www.abpvs.com.br