REGULATORY AFFAIRS
IN
BRAZIL

TORONTO

NOVEMBER / 2016

LATINI GROUP
Integrated
Business
Solution

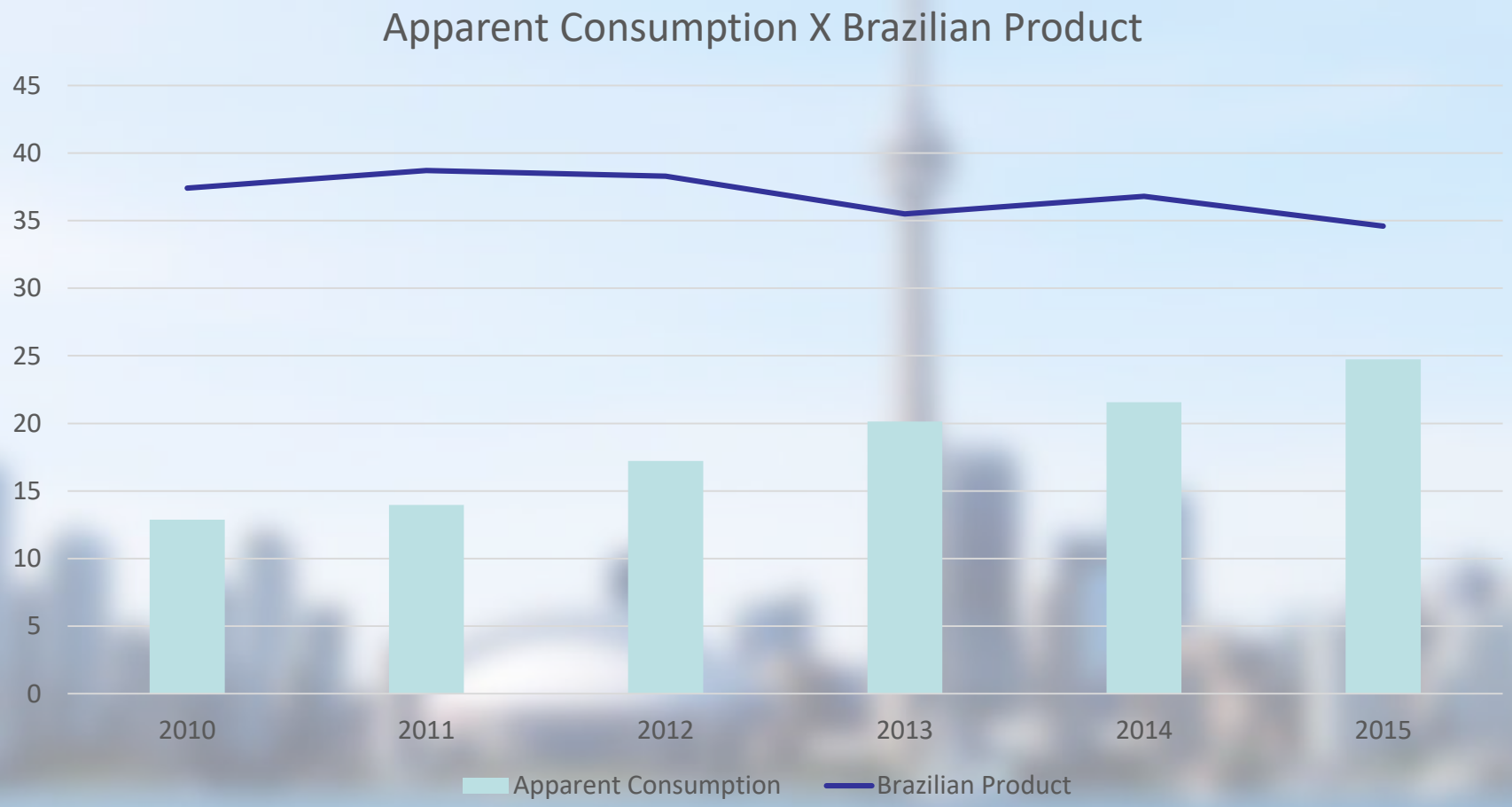
Brazilian Market Numbers

- Total Brazilian Market (in USD):
  - 5,570,715,767.00 (2014)
    - Brazilian Product:
      - 795,088,775.00 (14,2%)
    - Imported Product:
      - 4,775,626,992.00 (85,8%)

Brazilian Market Numbers
(USD)

2014			
	EXPORTATION	**IMPORTATION**	**TOTAL**
DENTAL	117,621,897.00	114,668,452.00	232,290,349.00
CLINICAL LAB.	84,840,535.00	1,050,598,523.00	1,135,439,058.00
RADIOLOGY	27,567,442.00	652,840,292.00	680,407,734.00
MEDICAL DEVICES	65,714,892.00	1,012,638,651.00	1,078,353,543.00
IMPLANTS	135,930,256.00	727,663,858,00	863,594,114.00
CONSUMABLES	363,773,753.00	1,217,217,216.00	1,580,990,969.00
TOTAL	**795,088,775.00**	**4,775,626,992.00**	**5,570,715,767.00**

Brazilian Market Numbers
(in Brazilian Real - Billions)



Sources of Information about Health, Regulatory Affairs and Economy in Brazil

Local Sources

- Brazil:
- www.anvisa.gov.br
- www.ans.gov.br
- www.anahp.com.br
- www.ibge.gov.br
- www.abimo.org.br
- www.abimed.org.br
- www.cbdl.com.br

International Sources

- Mercosur: www.mercosursalud.org
- PanAmerican Health Organization: www.paho.org
- World Bank: www.worldbank.org
- International Monetary Fund: www.imf.org

LATINI GROUP
Integrated Business Solution

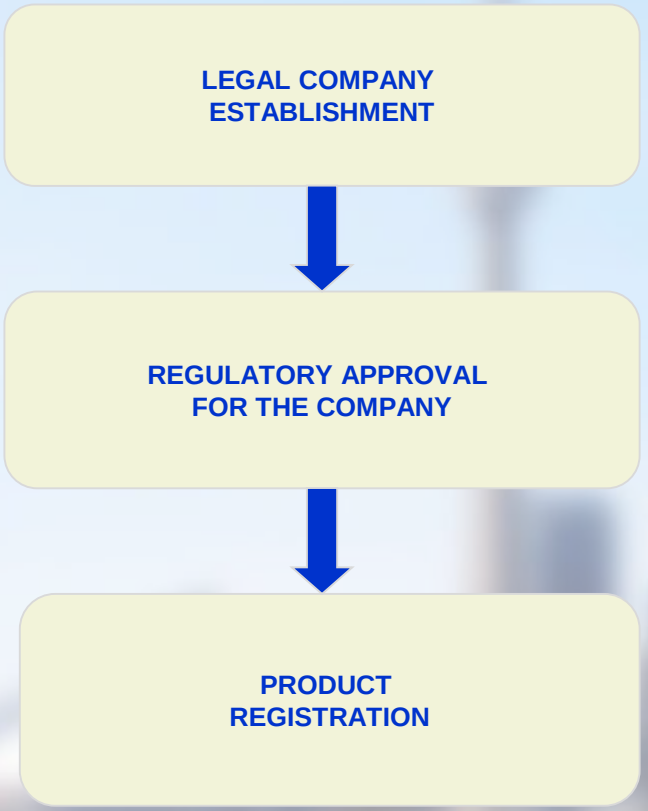
WAYS TO GET INTO THE BRAZILIAN MARKET

TORONTO

NOVEMBER / 2016

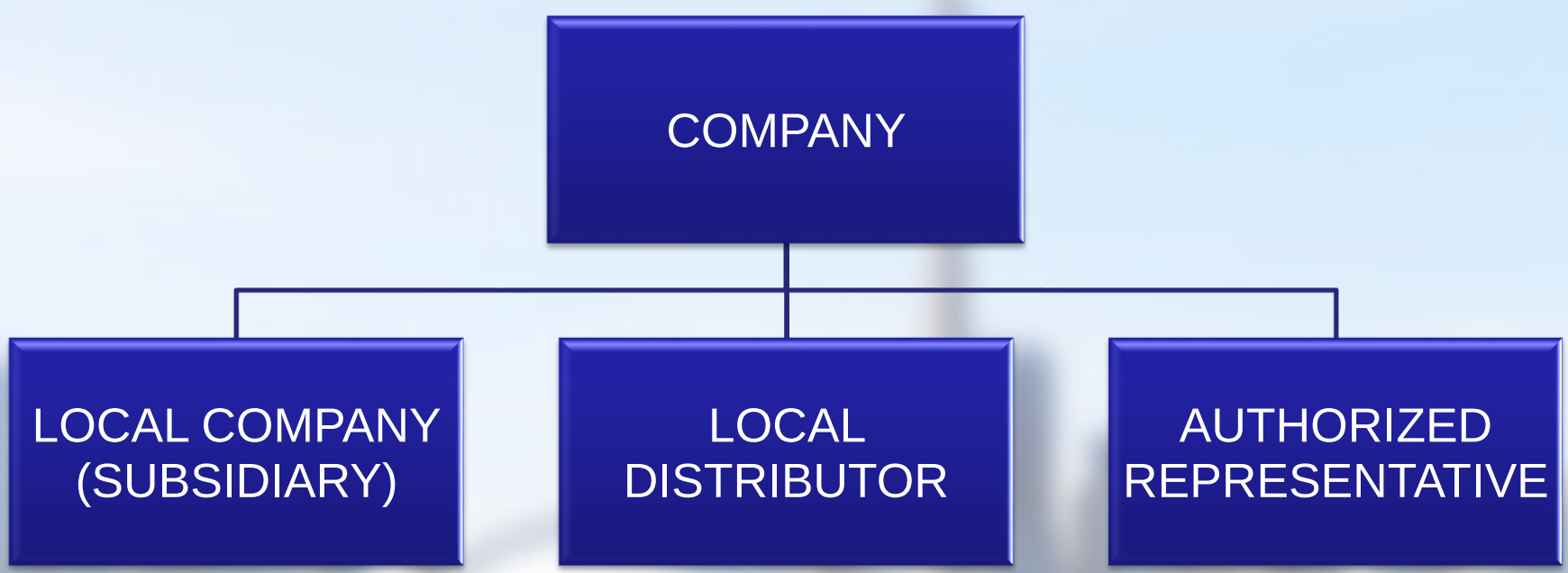
LATINI GROUP
Integrated
Business
Solution

GETTING STARTED



LATINI GROUP
Integrated
Business
Solution

WAYS TO GET INTO THE BRAZILIAN MARKET



LATINI GROUP
Integrated Business Solution

WAYS TO GET INTO THE BRAZILIAN MARKET

Establishment of a Subsidiary in Brazil:

- Advantages: the company will hold the registrations on behalf its own name. This way, the company will be free to choose and change distributors any time that may find convenient.
- Disadvantage: this process is more time consuming, once the company has to get the state (or city) regulatory license and the federal regulatory authorization (a.k.a. AFE), before submit the registration of the products. The time to get the regulatory licenses is about 10 to12 months. The average time to register products vary, as follows:
  - ◊ Medical Devices / IVD: 4~6 months.
  - ◊ Medical consumables and disposables: 4 months

LATINI GROUP
Integrated Business Solution

WAYS TO GET INTO THE BRAZILIAN MARKET

Registration on behalf Distributor's name:

- Advantages: this option is faster than the establishment of a subsidiary, once the distributor already has the regulatory licenses. The timing of this operation will be only that described below, considering that all documents were sent to the distributor by the manufacturer:
  - Medical Devices / IVD: 4~6 months.
  - Medical consumables and disposables: 4 months.
- Disadvantage: the main disadvantage is that the distributor will hold the registrations, which may be transferred, under specific conditions. However, various distributors can hold the registration of the same product. In this case, each one will have its own registration number.

LATINI GROUP
Integrated Business Solution

WAYS TO GET INTO THE BRAZILIAN MARKET

Registration Using a Authorized Representative (Non Commercial Holder)

- Advantages: the two basic advantages of this option are:
  - ◊ It is faster than the establishment of a local subsidiary, once the Authorized Representative company already has the regulatory licenses. The timing of this operation will be only that considered to assemble and submit the technical dossiers in the in the Local Regulatory Agencies.
  - ◊ The other important advantage is that the mother company can change the distributor any time, once the holder of the registrations will allow the distributor to import the products using the registration number.

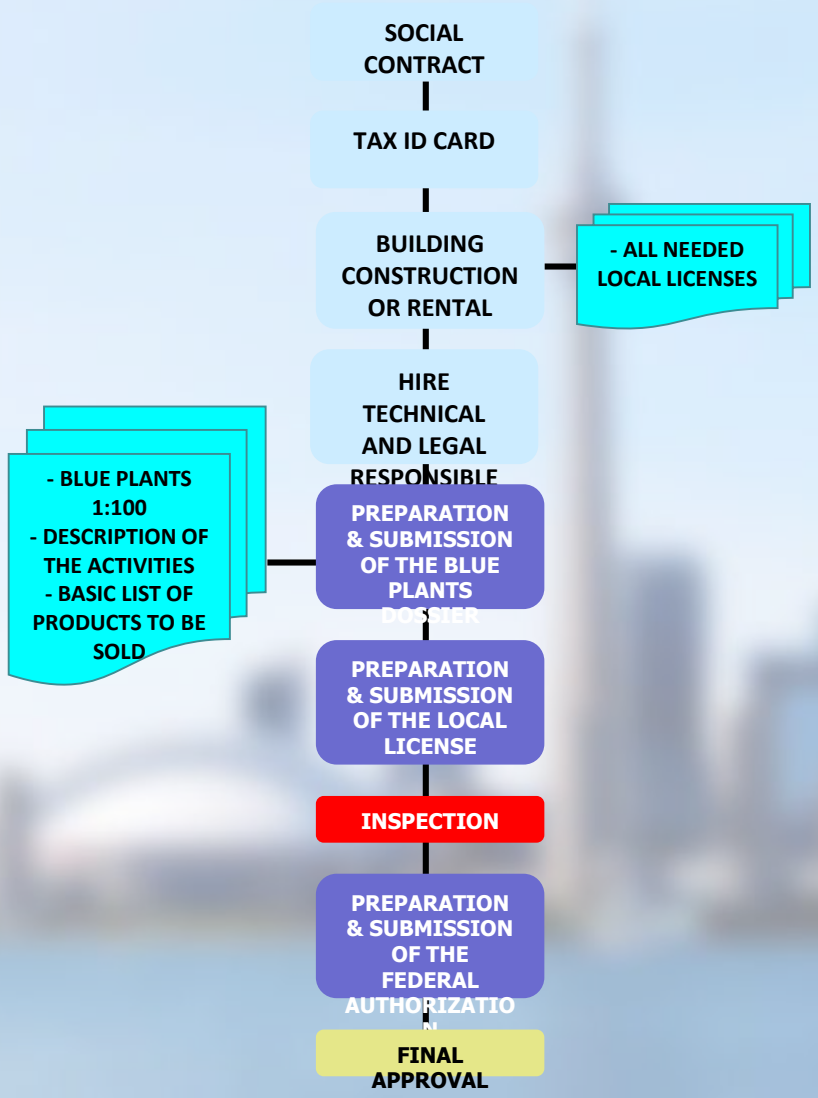
- Disadvantage: the holder of the registrations will not be the mother company, but another one with a legal agreement to represent it in Brazil, regarding the registration of the products only.
- **Important:** the holder of the product's registration can authorize another company (local distributors) or final consumer (as Hospitals, Labs and Clinics) to import the products under the registration number of the holder. This is perfectly legal, once the holder continues to be technically and legally responsible for the product itself.

LATINI GROUP
Integrated Business Solution

COMPANIES APPROVAL

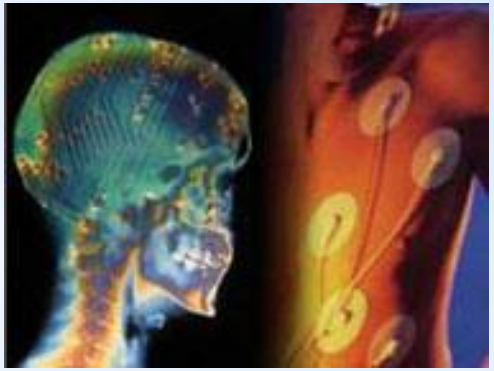
LATINI GROUP
Integrated
Business
Solution

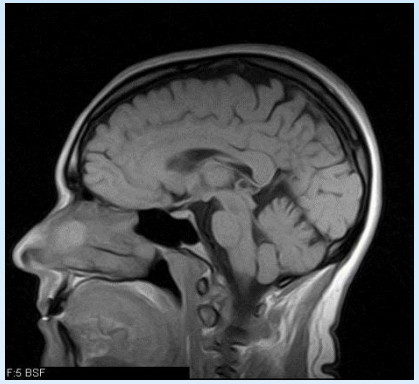
COMPANIES APPROVAL IN LATIN AMERICA

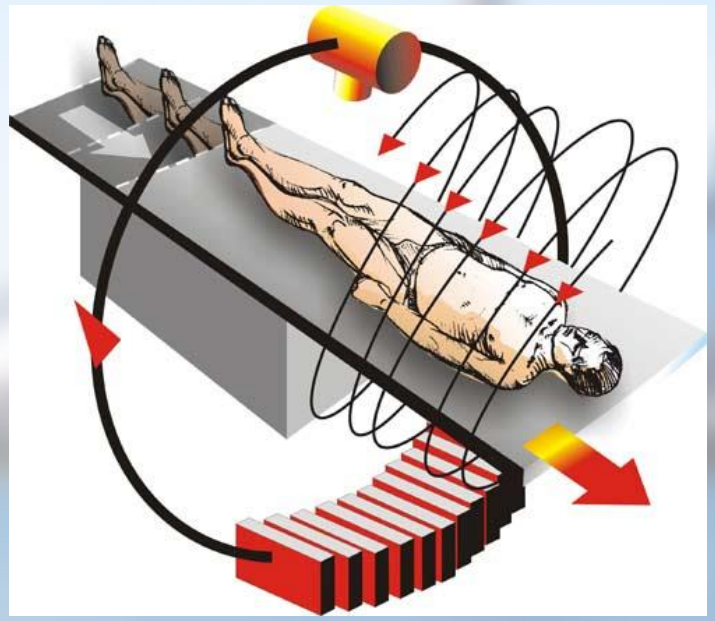


LATINI GROUP
Integrated Business Solution

PRODUCT REGISTRATION







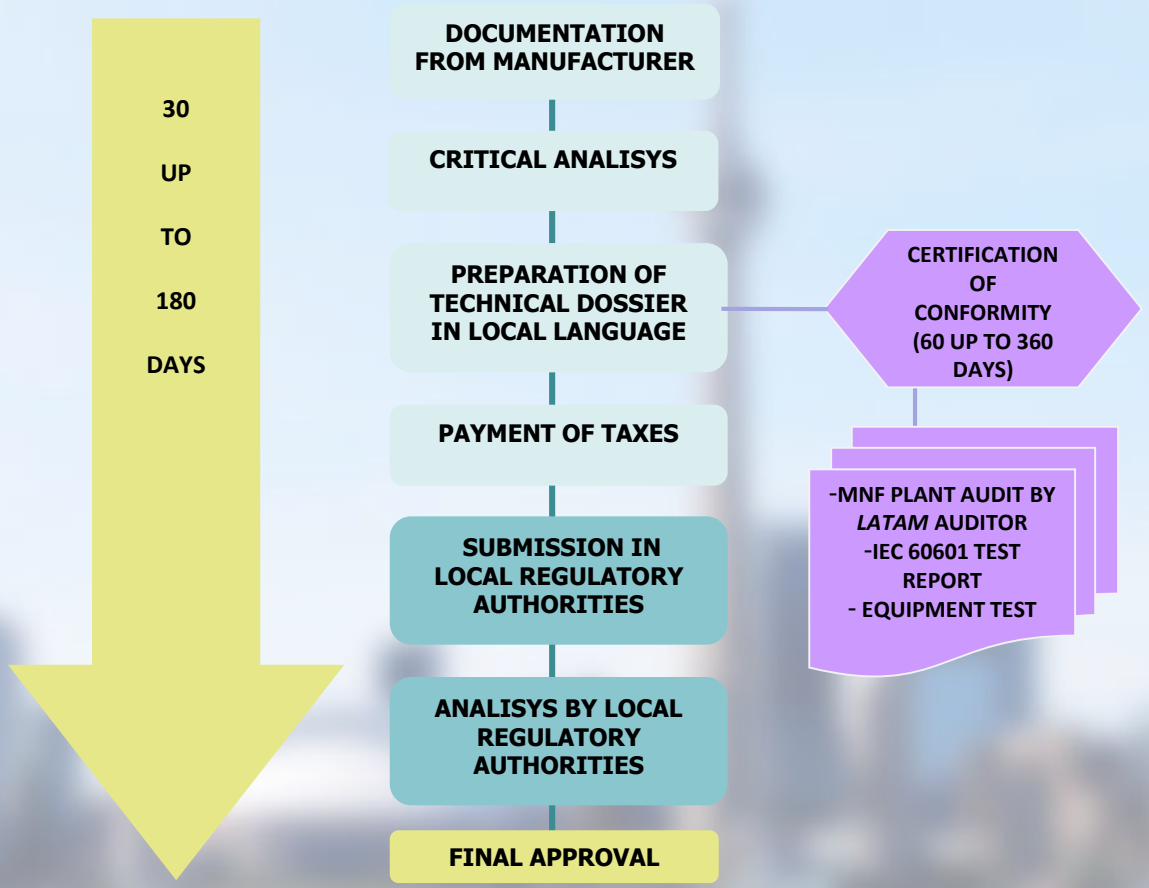
LATINI GROUP
Integrated
Business
Solution

BASIC DOCUMENTS TO REGISTER MEDICAL DEVICES IN BRAZIL

- COMPANY'S BRAZILIAN WORKING PERMIT
- BRAZILIAN TECHNICAL RESPONSIBILITY CERTIFICATE
- FREE SALES CERTIFICATE*
- LETTER OF DISTRIBUTION*
- INSTRUCTIONS FOR USE / INSERTS
- SERVICE / INSTALATION MANUAL
- LABELING
- PACKING
- BILL OF MATERIALS
- BASIC MANUFACTURING FLOWCHART
- CERTIFICATION OF CONFORMITY (IF APPLICABLE):
  - IEC 60601 TEST REPORT
  - MNF PLANT AUDIT BY BRAZILIAN AUDITOR
  - TEST OF THE EQUIPMENT IN LOCAL LABORATORY
- VALIDATION OF STERILIZATION PROTOCOL (IF APPLICABLE)
- PROOFS OF SAFETY AND EFFECTIVENESS

(*) CONSULARIZATION REQUIRED IN THE CLOSEST EMBASSY/CONSULATE OF THE COUNTRY WHERE THE PRODUCT WILL BE REGISTERED.

MEDICAL DEVICE REGISTRATION FLOWCHART



Latini & Associados®
Experts in Regulatory Affairs

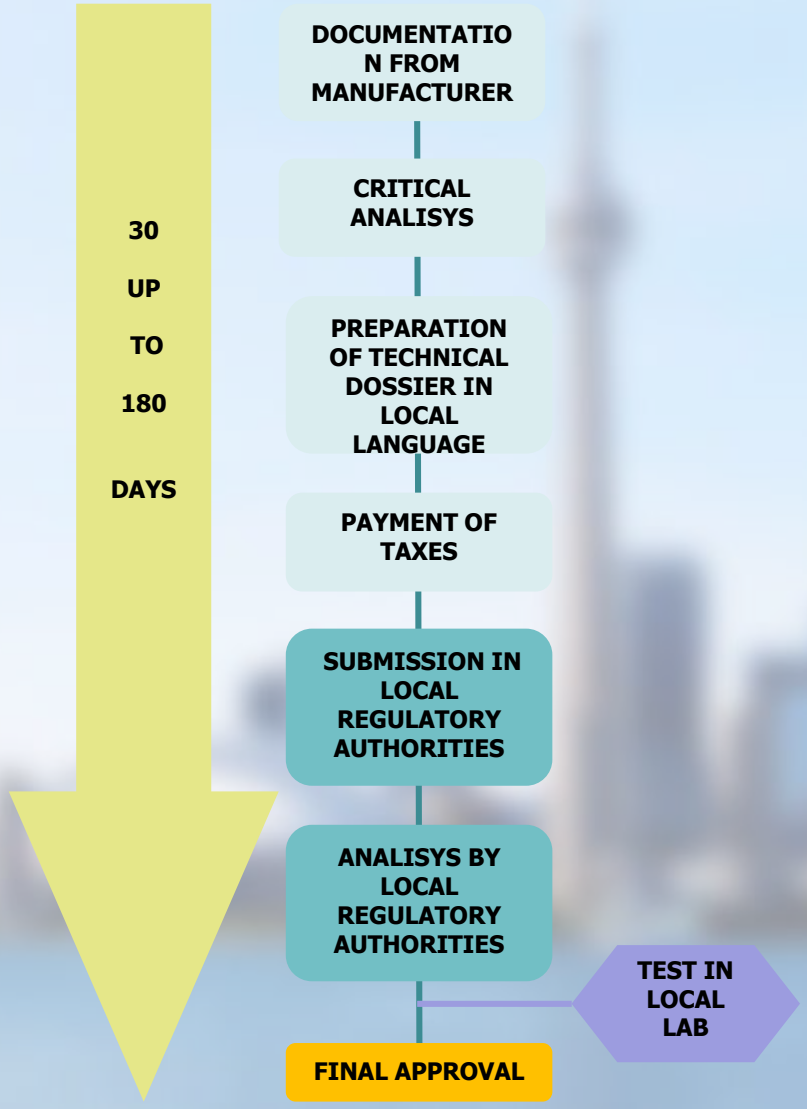
BASIC DOCUMENTS TO REGISTER IN-VITRO DIAGNOSTIC (IVD) IN BRAZIL

- COMPANY'S BRAZILIAN WORKING PERMIT
- BRAZILIAN TECHNICAL RESPONSIBILITY CERTIFICATE
- FREE SALES CERTIFICATE*
- LETTER OF DISTRIBUTION*
- INSTRUCTIONS FOR USE / INSERTS
- ADITIONAL MATERIALS REQUIRED
- LABELING
- PACKING
- BILL OF MATERIALS / QUALI-QUANTI (CENTESIMAL) FORMULA
- BASIC MANUFACTURING FLOWCHART
- TEST REPORT FOR CRITICAL ITEMS AS SENSITIVITY, ACCURACY, CALIBRATION CURVES, ETC. (LOCAL TEST MAY BE REQUIRED)
- VALIDATION OF STERILIZATION PROTOCOL (WHEN APPLICABLE)
- PROOFS OF SAFETY AND EFFECTIVENESS

(*) CONSULARIZATION REQUIRED (IN THE COUNTRY OF ORIGIN) IN THE CLOSEST EMBASSY/CONSULATE OF THE COUNTRY WHERE THE PRODUCT WILL BE REGISTERED.

Latini & Associados®
Experts in Regulatory Affairs

IVD
REGISTRATION FLOWCHART



LATINI GROUP
Integrated Business Solution

BASIC STRUCTURE OF A REGISTRATION DOSSIER

1. FORMS ACCORDING TO LOCAL LEGISLATION
2. TAX PAID
3. CERTIFICATE OF TECHNICAL RESPONSIBILITY
4. LOCAL WORKING PERMIT
5. FEDERAL WORKING PERMIT
6. LABELING ACCORDING TO LOCAL LEGISLATION
7. INSTRUCTIONS OF USE / USER MANUAL ACCORDING TO LOCAL LEGISLATION
8. TECHNICAL REPORT
9. CERTIFICATE OF CONFORMITY (FOR ELECTROMEDICAL DEVICES ONLY)
10. PROOFS OF EFFICACY AND SAFETY
11. NOTARIZED COPY OF THE FREE SALES CERTIFICATE*
12. NOTARIZED COPY OF THE LETTER OF DISTRIBUTION*
13. QUALI/QUANTI FORMULA ISSUED BY THE MANUFACTURER* (JUST FOR IVD)
14. LOCAL GMP CERTIFICATE

(*) DOCUMENTS MUST BE CONSULARIZED (IN THE COUNTRY OF ORIGIN) IN THE CLOSEST CONSULATE OF THE COUNTRY WHERE THE PRODUCT WILL BE CONSULARIZED

Latini & Associados®
Experts in Regulatory Affairs

TAKE INTO CONSIDERATION…

- UNEXPECTED CHANGES MAY OCCOUR IN THE LEGISLATION.
- INFLUENCE OF OTHER AUTHORITIES THAN THE REGULATORY ONES (METROLOGY, LABOR, ENVIRONMENTAL, ETC).

REGULATORY AFFAIRS
IN
LATIN AMERICA

Q&A

LATINI GROUP
Integrated
Business
Solution

DEFINITION OF MEDICAL DEVICE

- Product, equipment, device, material, article or system of Medical, Dental or Laboratorial (*Clinical Lab)* use or application, used for prevention, diagnostic, therapeutic, rehabilitation or anti-conception that does not use pharmacological, immunological or metabolic methods to perform its main function but may be helped in its functions by these methods.

Class of Risk

- Class I (low risk)
- Class II (medium risk)
- Class III (medium/high risk)
- Class IV (high risk)

Used Equipments / Materials

- It is forbidden by Brazil legislation to sell used products. The equipment must be refurbished by the manufacturer or by some service company duly authorized by the manufacturer. The product must have its registration valid.

- Some materials can be re-used if re-processed properly by the hospitals.

Harmonization

- Many norms are already harmonized in *Mercosur*. Nevertheless it was expected to harmonization to be concluded and registrations accepted among the countries since 2003. The harmonization is delayed because of the economic situation of some partners and also because new technologies were introduced in the LATAM market what lead the countries to take he discussion to a totally new different level.

Softwares

- In general, softwares are classified as follows:
  - If they are designed only for images or data filing then they will be considered as Class I products – Low Risk;
  - If they give to the operator the possibility to alter the image or the collected data, then they will be considered as Class II – Medium Risk.

    Note: it is important to re-enforce that when a product is to be used with another higher risk class product then the first one has to be considered in the same class of risk of the second one.

Spare Parts

- Once one product is registered in Brazil all its parts and components are automatically considered as registered also but some accessories that can be sold separately like disposables. It is not necessary to keep the registration alive to import spare parts for servicing but the importer has to prove that the said product was imported during the validity of the registration.

After Sales Monitoring
(Techno Vigilance)

- The Brazilian market (specially Mercosur) already adopted the Techno Vigilance system. All recalls and malfunction have to be reported to the local authorities. The Brazilian Regulatory Authorities also monitor the global market looking for problems with products that can be sold in Brazil.

What happen when I have these changes? (1)

- Change the Manufacturing Address: it is possible to update the registration.
- Change of the Manufacturer: it is possible to update the registration but it is strongly suggested that the company applies for a new registration. It is faster and less complicated.
- My company wants to add a new manufacturing site: no problem. It is just a matter of updating the registration.

What happen when I have these changes? (2)

- When I have a major change in my product? The company should report to the RA authorities or submit a new registration.
- Can I add new products to the approved registration? Yes, if the new product fits the criteria of registration per family of products.

What happen when I have these changes? (3)

- What are the basic criteria for registration as Family of Products?
  - Same manufacturer;
  - Same technology;
  - Same composition;
  - Same use;
  - Same side effects, warnings and special care.

Is It possible to have more than one company holding the registration of the same product?

- Yes, since the manufacturer authorizes each applicant. Then each applicant will have its own registration number.

Latini & Associados®
Experts in Regulatory Affairs

Importation Process

- All Medical Devices / IVD and products under the control of the Brazilian regulatory authorities must go under physical inspection. It is strongly suggested that your local companies / distributors / AR try to import using points (harbours and airports) with big volumes of importation so the inspectors are trained avoiding delays.

Thanks for your attention.

Contact us:

LATINI GROUP
Integrated
Business
Solution

São Paulo – Brasil

E-mail: latini@latini.com.br

www.latini.com.br

A Latini Group Company