Medical Device Success in Latin America

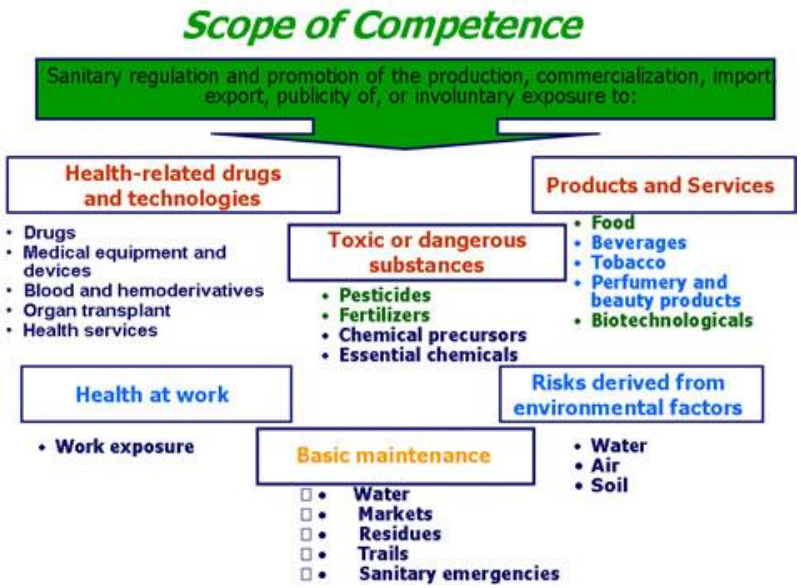
Current as of 3 May 2013

Regulatory Changes in Brazil: 2012 to Date

- Breast Implants require INMETRO certification (batch testing or additional 3rd party audits)
- New IVD regulations issued
- Customs and ANVISA Strike
- INMETRO certificates require Brazilian Holder
- ABIMED and CBDL file lawsuits against ANVISA: wins
  - ANVISA appeals judge's preliminary injunction
- New Brazil Good Manufacturing Practices Regulation issued
- 2013: 50% of all GMP certificates issued due to court ordered inspections

Regulatory Changes in Mexico: 2012 to Date

- List of 1700 deregulated products
- New low-risk classification introduced (“class Ia”)
- Third Party Reviewers introduced
- Japan Equivalency Agreement
- Technovigilance requirements



Things to consider for Latin America

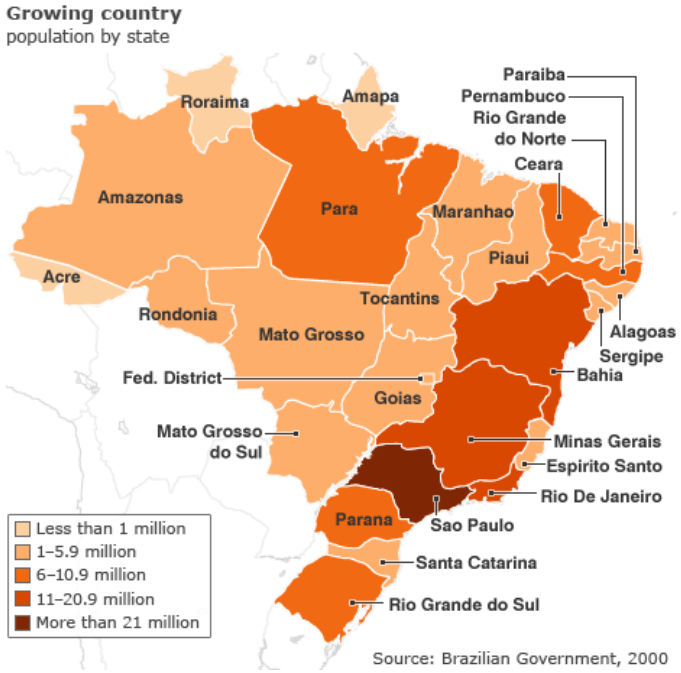
- Shifting Regulatory Environment
- Control of approvals
- Understanding the market

Understanding the Regulatory Requirements

- Law of the Land: i.e., the perils of international travel
  - Bureaucracy
  - Fast changing environment
  - Time
  - Cost
  - Language

Ownership of Approvals

- Control of device registrations
  - Representation and reach



Understanding the Market

- Gambling on Success
  - Letting distributors choose you
  - Import duties
  - Product acceptability
    - Market research!

Additional Resources

Thank you for your time!

For more information, please contact:
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