Regulatory Aspects of IVD/Medical Device Regulations in Brazil

ANVISA
Agência Nacional de Vigilância Sanitária

Brazil: an overview

Population: 208,500,000

Area: 8,514,876 Km²

Federative States: 27

Municipalities: 5,570

ANVISA
Agência Nacional de Vigilância Sanitária

ANVISA – Brazilian Health Regulatory Agency

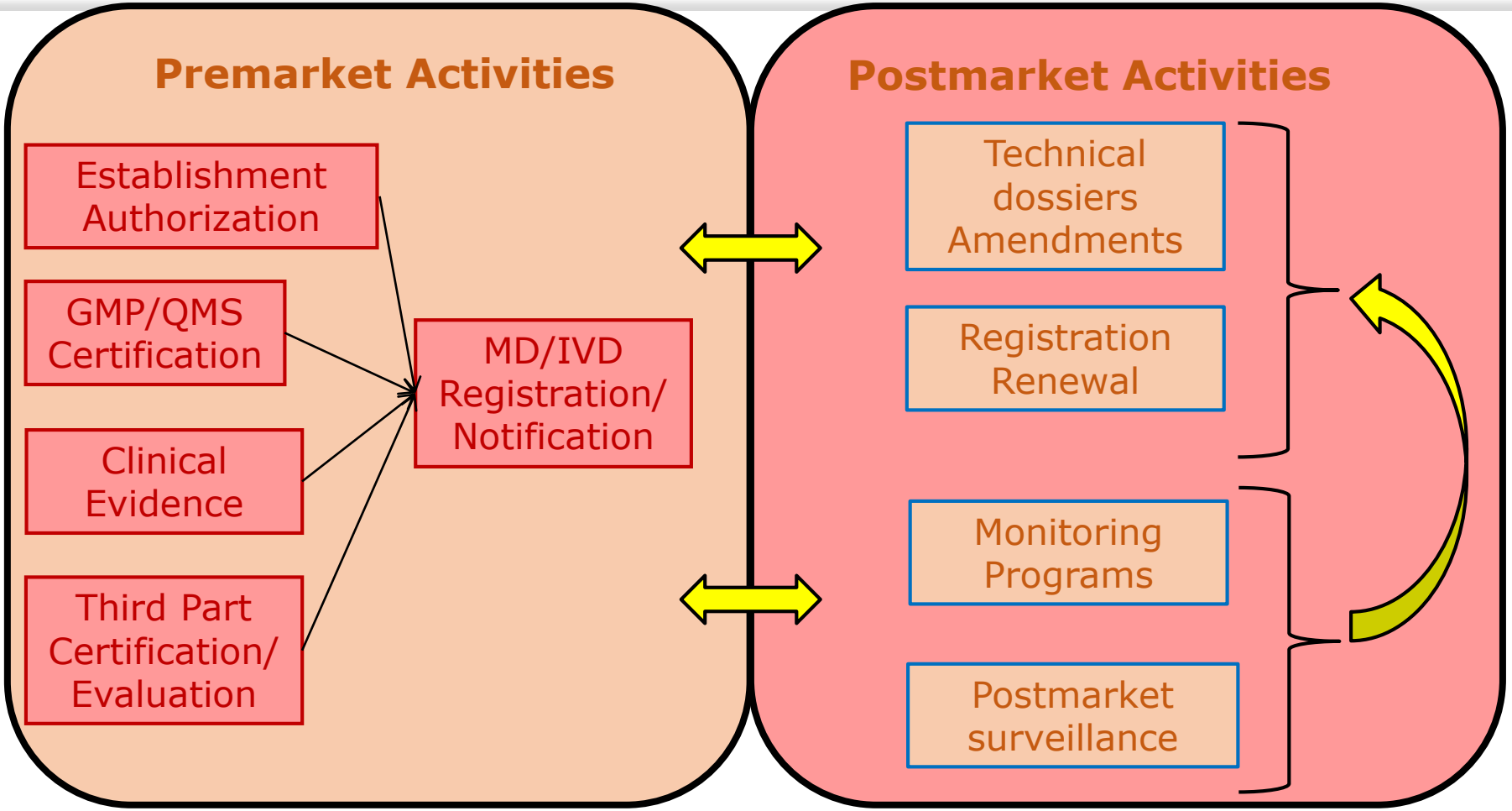
- Established by Law nº 9.782, of January 26th 1999

Mission

To protect and promote the health of population, intervening in risks associated with production and use of products and services subject to health surveillance, in a coordinated and integrated action within the National Health System (SUS)

ANVISA
Agência Nacional de Vigilância Sanitária

Overview of the IVD Regulatory Scheme



ANVISA
Agência Nacional de Vigilância Sanitária

Main Current Regulations

- **Resolution RDC 36/2015** and **RDC 270/2019** – Premarket approval pathway
- **Resolution RDC 16/2013** – Good Manufacturing Practices Requirements for MD/IVD
- **Resolution RDC 183/2017** – GMP Certification pathway for MD/IVD
- **Resolution RDC 67/2009 –** MD/IVD Post market surveillance / Adverse events Reporting
- **Resolution RDC 302/2005 –** Technical requirements for clinical laboratories

Premarket Approval

➢ Resolution RDC 36/2015

- Risk Classification – based on 9 rules*
  - Class I: Low Individual Risk and Low Public Health Risk
  - Class II: Moderate Individual Risk and Low Public Health Risk
  - Class III: High Individual Risk and Moderate Public Health Risk
  - Class IV: High Individual Risk and High Public Health Risk

* SG1(PD)/N045R12/2007 - Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

GHTF

ANVISA
Agência Nacional de Vigilância Sanitária

Premarket Approval

- **Pathways**

  - "Registro": Class III and IV
  - "Cadastro": Class II
  - Notification: Class I (Resolution RDC 270/2019)

Premarket Approval

REQUIREMENTS			
	Class III and IV	**Class II**	**Class I**
Technical Dossier	Yes	Yes	No
GMP certificate	Yes	No	No
Clinical evaluation	Yes	No	No
Expiration	Yes (10 years)	No	No

Premarket Approval

➢ Resolution RDC 36/2015

- Technical Dossier (Classes II; III and IV)*
    - Product description
    - Labeling/IFU
    - Risk management report
    - Analytical performance
    - Clinical performance (III e IV)
    - Stability
    - Manufacturing flowchart and sites

IMDRF/RPS WG/N13FINAL:2014

IMDRF International Medical Device Regulators Forum

Final Document

Title: In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)

Authoring Group: Regulated Product Submissions Table of Contents Working Group

Date: 30 June 2014

Jeffrey Shuren, IMDRF Chair

* IMDRF/RPS WG/N13 FINAL:2019 (Edition 3) - In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)

ANVISA
Agência Nacional de Vigilância Sanitária

Premarket Approval

➢ Art. 16 Law n. 6.360/76

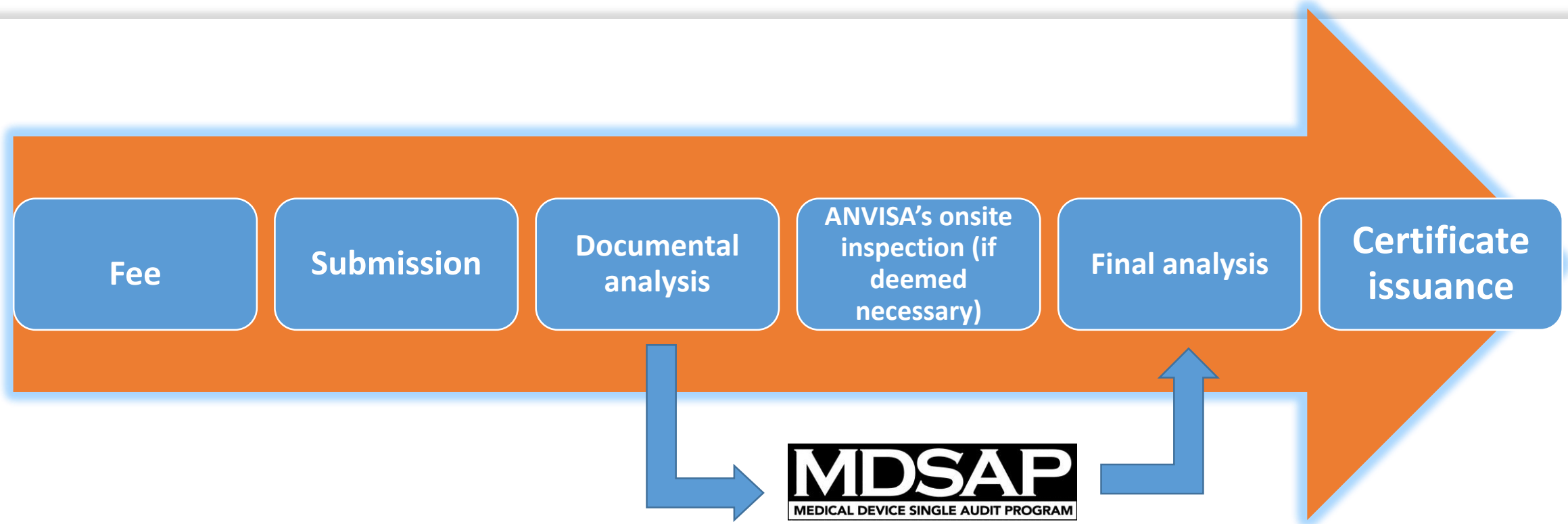
- Laboratory evaluation
  - Some products require previous testing against characterized serological panels, carried out by "INCQS" (National Quality Control Laboratory)

– **Chagas disease** – **HBV** – **HCV** – **HIV** – **HTLV**	– **Syphilis** – **Blood grouping** – **Dengue** – **CHIKV*** – **Blood glucose monitoring devices*** ***Future implementation**

INCQS
Instituto Nacional de Controle de Qualidade em Saúde

ANVISA
Agência Nacional de Vigilância Sanitária

GMP CERTIFICATION



ANVISA
Agência Nacional de Vigilância Sanitária

Post Market Surveillance

➢ Resolution RDC 67/2009

- Require companies in Brazil to implement a post market vigilance system integrated to QMS
- Set reporting rules for major occurrences originated in the country or affecting products imported into Brazil:
    - **72 hours:**
        - Death
        - Threat to public health
        - Product falsification
    - **10 calendar days:** Serious adverse event with no associated death
    - **30 calendar days:** Event that could lead to serious adverse event in patient, user or other person

Additional Information

- All labeling must be in Portuguese. It is allowed to the sponsor to place the Portuguese labeling and insert at product after customs, before distribution
- E-labeling is allowed according to requirements of IN 04/2012, except for some types of devices (e.g. the ones indicated for home use and/or operation by lay user).
- “Research use only” (RUO) labeled reagents are not regulated
- LDTs must undergo validation as per Resolution - RDC 302/15

Perspectives

- **International initiatives for regulatory convergence**

- Document **GHTF SG1(PD)/N045R12/2007 - Principles of In Vitro Diagnostic (IVD) Medical Devices Classification** is under revision by IMDRF. Draft to be released for public consultation on spring (Stay tuned!)

IMDRF International Medical Device Regulators Forum

ANVISA
Agência Nacional de Vigilância Sanitária

Perspectives

➢ International initiatives for regulatory convergence

Established in 1991 by the Asunción Treaty with the purpose of promoting free trade and the free circulation of goods, people and financial assets. Currently considered a customs union and a trading bloc.

Member States: **Argentina, Brazil, Paraguay, Uruguay and Venezuela** (suspended)**.**

Associated members: Bolivia (ascending member), Chile, Colombia, Ecuador, Guiana, Peru and Surinam.

*Active WG to propose “Resolution GMC” on **In Vitro Diagnostic (IVD) Medical Devices Classification.**
Brazil, as an IMDRF member state, has recently proposed to postpone the discussions in Mercosur, until release of IMDRF’s final document.

Perspectives

➢ **PoCT**

- **Resolution RDC 302/2005** (Technical requirements for clinical laboratories) is under revision. Some provisions for the PoCT may be included to address concerns on testing reliability.

Thank you for your attention!

gevit@anvisa.gov.br

Agência Nacional de Vigilância Sanitária - Anvisa
SIA Trecho 5 - Área especial 57 - Lote 200
CEP: 71205-050
Brasília - DF

www.anvisa.gov.br
www.twitter.com/anvisa_oficial
Anvisa Atende: 0800-642-9782

ouvidoria@anvisa.gov.br