Efficiency of product review on medical devices

General Office of Medical Devices – GGTPS

National Health Surveillance Agency - BRAZIL

Brasília, 02/08/2014

Medical Device Regulation in Brazil

Agenda

- Brazilian Legal Framework;
- General Aspects;
- Overview of the Regulatory Scheme;
- Anvisa's Organization for Medical Device;
- Medical Device Classification;
- Essential Principals of Safety and Effectiveness;
- Medical Device Premarket Review and Approvals.
- Management Modernization

Assumptions

Art. 196. Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery.

Constitution Of The Federative Republic Of Brazil, 1988

Assumptions

Art. 197. Health actions and services are of public importance, and it is incumbent upon the Government to provide, in accordance with the law, for their regulation, supervision and control, and they shall be carried out directly or by third parties and also by individuals or private legal entities.

Constitution Of The Federative Republic Of Brazil, 1988

Assumptions

Art. 200. It is incumbent upon the unified health system, in addition to other duties, as set forth by the law:

I - to supervise and control proceedings, products and substances of interest to health and to participate in the production of drugs, equipments, immunobiological products, blood products and other inputs;

V - to foster, within its scope of action, scientific and technological development;

Brazilian Federal Constitution 1988

- Chapter II – section II

“Health is a right of all and a duty of the State”

All actions within this objective are part of the Brazilian Single Health System (SUS), and regulation of product and services related with healthcare are under this scope.

Federal Law and Decrees

- **Act 6360/76** (beyond other purposes, gives legal provision for product registration);
- **Act 6437/77** (sets violations of federal health legislation and establishes their respective sanctions);
- **Act 8080/90** (defines the Unique Health System);
- **Act 9782/99** (establishes Anvisa's roles and responsibilities, defines the National Health Surveillance System);
- **Decree 8077/13** (has replaced Decree 79094/77 - gives interpretation of Act 6360/76).

Main Anvisa's RDC for MD

- RDC n. 185/01 – Premarket technical review for device and family of devices (non IVDs);
- RDC n. 206/06 – Premarket technical review for device and family of devices (IVDs);
- RDC n. 56/01 – Essential Requirements of Safety and Effectiveness;
- RDC n. 16/13 – Good Manufacturing Practices Requirements for MD;
- RDC n. 25/09 – GMP Certification for MD;
- RDC n. 24/09 – MD Notification (nIVDs).
- There are other RDCs which defines additional requirements for specifics devices.

Principles of National HealthCare System:

- Universality in attendance;
- Full healthcare access;
- Equity;
- Decentralization to states and municipalities.

Vaccination Program

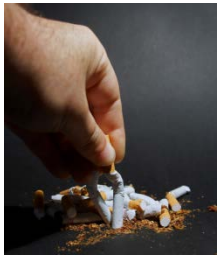
http://pni.datasus.gov.br/

Sexually Transmitted Diseases and HIV/AIDS

DST·AIDS HEPATITES VIRAIS

http://www.aids.gov.br/

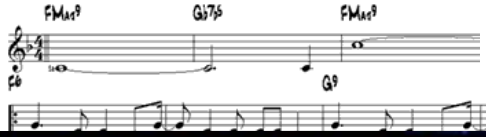
Anti-smoking program



http://www.inca.gov.br/tabagismo/

Brasil

THE GIRL FROM IPANEMA



Rio de Janeiro

Brasília

São Paulo

Fonte: IBGE, 2009. www.ibge.gov.br. Julho, 2009

- 26 States + Federal District (Brasília)
- Language: Portuguese
- Area 8.514.876 km²
- Public Universal HeathCare System + Private System (¼ Population)

Population (2014): 201 millions

- 1) São Paulo: 11,8 millions
- 2) Rio de Janeiro: 6,3 millions

...

- 6) Brasília: 2,8 millions

Source: IBGE

OUTPATIENT ESTABLISHMENTS	**182.817**
HOSPITALS	**8.592**
OTHER ESTABLISHMENTS	**21.409**
TOTAL HEALTH CARE ESTABLISHMENTS	**212.818**

Source: MS – DATASUS – CNES/MS – March, 2010

INTERNATIONAL TRADE DATA

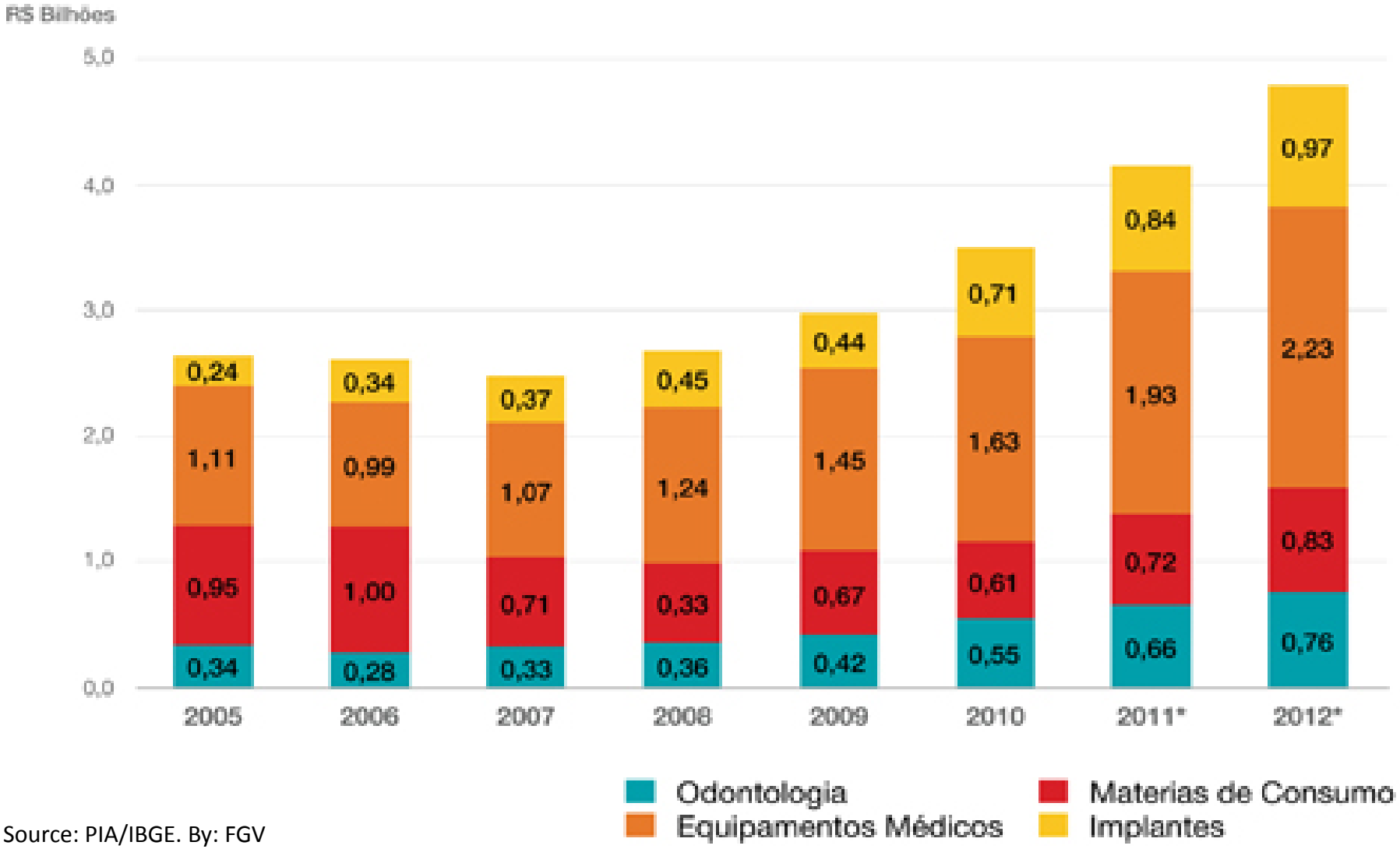
EXPORTS FROM BRAZIL - 2011

Position	Countries	US$ 1,000	%
1	USA	172,423	24.4
2	Argentina	83,255	11.8
3	Venezuela	54,374	7.7
4	Mexico	34,706	4.9
5	Colombia	30,188	4.3
6	Chile	28,907	4.1
7	Belgium	24,179	3.4
8	Germany	22,615	3.2
9	Paraguay	19,126	2.7
10	Peru	17,479	2.5
Subtotal		487,252	68.9
Others		219,817	31.1
Total		707,070	100

IMPORTS TO BRAZIL – 2011

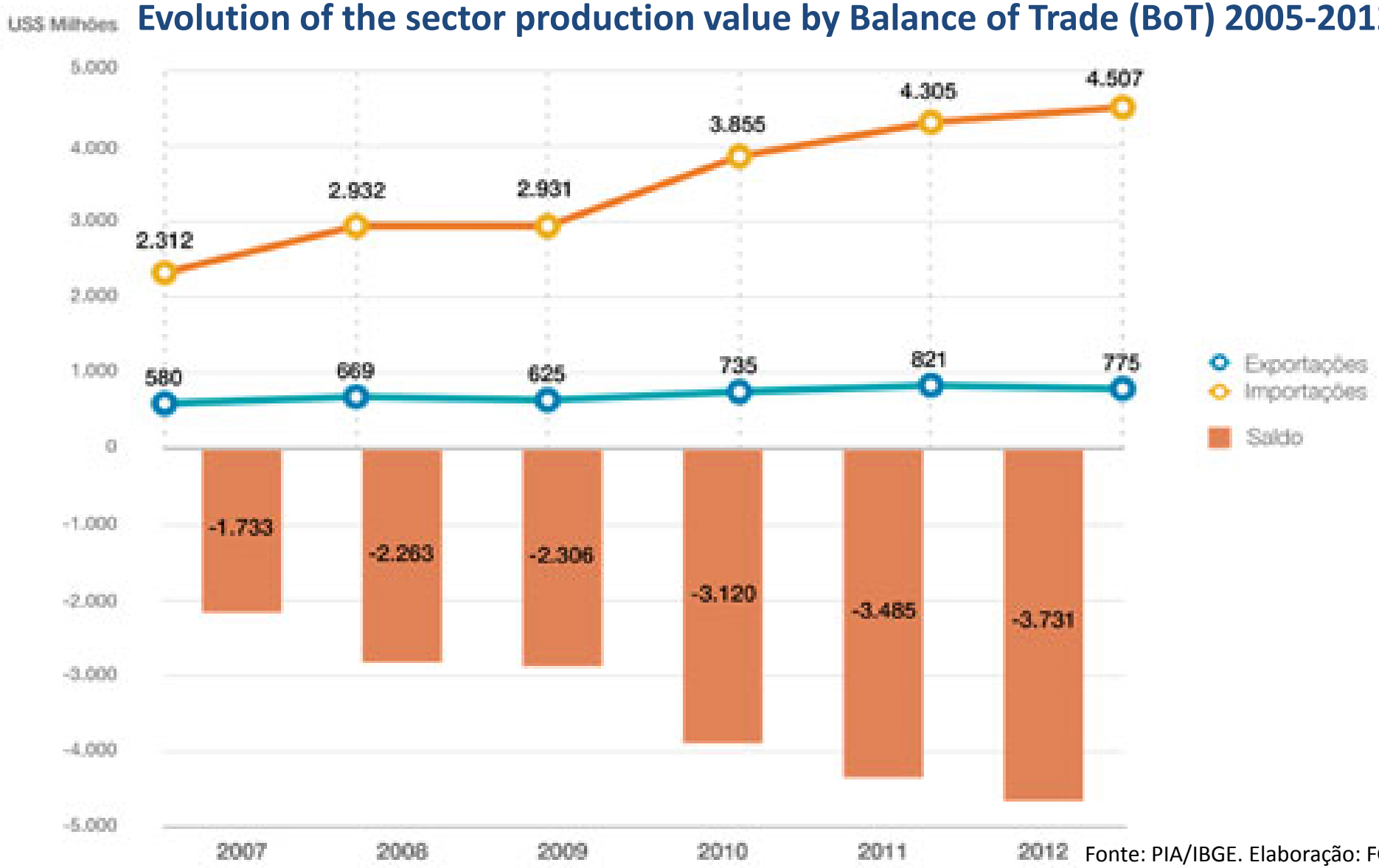
Position	Countries	US$ 1,000	%
1	USA	1,309,590	32.2
2	Germany	643,741	15.8
3	China	303,746	7.5
4	Japan	250,163	6.2
5	Switzerland	163,062	4.0
6	Malaysia	142,124	3.5
7	France	121,607	3.0
8	Ireland	115,479	2.8
9	UK	99,162	2.4
10	Holland	83,618	2.1
Subtotal		2,914,649	71.7
Others		1,151,693	28.3
Total		4,066,342	100

Evolution of the sector production value by industry segment - 2005-2012



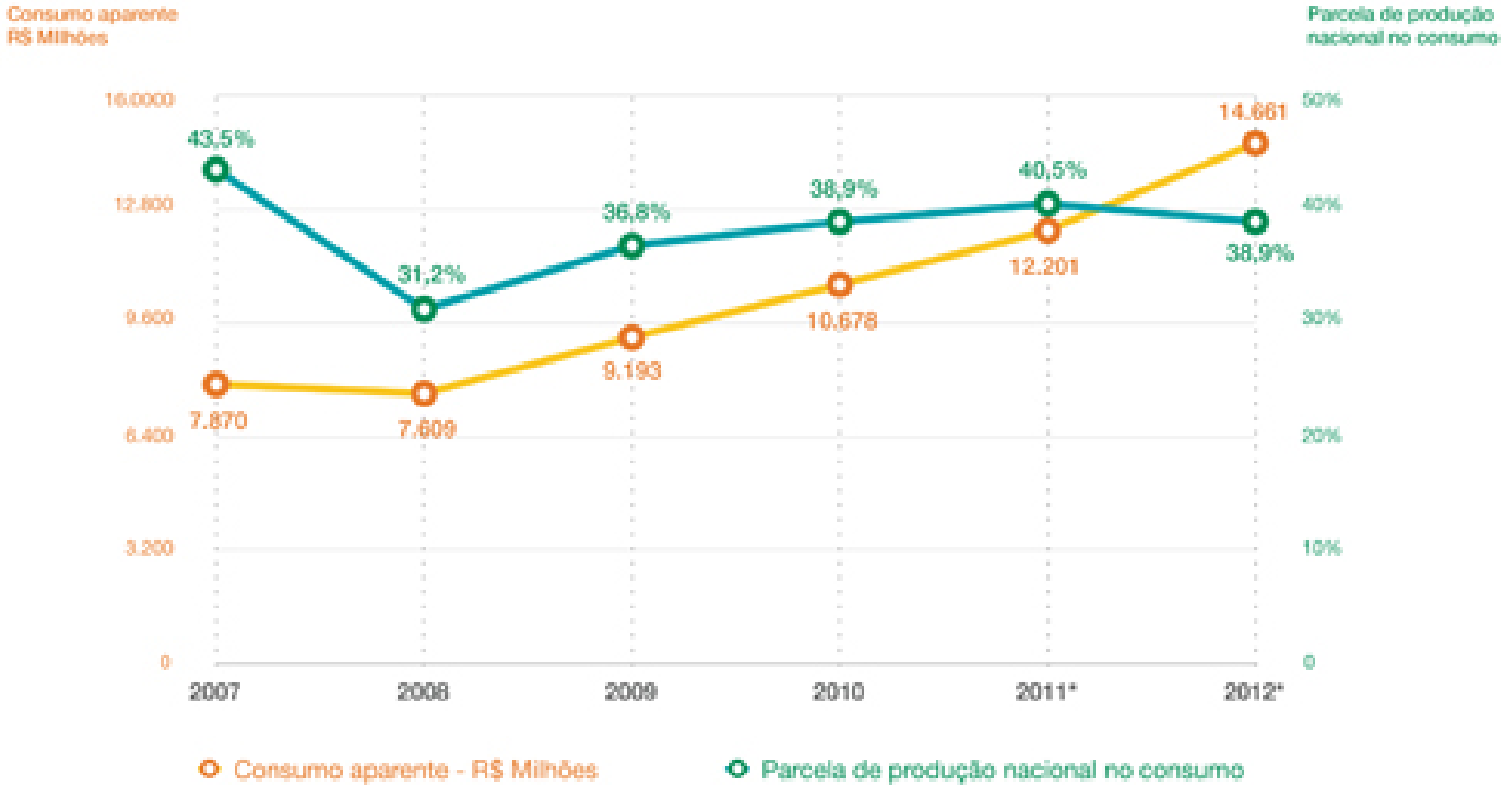
Source: PIA/IBGE. By: FGV

Evolution of the sector production value by Balance of Trade (BoT) 2005-2012



Fonte: PIA/IBGE. Elaboração: FGV

Domestic production X Apparent consumption



Fonte: PIA/IBGE. Elaboração: FGV

Control structure in medical devices

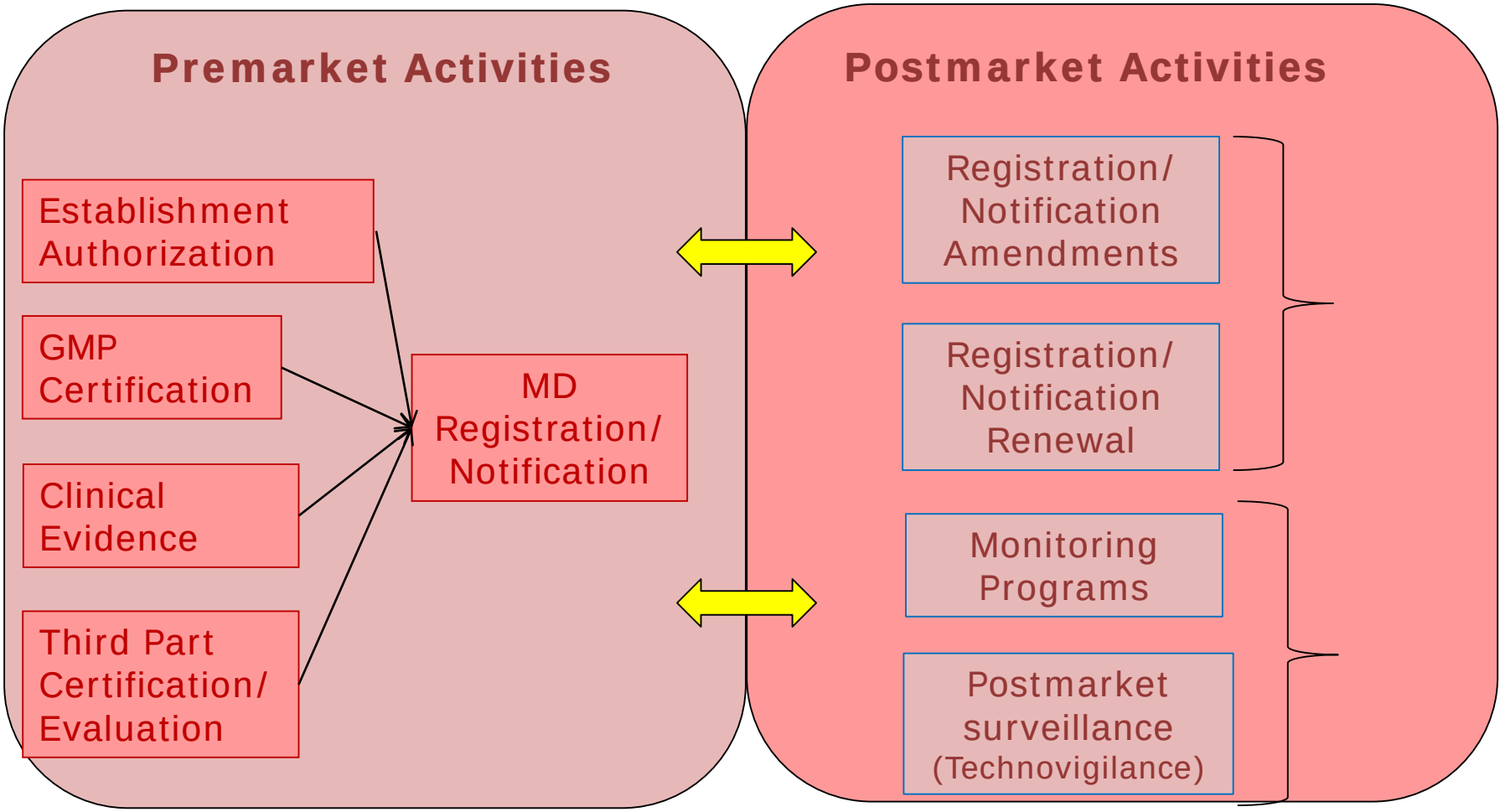
Pre-market
Registration

GMP inspection (pre-market)

Post-market surveillance

Regulatory
HealthCare
Service

Overview of the Regulatory Scheme



Anvisa's Organization for MD
(Premarket review and approvals)

- **General Office of Medical Device** – GGTPS (Gerência Geral de Tecnologia de Produtos para Saúde):
  - Office of Equipments (GQUIP): medical equipments (e.g. Electromedical equipments) and software;
  - Office of Material (GEMAT): materials, articles (e.g. Orthopedic implants, seringes);
  - Office of IVD (GEVIT): reagents, calibrators, controls (e.g. HBsAg assay).

Medical Device Classification

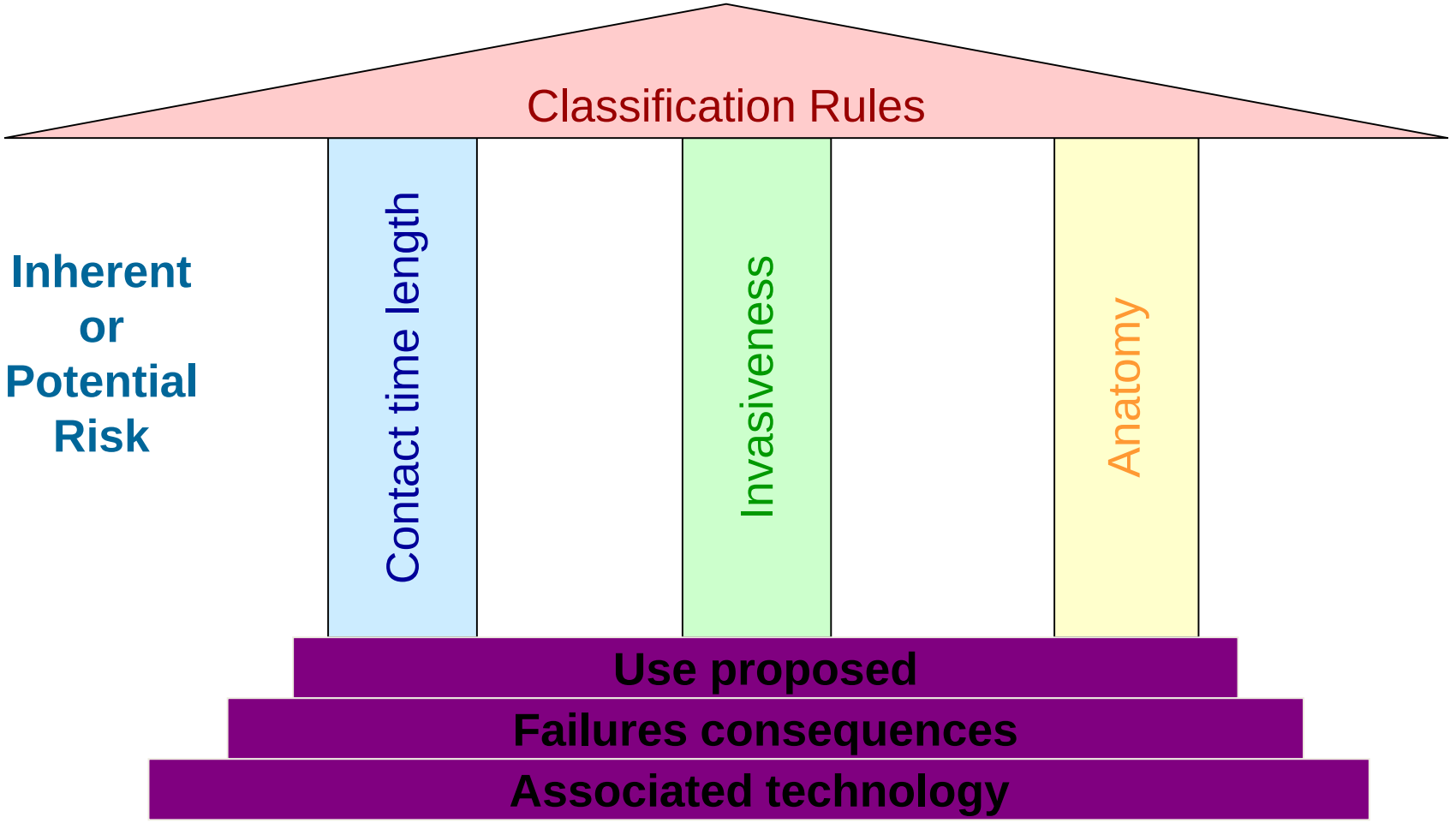
- For regulatory purposes MD are separated into:

Non IVD: e.g. equipment, software, articles, and materials.

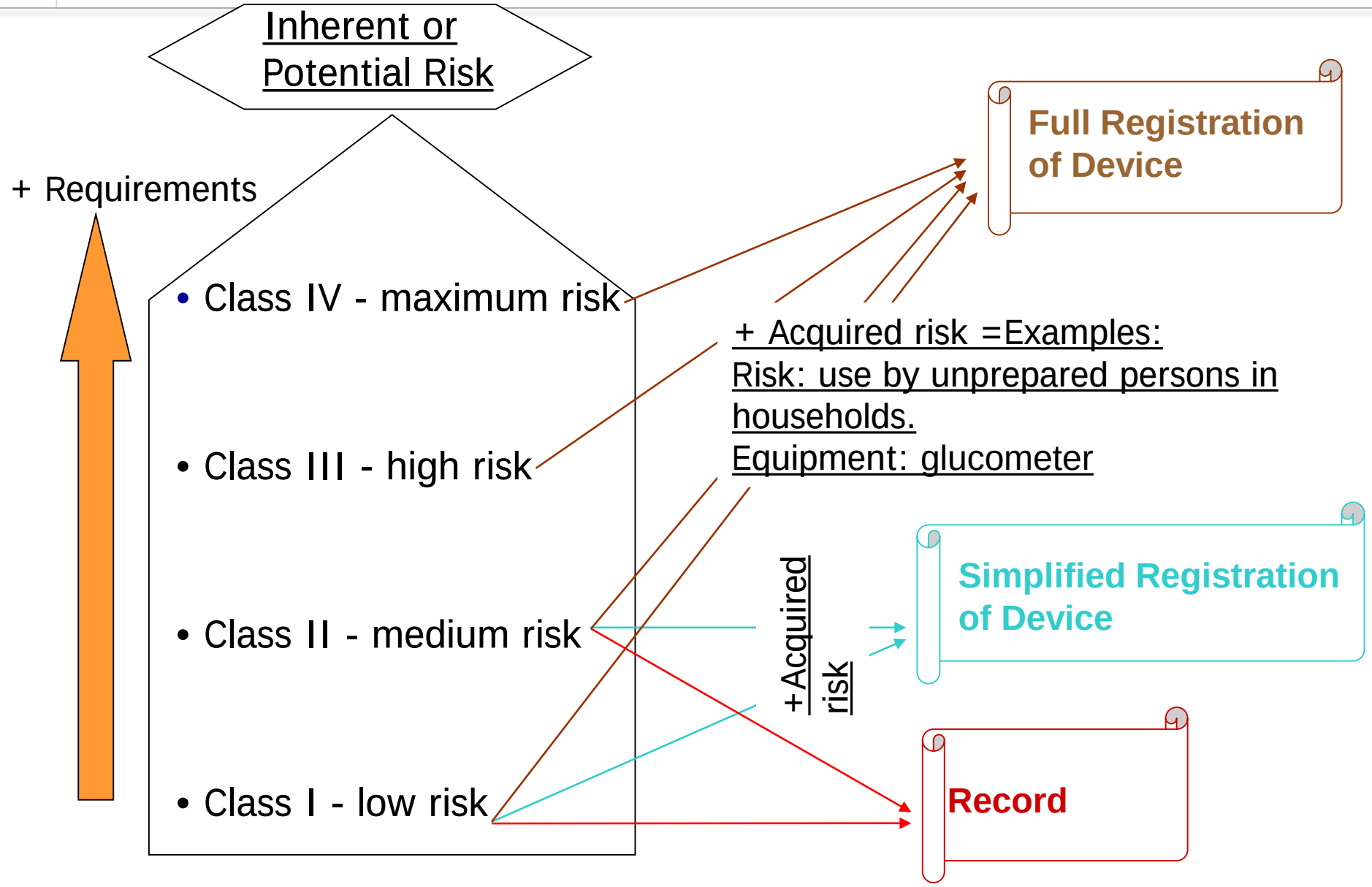
IVD: e.g. reagents, calibrators, standards and controls.

Each of them have their specific legislations and requirements, including classification.

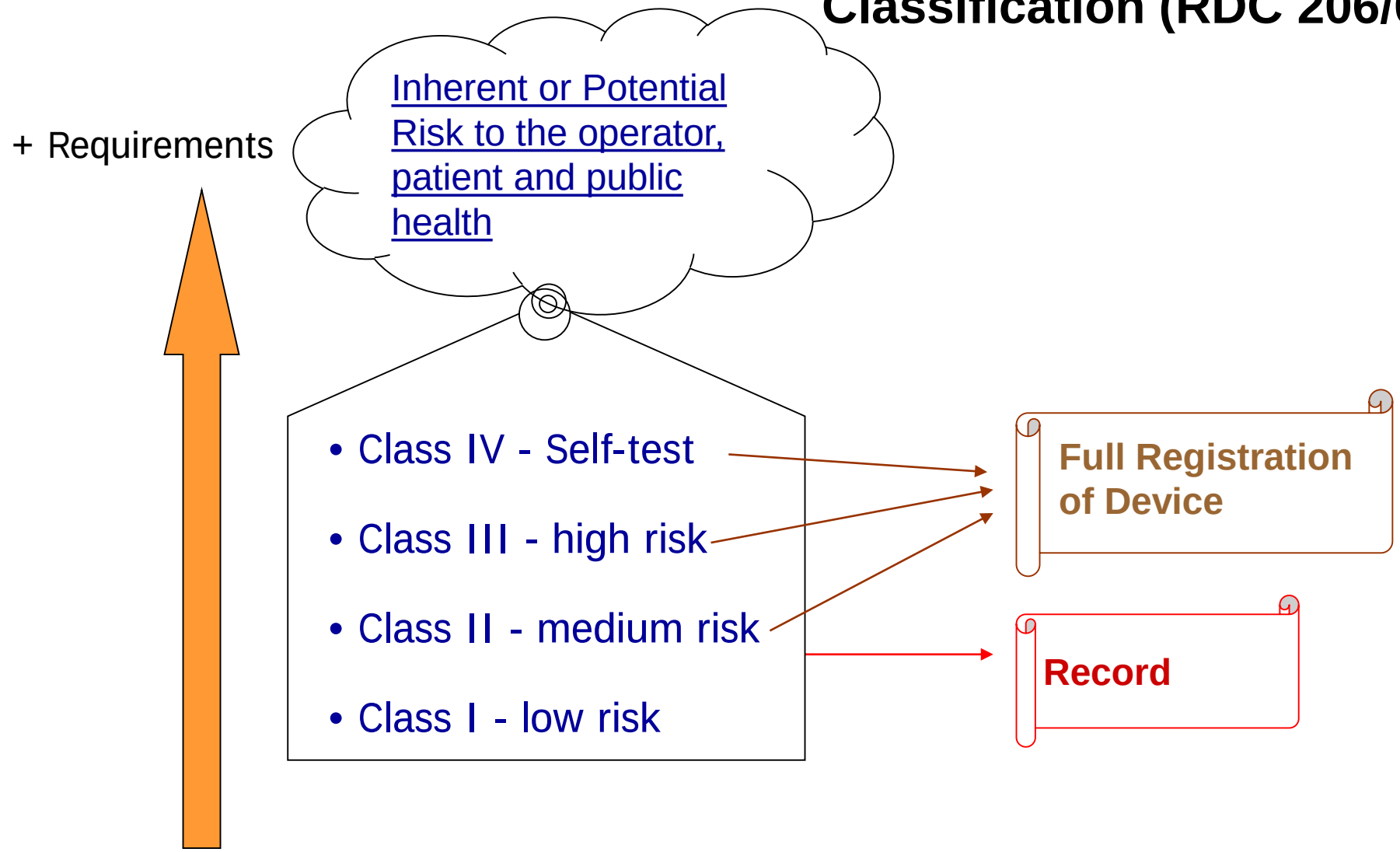
Materials and Equipment Classification



Materials and Equipment Classification



In Vitro Diagnostics Classification (RDC 206/06)



Laboratory tests in ANVISA recognized institutions for detection the following disease:

- Chagas;
- Hepatitis types B and C;
- HIV/AIDS;
- HTLV;
- Syphilis;
- And Immunohematology Reagents (not disease).

ANVISA Good manufacturing practices (GMP) certification = All Registrations (not for Record);

- **3th- party device certification** by accredited bodies (Using the net laboratories of 'International Laboratory Accreditation Cooperation' - ILAC) = mandatory for some devices (Ex.: Family IEC 60601, gloves, condoms, blood bags, intrauterine contraceptive device);

- **Technical Analysis** from Anvisa, based on the International Standards and Risk Analisys = For all medical devices;

- **Establishment Registration for all medical device establishment** (manufacturers, importers, distribuitors,...)**;**

- **Medical Devices Tracking**
  - Implantable pacemaker pulse generator;
  - Knee and hip implants;

- **“Clinical Trials”:**
  - New technology and intended uses;
    - Needs pre-approval;
    - Used on human to collect safety and effectiveness data;
    - Protection of human subjects.

- **NOTIVISA =** WebSystem for Adverse Event Reports;
  - **Mandatory Adverse Event Reporting rules (RDC 67/09);**
    - Events: Death, Serious Injury and Malfunction with potential serious injury;
    - Reported by: Manufacturer, Healthcare Facility (not yet), and Importers;
  - **Sentinela Project =** Hospitals with special notifications status, because they have additional support from ANVISA;

- **ECRI's Database for Post-Market Monitoring;**

- **SISTEC =** WebSystem for Alert Publishing;

- **Recalls rules in development;**

- Local Authorities may create regional regulations;

- Risk management decentralized to states and municipalities;

- Federal regulations are mandatory to public and private healthcare facilities;

- Main training programs in healthcare regulations:
  - Infection controls;
  - Infrastructure and building specifications;
  - Risk Management in Healthcare Technology;

Essential Principals of Safety and Effectiveness

- Defined by **RDC 56/01**, establishes the essential requirements that the device must comply with, in order to receive Anvisa approval.

Essential Principles

1. Use of medical devices not to compromise health and safety;
2. Design and construction of medical devices to conform with safety principles;
3. Medical devices to be suitable for intended purpose;
4. Risk Management to be implemented in order to control inacceptable risks;
5. Medical devices not to be adversely affected by transport or storage;
6. Benefits of medical devices to outweigh any undesirable effects;

Essential Principles

(cont.)

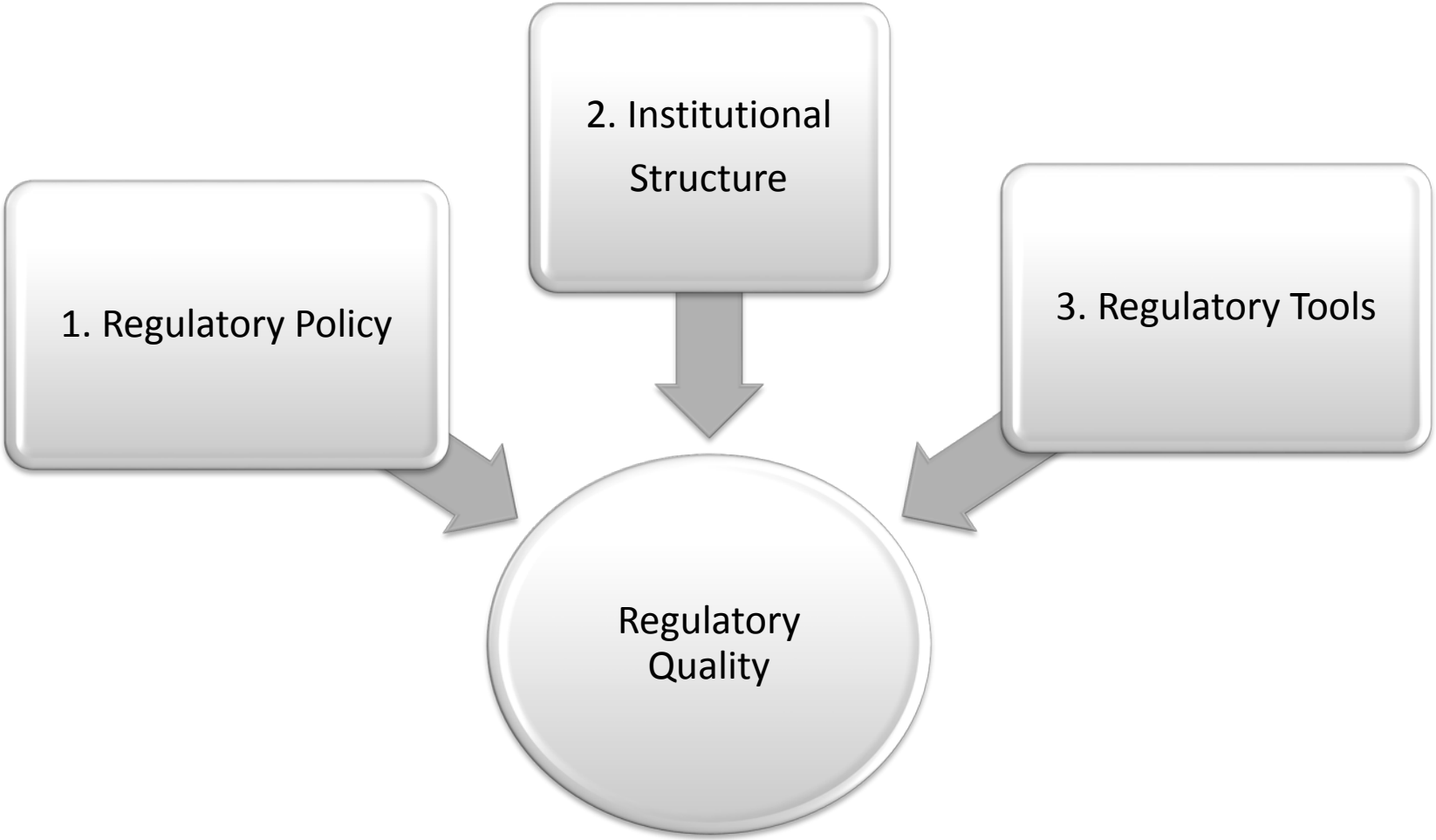
7. Chemical, physical and biological properties;
8. Infection and microbial contamination;
9. Construction and environmental properties;
10. Medical devices with a measuring function;
11. Protection against radiation;
12. Medical devices connected to or equipped with an energy source;

Registration of Medical Devices

- It is submitted by domestic manufacturer or importer (this last, on behalf of the foreign manufacturer);
- Requests a comprehensive documentation, including all technical data and tests about the device, and for some types of devices, clinical data are also requested;
- Requirements defined by RDC 185/01 (nIVD) and RDC 206/06 (IVD);
- GMP Certification shall be obtained before the submission of the registration application.

CHALLENGES

How to increase regulatory quality?



Source: Adapted from Rodrigo, Délia. "Calidad regulatoria en un contexto federal: herramientas y políticas" Extraordinary Meeting of Subgroup GTVS/CIT, Brasília, 2010.

MANAGEMENT MODERNIZATION

Premises

- Provide stable, predictable and efficient regulatory environment;
- Ensure access to health technologies that are effective, safe and of quality;
- Enlarge competitiveness and investments of the health industry, particularly those important innovative technologies applied at the Unified Health System (SUS).

Objectives

1. Enlarge ANVISA operational capacity;
2. Modernize health regulatory framework;
3. Simplify internal processes and focus on actions of ANVISA decided by health risk management;
4. Expand ANVISAs' cooperation with other international agencies.

MORE EFFICIENCY, MORE HEALTH AND MORE ECONOMICAL AND SOCIAL DEVELOPMENT

Adoption of Decree 8077/2013 which replaced Decree No. 79.094/77 and regulated Law No. 6.360/76

This Act is the basis for the regulation of Law No. 6.360, of 23 September 1976, which is the main health surveillance law.

The new Decree allows ANVISA to define requirements that are compatible to the current regulatory and technical environment. The previous decree had 171articles. The current version has 25 articles.

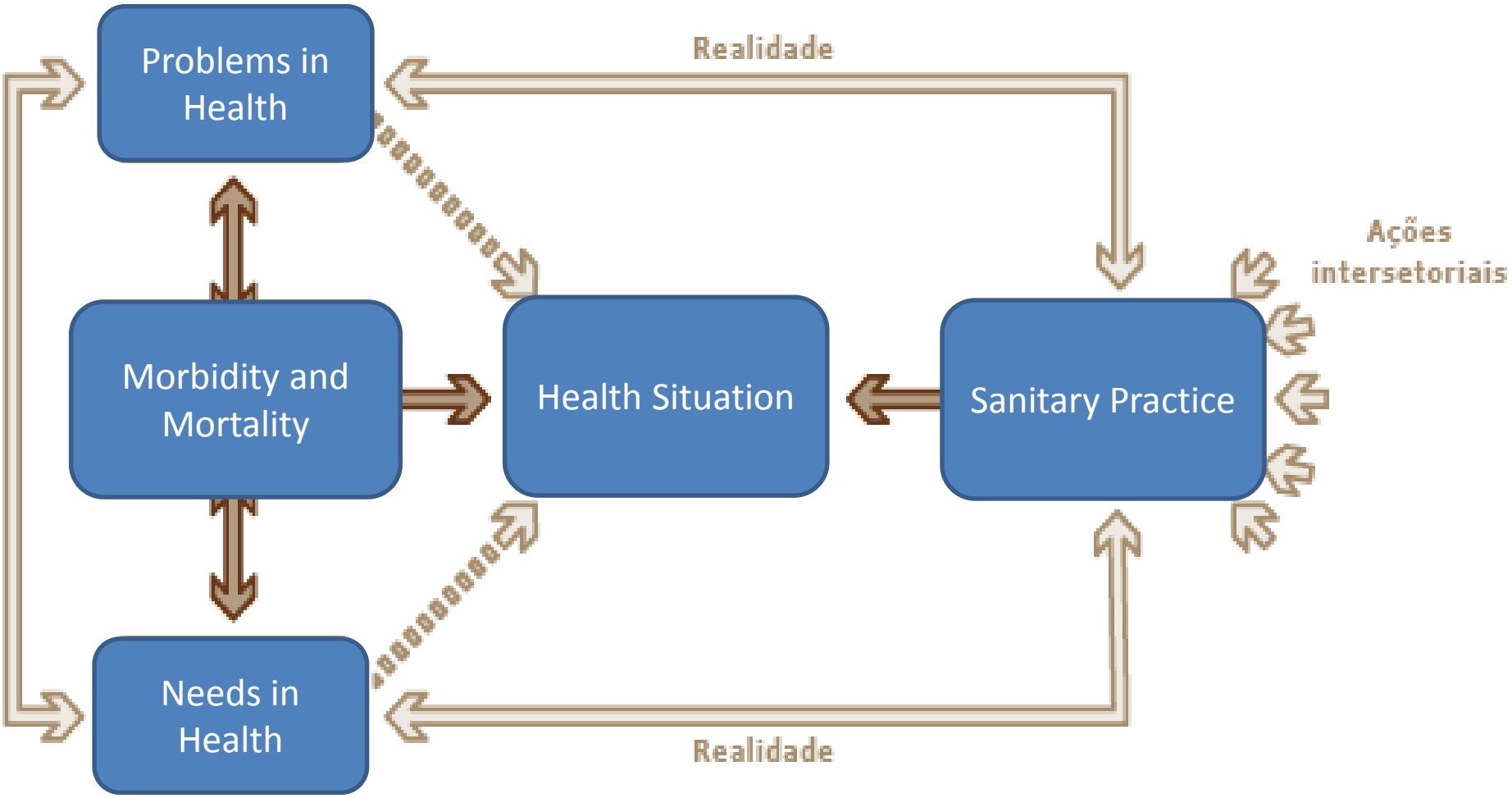
MORE EFFICIENCY, MORE HEALTH AND MORE ECONOMICAL AND SOCIAL DEVELOPMENT

Strategic Actions

- Strategic Approach with foreign authorities;
- Following of technology transfer processes, considered strategic by the Ministry of Health of Brazil;
- Participation on technical forums of international reference (such as IMDRF)
- Adoption of joint work programs with other authorities to increase control of medical products (such as MDSAP)
- Regional Discussions (Mercosur) and follow on negotiations related to health and trade (WTO).
- Strategic Projects of evaluation of Medical Device;
- Professional Qualification – 25/43 – Masters, 4/43 doctors.

MORE EFFICIENCY, MORE HEALTH AND MORE ECONOMICAL AND SOCIAL DEVELOPMENT

Health Situation and Sanitary Practice (social answers)



Source: Adapted from Castellanos, 1995.

Control of Risk: Hazard X Risk

Clinical Hazard Classification
(Human Physiology affected)

Device Hazard Classification
Contact
Substance
Energy
Information
Biologycal Materials
Enviromental Condition
Patient/User/Health Service

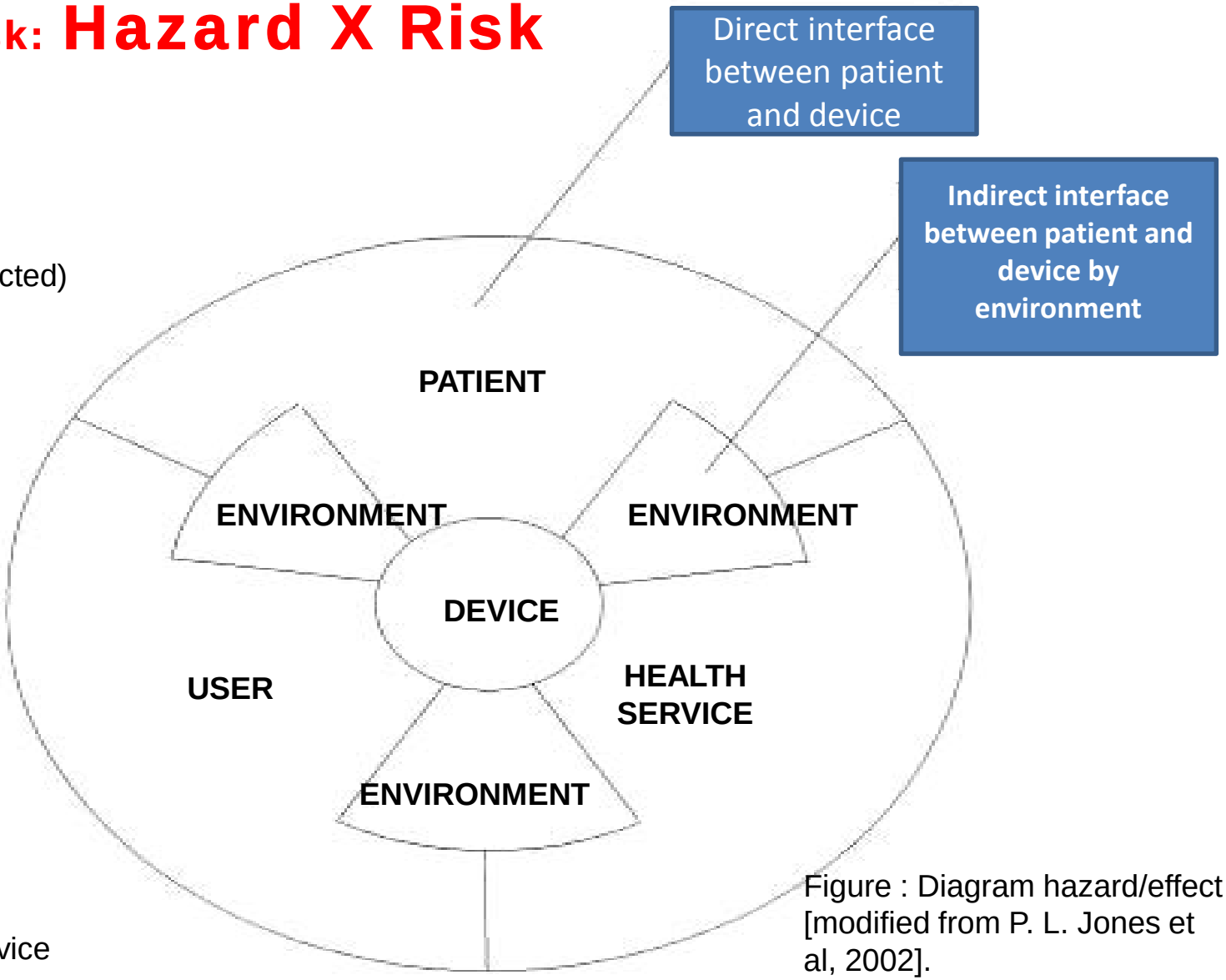
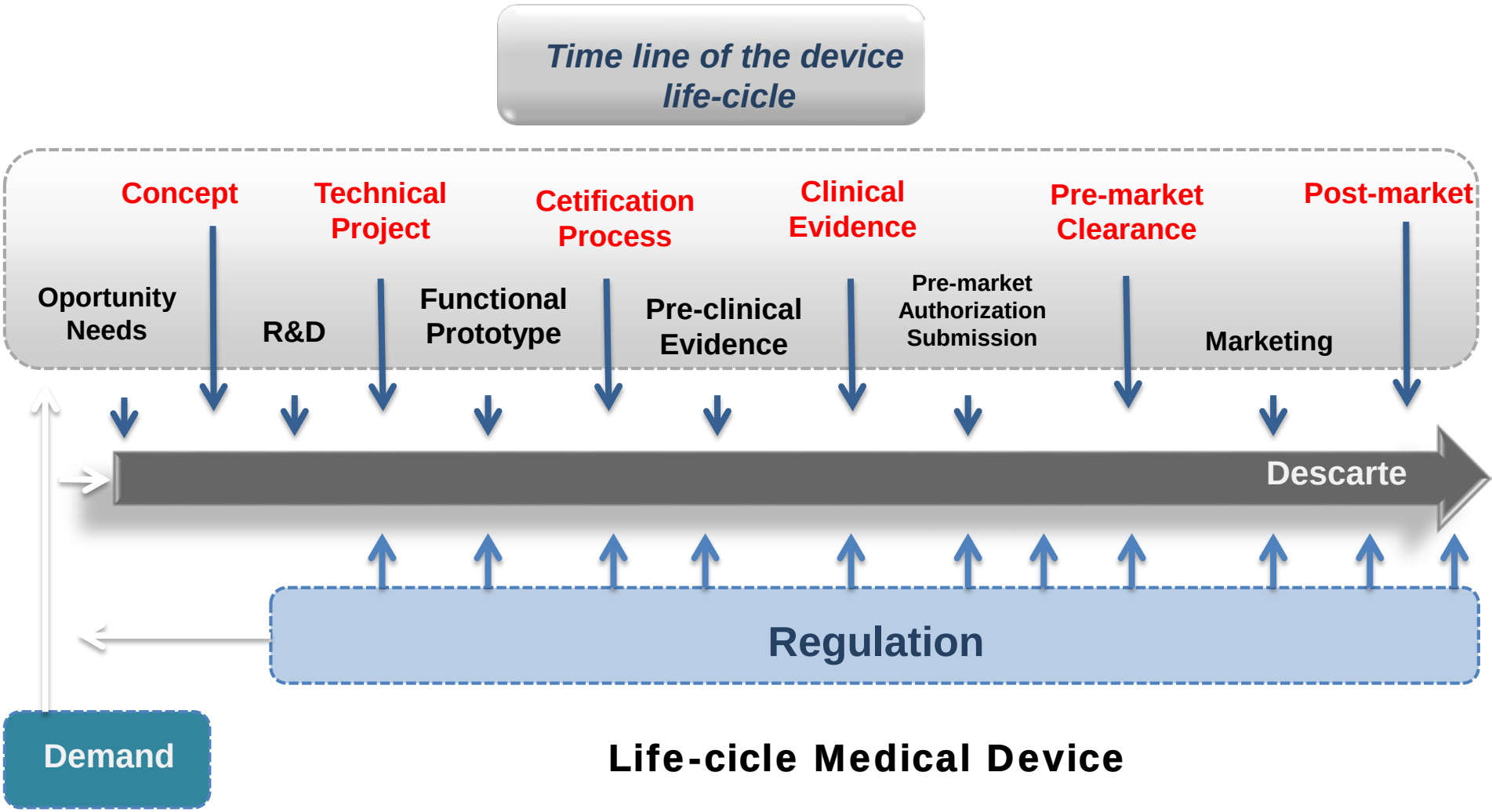


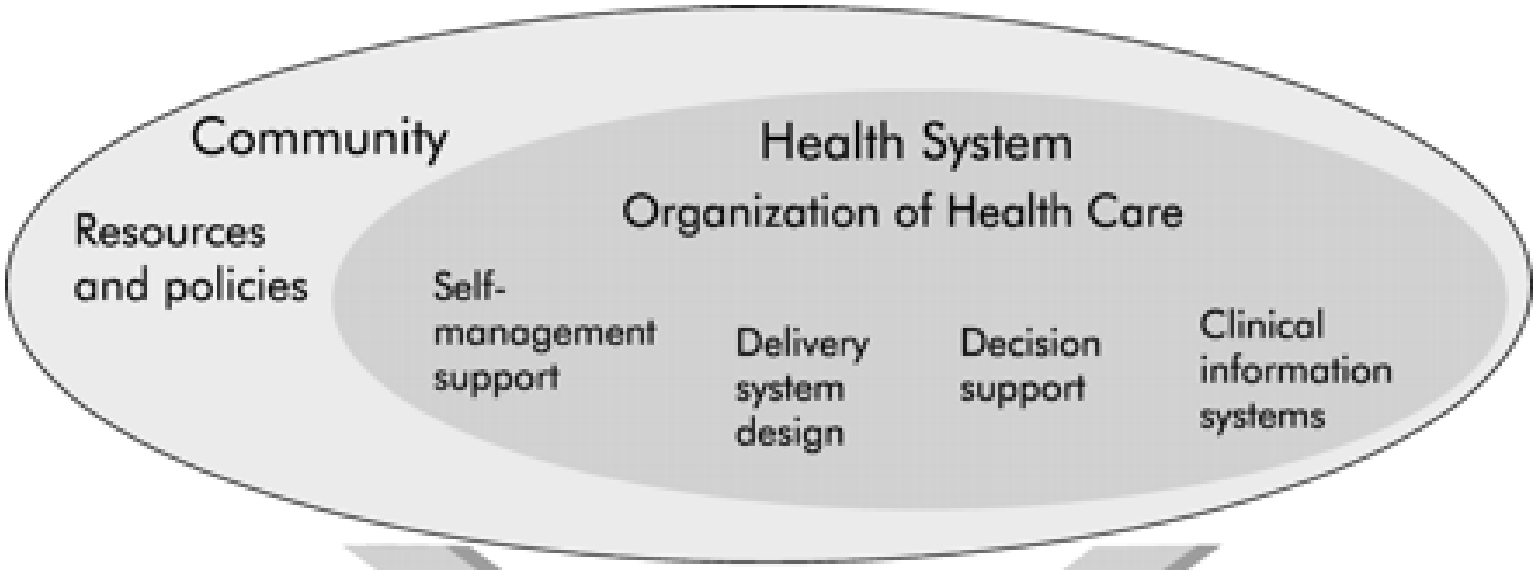
Figure : Diagram hazard/effect [modified from P. L. Jones et al, 2002].

Productive Chain- Evidence for Sanitary Regulation



Life-cicle Medical Device

- MODEL OF ATTENTION TO CHRONIC CONDITIONS



Manufacturer Distributor

Productive interactions

Health Sevices, Hospitals, Health Departments

RISK

RISK

Technology Performanc

Clinical and Functional Results

Source: WAGNER (1998), addapted


1825

Thank You!

Joselito Pedrosa

GGTPS@anvisa.gov.br

(61) 3462- 6504

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Agência Nacional de Vigilância Sanitária