Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

Virtual Meeting
Regulation for IVD

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Disclaimer

The views and opinions expressed in this session are those of the individual presenter and should not be attributed to the organization with which the presenter is employed or affiliated.

Perspectives for IVD

Background

The regulations in Peru for In Vitro Diagnosis (IVD) are 24 years old: Supreme Decree No. 010-97 (*)

CLV
Technical Specifications
Primary and Secondary Labeling
Insert

Requirements

- Class M10
- Sub-clasification according to usage
  (Hematology, Immunology, Chemistry and Biochemistry, Nuclear Medicine, Serological, Toxicological, Molecular Typing, etc.)

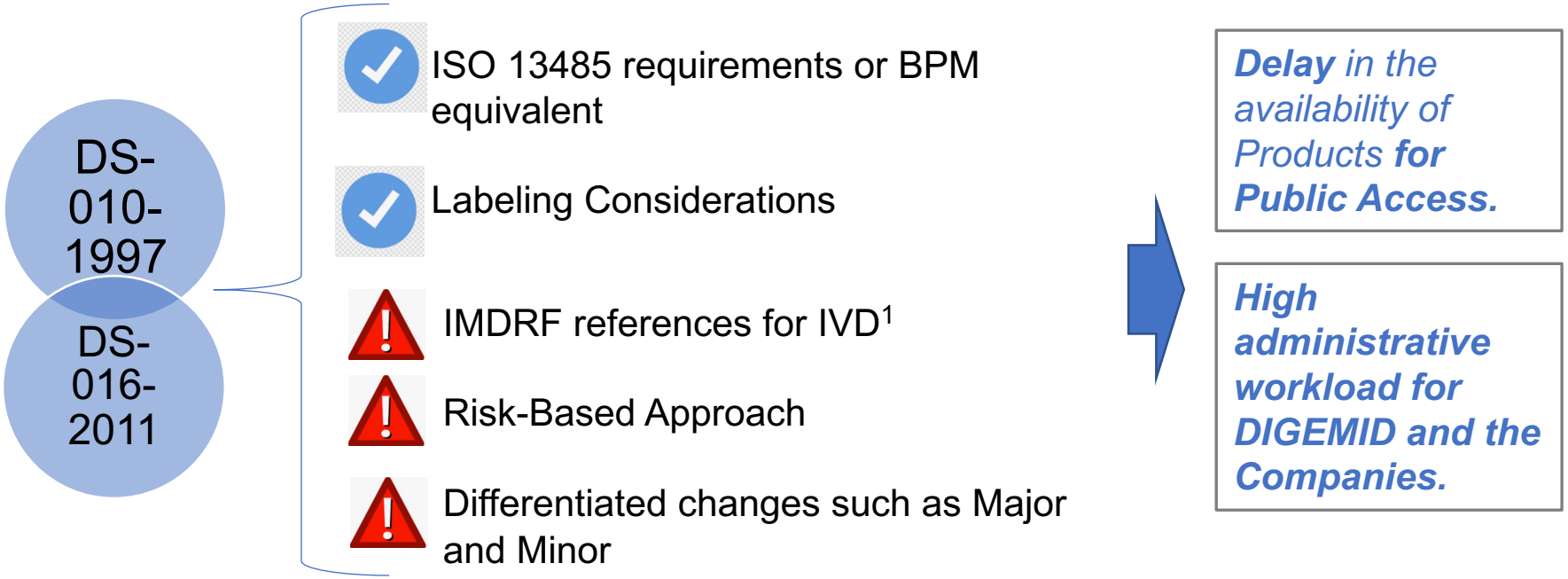
Classification

(*) Effective again with DS-001-2012 - First Transitional Final Provision

Panorama for IVD

Current Situation

The regulations for IVD are based on DS-010-97 and DIGEMID adopts certain criteria of DS-016-2011 and amendments.



[1]http://www.imdrf.org/documents/documents.asp

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Panorama for IVD

Future Situation?

Challenges in IVD Regulation

Change Boosters

Regulations worldwide are changing and evolving…

- **IMDRF:** Adaptation to technical/scientific progress needed
  - ✓ Combination of Devices/Drugs.
  - ✓ "Companion diagnostics"
  - ✓ Decentralized management of hospital-to-home health alternatives.
  - ✓ Digitalization of health: E-Health and m-Health
- **IVDR EU**
  - ✓ Countries interpreted the rules differently reinforcing the need to establish a regulation interpreted in the same way to standardize criteria.
- **GLOBALIZATION**
  - ✓ Good Regulatory Practices[1] (GRP) and Good Reliance Practices (GRelP)[2].

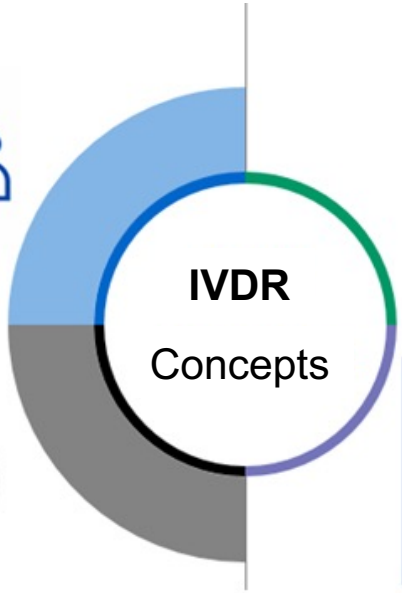
[1] https://www.interamericancoalition-medtech.org/regulatory-convergence/policy/medical-device-sector-regulatory-convergence/documentos-de-la-organizacion-mundial-de-la-salud/buenas-practicas-regulatorias/?lang=es.
[2] https://www.interamericancoalition-medtech.org/regulatory-convergence/policy/medical-device-sector-regulatory-convergence/documentos-de-la-organizacion-mundial-de-la-salud/buenas-practicas-de-reliance/?lang=es.

Overview of challenges in IVD Regulation

Good principles but with several factors that will be known in the implementation.

Risk-based approaches

Global Convergence



The conundrum we have

What are the local challenges for the implementation of a robust IVD regulation in Peru?

IVD Regulation Overview

Modern Regulatory Pathways

ANMAT
Agile Modifications

INVIMA
Regulatory Framework for Post-Approval Changes

ARCSA
Expedited Process for Approval by Reference Authorities

Overview of IVD regulation

Key additional elements of modern, flexible regulation

- **Reliance and Recognition.** Crucial concepts that optimize resources of the health authority without lowering the regulatory standard.
- **Good Regulatory Practices.** To ensure that regulations and standards are convergent where appropriate and administrative practices exist that allow for collaboration.
- **Expedited Ways of Approval and Emergency Use.** To ensure that patients have timely access to innovative treatments.
- Innovative approaches to clinical evidence, such as using accurate clinical databases, **Real World Evidence (RWE)**, and reliance on external data for regulatory decision-making.
- Manufacturer-based **Software Pre-Certification** Programs.

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IVD Regulation

Patient-centered approach

Industry and regulators *in the region will need to ensure that* ***patient's*** *access to* ***timely diagnosis*** *and* ***improved healthcare*** *can continue without interruption or delay.*

Thank you for your attention

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Thank you