



IMDRF International Medical Device
Regulators Forum



25 YEARS AND BEYOND

30th IMDRF 2026

Day 2 IMDRF Stakeholder Forum | 15 September 2026

ANMAT – NATIONAL INSTITUTE OF MEDICAL DEVICES

REGULATORY UPDATE ON MEDICAL DEVICES IN ARGENTINA

Building Regulatory Capacities

Lorena Terrizzano, Eng.
National Director

IMDRF – Singapore
September 2026



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★ FROM PRIOR CONTROL TO AN EX POST RISK-BASED CONTROL MODEL



This new approach does not entail a decreased responsibility of the regulatory agency, but rather more efficient control.

★ NEW MEASURES IMPLEMENTATION IN NUMBERS



111

COMPANIES Licensed via affidavit

Regulation 8799/25



253

CLASS I AND II PRODUCTS Registered by a simplified procedure

Regulation 236/26



10.719

IMPORT NOTICES Operations with no prior authorization

Regulation 4446/25



★ TOWARDS A MORE ACTIVE POST-MARKET SURVEILLANCE

TECHNOVIGILANCE REPORTS

**120**

Adverse events

**249**

Failure reports

FROM REPORT TO ACTION

**REPORTS****RISK PROFILES****PRIORITIZATION****ACTION**

• Vigilance

• Monitoring

• Regulatory response



A more robust and active post-market surveillance with an increased response capacity

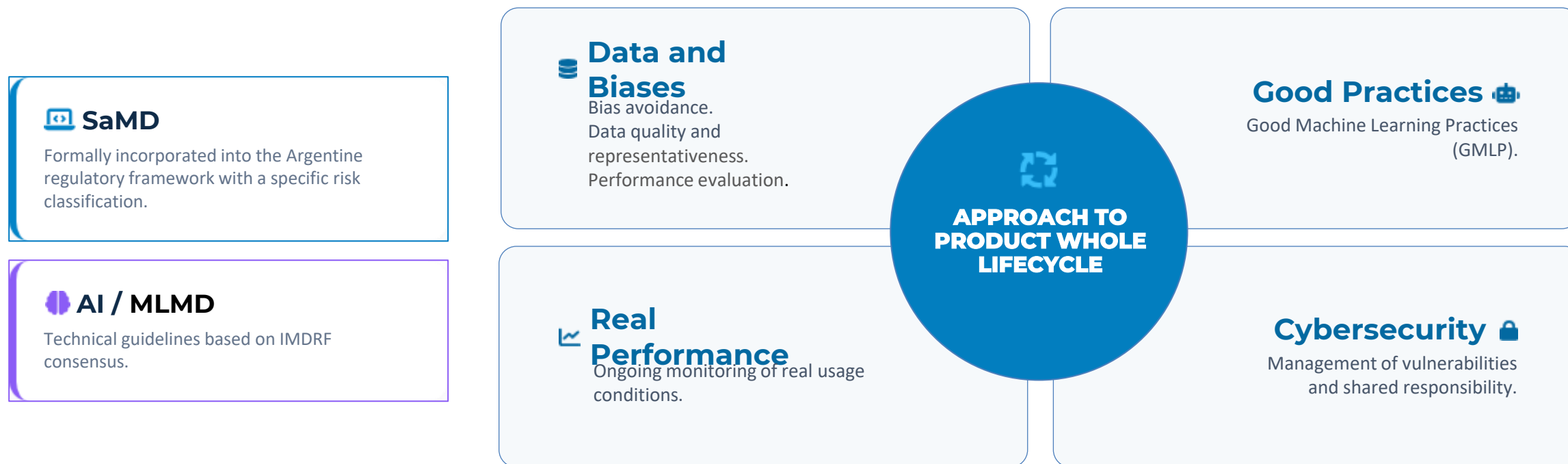


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★ NEW REGULATORY CHALLENGES: SOFTWARE AND AI



Technical guidance based on international / IMDRF principles



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HSA
Health Sciences Authority

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★ REGULATORY COOPERATION IN THE AMERICAS



TRAINING AND TECHNICAL EXCHANGE

Training performed on September 3, 2026: Argentina's experience in the implementation of Medical Devices Post-market Surveillance.

-  Sharing experiences and regulatory tools
-  Strengthening common capacities in the region
-  Promoting international regulatory convergence



★ BUILDING REGULATORY CAPACITIES

A lifecycle-oriented risk-based system, which is internationally integrated and capable of going along with innovation



INFORMATION

Intelligent use



RISK

Detection and
consistent action



LIFECYCLE

Integral perspective



INNOVATION

Adaptation to changing and
evolving technologies



COOPERATION

Regulatory convergence



★ FINAL REMARK

"Regulatory transformation brings about new challenges and new capacities, with one single purpose: to protect public health."