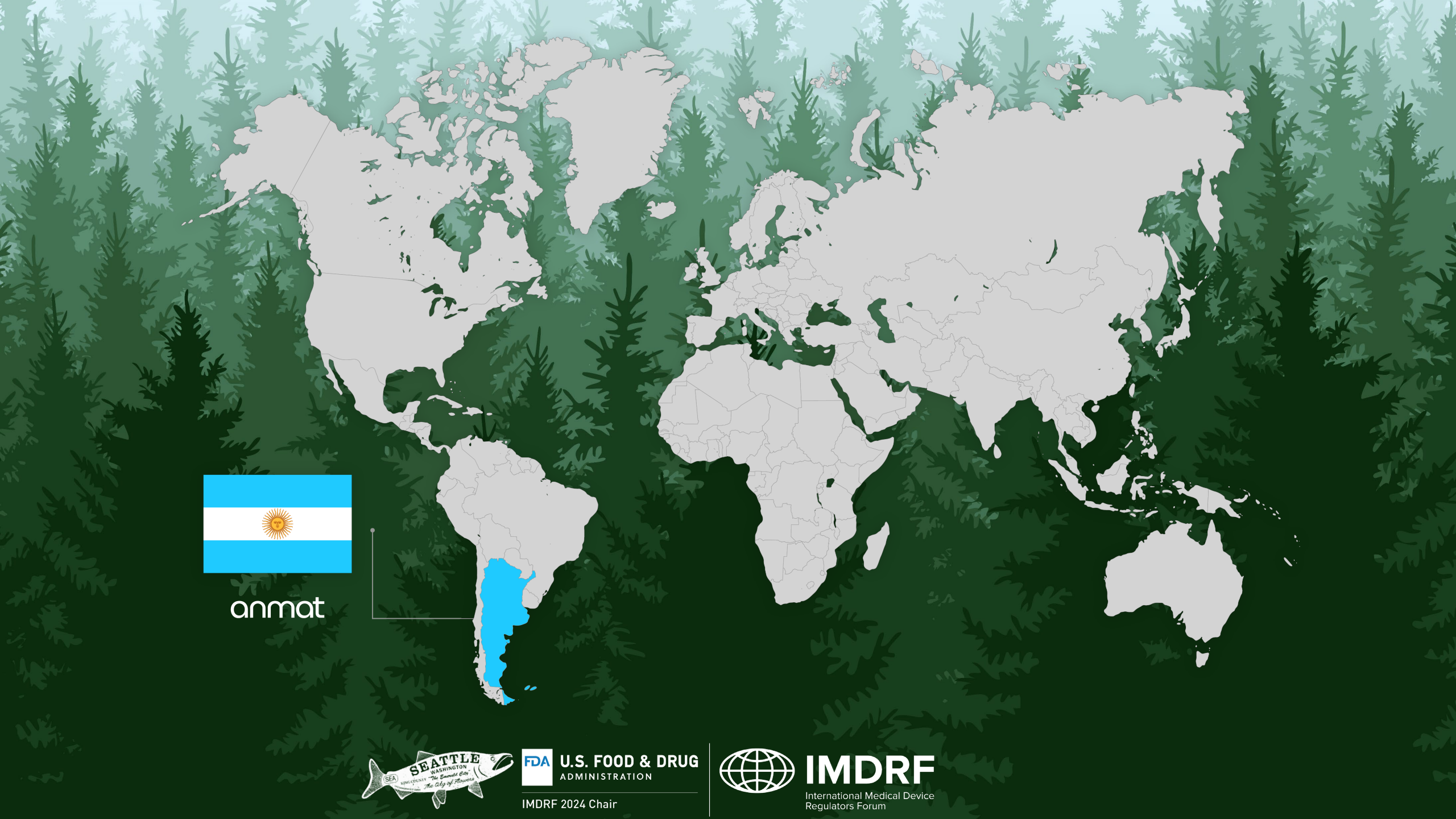
IMDRF International Medical Device Regulators Forum | 26th Session

Regulatory update ANMAT - ARGENTINA

Lorena Terrizzano
National Director - National Institute of Medical Devices
National Administration of Drugs, Food and Medical Devices – ANMAT



SEATTLE WASHINGTON
SEA KING COUNTY "The Emerald City" The City of Flowers

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF
International Medical Device Regulators Forum

Essential Principles of Safety and Performance

- Harmonized in MERCOSUR 

- Currently in the process of transposition into the Argentine regulatory framework.
- Internal and external trainings.

Based on: IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices.

Software Regulation

Based on:

IMDRF/SaMD WG/N23 Software as a Medical Device (SaMD): Application of Quality Management System
IMDRF/AIMD WG/N67 Machine Learning-enabled Medical Devices: Key Terms and Definitions
IMDRF/SaMD WG/N10 Software as a Medical Device (SaMD): Key Definitions

ARGOS Post-market Surveillance System

October 2023 – August 2024

Procedures

Serious adverse event	45
Field Safety Corrective Action	247
Post-marketing monitoring	1
TOTAL	**293**

Field Safety Corrective Action

Market recall	67
Product modification	180
TOTAL	**247**

SEATTLE · WASHINGTON · The Emerald City · The City of Flowers

U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF

International Medical Device Regulators Forum

Medical Device Post-marketing Vigilance

- Developed in the framework of MERCOSUR.
- Harmonized in the ordinary meeting of the Pro-Tempore Presidency held by Uruguay (PPTU), September 2024.
- Recommendation for Member Parties.

Based on the WHO document *Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics (2021)*.
Takes as reference
IMDRF/AEWG/N43 IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes
IMDRF/AE WG/N44 Maintenance of IMDRF AE Terminologies.

SEATTLE WASHINGTON
U.S. FOOD & DRUG ADMINISTRATION
IMDRF 2024 Chair
IMDRF
International Medical Device Regulators Forum

Guideline on Personalized Medical Devices

Draft started in MERCOSUR September 2024.

Based on:
IMDRF/PMD WG/N49 FINAL:2018 Definitions for Personalized Medical Devices
IMDRF/PMD WG/N58 FINAL:2020 Personalized Medical Devices - Regulatory Pathways.

Technovigilance Inspections

MERCOSUR working document on Technovigilance Inspections, beginning of drafting in September 2024.

Based on WHO document Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics (2021).

Initiative to foster innovation in Argentina

REGULATORY ASSISTANCE PROGRAM FOR RESEARCH AND DEVELOPMENT OF HEALTH PRODUCTS
RA R+D

This program is intended to foster information flow and contact by stakeholders with ANMAT technical areas.

SEATTLE WASHINGTON "The Emerald City" The City of Flowers

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF International Medical Device Regulators Forum

Training

Participation as trainers

- Specialization Course in Design and Development of Medical Devices. UNER. May 2023.
- XI Regional Meeting on Medical Devices Regulation, October 2023.
- Course “Introduction to the competencies of the inspector in GMP in Medical Devices” - Phase II - Mercosur. October 2023.
- Strengthening Medical Devices regulatory capacities. DINAVISA and ISP, 2024.

Career design and implementation

- Master´s Degree Program on Health Product Regulatory Sciences. School of Pharmacy and Biochemistry, UBA. Since March 2020.

Next steps

- Implementation of IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices.
- Finalization and publication of the Guide Software as a Medical Device (SaMD) and Machine Learning Medical Devices (MLMD) –> late 2024/early 2025.
- Public consultation on the Guidelines on post-marketing clinical follow-up of registered products.
- Development of an information-gathering instrument intended to supplement the current database on personalized medical devices.
- Planning of the implementation of cybersecurity documents *N70 Principles and Practices for the Cybersecurity of Legacy Medical Devices* and *N73 Principles and Practices for Software Bill of Materials for Medical Device Cybersecurity.*
- MERCOSUR working documents on technovigilance inspections and personalized medical devices.

anmat | Ministerio de Salud
República Argentina

SEATTLE WASHINGTON
SEA KING COUNTY "The Emerald City" "The City of Flowers"

FDA U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF
International Medical Device Regulators Forum

U.S. FOOD & DRUG ADMINISTRATION

IMDRF 2024 Chair

IMDRF
International Medical Device Regulators Forum

THANK YOU

relaciones.internacionales@anmat.gob.ar
lorena.terrizzano@anmat.gob.ar