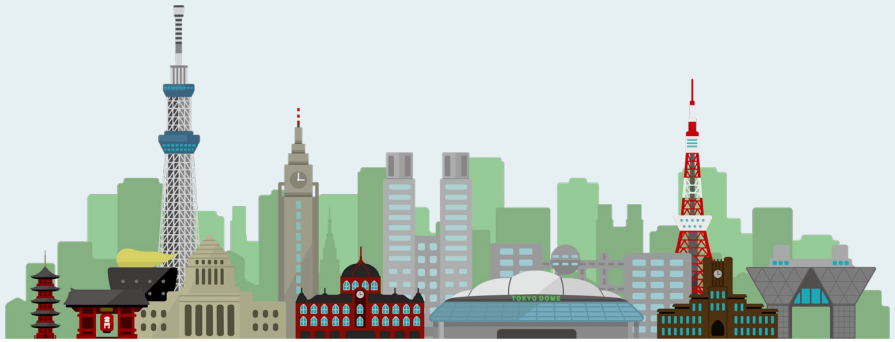
IMDRF International Medical Device Regulators Forum



Regulatory update
ANMAT - ARGENTINA

Lorena Terrizzano
National Director - National Institute of Medical Devices

IMDRF International Medical Device Regulators Forum

Reliance

Vision

"To be a national and international leading technical and scientific health authority which is innovative, opportune, reliable and committed to the health of the Argentinians and the world".

Working Group

"Good Regulatory Review Practices" (GRRP)

- Takes as reference ANMAT´s "GOOD RELIANCE PRACTICES".
- We intend to develop a reliance manual specific to medical devices.

MERCOSUR

Harmonizing the criteria for facilitating the inter-regional commerce of these products with due compliance with the safety and efficacy standards that protect users

Incorporation of new regulations into the National Legislation

- Mercosur Technical Ruling on the Registration of Medical Devices".
- Mercosur Technical Ruling on Essential Safety and Performance Requirements for Medical Devices and In Vitro Diagnostic Medical Devices".
- Common Procedures for Inspections on Medical Devices and In Vitro Diagnostic Medical Devices

SaMD

Development of a "Software as a Medical Device (SaMD)" Guideline

- Redefinition of classification rules to incorporate software as classes III and IV
- Updating of essential requirements to evaluate its safety and performance
- Publication of IMDRF SaMD technical documents

REDESIGN OF SaMD GUIDELINE

Personalized medical devices (1)

MERCOSUR: we are working on the development of a “Personalized Medical Devices” working document

- Definitions of Personalized Medical Device (custom-made medical device, patient-matched medical device and adaptable medical device)
- Regulation proposal to include aspects related to pre-market and post-market requirements
- Annex with examples.

Personalized medical devices (2)

INSTRUMENT FOR COLLECTING DATA on Personalized Medical Devices

- Online questionnaire intended for manufacturers and importers of customized medical devices in Argentina.
- It will allow to update our data bases to gather valuable and precise information.

Post-market vigilance

ARGOS library with public access to adverse event reports and Field Safety Corrective Actions

ARGOS

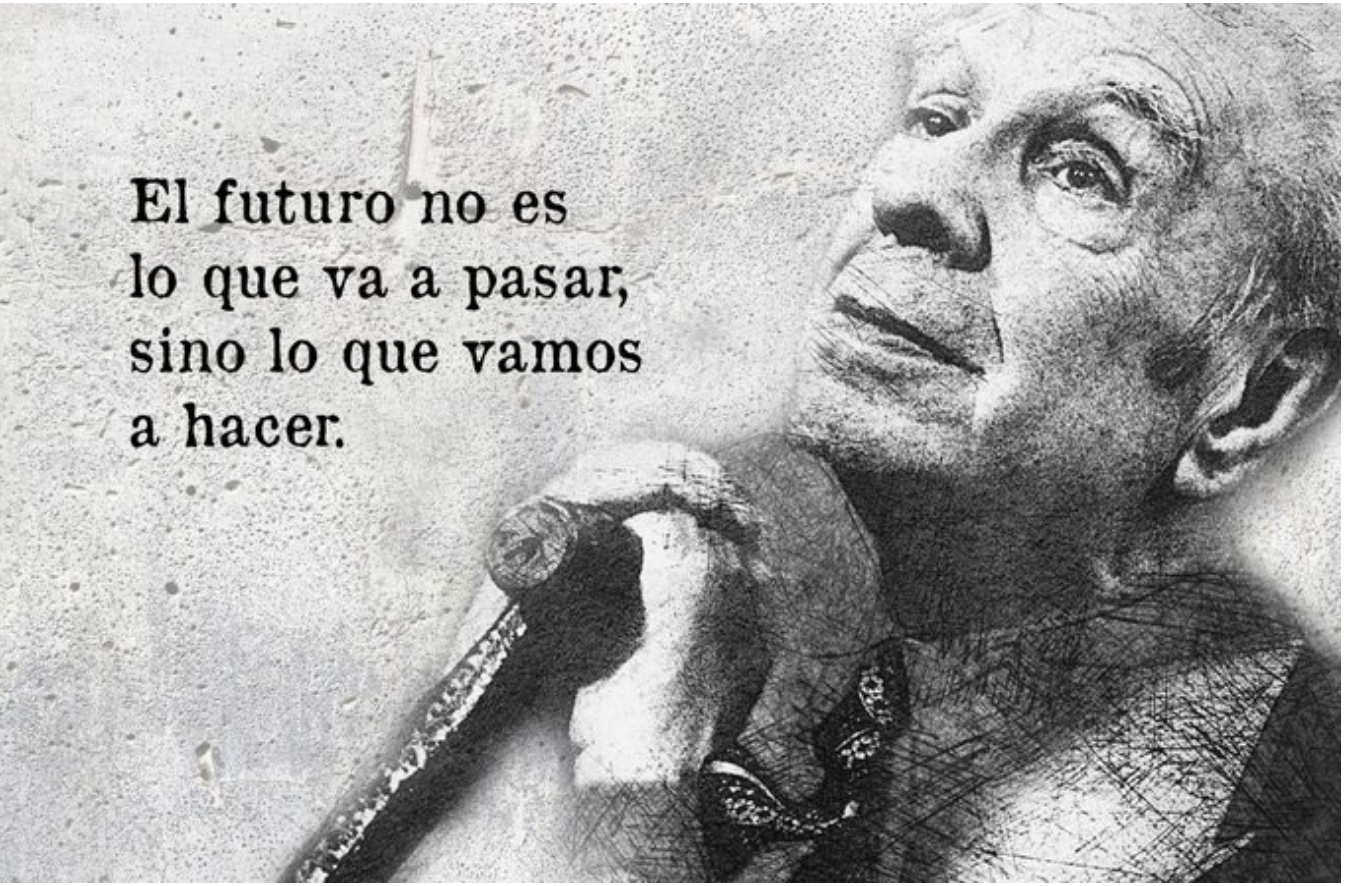
- Reinforces transparency and access to information on medical devices safety in the country.
- Contributes to international cooperation on collection of information about adverse events.

MERCOSUR

- A post-market vigilance recommendation document was finalized.
- A technovigilance inspection guideline started to be developed.

Challenges and next steps

- To implement a reliance manual specific to medical devices.
- To redesign and publish the SaMD Guideline.
- To finish the draft document on the regulation of “Personalized medical devices” and submit it for public consultation in MERCOSUR working group.
- To collect and analyze the feedback on “Personalized medical devices” public consultation.



"Future is not what will happen, but rather what we are going to do".

Jorge Luis Borges
(Argentine writer)

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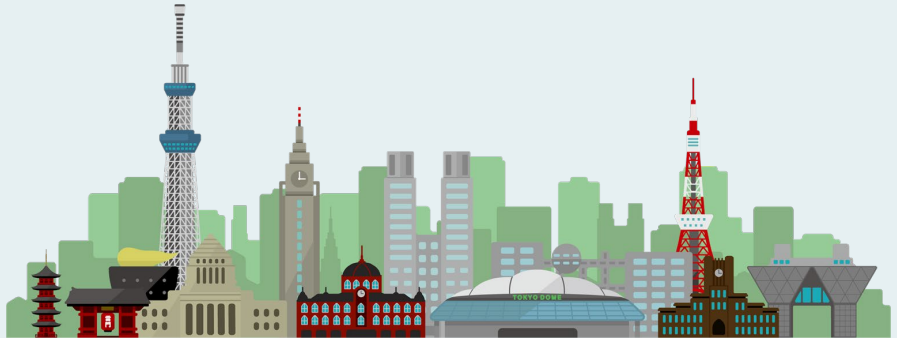

Thank you!