

**e-IFU: Strategies
to implement as
general practice**

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INTER-AMERICAN COALITION FOR
**REGULATORY
CONVERGENCE**

MEDICAL TECHNOLOGY SECTOR



ANNIVERSARY

e-IFU Working Group

Problem Statement

- Some countries in LATAM do not accept e-IFU, however, it is a trend adopted for many companies

Main Objective

Provide documents/position that support the strategies to advocate e-IFU adoption across the countries.

LATAM state of art

| GROUP | COUNTRY CLASSIFICATON | COUNTRIES | STRATEGY |
|---------|--|--|--|
| Group 1 | Regulation indicates IFU must be physically with the product, it means a regulatory restriction to adopt e-IFU. | Colombia-IVD, México, Paraguay – MD, Peru | Advocacy for regulation change |
| Group 2 | Regulation does not mention IFU release method, it generates uncertainty regarding e-IFU adoption | Argentina, Bolivia, Costa Rica, Dominican Rep., El Salvador, Guatemala, Honduras, Nicaragua, Panamá, Uruguay | Request an official position |
| Group 3 | Despite regulation includes e-IFU option (Digital IFU), it is not explicit, or regulator do not accept to replace paper IFU by e-IFU | Colombia – MD Ecuador | Advocacy for clarifying interpretation of regulation |
| Group 4 | Regulation accept e-IFU for some products, however it is considering the scope is not enough | Brazil Chile* | On hold – depend on need |
| Group 5 | Regulation already accept e-IFU | Paraguay - IVD | Not applicable |

---- Regulation draft included e-IFU. Awaiting for final regulation to reclassify them.

----- Countries classification under revision

* It is not a fully regulated country

General activities

| | | | 2025 | | | | | | | 2026 | | |
|-----|--|-------------|------|-----|-----|-----|-----|-----|-----|------|-----|-----|
| | Activity | Estatus | May | Jun | Jul | Aug | Oct | Nov | Dec | Jan | Feb | Mar |
| 1 | Compiling state of art | Completed | | | | | | | | | | |
| 2 | Discussion position papers available | Completed | | | | | | | | | | |
| 3 | Main concerns of Health Authorities | In progress | | | | | | | | | | |
| 3.1 | Internet connection | Completed | | | | | | | | | | |
| 3.2 | Users do not feel comfortable with e-IFU (Survey) | In progress | | | | | | | | | | |
| 3.3 | IFU printed on demand | Completed | | | | | | | | | | |
| 3.4 | Version control | Completed | | | | | | | | | | |
| 4 | Position document to recommend e-IFU | In progress | | | | | | | | | | |
| 5 | Consultation to Health Authorities countries group 2 | Not started | | | | | | | | | | |
| 6 | Define strategies for countries groups 1 & 3 | Not started | | | | | | | | | | |

Survey:

| Methodology | |
|-----------------------|---|
| Audience | Health Care professionals |
| Scope | Argentina & Colombia |
| Distribution strategy | Argentina: CAPRODI- ALAC (Released Aug-25) Colombia: ANDI (Pending release) |
| Data collection | 1 -2 months |
| Type of questions | Intended to understand what are the preferences of HCP regarding IFU (paper vs. e-IFU). |

- Lay user products excluded from survey.
- Survey already validated by HCPs into the companies.



THANK YOU

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