Reliance Experience in Mexico a Regional perspective

Sandra Ligia González
Executive Secretary, IACRC

Sample of Submissions via Abbreviated & Equivalence Agreements Pathways Still in Queue

Submission period	Devices	Reference authority
2025	• Device A • Device B	• US FDA • Brazil
January 2026	• Device C • Device D • Device E	• EU • US FDA • Brazil
February 2026	• Device F • Device G	• EU
March 2026	• Device H • Device I	• EU
May 2026	• Device J • Device K	• EU

Equivalence Agreements: USFDA, HC & PMDA*	
All Risk Classes	30
Abbreviated Pathways Agreement*	
All Risk Classes	30
Processes Simplification Agreement Traditional Pathway*	
Class I	20
Class II	25
Class III	35

*Working Days

Observations Noted in Practice

Public Health Impact	Administrative changes	Technical / manufacturing changes
Delays in reliance pathway can postpone access to authorized medical technologies in Mexico, even when the same devices & IVDs are being used by trusted reference authorities	Distributor additions and similar low-risk updates frequently require very long approval times, limiting continuity even when device risk and intended use are unchanged	Some amendments and manufacturing-site changes require approval before importation, which can increase the risk of supply interruptions

Opportunities

- Make reliance risk-based and operationally predictable
- Publish publicly available timeline metrics
- Strengthen alignment with international best practices
- Move away from re-performing extended assessment already completed by a trusted authority
- Apply efficient reliance principles to post-approval changes, including product and manufacturing site changes
- Strengthen technical capacities at all relevant stakeholders

IMDRF Playbook for Medical Device Regulatory Reliance Program, IMDRF/GRRP WG/N89, February 2026.