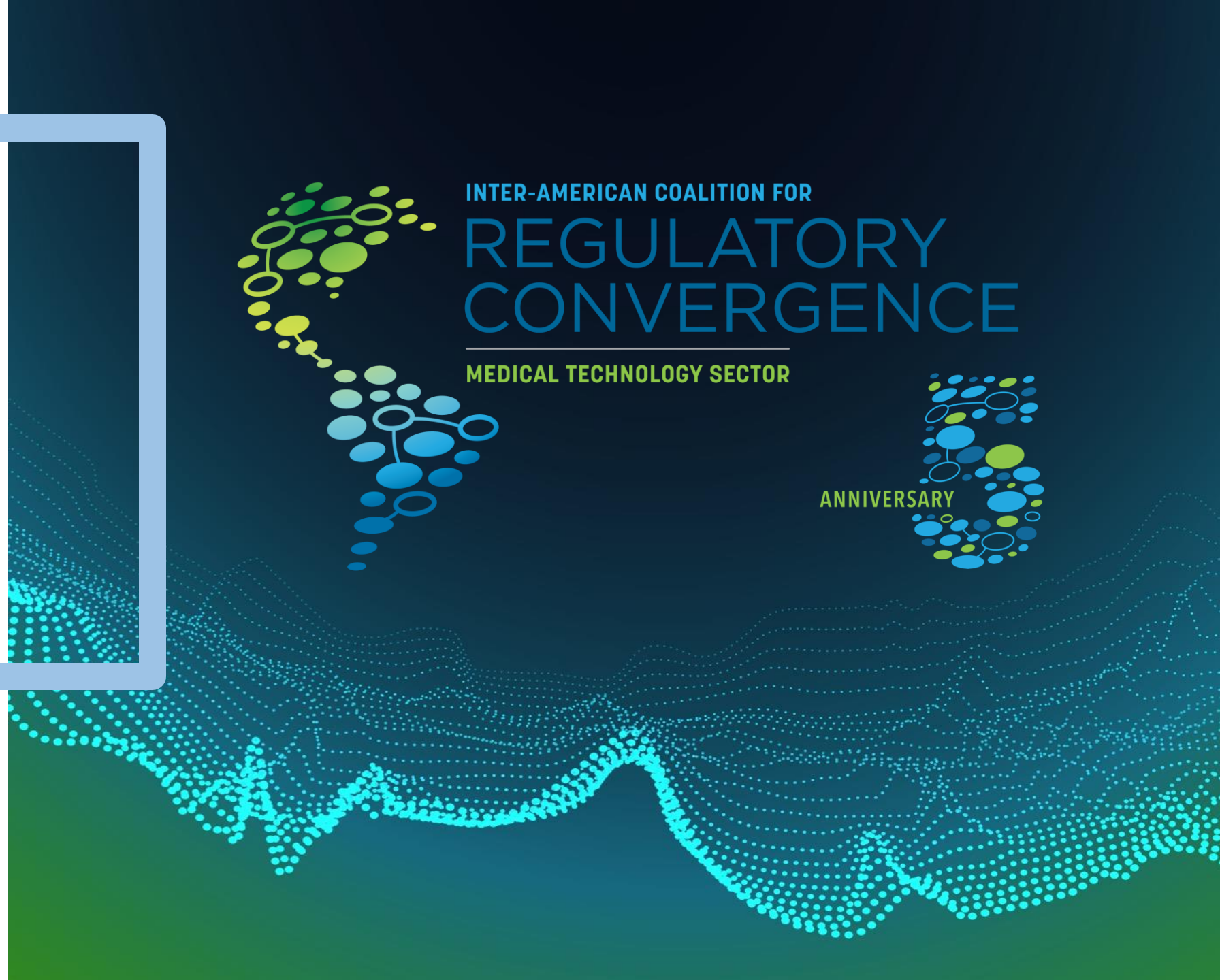
CFG / FSC Apostille

08-May-25



Working Group:
CFG & FSC – Apostille

14-NOV-2024

INTER-AMERICAN COALITION FOR
REGULATORY
CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

CFG & FSC – Apostille.

Strategies to simplify and eliminate the requirement

One standard, one test, accepted everywhere for any medical technology scope

– EXECUTIVE COMMITTEE

Main Objective

Develop strategies to work with LATAM regulators to:

- ***Accept electronic CFG/FSC (document and apostille);***
- **Remove the requirements (when possible);**

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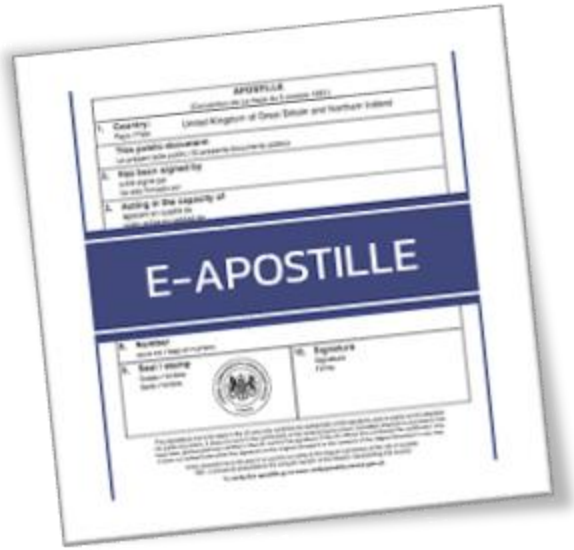
IACRC Position on CFG/CFS Acceptance

- **Acceptance of Electronic Certificates**: Countries requiring CFS/CFG should accept official electronic formats without Apostille or legalization requirements.
- **Removal of CFS/CFG Requirement**: authorities should eliminate the need for CFS/CFG if the medical device (MD) or in vitro diagnostic (IVD) is approved by internationally recognized regulatory bodies or exported to countries like the U.S. and Brazil that do not always require these certificates.



Rationale

- **Lack of Data:** No public data shows that Apostille requirements reduce falsified documents.
- **No Regulatory Impact Assessment (RIA):** No RIA conducted on the necessity of CFS/CFG. Apostille is not risk-based and modern digital tools offer better security.
- **Trust in NRAs:** Documents from trusted NRAs like FDA and ANVISA do not need further authentication.
- **Bottleneck:** CFG/CFS issuance and legalization can take weeks/months, delaying market authorization.

Challenges – CFG / CFS

Legal and Regulatory Variations: Different countries have varying legal requirements and standards for accepting these certificates.

Authentication and Verification: Ensuring the authenticity of these certificates is crucial. Some countries require extensive verification processes to confirm that the documents are genuine and not forged.

Harmonization of Standards: There is a need for international harmonization of standards and procedures to simplify the acceptance process. This involves cooperation between various regulatory bodies to establish common guidelines

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- Survey through TAs
- Define a strategy to influence small countries to accept electronic documentation.

- Share the document with a key regulator to ask feedback.
- Share WI with local TA and Regulators

ANVISA

Q1-2024

- Analyze all available position papers;
- Understand the impact in an informal way;

Map the impact per country of the e-CFG issued by FDA.

Q2-2024

Q3-Q4 2024

- Work in a document to support regulators to find approvals in key regulators websites.

Q1-Q2 2025

Q3-2025

- Keep Education work…

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Next steps…

Case Studies

- Collect and present data showing that CFG/CFS requirements do not significantly reduce the risk of falsified documents.
- Share practices from countries that eliminated CFG/CFS requirements without compromising safety or regulatory compliance.

Engage with Stakeholders

- Partnership with local Trade associations to collaborate with industry to create a unified voice

Leverage Technology / Education

- Demonstrate the effectiveness of digital tools in ensuring regulatory compliance
- Implement pilot programs to show the feasibility of eliminating CFG/CFS requirements

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THANK YOU

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CFG & FSC – Apostille

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