COALICIÓN INTERAMERICANA PARA LA CONVERGENCIA REGULATORIA
SECTOR DE TECNOLOGÍA MÉDICA

COALIZÃO INTERAMERICANA PARA CONVERGÊNCIA REGULATÓRIA
SETOR DE TECNOLOGIA MÉDICA

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE
MEDICAL TECHNOLOGY SECTOR

Inter-American Coalition for Regulatory Convergence, Medical Technology Sector External Stakeholder Session

14 March 2024

Notes

Scott Colburn, Director, Office of Readiness and Response USFDA/CDRH/OST

The Role of Manufacturers in Ensuring Quality, Safety & Performance (40 min) - **Regulatory Authority Views**

- Private Public Partnership with manufacturer, regulatory authorities (RAs) and the key stakeholders that are a critical of building the trust and confidence in ensuring quality safety and performance.

  Working with organization like:
  - Standards Developing Bodies (SDOs) and Conformity Assessment Bodies (CABs)
    - Participation at all levels and communicating with RAs on best approach on using standards.
    - Working with
  - Academia – driving research and innovation as well as areas of regulatory science convergence.
  - Health Care Providers (HCPs) and Patients providing feedback on how devices are meeting the needs for safety and quality.
- Regulators rely on manufacturers. to give RAs feedback on how regulations are not too burdensome and where convergence.
- Everything is better when the Quality Management System (QMS) is at the forefront of driving the total product lifecycle (TPLC) ○ Design and Development Planning, Inputs, Outputs, Verification and Validation,
  Commercialization, Post-Market and Design Changes
  - Risk Management ○ Patient safety
  - Supply chain management
    - Includes third parties like testing labs and ensuring that data is of high quality and true.
  - Continuous improvement
- RAs need to be clear and able to provide the high-level requirements to allow the proper guidance on what 'tools' are needed to demonstrate safety, performance and effectiveness for high quality medical devices.
  - Manufacturers need to be in continuous communication with RAs to ensure requirements are understood and can be met with undue burden and cost.