

Standards Alliance Phase 2 COVID-19 Medical Technology Regulatory Convergence (MDRC) Project Latin America

S T A N D A R D S A L L I A N C E - P H A S E 2



Overview

- Background – Standards Alliance
- Activity Focus: Standards and good regulatory practices for medical devices
- Standards Alliance Phase 2, Medical Devices and the COVID-19 Response



Standards Alliance: Phase 2

- Leading Organizations:

- USAID
- American National Standards Institute (ANSI)

- Funding Structure:

2019 - 2024

USAID

ANSI/private sector



COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Recovery from the pandemic, and strengthening resilience for future global health crises, will require a concerted effort to:

- Strengthen collaboration to rapidly implement medical device sector-specific regulatory convergence and cross-sectoral GRPs.
- Invest in global medical device regulatory infrastructure

COVID-19 has demonstrated the dire need to build up the soft infrastructure of medical device regulatory agencies:

- Implementing foundational ‘whole-of-government’ GRPs using international standards and conformity assessment (institutional/consistent)
- Implement GRP policies within the regulatory processes of the agencies
- Implementing a Standards and Conformity Assessment program



COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Latin America Objectives

- **Project Countries:** Brazil, Colombia, Mexico, Peru
- **Tier 1: GRP Implementation (Cross-Sectoral)**
 - Phase One: Update GRP international reference and implementation guide
 - Phase Two: GRP gap analysis
 - Phase Three: GRP implementation (bilateral)
 - Phase Four: GRP implementation (multilateral)
- **Tier 2: Medical Device Sector-Specific Regulatory, Standards and Conformity Assessment Convergence**
 - Phase One: Update MD sector-specific regulatory, standards, and CA convergence International Reference and adopt a core training curriculum
 - Phase Two: MD technical regulations, standards and CA gap analysis
 - Phase Three: MD technical regulations, standards, and CA implementation (bilateral)
 - Phase Four: MD technical regulations, standards, and CA implementation (multilateral)



COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Latin America Objectives



- **Novel and significant component of Standards Alliance (Phase 2)**
- **Vision: One standard, one test, accepted everywhere**
- **Technical Secretariat Team (based in U.S., Mexico, and Brazil)**
- **Focus of project funding:**
 - Implement structural policy changes aligned with the project goals
 - Maximize interaction with government authorities and key stakeholders in project countries.



COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Key Methodologies

- **International Dimension / Leveraging Global Institutions, Alliance and Benchmarks**
- **Good Regulatory Practices and MD Regulatory Convergence**
- **Recognizing the Difference b/w MedTech and Pharmaceuticals**
- **Addressing Customs-Related Barriers through Health and Regulatory Authorities**
- **Diagnostics Elements**
- **Development Context and Gender Balance**



COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Government Engagement and Partner Orgs

- Medical Device Regulatory Authorities
- Ministries of Health / Centers for Disease Control
- Central Regulatory Coordination Bodies
- Ministries of Trade / Foreign Affairs
- National Standards Bodies
- Customs and Border Authorities



COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Partner Organizations

- **Global Collaboration** (i.e., GMTA, ISO, etc.)
- **USAID Project Collaboration** (i.e., PQM+, MTaPS, etc.)
- **Diagnostics Collaboration** (i.e., GDA, LSHTM-IDC, etc.)
- **Latin America** (i.e., national industry and standards bodies, IDB, PAHO, etc.)



COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Performance Measures

• **Global Outcomes:**

- *Establishment at the global level by medical regulators, taking medical device industry recommendations into consideration, of the international benchmarks for Emergency Use Authorizations and related emergency regulatory frameworks, based on international standards, providing a transparent, convergent, predictable and agile international mechanism to most readily bring medical technology to points of care and patients in times of health crises.*

• **Latin America Outcomes:**

- The alignment of medical device regulatory frameworks, technical regulations, standards, and conformity assessment requirements across a core set of countries in each region
- Increased regulatory efficiency, improved patient access to innovative healthcare technologies and lowered barriers to trade across a core set of countries in each region
- Lowered regulatory, customs and technical barriers to MDs required to combat COVID-19
- Improved medical device regulatory agency efficiency to increase bandwidth for COVID-19 as well as for non COVID-19 health matters in the road to recovery post pandemic



Contact Information

For USAID:

Daniel Vazquez
Sr. Standards Specialist
mdvazquez@usaid.gov

For ANSI:

Leslie McDermott
**Senior Director, International
Development**
lmcdermott@ansi.org

S T A N D A R D S A L L I A N C E - P H A S E 2



Contact Information Inter-American Coalition

Sandra Ligia González

Executive Secretary

sandra@interamericancoalition-medtech.org

Andrew Blasi

Director, C&M International

ablasi@crowell.com

Steven Bipes

Vice President, Global Strategy and Analysis

AdvaMed

SBipes@AdvaMed.org

S T A N D A R D S A L L I A N C E - P H A S E 2

