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COVID-19 MEDICAL DEVICE REGULATORY CONVERGENCE PROJECT (MDRC)

Amidst the COVID-19 pandemic, nations have scrambled to increase production and access to medical devices to prevent and treat the virus, such as rapid diagnostic test kits, ventilators, and personal protective equipment (PPE). However, countries cannot safely deploy these products without a strong medical device regulatory framework and knowledge of emergency use authorization (EUA) procedures and rules.

Medical device regulatory agencies that forgo relying on the regulations and standards of the global community must use their limited public health resources to develop agency and country-unique technical regulations. The Advanced Medical Technology Association (AdvaMed) estimates that the lack of global medical device regulatory convergence costs public health systems and the medical technology industry \$4 billion per year, the majority of which occurs in developing countries.

The Standards Alliance Phase 2 COVID-19 Medical Device Regulatory Convergence Project (MDRC) increases the transparency and predictability of partner governments' regulatory ecosystems for medical devices, aligning them with international standards, and improving their overall National Quality Infrastructure.

PROGRAM DESCRIPTION

The MDRC will: (1) build capacity of partner countries for standards and conformity assessment procedures related to medical devices; (2) remove countries' technical barriers to trade for medical devices; (3) increase patients' access to needed high-quality PPE and other medical technologies to respond to and recover from COVID-19 and future global health crises; and, (4) foster private sector engagement in the (medtech) regulatory space. Spearheaded by the Advanced Medical Technology Association (AdvaMed) and supported by a diverse team of experts, the project:

- Delivers tailored training to a) central regulatory coordination bodies *on cross-sectoral good regulatory practices (GRPs) and international standardization* that is required for regulatory convergence in the medical device sector; and b) health regulatory bodies that directly facilitates regulatory convergence in the medical device sector.
- Advises on the adoption of international benchmarks for EUAs and related emergency regulatory frameworks and approval processes, providing a transparent, convergent, predictable, and agile reference so medical devices are received across and within borders at points of care in times of health crises.
- Assists customs authorities in following the import criteria and policies set by the health authorities for addressing COVID-19.
- Establishes an Internal Center for Emergency Regulatory Response in collaboration with the Global Medical Technology Alliance. The Center will set up a COVID-19 Medical Device Portal that compiles information from the U.S. Food and Drug Administration (FDA) and relevant agencies on the newest medical devices released by the industry to fight the COVID-19 pandemic.

REGIONAL OBJECTIVES

Latin American

- Foster implementation of foundational GRPs that codify good governance in the regulatory process, focusing on transparency, predictability, accountability, and international convergence
- Foster implementation of medical device sector-specific convergence in regulations, standards, and conformity assessment to reduce unnecessary non-tariff barriers
- Establish the novel Inter-American Coalition for Regulatory Convergence with the vision of “one standard, one test, accepted everywhere” to accelerate private-public cooperation in support of medical device regulatory convergence through the use of international standards
- Assist customs authorities in understanding and following the import criteria and policies set by the health authorities addressing COVID-19

Africa & Southeast Asia

- Foster implementation of foundational GRPs that promote good governance in the regulatory process, focusing on transparency, predictability and accountability
- Foster implementation of medical device sector-specific convergence in regulations, standards, and conformity assessment
- Assist customs authorities in understanding and following the import criteria and policies set by the health authorities addressing COVID-19

GOVERNMENT ENGAGEMENT AND PARTNER ORGANIZATIONS

MDRC is a partnership between USAID and the American National Standards Institute (ANSI) in collaboration with AdvaMed to advance regulatory convergence in partnership with standards developing organizations as well as national and regional health, trade, and regulatory authorities. The project will work through the Global Medical Technology Alliance (GMTA) and Global Diagnostics Alliance, and the Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector in conjunction with the International Medical Device Regulators Forum (IMDRF).

About ANSI: ANSI is a private, non-profit organization that administers and coordinates the U.S. voluntary standards and conformity assessment system.

About AdvaMed: AdvaMed is a trade association of over 400 member companies, ranging from the largest to the smallest medical technology innovators and enterprises that produce medical devices, diagnostic products and digital health technologies that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments.

About GMTA: An alliance of national or regional medical technology associations, which represent companies that currently develop and manufacture 85 percent of the world's medical devices, diagnostics, and equipment.

FOR FURTHER INFORMATION, CONTACT:

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