STANDARDS ALLIANCE PHASE 2 COVID-19 MEDICAL DEVICE REGULATORY CONVERGENCE (MDRC) PROJECT

FINAL PROJECT REPORT

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I. Acknowledgements

The Medical Device Regulatory Convergence (MDRC) Project has been a multi-year, collaborative, public-private effort, launched at the onset of the COVID-19 pandemic, working with relevant stakeholders to identify and resolve acute and systemic bottlenecks to medical technology access as a part of a global effort to combat and recover from the health emergency. The MDRC takes this opportunity to extend its gratitude to the partners whose engagement and participation were integral and critical to the project's outputs, outcomes, and legacy.

Standards Alliance Phase 2 Partners

U.S. Agency for International Development (USAID), American National Standards Institute (ANSI), Advanced Medical Technology Association (AdvaMed) and those acknowledged in Section X (Pages 54-57).

II. Acronyms and Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
ABIIS	Brazilian Innovative Health Industry Alliance
ABIMED	Brazilian High-Technology Health Product Industry Association
ABNT	Brazilian Association of Technical Standards
ABRAIDI	Brazilian Health Products Importers and Distributors Association
ACCSQ	ASEAN Consultative Committee on Standards and Quality
AdvaMed	Advanced Medical Technology Association
ALAFARPE	Peruvian Association of Pharmaceutical Laboratories
AMCHAM	American Chamber of Commerce
AMDC	ASEAN Medical Device Committee
AMDF	Africa Medical Devices Forum
AMID	Mexican Association of the Innovative Medical Device Industry
ANDI	National Business Association of Colombia
ANSI	American National Standards Institute
ANVISA	Brazilian National Health Regulatory Agency
APEC	Asia-Pacific Economic Cooperation
ARSO	African Organisation for Standardization
ASEAN	Association of Southeast Asia Nations
AU-NEPAD	Africa Union - New Partnership for Africa's Development
CA	Conformity Assessment
CAMEX	Brazilian Inter-Ministerial Trade Chamber
CANIFARMA	National Chamber of the Pharmaceutical Industry, Medical Device Division (Mexico)
CBDL	Brazilian Chamber of Laboratory Diagnostics
CDC	Centers for Disease Control and Prevention
CDMMAA	Peruvian ALAFARPE – AMCHAM Joint Committee for Medical Devices
CDRH	Center for Devices and Radiological Health (FDA)
CLSI	Clinical Laboratory Standards Institute
COFEPRIS	Federal Commission for Protection against Sanitary Risks (Mexico)
CONAMER	National Commission for Regulatory Improvement (Mexico)
COPANT	Pan American Standards Commission
DAC	Diagnostic Advisory Committee (Africa)
DAFP	Administrative Department of the Public Function (Colombia)
DGN	National Directorate of Standards (Mexico)
DIGEMID	Directorate General of Medicines, Supplies and Drugs (Peru)
DNP	National Planning Department (Colombia)
DOC	Department of Commerce (U.S.)
DTIC	Department of Trade, Industry and Competition (South Africa)
EUA	Emergency Use Authorization
FDA	(See USFDA)
FEUM	Pharmacopeia of the United Mexican States
GDA	Global Diagnostics Alliance
GFDA	Food and Drug Administration (Ghana)
GHWP	Global Harmonization Working Party
GMRF	Global Model Regulatory Framework for Medical Devices
GMTA	Global Medical Technology Alliance
GRP	Good Regulatory Practices
HSA	Health Sciences Authority (Singapore)

IACRC	Inter-American Coalition for Regulatory Convergence - Medical Technology Sector
ICONTEC	Colombian Institute of Technical Standards and Certification
IDB	Inter-American Development Bank
IEC	International Electrotechnical Commission
IES	Brazilian Health Ethics Institute
IMDRF	International Medical Device Regulators Forum
INACAL	National Institute of Quality (Peru)
INDEX	National Council of Contract Manufacturers and Export Manufacturing (Mexico)
INMETRO	National Institute of Metrology, Quality and Technology (Brazil)
INVIMA	Colombia National Food and Drug Surveillance Institute
ITA	International Trade Administration (U.S. DOC)
KEBS	Kenya Bureau of Standards
MDMSA	Medical Device Manufacturers of South Africa
MDRC	Medical Device Regulatory Convergence
MDSAP	Medical Device Single Audit Program
MEDAK	Medical Technology Industry Association of Kenya
MOE/SEAE	Ministry of Economy/Secretariat of Economic Monitoring
MINCETUR	Ministry of Foreign Trade and Tourism (Peru)
MinCIT	Ministry of Commerce, Industry and Tourism (Colombia)
MinSalud	Ministry of Health (Colombia)
NIST	National Institute of Standards and Technology (U.S.)
NQI	National Quality Infrastructure
NRA	National Regulatory Authority
OGPS	Office of Trade and Global Partnerships (USFDA)
OMB/OIRA	Office of Management and Budget – Office of Information and Regulatory Affairs (U.S.)
PAHO	Pan American Health Organization
PPB	Pharmacy and Poisons Board (Kenya)
SA	Standards Alliance
SABS	South African Bureau of Standards
SAHPRA	South African Health Products Regulatory Authority
SALDA	Southern Africa Laboratory Diagnostics Association
SAMED	South African Medical Device Industry Association
SCPR	Secretariat of Competitiveness and Regulatory Policy (Brazil/MDIC)
SCSC	APEC Sub-Committee on Standards and Conformance
SDO	Standards Developing Organization
SE	Ministry of Economy (Mexico)
SEAE	Secretariat for Economic Monitoring (Brazil – now MDIC/SCPR)
SECEX	Brazilian Foreign Trade Secretariat (MDIC/Economy)
SOM	APEC Senior Officials Meeting
SOP	Standard Operating Procedure
TBT	Technical Barriers to Trade
TGA	Therapeutic Goods Administration (Australia)
TOR	Terms of Reference
USAID	U.S. Agency for International Development
USFDA	Food and Drug Administration (United States)
USMCA	United States-Mexico-Canada Agreement
USTDA	U.S. Trade and Development Agency
USTR	Office of the U.S. Trade Representative
WHO	World Health Organization
WTO	World Trade Organization

III. Background

The Standards Alliance Phase 2 (SA2) COVID-19 Medical Device Regulatory Convergence Project (MDRC) is a partnership between the U.S. Agency for International Development (USAID) and the American National Standards Institute (ANSI) in collaboration with the Advanced Medical Technology Association (AdvaMed) to advance medical technology (medtech) regulatory convergence working together with the global medtech industry, standards developing organizations (SDOs), as well as with national, regional and international health, trade, and regulatory authorities.

The overarching MDRC project objective is to accelerate coordinated medtech sector, supply chain, trade, and regulatory efforts to coherently combat and recover from the COVID-19 pandemic in alignment with foundational Good Regulatory Practices (GRPs) that support regulatory convergence, reliance and use of international standards to improve access to life-saving technology. Under the Standards Alliance Initiative, the MDRC provides capacity building assistance specifically related to implementation of the World Trade Organization Technical Barriers to Trade Agreement (WTO/TBT), which is one of the strongest GRPs. To achieve this objective, the MDRC increases the transparency and predictability of partner governments' regulatory ecosystems for medical devices, improving their overall National Quality Infrastructure (NQI). NQI promotes high-quality, safe products and services and facilitates international commerce by reducing unnecessary barriers to trade.

In partnership with eight project countries in Africa, Latin America, and Southeast Asia, the MDRC aims to:

01.

Build capacity of partner countries for international standards and conformity assessment procedures related to medical devices;

02.

Remove countries' technical barriers to trade for medical devices;

03.

Increase access to needed high-quality personal protective equipment (PPE) and other medical technologies to respond to and recover from COVID-19 and future global health crises; and

04.

Foster private sector engagement and co-responsibilities in public consultations and WTO notifications of draft technical regulations and standards regarding medical technologies.

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The World Trade Organization Technical Barriers to Trade Agreement (WTO/TBT) aims to ensure that technical regulations, standards, and conformity assessment (CA) procedures are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, it recognizes WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health, safety, and protection of the environment. The TBT Agreement requires members to base their measures on international standards to facilitate trade. Through its transparency provisions, it also aims to create a predictable trading environment.

Good Regulatory Practices (GRP) refers to a formalized, mandatory, whole-of-government policy that defines the common and transparent rules by which regulatory agencies develop technical regulations for all regulated sectors (i.e., cross-sector, transverse, horizontal, foundational) following international standards for GRP. GRP is the quality control mechanism for the development of regulations, ensuring on a continuous and systematic basis that government rules are relevant, of the highest quality, cost-effective, internationally aligned and least economically restrictive amongst alternatives to achieve the same purpose.

Medical Device Sector Regulatory Convergence is a concerted public-private effort to systematically pursue and maximize alignment of medical device sector-specific technical regulations, standards, and CA criteria to harmonized international standards.[1]

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THE VALUE OF MEDICAL TECHNOLOGY

Medical technology is essential to patient care. Spanning over 14,000 diverse product categories–ranging from basic bandages to sophisticated imaging devices and mobile applications–these innovations are critical to the prevention, diagnosis, and treatment of health conditions.

The COVID-19 pandemic underscored the importance of medical devices in maintaining public health and safety. Persistent shortages of essential medical technology–such as ventilators, test supplies, and vaccination equipment–highlighted vulnerabilities in national and global supply chains. Shortages not only impacted PPE but also posed a serious threat to the healthcare system, affecting patients on a global scale.

Effectively addressing disruptions in the medical device supply chain necessitates proactive measures to prevent severe shortages. The MDRC has played a crucial role in this endeavor by working toward the removal of barriers to trade through promotion of medical device regulatory convergence and GRP in line with internationally harmonized reference documents.

[1] The WHO provides a more detailed definition of regulatory convergence at: https://www.interamericancoalition-medtech.org/regulatory-convergence/policy/medical-device-sector-regulatory-convergence/world-health-organization-documents/. The MDRC promoted compatibility with this WHO guidance definition as well as with the international treaty obligations as defined in the WTO TBT agreement, particularly the article 2.4 requirement for WTO members to base national regulations on international standards.

IV. Introduction

STRUCTURE

From 2020-2023, the MDRC was a public-private cooperative agreement where USAID provided $3m in funding that was matched and exceeded by an additional $1m in funding provided by the private sector, via Advamed, toward common goals. These goals were geared toward systemic identification and alleviation of medtech market access bottlenecks, particularly those that were acute and hindering effective COVID-19 response, but where efforts are now focused on upgrading medical device regulatory frameworks to incorporate the lessons learned from the global pandemic and to better prepare health systems for future health emergencies.

MDRC Structure under SA2 (2020-2023)

$3,000,000 from USAID + **$4,000,000** from AdvaMed = **$7,000,000**

$3,500,000 via AdvaMed In-Kind Contributions of Staff Time
$500,000 via Direct Contributions from AdvaMed LatAm budget

- USAID funding was allocated to expenses such as foreign government delegation travel and training costs and support of the MDRC programmatic and administrative team.
- AdvaMed funding was allocated to staff time toward MDRC deliverables, technical expert participation and core MDRC functions such as online resources.

DIAGNOSIS

At the onset of the COVID-19 pandemic, the AdvaMed-led MDRC team assessed that one of the primary obstacles of patient and health system access to medical technologies and effective pandemic response and recovery was unnecessary non-alignments between the regulatory requirements for medical technologies from country to country. While countries maintain the sovereignty to establish their own regulations to protect their citizens, countries have also, in their sovereignty, committed via membership in multilateral organizations and treaty obligations to use relevant international reference documents and standards as a basis for their respective technical regulations for medical devices with a view toward the goal of eliminating unnecessary regulatory differences between themselves.

These commitments were specifically established to minimize health and trade barriers in the global medtech supply chain. The reference documents themselves are developed by the global community via the International Medical Device Regulators Forum (IMDRF), the World Health Organization (WHO), and SDOs but their use is codified in international law via the treaty obligations of the WTO/TBT. **Yet implementation of the TBT agreement is insufficient in many jurisdictions where health authorities are often not aware of the trade obligations they maintain.**

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KEY SUCCESS FACTORS

The MDRC built upon the success of Standards Alliance Phase I to support the capacity of developing countries in the areas of legal and regulatory framework, standards development, conformity assessment procedures, and private sector engagement.

Key success factors of the MDRC include:

Tailored training to central regulatory coordination bodies (or similar bodies) on cross-sectoral GRP and international standardization that is required for regulatory convergence in the medical device sector.

Tailored technical training on medical device-specific GRP and international standardization and conformity assessment, to health regulatory bodies, that directly facilitates regulatory convergence in the medical device sector.

Advice for agencies of partner governments on the adoption of international benchmarks for emergency use authorizations (EUAs) and related emergency regulatory frameworks and approval processes, providing a transparent, convergent, predictable, and agile international reference so medical devices are received across and within borders at points of care.

Assistance to customs authorities in understanding and following the import criteria and policies set by the health ministries and centers of disease control for addressing COVID-19.

Establishment of an international reference center for Emergency Regulatory Response, in collaboration with the Global Medical Technology Alliance, including an easy-to-use digital library that compiles information from the FDA or other relevant agencies on the newest medical device regulatory benchmarks to fight the COVID-19 pandemic.

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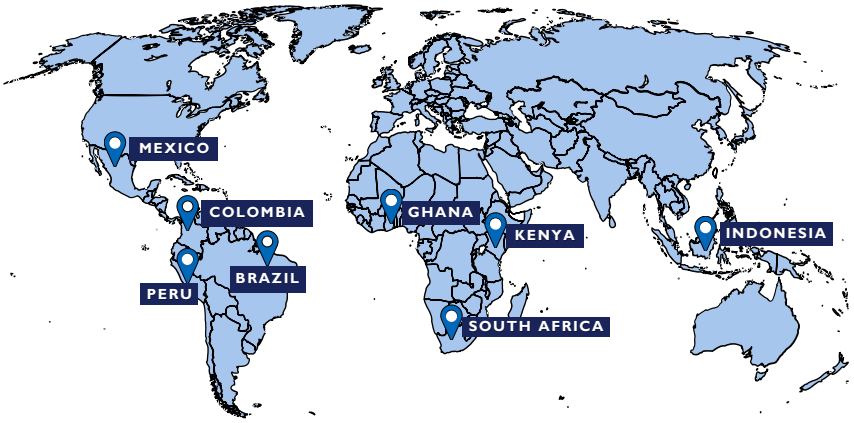
METHODOLOGY

The MDRC advanced implementation of GRP within a two-tier architecture: **Tier One** focuses on implementation of foundational GRP as it applies to all sectors including medical technologies. **Tier Two** focuses on implementation of foundational and sector-specific GRP by National Regulatory Authorities (NRAs) for medical technologies.

Within each Tier, the MDRC applied a similar approach: (1) conduct a GAP assessment of policies at the national level against the established international benchmarks; (2) design and conduct training on both medical device regulatory processes and technical topics–prioritizing COVID-19 recovery and deferring to national NRA health needs; (3) work to fill gaps in regulatory frameworks to increase global alignment and decrease patient medtech access barriers. Additional information on project review and analysis may be found on page 35.

PROJECT COUNTRIES

The MDRC project countries include:
Africa: Ghana, Kenya, South Africa
Latin America: Brazil, Colombia, Mexico, Peru
Southeast Asia: Indonesia



In Project Year 1 (PY1) and Project Year 2 (PY2), the MDRC undertook the extensive process of outreach and relationship building with project country government stakeholders. This process was predicated on the official concurrence of each project country USAID Mission. In Latin America, MDRC secured concurrence in Brazil, Colombia, Mexico, and Peru.

In Africa, MDRC secured concurrence from Ghana, Kenya, and South Africa. In Southeast Asia, MDRC secured concurrence from Vietnam and Indonesia.

PROJECT IMPLEMENTERS

Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector

The Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (the "IACRC" or "Coalition") was launched virtually in 2020 and partners with global, regional, and local project country stakeholders to advance GRP implementation and medical device regulatory convergence. The Technical Secretariat of the IACRC provided a mechanism to accelerate coordination of MDRC partners in the Western Hemisphere by serving as the primary MDRC implementing partner. The Technical Secretariat also served as the primary MDRC team leading glMDRC work at the international level as well as with MDRC partners in Africa and Southeast Asia.

The IACRC operated as lead MDRC global implementer of Tier One and Two workstreams by organizing project engagements with global organizations such as the World Trade Organization (WTO), the World Health Organization (WHO), the International Medical Device Regulators Forum (IMDRF), the Global Medical Technology Alliance (GMTA), the Global Diagnostics Alliance (GDA), et al. On behalf of the MDRC, the IACRC also led project outreach in the Latin American, African, and Southeast Asian regions and hosted numerous trainings at the Tier One and Tier Two levels.

To advance its workstreams, the IACRC developed and released an online resource library through an easily-navigable website. This website is a tool to convene stakeholders for events, share translated recordings of trainings and capacity building exercises, and publish and disseminate resources pertaining to GRP and medical device regulatory convergence.

[2] During the final MDRC project year, USFDA withdrew from the GHWP, former AHWP, citing concerns with divergent harmonization efforts for medical devices and misalignment with international best practices. MDRC implementing partners will take this into consideration for ongoing capacity building efforts. MDRC recommendations for GHWP may be found on page 47.

In June 2022, senior medtech leaders and medtech association members of the IACRC conducted a formal signing ceremony of the Coalition's Terms of Reference in conjunction with the IX Summit of the Americas in Los Angeles, California, United States.

Colombia Liaison

During Project Year 2 (PY2), USAID approved the Government of Colombia and MDRC's request to establish a dedicated project liaison to Colombia to coordinate project implementation among local stakeholders. Following approval, MDRC's Colombia Liaison rapidly advanced project objectives in the country. **The Colombia Liaison also worked to implement formal processes and procedures to institutionalize GRP in Tier One and Tier Two contexts.**

Africa Liaison

During Project Year 3 (PY3), leveraging the impactful outcomes from the Colombia Liaison model, the MDRC submitted a new budget proposal to reallocate resources to an Africa Liaison. The primary functions of the Africa Liaison included:

ROLE 1

(Kenya National Focus)

Provide dedicated support to MDRC partners in Kenya focused on national Monitoring, Evaluation, and Learning (MEL) plan implementation.

ROLE 2

(South Africa and Ghana Focus)

Provide dedicated support to MDRC partners in South Africa and Ghana, focused on national MEL plan implementation in those countries.

ROLE 3

(Africa Medical Devices Forum Focus)

Provide dedicated support to MDRC partners in Africa Medical Devices Forum focused on national MEL plan implementation.

Beginning work in July 2023, the Africa Liaison facilitated on the ground collaboration with project country NRAs, culminating in capacity building activities with PPB, SAHPRA, and the AMDF. Photo: Pictured from left to right: MDRC Africa Liaison David K. Wang'ombe; MDRC Tier 2 Lead Sandra Ligia González; David Karenye, MEDAK; Maureen Njeri, MEDAK; Ednah Kiprop, KEBS; Wycliffe Choge, MEDAK; and Mary Kinyanjui, MEDAK.

V. Stakeholders

GLOBAL AND REGIONAL PARTNERS

Global

At the global level, MDRC partnered with international organizations, U.S. government partners, standards bodies, regulatory authorities, and other stakeholders to execute capacity building programming. The IACRC was accepted as a member to the Global Medical Technology Alliance (GMTA), the Global Diagnostics Alliance (GDA), and the Global Harmonization Working Party (GWHP). Additionally, the MDRC established a formal GMTA-GDA COVID-19 Workstream, thereby constituting the International Center for Emergency Regulatory Response.

Global partners, including but not limited to the organizations below, provided a platform to engage with key project stakeholders and encourage their participation in international standards activities.

International Medical Device Regulators Forum (IMDRF)	
World Health Organization (WHO)	Global Diagnostics Alliance (GDA)
World Trade Organization (WTO)	London School of Hygiene and Tropical Medicine
Global Medical Technology Alliance (GMTA)	International Diagnostics Centre
Global Harmonization Working Party (GHWP)	Global Alliance for Diagnostics (FIND)

The World Health Organization (WHO) is a source of key international reference documents, including the WHO Global Model Regulatory Framework for Medical Devices (GMRF).[3] The GMRF "is intended to provide guidance and support to WHO Member States that have yet to develop and implement regulatory controls relating to medical devices, as well as to jurisdictions that are continuing to improve their regulatory frameworks as they take steps to ensure the quality and safety of medical devices available in their countries." Chapter 4 offers a "stepwise approach in regulating medical devices" that acknowledges countries' differing levels of development and puts forth a prioritized layering of regulatory responsibilities. The WHO principles of reliance and recognition are core components of the approach:

Reliance is the process whereby a regulatory authority may consider and give significant weight to (i.e. rely upon) assessments performed by another regulatory authority or other trusted institution in reaching its own decision.

Recognition is the acceptance of the regulatory decision of another regulator or trusted institution. Recognition should be based on evidence that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority.

[3] https://www.interamericancoalition-medtech.org/regulatory-convergence/policy/medical-device-sector-regulatory-convergence/world-health-organization-documents/

Latin America

The MDRC through the IACRC consistently engaged key regional and local partners throughout the project. These partners included, but were not limited to:

- Inter-American Development Bank (IDB)
- OECD-IDB Ibero-American Regulatory Improvement Network
- Pan American Health Organization (PAHO)
- Americas Business Dialogue (ABD)
  - Transparency & Regulatory Working Group
  - Health Working Group
- Americas RISE for Health (RISE)
- Latin American Medical Device Alliance (ALDIMED)
- Latin American Alliance for In Vitro Diagnostic Development (ALADDIV)
- Pan American Standards Commission (COPANT)

Mileydi Guilarte, Deputy Assistant Administrator, Bureau for Latin America and the Caribbean, USAID together with Hector Orellana - Medtronic, engages with the Inter-American MedTech Coalitions and MDRC team – 7 June 2022 in conjunction with the IX Summit of the Americas – Los Angeles, CA, USA.

The MDRC joins regional partners in Latin America including medtech associations CBDL, AMID and ABIMED, together with PAHO, to further advance Regulatory Convergence and Regulatory Reliance, San Salvador, El Salvador – 10-12 October 2023.

Africa

Paulyne Wairimu, Medical Devices and Diagnostics Lead, Kenyan Pharmacy and Poison Board (PPB) and AMDF chair opens the day 1 proceedings of the MDRC USFDA-AMDF Trainings in Nairobi, Kenya, 6 November 2023.

Dr. Dimakatso Mathibe, Senior Manager for Medical Device & Radiation Control (Program 5) with the South African Health Products Regulatory Authority (SAHPRA) and AMDF vice chair closes the day 1 proceedings of the MDRC USFDA-AMDF Trainings in Nairobi, Kenya, 6 November 2023.

The MDRC consistently engaged key African continental partners throughout the project. These partners included, but were not limited to:

- Africa Union - New Partnership for Africa's Development (AU-NEPAD)
- Africa Medical Devices Forum (AMDF) under the AU-NEPAD African Medicines Agency (AMA)
- Africa Center for Disease Control (CDC)
- Africa Diagnostic Advisory Committee (DAC)
- African Organisation for Standardization (ARSO)

In each project year, the MDRC explored partnership opportunities with the AMDF, which received approval as a Regional Harmonization Initiative by the IMDRF during the project. These efforts were bolstered by regular coordination with the AMDF Chair and Vice-Chair, who were also MDRC's Tier Two points of contact leading the medical device divisions of the Kenyan and South African NRAs, respectively. This collaboration supported regulatory capacity building, which was a key pillar in the MDRC-AMDF strategy to achieve regional initiative status.

MDRC presents the MDRC-FDA-AMDF training objectives, including the exchange of information between partner NRAs, Africa CDC, and industry - Nairobi, Kenya, 6-10 November 2023.

Leslie McDermott of ANSI and Daniel Vazquez of USAID overview the Standards Alliance Initiative and the partnership with AdvaMed and MDRC global partners in Nairobi, Kenya.

The MDRC also cultivated partnerships with key medical device industry bodies to accelerate project implementation in Africa. In 2021, MDRC began its partnership with Mecomed, the medical device, imaging and diagnostics trade association for the Middle East and Africa, together with the South African Medical Device Industry Association (SAMED).

In 2022, Mecomed, SAMED, and MDRC secured the approval of the Global Medical Technology Alliance (GMTA) to establish a GMTA Africa Working Group as a pan-African coordination mechanism to work with global and continental partners to identify industry priority areas, develop capacity building workshops, and train local industry members on both Tier One and Two elements.

Enoch Nyarko of Ghana FDA participates in the MDRC-FDA-AMDF Workshop.

Southeast Asia

The AdvaMed-led MDRC team leveraged regional platforms to ensure MDRC implementational alignment with related regional activity. These fora include the Asia-Pacific Economic Cooperation Subcommittee on Standards and Conformance (APEC SCSC), ASEAN Consultative Committee on Standards and Quality (ACCSQ), and ASEAN Medical Device Committee (AMDC).

Throughout the project, the MDRC also coordinated with key government stakeholders including the U.S. Department of Commerce – International Trade Administration (DOC/ITA) on Tier One and Tier Two workstreams.

PROJECT COUNTRY PARTNERS

The MDRC led efforts to formalize partnerships with local stakeholders to advance Tier One and Two objectives in-country. Coordination with government stakeholders facilitated health system strengthening by supporting the alignment of medtech regulatory requirements within economies and across borders. Through its workstreams with government partners–including health and trade authorities–the MDRC discouraged use of standards that differ from internationally harmonized reference documents, encouraged the implementation of good regulatory and reliance practices, and promoted the efficient use of health resources. This capacity building complemented MDRC's partnership with private sector stakeholders and collective efforts to eliminate barriers to trade.

Brazil

At Tier One, MDRC coordinated with the following:

- Ministry of Development, Industry, and Foreign Trade (MDIC)'s Secretariat of Foreign Trade (SECEX)[4]
- Ministry of Development, Industry, and Foreign Trade (MDIC)'s Inter-Ministerial Trade Chamber (CAMEX)
- Ministry of Development, Industry, and Foreign Trade (MDIC)'s Secretariat for Competition Advocacy and Competitiveness (then SEAE, now reorganized as Secretary of Competitiveness and Regulatory Policy - SCPR under the Lula administration)
- National Institute of Metrology, Standardization, and Industrial Quality (INMETRO)
- Brazilian National Confederation of Industry (CNI)
- Ministry of Foreign Relations

At Tier Two, MDRC partnered with the following:

- Brazilian National Health Regulatory Agency (ANVISA)
- Brazilian Innovative Health Industry Alliance (ABIIS)
- Brazilian Association of Health Technologies Industries (ABIMED)
- Brazilian Health Product Importers and Distributors Association (ABRAIDI)
- Brazilian Chamber for In-Vitro Diagnostics (CBDL)
- Brazilian Technical Standards Association (ABNT) Technical Committee CB-36 Diagnostics
- Brazilian Society for Clinical Analysis (SBAC)

The MDRC convenes Brazilian partner representatives during the IACRC's first-ever in-person session on the sidelines of the IX Summit of the Americas in Los Angeles, California, United States.
Pictured from left: GeanLuca Lorenzon, (MOE/SEAE), Jorge Khauuaja (ABIMED), Bruno Bezerra (ABRAIDI), Angelica Marques (ABIMED), Jose Marcio Gomes ABIIS), Marcos Heleno Guerson de Oliveira Junior (INMETRO), Carlos Gouvêa (CBDL / IES), Leticia Fonseca (MDRC / IACRC), Marcos Borges (INMETRO), Lorena Brito da Justa Croitor (CGU), Jorge Emanuel Reis Cajazeira, (ABNT), Diego Pizetta (INMETRO), Karina Ninzoli Luro Nazello (ABNT).

[4] In the period 2019-2022, the MDRC engaged with the Brazilian Ministry of Economy which was a "Super Ministry" combing several previous ministries including the Ministry of Finance; the Ministry of Planning, Budget and Management; the Ministry of Labor and Employment; the Ministry of Social Security; the Ministry of Planning, as well as the Ministry of Development, Industry and Foreign Trade (MDIC) and its divisions such as SECEX and SEAE. In 2023, the Ministry of Economy was reorganized back into separate ministries where MDRC engagement continued principally with MDIC.

Colombia

Under the leadership of the Colombia Liaison, the MDRC coordinated project implementation among local stakeholders. Those local stakeholders include, but are not limited to the following:

- National Planning Department (DNP)
- Administrative Department of the Public Function (DAFP)
- Ministry of Health and Social Protection (MinSalud)
- Ministry of Commerce, Industry and Tourism (MinCIT)
- Colombia National Food and Drug Surveillance Institute (INVIMA)
- National Business Association of Colombia - Medical Device Chamber (ANDI-CDMIS)
- Colombian Institute of Technical Standards and Certification (ICONTEC)

Mexico

The MDRC engaged with public and private sector stakeholders to advance Tier One and Tier Two workstreams in Mexico.

The MDRC engaged at the Tier One level with:

- Ministry of Economy (SE)
- National Commission for Regulatory Improvement (CONAMER)
- National Directorate of Standards (DGN)
- Government of Baja California

The MDRC engaged at the Tier Two level with:

- Federal Commission for Protection against Sanitary Risks (COFEPRIS)
- Pharmacopeia of the United Mexican States (FEUM)

At the Tier Two level, the MDRC signed a Letter of Intent (LOI) with COFEPRIS in PY2. The LOI formalized a partnership to advance GRP, work towards regulatory convergence for medical devices, and leverage international best practices and guidance. To achieve this objective, the MDRC also engaged the Pharmacopoeia of the United Mexican States (FEUM) to address the need of systematic compliance with Mexico's domestic legal and international treaty obligations GRP.

Following a review of COFEPRIS's relevant legally-binding international obligations (including those in the United States-Mexico-Canada Agreement, USMCA), COFEPRIS formally requested support from MDRC to draft a comprehensive checklist – in consultation with local and regional stakeholders – to promote full compliance with those obligations in the agency's Standard Operating Procedures (SOPs). These obligations include the use of international standards and GRP in the Tier Two context. For more information on the work to address non-alignments, see "Outputs and Outcomes."

MDRC also engaged with the private sector through:

- Mexican Association of Innovative Industry of Medical Devices (AMID)
- National Chamber of the Pharmaceutical Industry, Medical Device Division (CANIFARMA)
- National Council of Contract Manufacturers and Export Manufacturing (INDEX)

Peru

In the early stages of the project, Peru's Directorate General of Medicines, Supplies and Drugs (DIGEMID), the Ministry of Foreign Trade and Tourism (MINCETUR), and the National Institute of Quality (INACAL) committed to addressing challenges related to COVID-19, accessing international standards, and developing SOPs for the implementation of GRP.

The MDRC partnered with the Peruvian ALAFARPE-AMCHAM Joint Committee for Medical Devices (CDMMAA) to assess DIGEMID's regulatory procedures and adhere to international standards and references. The MDRC held dedicated sessions with the joint committee to explore how the IACRC could effectively partner with the member organizations and advance MDRC objectives.

Ghana

The MDRC mobilized its Ghana workstream in conjunction with the MDRC-FDA-AMDF continental level training which took place in Nairobi, Kenya in November 2023. The MDRC sponsored Ghana Food and Drug Administration (GFDA) participation in the MDRC-FDA-AMDF training, met with GFDA together with USFDA, USAID, and ANSI while in Nairobi, and subsequently held a virtual follow-up meeting in December 2023, confirming plans to continue virtual training in 2024 as an MDRC legacy activity.

Kenya

In Kenya, the MDRC formalized a partnership with the Pharmacy and Poisons Board (PPB) and signed an MoU to develop a dedicated Tier Two workstream. Following meetings with the Kenyan Bureau of Standards (KEBS) and the Kenyan Customs and Border Control Department, KEBS formally agreed to partner with MDRC in February 2022.

In 2023 on the sidelines of regional trainings, MDRC held meetings with key public and private sector stakeholders in Nairobi including but not limited to:

- African Regional Organisation for Standardisation (ARSO)
- Medical Technology Industry Association of Kenya (MEDAK)
- Kenya National Chamber of Commerce and Industry
- AmCham Kenya
- Pharmacy and Poisons Board (PPB)
- Kenya Bureau of Standards (KEBS)
- Africa Medical Devices Forum (AMDF)

The MDRC met with the PPB Leadership in Nairobi, Kenya in January 2023 to mobilize the in-person Kenya NRA workstream.

The MDRC met with the KEBS Leadership in Nairobi, Kenya in January 2023 to mobilize the in-person Kenya Standards, Conformity Assessment and TBT workstream.

South Africa

The MDRC partnered with the U.S. Department of Commerce, Office of the U.S. Trade Representative, and local partners such as the South African Medical Device Industry Association (SAMED), the Southern Africa Laboratory Diagnostics Association (SALDA), and the Medical Device Manufacturers of South Africa (MDMSA) to extend outreach to Tier One stakeholders in South Africa. Subsequently, the MDRC introduced the project to the Department of Trade, Industry and Competition (DTIC) and the South African Bureau of Standards (SABS) in April 2022.

The South African Health Products Regulatory Authority (SAHPRA) formally agreed to begin workstream development with MDRC in December 2021. In February 2023, SAHPRA and the MDRC finalized all signatures on the terms of reference (TOR), which formalized their partnership in executing Tier One and Two workstreams.

MDRC, USAID, and ANSI meet SAHPRA as part of the USTDA-organized meetings at AdvaMed in Washington, DC in August 2023.

Indonesia

The MDRC's workstream with the Ministry of Health was formally approved in April 2022. From 2022-2023, alongside MOH, MDRC hosted capacity building events to train local public and private sector stakeholders on GRP implementation in the Tier Two context.

Additionally, MDRC organized hybrid, small-group discussions with Indonesian Ministry of Health officials covering foundational GRPs, Quality Management Systems (QMS), conformity assessment, and personalized medical devices.

Photo: Adobe Stock

Regulatory Training on Medical Device-Related Standards and Guidance, 8-9 September 2022 with Ministry of Health Indonesia and Industry – Bogor, Indonesia.

VI. Outputs and Outcomes

PUBLIC AND PRIVATE SECTOR ENGAGEMENT

In addition to external stakeholders, the MDRC also worked closely with USAID and the U.S. government inter-agency process to coordinate coherent USAID technical assistance provision with MDRC countries from projects spanning trade and global health.

On Tier Two, the MDRC worked closely with the U.S. Food and Drug Administration (USFDA) including with the Center for Devices and Radiological Health (CDRH), the Office of Trade and Global Partnerships (OTGP), and the FDA Latin America Office. USFDA supported the MDRC in six principal workstreams:

1. Coordinated with the MDRC and provided project guidance and support from project inception to completion;
2. Provided in-person and virtual speakers for dozens of MDRC training sessions over the course of the program;
3. Worked with the MDRC to jointly develop a first ever global Medical Device Technical Assistance Training Curriculum;
4. Extended invitations to NRAs for MDRC Latin America regional events;
5. Reinforced advancement of global medical device regulatory convergence, good regulatory practices, use of medical device standards and conformity assessment in its government-to-government dialogues;
6. Publicly emphasized its role as an NRA in complying with trade obligations including at the WTO Public Forum in Geneva in September 2022.

On Tier One, the MDRC worked closely with the Office of the U.S. Trade Representative (USTR), the U.S. Department of Commerce and the National Institute of Standards and Technology (NIST) to ensure alignment with U.S. trade policy, obligations and initiatives. MDRC also coordinated with the Office of Management and Budget – Office of Information and Regulatory Affairs (OMB/OIRA) to ensure alignment with U.S. Good Regulatory Practice policy as practiced domestically.

The MDRC also coordinated with the U.S. Trade and Development Agency (USTDA), its Coalition for Healthcare Infrastructure in Africa, and the three USAID project teams interfacing with Kenya and South Africa on medical device regulatory improvement to ensure alignment of approaches.

In addition to leveraging relationships with U.S. government stakeholders to build capacity in MDRC project countries, the work under MDRC expanded South-South alliances, facilitating the sharing of best practices between project countries. For example, in August 2023 MDRC led a three-day capacity- building workshop with Pharmacy and Poisons Board (PPB), in which the National Agency of Sanitary Surveillance (ANVISA) of Brazil, the Australian Therapeutic Goods Administration (TGA) and the Health Sciences Authority (HSA) of Singapore, participated as trainers alongside USFDA and the National Institute of Standards and Technology (NIST).

ANVISA became a material supporter of the MDRC project through the consistent contribution as panelist in 17 capacity building sessions hosted by the MDRC, in different subjects: (i) reliance; (ii) the Medical Device Single Audit Program (MDSAP)[5] ; (iii) IMDRF N47 Essential Principles of Safety and Performance; (iv) regulation of medical devices; (v) good regulatory practices; (vi) clinical research; (viii) conformity assessment procedures; (ix) software as medical device; (x) emergency use authorization.

Engagement of government partners is critical to ensuring that regulatory policy environments are rooted in a strong legal foundation and that regulatory processes follow international standards. Without private sector involvement, however, the likelihood that regulations meet market realities is diminished. Healthy private sector participation in the regulatory process helps governments ensure that standards and regulations are accurate, necessary, and tailored to the domestic context whilst preventing the creation of barriers to trade.

The MDRC's consistent engagement with both public and private sector stakeholders to develop training curricula, convene workshops, and align regulatory processes with treaty obligations and international standards facilitated development of its outcomes and outputs.

The following sections provide an overview of MDRC workstreams at the regional and project country level.

REGIONAL WORKSTREAMS

Photo: Adobe Stock

MDRC OBJECTIVES

- Build capacity via ripple effect of MDRC on standards and conformity assessment procedures related to medical devices
- Remove technical barriers to trade for medical devices
- Increase access to needed high-quality PPE and other medical technologies to respond to and recover from COVID-19 and future global health crises
- Foster private sector engagement in the medtech regulatory space

[5] Developed by the IMDRF, the Medical Device Single Audit Program allows a recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.

Latin America

The relationships MDRC built in Standards Alliance Phase I provided the foundation for MDRC to execute virtual and hybrid capacity building activities across the region under SA2. Engagement with regional stakeholders not only advanced important multilateral Tier One and Tier Two 2 objectives for the region but also complimented MDRC workstreams in each project country.

Advancing Workstreams on the Sidelines of Key Regional Convenings

In October 2023, the MDRC, in partnership with the IACRC and Pan American Health Organization (PAHO), organized a gathering of more than 230 stakeholders, both in person and virtually, during the XI Regional Meeting on the Regulation of Medical Devices in San Salvador, El Salvador. This meeting provided a platform for discussion and engagement among National Regulatory Authorities (NRAs), industry representatives, and other relevant stakeholders on topics including emergency use authorization (EUA) and the implementation of regulatory reliance.

The MDRC, in collaboration with PAHO, also developed a program to facilitate the exchange of experiences regarding reliance among NRAs and stakeholders in Latin America. The participating countries included Brazil, Colombia, and Mexico. The program was hosted by the National Directorate of Medicines (DNM) in San Salvador, El Salvador, with over 100 attendees participating in person.

On the sidelines of the PAHO regional meeting, which provided a timely opportunity for MDRC to advance MEL plan metrics with national and regional partners, IACRC convened its semi-annual meeting of its medtech association members to advance collaborative efforts in the areas of reliance, GRP, public consultations, increased participation in SDO Committees, MDSAP, and the utilization of electronic tools.

The MDRC, in collaboration with PAHO, also developed a program to facilitate the exchange of experiences regarding reliance among NRAs and stakeholders in Latin America. The participating countries included Brazil, Colombia, and Mexico. The program was hosted by the National Directorate of Medicines (DNM) in San Salvador, El Salvador, with over 100 attendees participating in person.

Africa

In Africa, coordination with USFDA/CDRH, the AMDF, and regional and in-country project stakeholders built the capacity of African NRAs regarding foundational GRP, CA procedures related to medical devices, and cross-sector collaboration.

MDRC-FDA-AMDF Capacity Building Workshop

Collaboration with USFDA alongside Africa regional and project country stakeholders facilitated development of the first ever USFDA-industry developed "menu" of medical device NRA training options, the "Medical Device Technical Assistance Training Curriculum", from which to develop training sessions aligned with international reference documents and with an emphasis on GRP and use of standards.

During the final project year in November 2023, MDRC in collaboration with USFDA and AMDF, held an extensive capacity building event using the newly approved curriculum.

The MDRC-FDA-AMDF capacity building workshop included participation from representatives of 8 African NRAs. NRAs from Ghana, Kenya, and South Africa participated under MDRC sponsorship, and NRAs from Botswana, Central African Republic, Ethiopia, Nigeria, and Tanzania attended attend under the sponsorship of the Africa CDC as well as companies organized under Mecomed, MEDAK, SAMED, SALDA and MDMSA.

Southeast Asia

In August 2021, AdvaMed virtually attended the Asia-Pacific Economic Cooperation Subcommittee on Standards and Conformance (APEC SOM3 SCSC) meetings as an accredited U.S. delegate to ensure MDRC implementational alignment with related regional activity. Those meetings include the SCSC Workshop on GRP.

Throughout the project, the MDRC coordinated with key government stakeholders to execute trainings and align best practices. For example, MDRC collaborated with U.S. Department of Commerce – International Trade Administration (DOC/ITA) to lead a Tier One and Tier Two regional training hosted alongside the ASEAN Consultative Committee on Standards and Quality (ACCSQ) and the ASEAN Medical Device Committee (AMDC).

PROJECT COUNTRY WORKSTREAMS

The MDRC worked with stakeholders in each project country to identify key objectives and subsequently develop and execute capacity building activities as well as provide guidance through review and analysis of internal procedures.

KEY OBJECTIVES

- Build capacity for standards and conformity assessment procedures related to medical devices
- Remove technical barriers to trade for medical devices
- Increase access to needed high-quality PPE and other medical technologies to respond to and recover from COVID-19 and future global health crises
- Foster private sector engagement in the medtech regulatory space

Country-specific objectives, capacity building activities, and analysis for each project country is included in the following sections with additional case studies demonstrating how the project met its objectives.

Brazil

MDRC OBJECTIVES

- Build capacity via halo effect of MDRC on standards and conformity assessment procedures related to medical devices
- Remove technical barriers to trade for medical devices
- Increase access to needed high-quality PPE and other medical technologies to respond to and recover from COVID-19 and future global health crises
- Foster private sector engagement in the medtech regulatory space

ACTIVITIES AND OUTPUTS - CAPACITY BUILDING

Activities focused on capacity building for Brazilian Ministry staff; in total, 3 events were held between 2021 and 2023 on the following thematic areas:

- GRP and international trade
- Conformity assessment for medical devices
- Post-market surveillance

ACTIVITIES AND OUTPUTS - REVIEW AND ANALYSIS

- Dissemination of GRP/Conformity Assessment Checklist (U.S.-Brazil ATEC Protocol Annex II GRP implementation)
- Incentive to improve the INMETRO/ANVISA workstream (including through contribution to the MDIC public consultation on regulatory costs)
- Support to INMETRO to review the TBT/Conformity Assessment Checklist as benchmarking for an internal standard operating procedure (SOP)

Photo: Adobe Stock

Implementation of Foundational GRP

The MDRC collaborated closely with the Secretary of Competitiveness and Regulatory Policy at MDIC to implement foundational GRP as outlined in Annex II of the ATEC Protocol. They also advocated for INMETRO to establish formal processes and procedures to institutionalize GRP at the Tier One level. The GRP/Conformity Assessment Checklists served as the foundation for developing a future SOP. Additionally, this engagement involved participating in MDIC's public consultation on regulatory costs.

Participation in International Standards Activities

Throughout the project, the MDRC promoted increased and sustained participation in SDOs to ensure that national stakeholders' inputs are considered during the policymaking process.

In Brazil, the MDRC supported the involvement of the Brazilian Health Regulatory Agency (ANVISA), the Chamber of Laboratory Diagnostics (CBDL), and the Inter-American Coalition for Regulatory Convergence in the Brazilian National Standards Organization's (ABNT) CB-36 Committee on Clinical Analyses and In Vitro Diagnosis. This committee's work facilitated Brazil's adoption of the ISO 15197:2013 Standard for in vitro diagnostic test systems, specifically the requirements for blood-glucose monitoring systems used in managing diabetes mellitus.

Adoption of International Standards

By adopting or aligning domestic standards with international best practices, partner countries and domestic businesses can gain numerous benefits in trade, commerce, health, and COVID-19 response. These advantages include reduced costs for importing and exporting goods, increased consumer safety and confidence, and improved quality of medical technologies available in the market. Under the work of the MDRC, project countries began referencing and adopting international standards. For example, in Brazil, ANVISA published RDC No. 657 in 2022, which provides for the regulation of software as a medical device.

Colombia

ACTIVITIES AND OUTPUTS - CAPACITY BUILDING

- Workshop on GRP
- Workshop on Standard Operating Procedures for Implementation of GRP
- Workshop on Ex-Post Analysis
- Workshop on Ex-Ante Analysis
- Workshop on the GRP "Problem Tree"
- Workshop on Good Manufacturing Practices of Medical Devices

ACTIVITIES AND OUTPUTS - REVIEW AND ANALYSIS

At the start of the project, the MDRC agreed to support the development of a U.S.-Colombia PPE Guide with NIST to facilitate trade and exports and promote transparency.

As MDRC supported the guide's development, the Colombian Institute of Technical Standards and Certification (ICONTEC) worked with both INVIMA and the Ministry of Health to incorporate the guide into an inter-agency guide to PPE requirements for COVID-19 and other national PPE requirements. NIST also completed a reciprocal guide to PPE requirements in the workplace in the United States, excluding nuclear and medical settings.

More information on activities and outputs may be found below.

Implementation of Foundational GRP

The Colombia Liaison worked to implement formal processes and procedures to institutionalize GRP in Tier One and Tier Two contexts. At Tier Two, the Ministry of Health formally approved and published an SOP including GRP requirements for all Ministry regulatory processes in line with international obligations and reference documents. Following their approval, the MDRC conducted additional capacity building to formally train public servants on the new procedures. At Tier One, the National Planning Department (DNP) informed MDRC it would implement those GRP requirements across the whole-of-government both at national and territorial levels.

WORKSTREAMS - TIER 2	RESULTS	DOCUMENT ADOPTED	DRAFT DOCUMENT CONFIDENTAL	LINKS
Ex-post evaluations of Decrees 4725 and 3770 (medical device regulatory framework)	1. Design of the ex post evaluation Decrees 4725 and 3770 2. Response to ex post evaluation design comments 3. Results of the ex-post evaluation Decrees 3770 of 2004 and 4725 of 2005	×		https://www.minsalud.gov.co/Anexos_Normatividad_Nuevo/20232400028190300004%20%281%29.pdf
Ex-ante evaluations of Decrees 4725 and 3770 (medical device regulatory framework)	4. Draft problem tree - Decrees 4725 and 3770		×	
Ex-ante evaluation for regulation pertaining to Emergency Use Authorizations (EUA)	5. Draft problem tree - EUA		×	

WORKSTREAMS - TIER 2	RESULTS	DOCUMENT ADOPTED	DRAFT DOCUMENT CONFIDENTAL	LINKS
Ex-ante evaluation for Good Manufacturing Practices	6. Problem tree - Good Manufacturing Practices	X		https://www.minsalud.gov.co/Anexos_Normatividad_Nuevo/AIN%20BPM%20DM+RDIV%20VERSI%c3%93N%20DE%20PUBLICACI%c3%93N%20JULIO%2012%20DEL%202022.pdf
Ex-ante evaluation for clinical research	7. Problem tree - Clinical Research	X		https://www.minsalud.gov.co/Normativa/Paginas/analisis-de-impacto-normativo.aspx
Standard Operating Procedure for Implementation of GRP at Ministry of Health	8. Standard Operating Procedure-MoH	X		
Checklist for TBT Agreement and Pacific Alliance at Ministry of Health	9. Check list TBT- MoH	X		
U.S.-Colombia Reciprocal PPE Guide	10. English and Spanish guides navigating Colombian PPE requirements for COVID-19 and other health and protective emergencies	X		https://share.ansi.org/Shared%20Documents/Standards%20Activities/International%20Standardization/Standards%20Alliance/PPE%20Guide_Final_English.pdf https://share.ansi.org/Shared%20Documents/Standards%20Activities/International%20Standardization/Standards%20Alliance/PPE%20Guide_Final_Spanish.pdf
NIST PPE Guide	11. Guide to PPE requirements in the workplace in the United States, excluding nuclear and medical settings	X		https://www.nist.gov/publications/guide-united-states-personal-protective-equipment-compliance-requirements

WORKSTREAMS - TIER 1	RESULTS	DOCUMENT ADOPTED	DRAFT DOCUMENT CONFIDENTAL	LINKS
Standard Operating Procedure for Implementation of GRP at National and local Level	12. Standard Operating Procedure-National Level 13. Standard Operating Procedure-Territorial Level 14. Format for Stakeholders Participation- Ex ante evaluation 15. Format for Stakeholders Participation- Ex post evaluation	X		
Checklist to promote full compliance with the TBT Agreement and Pacific Alliance at National and local Level	16. Check List TBT- National Level	X		

Mexico

ACTIVITIES AND OUTPUTS - CAPACITY BUILDING

- GRP and medical device regulation (GRP & CA Checklists)
- Utilization of International Standards and Conformity Assessment
- Quality Management Systems for MDs Manufacturing: ISO 13485 & MDSAP
- Stability studies for medical devices
- Software as a medical device and unique device identification (UDI)

ACTIVITIES AND OUTPUTS - REVIEW AND ANALYSIS

- GRP Checklist
- CA Checklist
- COFEPRIS applied to become an IMDRF Affiliate Member
- COFEPRIS applied for "Affiliate Member" status at MDSAP
- Strategy for Regulatory Certainty of the Medical Devices Sector and commitment to publish a broader recognition agreement for medical devices
- Position paper on Good Manufacturing Practice (GMP) regulation

Adoption of International Standards and Conformity Assessment – Mexico

According to the WTO, Technical Barriers to Trade (TBT) are regulations, standards, and procedures which create unnecessary obstacles to trade, distort trade, and increase the cost for companies to export. Throughout the project, MDRC aimed to increase awareness on TBTs in project countries and identify medtech legal/regulatory non-alignments that may constitute a specific-trade concern (STC).

In Mexico, the MDRC identified NOM-241, regarding Good Manufacturing Practices (GMP) for establishments engaged in the manufacture of medical devices, as a regulatory potential non-alignment with international standards. The MDRC through the IACRC drafted a position paper on NOM-241 with the input of local partners, including the Mexican Association of Innovative Industry of Medical Devices (AMID) and the National Chamber of the Pharmaceutical Industry (CANIFARMA), Medical Device Division. This position paper was also shared with the Enquiry Points in Mexico and the US.

NOM-241 entered into force 20 June 2023 and does not allow for the recognition by COFEPRIS of inspection audits of medical device manufacturing facilities consistent with international standards and Mexico's commitments under the United States-Mexico-Canada Agreement (USMCA).

In the months before and after the NOM went into effect, MDRC engaged COFEPRIS in frequent meetings to advance progress mitigating this trade concern. The MDRC met with COFEPRIS in March 2023 where COFEPRIS committed in writing to issue three Official Notices ("Circulares") with the effect of expressing COFEPRIS's intention to: (1) exempt the Mexican export-only industry form the scope of NOM-241; (2) MDSAP audit reports recognition consistent with the USMCA; and (3) recognition of ISO 13485 certifications.

COFEPRIS subsequently issued two such Official Notices ("Circulares"):

OFFICIAL NOTICE NO. COFEPRIS-CFS-214-2023

Dated 28 April 2023

Exempts the export only industry from the scope of NOM-241

OFFICIAL NOTICE NO. COFEPRIS-CFS-305-2023

Dated 6 July 2023

Recognizes certifications issued through the Medical Device Single Audit Program (MDSAP) as equivalent to the ones issued by COFEPRIS.

Accepting these Notices as valid statements of COFEPRIS regulatory intent, while these provisions were properly placed in the corresponding regulatory instruments, but duly subject to GRP requirements for technical regulations (binding, published in the Official Gazette and notified to the WTO TBT Committee). Then, COFEPRIS finally submitted NOM-241 to the Ministry of Economy for inclusion within the 2024 regulatory agenda for full review.

In October 2023, COFEPRIS issued the Strategy for Regulatory Certainty of the Medical Devices Sector which refers to MDRC contributions, the creation of a Committee of GRP as well as the GRP and CA Checklist. Additionally, COFEPRIS confirmed the formal submission of their application to become an affiliate member of MDSAP, which is a major milestone achieved through the years-long joint effort by COFEPRIS, USFDA, and MDRC. Finally, constituting a significant MDRC achievement, on 31 October, COFEPRIS submitted NOM-241 to the Ministry of Economy for inclusion for revision within the Mexican regulatory agenda for 2024.

Peru

ACTIVITIES AND OUTPUTS - CAPACITY BUILDING

- GRP Workshop engaging public and private sector stakeholders
- Capacity building workshop on GRP for the private sector

ACTIVITIES AND OUTPUTS - REVIEW AND ANALYSIS

- Medical Device Procedures Triannual Update

Implementation of Foundational GRP - Peru

In 2022, under the ACR triannual Procedures Review the Peruvian ALAFARPE – AMCHAM Joint Committee for Medical Devices (CDMMAA), in alignment with MDRC, provided comments to address misalignments with international standards and references included in relevant procedures to approve medical technologies for commercialization in the country.

Ghana

ACTIVITIES AND OUTPUTS

Given the initial pace of MDRC communications with the Ghanaian authority partners, MDRC opted to schedule MDRC Ghana workstream engagement following the MDRC-FDA-AMDF continental level training which took place in Nairobi, Kenya in November 2023. The MDRC sponsored GFDA participation in the MDRC-FDA-AMDF training, met with GFDA together with USFDA, USAID and ANSI while in Nairobi, and subsequently held a virtual follow-up meeting in December 2023, confirming plans to continue virtual training in 2024 as an MDRC legacy activity. As an additional output of the newly acquired knowledge, GFDA reported their interest to recognize ISO13485.

Kenya

Activities focused on capacity building with the Pharmacy and Poisons Board (PPB). In total, three events were held in 2023 on the following thematic areas:

ACTIVITIES AND OUTPUTS - CAPACITY BUILDING

- GRP and medical device regulation
- Utilization of international standards and references
- Quality management systems–regulatory process and medical device manufacturing
- CA for medical devices
- Regulatory reliance

See "Training and Events" for more information on capacity building activities in Kenya.

ACTIVITIES AND OUTPUTS - REVIEW AND ANALYSIS

- Development of regulatory instruments and open public consultations –Gap Analysis
- Strategic Plan
- GBT+ – MDRC recommendations on GRPs
- CA streamline–PPB and KEBS coordination
- General recommendations on implementation of GRP & CA Checklists

South Africa

ACTIVITIES AND OUTPUTS - CAPACITY BUILDING

- GRP and medical device regulation
- Utilization of international standards and references
- Quality management systems–regulatory process and medical device manufacturing
- CA for medical devices
- Regulatory reliance

ACTIVITIES AND OUTPUTS - REVIEW AND ANALYSIS

- Quality management system for regulatory process–IMDRF membership
- General recommendations on implementation of GRP–GRP & CA Checklists
- Inter-institutional Coordination for GRP Implementation–SAHPRA/KEBS Enquiry Point
- Inter-institutional Coordination for Standards Development–SAHPRA/KEBS (establish inter-agency MoU for WTO/TBT, standards and conformity assessment coordination (SAHPRA – SABS)

Left to right: Dineo Hexana, South African WTO TBT Enquiry Point at SABS; Marina Carvalho, MDRC GRP Lead, Dimakatso Mathibe, Sr. Manager Medical Devices SAHPRA; Mapaseka Gumbi, Leader Technical Committee Medical Devices, SABS; Sandra Ligia González, MDRC Tier 2 Lead; Steven Bipes, MDRC Lead.

In November 2023, the MDRC engaged with SABS and SAHPRA to reestablish the communication mechanism among the two institutions and to establish the proper procedures for South Africa to notify regulations produced by SAHPRA. A follow up meeting among the CEOs of the two institutions to formalize the agreements was committed. This timely engagement opened up the opportunity for the medical device regulatory framework under revision, to properly comply with GRP obligations.

Implementation of Foundational GRP - South Africa

In August 2023, the MDRC held a meeting with SAHPRA as part of the USTDA-organized meetings at AdvaMed in Washington, D.C. During the meeting, SAHPRA requested insights into how international standards affect local medical device manufacturers. Participants also explored the complex dynamics of treaty obligations in relation to domestic legislation and regulations, including considerations related to the WTO/TBT agreement. A significant point of discussion was the role of the Department of Trade and Industry (DTI) in resolving conflicts between SAHPRA and South Africa's trading partners in the context of these treaty obligations.

In November 2023, the MDRC in collaboration with SAHPRA organized a workshop utilizing the Medical Device Technical Assistance Training Curriculum. The WHO and NRAs from Australia, Brazil, and Singapore contributed to the development of competencies by sharing their experience on implementation of reliance and utilization of international standards. Experts from USFDA presented technical topics as well as on GRP and CA, the latter alongside SABS and the South African National Accreditation System (SANAS). Notably, the WHO recognized the impact and relevance of the MDRC's work.

MDRC held a workshop on 14-16 November 2023 tailored to the needs of South Africa, utilizing the Medical Device Technical Assistance Training Curriculum.

Indonesia

Activities focused on capacity building for Ministry of Health (MOH) staff; in total, five events were held from 2022 to 2023 on the following thematic areas:

ACTIVITIES AND OUTPUTS - CAPACITY BUILDING

- GRP and medical device regulation
- Regulatory training on standards and guidance for medical devices
- Quality management systems
- CA for medical devices

ACTIVITIES AND OUTPUTS - REVIEW AND ANALYSIS

- General Recommendations on Implementation of GRP/TBT/CA Checklists
- Comparison of the MOH SOP to international GRP/TBT benchmarks
- Recommendations for MOH implementation of GRP within the medical device-relevant articles of the Omnibus Health Law

Implementation of Foundational GRP - Indonesia

Under the work of the MDRC, the Ministry of Health began integrating foundational GRP into government processes. Throughout the project, capacity building exercises, namely the webinar series and small group discussions, increased understanding of GRP and the need to formalize GRP within government processes. **The Ministry of Health requested support integrating GRP into their current SOP, which informs their approach to medical device regulation.**

The MDRC supported the refinement of the SOP and integration of GRP. **An additional opportunity for further impact arose given Indonesia's 2023 passing of the Health Omnibus Law, and the Ministry of Health also requested support to integrate some of the key articles of the new law pertaining to medical devices into the revised SOP, to make the latter a living document that can be used more prescriptively and in line with the new regulations. By incorporating GRP and new articles from the Omnibus Law, the SOP has the potential to improve the quality of medical device regulation in Indonesia over the long-term.**

TRAININGS AND EVENTS

After establishing workstreams in each project country and developing a workplan, the MDRC focused on implementation during the final project years. Recognizing the importance of both public and the private sector engagement, the MDRC convened NRAs and other stakeholders to foster a collaborative approach toward capacity building and regulatory reliance. These activities laid the foundation for sustainable improvements in regulatory processes, focusing on the use of international standards and conformity assessment, ensuring that public and private stakeholders are better prepared for future global health crises.

Higher levels of private sector participation can indicate increased awareness of regulatory and standards setting activities and potentially increased participation in these processes. With increased buy-in from the private sector, governments can have increased confidence that regulations will be effective in addressing regulatory objectives with market realities.

To promote gender representation in standards activities, MDRC tracked the participant breakdown by gender for each engagement and noted that female participants accounted for more than 50% of attendees during every engagement.

Photo: Adobe Stock

A breakdown of capacity building by project country and region may be found in the quarterly and annual reports.

Project Country/ Region	Capacity Building Activities	Total Participants
Latin America	13	1,316
Brazil	11	1,846
Colombia	5	391
Mexico	19	4,720
Peru	2	553
Africa	4	586
Kenya	4	363
South Africa	7	1,165
Southeast Asia	2	414
Indonesia	7	486

Although no country-specific training sessions were held for Ghana, representatives from GFDA and industry attended various sessions of the MDRC-AMDF-FDA Workshop. 46 participants from Ghana attended.

MDRC Workshops Capacity Building - Person Hours

Year	Workshops	Participants	Person Hours
2021	24	4,746	11,692
2022	26	3,587	12,195
2023	23	3,507	16,520
Total	**73**	**11,840**	**40,407**

Capacity Building Example - Kenya

In January 2023, MDRC met with the CEO and staff of PPB to align on the project workplan, including training dates and agendas with a focus on an overhaul of the Kenyan medical device regulatory framework implementing GRP, reliance models, and the use of international standards. The MDRC also held a session with KEBS, including the Kenyan representative to the WTO TBT Committee and leads for standards, conformity assessment and metrology. The meeting focused on details of a pathway to exempt medtech market access from the KEBS redundant Pre-Export Verification of Conformity (PVoC) regime and possible incorporation of GRP and USMCA Medical Device Annex type commitments in the ongoing Strategic Trade and Investment Partnership (STIP).

The MDRC held the Good Regulatory Practices & Technical Competencies training in Nairobi, Kenya from 22-24 August 2023. The aim of the workshop was to build joint knowledge on GRP to strengthen the medical device regulatory sector in Kenya. In 2023, PPB onboarded 50 additional staff, and the workshop provided an opportunity to provide all new employees with comprehensive training on regulated products.

The workshop convened over 110 unique participants over three days of trainings and engaged 10 countries through a combination of in-person and virtual attendance. Singapore's Health Sciences Authority (HSA), USFDA, Australia's Therapeutic Goods Administration (TGA), and Brazil's ANVISA representatives engaged in panel discussions and presentations covering critical topics included in the training curriculum jointly developed by USFDA and MDRC.

MDRC-PPB Workshop – Nairobi, Kenya – August 2023. The workshop convened representatives from PPB, the WHO, four NRAs, the U.S. National Institute of Standards and Technology (NIST), the Association for the Advancement of Medical Instrumentation (AAMI), and the private sector.

Key outcomes of the training include, but are not limited to:

Emphasis on reliance:	Kenyan Dossier Alignment:	International Standard Alignment:	WTO TBT Compliamce:
PPB noted reliance is pivotal for Kenya, signaling its commitment to expanding its reliance program	Championed the alignment with IMDRF TOC and USFDA/Health Canada's eSTAR pilot, emphasizing the industry's acknowledgment of its value	Key discussions with KEBS on synchronizing Kenya's standards with global benchmarks	PPB's regulatory counsel underscored the significance of WTO/TBT compliance, acknowledging the need to increase alignment

Following the workshop, a specific workstream on enhancing the rule making process at PPB was agreed upon, including GRP obligations under the WTO/TBT which are not currently considered. Another critical output was the decision to utilize MDSAP for ensuring medical devices are manufactured to the relevant international standard.

In November 2023, MDRC engaged PPB, KEBS, USFDA, MEDAK and IEC to identify opportunities to streamline the inspection processes and scope of responsibilities at PPB and KEBS.

PROJECT REPORTS

During the project, the MDRC conducted a review of the Phase One GRP Checklist in order to conduct further Tier One Analysis. The MDRC the packaged the findings of its Phase One, Tier One gap analyses and literature reviews from all project countries in a unified Tier One report. This report includes assessments of GRP implementation by country as well as an overarching chart to allow for comparison across project countries. Additional information on Tier Two Analysis may be found in the SA2 quarterly and annual reports.

In parallel efforts to the MDRC, USAID supported the development of a Capacity Building Guide for Good Regulatory Practices and coordinated with United States Trade Representative (USTR) to develop the Blueprint for Advancing Good Regulatory Practices in the Region ('APEC GRP Blueprint'). MDRC socialized both of these complementary resources with project stakeholders.

MDRC GLOBAL MEDTECH DIAGNOSIS

Through the development of project reports and engagement with global, regional, and project country stakeholders, the MDRC observed that the major causes of medical device bottlenecks around the world, during and recovering from COVID-19 are as follows:

- NRAs regulating beyond their institutional capacities and resources;
- NRAs creating country/region-unique technical regulations, standards and conformity assessment requirements rather than employing Regulatory Reliance;
- Improperly regulating medical devices as medicines; and
- Conducting regulations inconsistent with the proper legal foundations, both those of domestic legislation as well as international treaty obligations.

Improper and illegal medical device regulation inconsistent with international guidelines:

- Prevent medtech manufactured locally and imported from entering markets and from reaching points of care and patients;
- Impede national and global efforts to fully recover from the COVID-19 pandemic and better prepare for future health emergencies;
- Drain limited public health resources; and
- Sustain a government and policy environment unanchored by rule-of-law and that is neither transparent nor predictable.

As such, MDRC workshops and trainings endeavored to address these causes of medtech bottlenecks through the following measures:

- Training NRAs to regulate in accordance with their institutional capacities and public health resources (e.g., encouraging NRAs to accept MDSAP/ISO 13485 rather than conduct their own GMP facility inspections, guiding NRAs to leverage existing approvals rather than conduct their own dossier reviews);
- Training and assisting NRAs to employ Regulatory Reliance, under which they can leverage available international medical device-relevant reference documents and standards as a basis for national technical regulations and decisions made by reference agencies on the safety, quality and performance of the devices throughout their whole lifecycle;
- Identifying instances in which government FTEs are tasked with regulating both medicines and medical devices, which often leads to the improper differentiation of medicines and medtech standards;
- Grounding MDRC trainings with an overview of the proper legal foundations, both those of domestic legislation as well as international treaty obligations.

VII. Highlights and Success Stories

Advancement of Good Regulatory Practices and Development of National Quality Infrastructure Alongside the IX Summit of the Americas

In PY2, MDRC mobilized leaders from the public and private sectors across the Americas in an unprecedented manner to advance GRP and improve project countries' NQI. Alongside the IX Summit of the Americas, MDRC through the Coalition convened high-level representatives from industry, government, and civil society for the first time to advance regional GRP implementation across the Americas.

These representatives:

- **Delivered high-level presentations of ongoing GRP policy implementation within each country and exchanged best practices;**
- **Participated in in-depth examinations of work being conducted in each MDRC project country to implement GRPs, including timelines and plans for future implementation;**
- **Explored efforts to document GRP implementation within pilot project regulatory agencies; and**
- **Facilitated long-term GRP collaboration among the countries.**

Photo: Adobe Stock

During the Inter-American Coalition for Regulatory Convergence's first-ever in-person session, MDRC partner government representatives convened to share their work to implement GRP. The Office of the U.S. Trade Representative and U.S. Food and Drug Administration provided remarks on their efforts to advance GRP and regional medical device regulatory convergence at bilateral, sub-regional, and regional levels. The Pan American Health Organization also shared their initiatives to promote GRP, including the utilization of International Standards as well as Good Reliance Practices.

Brazil's Secretary for Competition Advocacy and Competitiveness, Colombia's Ministry of Commerce, Industry and Tourism, and Mexico's Secretariat of Economy provided a high-level report on their GRP trade commitment implementation efforts. The representatives spoke to long-term objectives for those efforts as well as challenges in their implementation. These reports were followed by a presentation by the President of the Brazilian National Institute for Metrology, Standardization and Industrial Quality (INMETRO) on Brazil's National Quality Infrastructure.

Photo: Adobe Stock

In MDRC's first in-person workshop, the initiative convened high-level government representatives of agencies and bodies responsible for cross-sectoral implementation of GRP in Brazil, Colombia, and Mexico. This workshop was comprised of two sessions. The first external session enabled private sector attendees from the Coalition events to learn directly from those MDRC representatives on their country's efforts to implement GRP and what they hope to achieve through partnership with MDRC in the coming years. The external session was followed by an afternoon, internal roundtable for MDRC government partners to share best practices and offer practical guidance on the advancement of their GRP initiatives.

Further information on the Summit events along with their resources (i.e. slide decks, agendas, etc.) may be found on the Coalition website here.

MDRC convenes partner representatives during the IACRC's first in-person session on the sidelines of the IX Summit of the Americas in Los Angeles, California, United States.

Colombia Ministry of Health Wins 2022 and 2023 National Contests on Good Regulatory Practices

Under the leadership of the MDRC Colombia Liaison, MDRC advanced the formal implementation and institutionalization of GRP requirements at Tiers One and Two. At Tier Two, following nine months of extensive coordination, the Ministry of Health approved and published GRP requirements in the form of a regulatory instrument, which updated the Ministry's processes and procedures to ensure compliance with domestic regulatory improvement policies – inclusive of technical regulations and other administrative acts – and international TBT requirements.[6] The approved instrument serves as a unique tool that streamlines and bolsters all stages of the regulatory process, outlining flow charts, tools, regulations, and responsible parties. Moreover, this tool incorporates national and international guidelines, following international regulatory best practices of the OECD and the World Health Organization (WHO).

In November 2022, the National Planning Department (DNP) recognized the Colombian Ministry of Health in the National Contest on Good Regulatory Practices under the "Institutional Adoption of Good Regulatory Practices" category for its formal approval and publication of GRP requirements for all Ministry regulatory processes in line with international obligations and reference documents. Participating government stakeholders included MOH, DNP, Ministry of Commerce, and the Public Function Department. The MDRC and USAID Colombia Mission representatives attended and participated in the Contest's award ceremony recognizing MOH on 23 November 2022.

In September 2022, the National Planning Department (DNP) informed MDRC it would implement the MDRC-developed GRP tool across government entities, impacting at least 1,300 governmental entities. The tool institutionalized GRP in Colombia at an unprecedented level. The institutionalization of GRP in Colombia at an unprecedented level marked a significant MDRC milestone, significantly improving the project country's NQI, regulatory resilience for future health crises, ability to address any regulatory non-alignments, implementation of international obligations, and more.

Photo: Adobe Stock

[6] The instrument details each stage of this process, including: regulatory agenda; ex-post analysis, complete ex-ante analysis, simple ex-ante analysis, regulations, and public consultation.

Left to right. Susan Suárez, MDRC Colombia Liaison; Quintiliano Pineda Céspedes, Deputy Director of Regulatory Affairs; Marta Isabel Liévano Cantor, Regulatory Affairs Coordinator; Alejandro Diaz, Alejandro Diaz Project Management Specialist - Health Venezuela Response and Integration Office USAID/Colombia; Nora Maresh Deputy Director, Venezuela Response and Integration Office USAID/Colombia.

Following the approval of the procedure, the MDRC conducted additional training activities to formally train MOH officials on the new procedures in 2023. These trainings were attended by all areas of the Ministry responsible for regulating including the directorate in charge of regulating medical devices. These capacity building activities and continued work of the Colombia Liaison and MDRC team resulted in additional achievements in 2023. These success stories may be found below.

01. Colombia Ministry of Health and INVIMA Win 2023 National Contests on Good Regulatory Practices

In November 2023, Ministry of Health and INVIMA of Colombia, were awarded the first prize at the GRP Annual Contest organized by DNP for the ex-post evaluation of Decrees 3725 and 4770 on medical devices.

Left to right. Yolima Gómez - Director of Medical Devices and Other Technologies INVIMA; Susan Suárez, Liaison Colombia, Medical Devices Convergence Project MDRC; María Fernanda Fuentes - Deputy Director of Government and International Affairs- DNP; Oscar Marín, Advisor- Coordinator, Medical Devices and Ionizing Radiation Group - Directorate of Medicines and Health Technologies MoH; Andrea García, Technical team, Medical Devices and Ionizing Radiation Group - Directorate of Medicines and Health Technologies MoH; Julián Lopez Murcía, Jury of the Good Regulatory Practices contest; Soleiny Marín, Technical team, Medical Devices and Ionizing Radiation Group - Directorate of Medicines and Health Technologies MoH; Andrés Home, Technical team, Medical Devices and Ionizing Radiation Group - Directorate of Medicines and Health Technologies MoH; Elsy Ramírez, Technical team, Medical Devices and Other Technologies INVIMA; Katty Díaz, Technical team, Medical Devices and Other Technologies INVIMA.

02. Ministry of Health of Colombia Adopts the GRP Checklist Developed by the MDRC

The Ministry of Health updated their SOP on GRP to include the checklist developed by MDRC to ensure compliance with TBT Agreement and Pacific Alliance obligations.

03. Ministry of Health of Colombia Implements Toolkit Developed with MDRC support

MDRC supported the development of a Toolkit to facilitate the implementation of the GRP SOP which includes related guidelines, references, etc.

04. DNP Adopts MDRC-developed Formats for Stakeholder Participation

DNP adopted the formats developed by MDRC for stakeholder participation through their incorporation to the official platform for citizenship participation in the regulatory process (Unique System for Public Consultations - SUCOP), standardizing the process to collect information.

05. DNP Implements the MDRC/MOH-developed GRP Procedure across Whole of Government

DNP adopted the MDRC/MOH-developed SOP across all government regulating entities through the Integral Model of Planning and Management (MIPG).

06. MinCIT Implements Guide to Facilitate the Identification of a Technical Regulation

MinCIT Implemented an MDRC-developed guide to facilitate the identification of a technical regulation across all government regulating entities through the Integral Model of Planning and Management (MIPG).

WTO Symposium on Technical Barriers to Trade Highlights MDRC

In the final week of September 2022, the Coalition operated in its capacity as lead MDRC global implementer of Tier One and Two workstreams by organizing project engagements with the World Trade Organization (WTO) and WHO in Geneva. MDRC team members and partners had the opportunity to engage with key partners, such as PPB, in Geneva through bilateral and multilateral meetings, as well as through panel sessions. The MDRC's increased collaboration with the WTO strengthens its ability to engage on medtech regulatory convergence efforts. The engagements highlighted the critical role health authorities have in implementing international trade obligations and served to educate critical project partner NRAs.

Additionally, these engagements enabled the MDRC to increase global awareness of the importance of compliance with international obligations in resolving technical barriers to trade, regulatory bottlenecks, and related challenges to the medtech sector – especially in the context of COVID-19. In October, the WTO held its Symposium on Technical Barriers to Trade. There, Deputy United State Representative and Chief of Mission (Geneva) María Pagán delivered remarks in which she specifically highlighted MDRC, noting the project's important role in not only identifying trade bottlenecks but also addressing them. Ambassador Pagán highlighted the project's work "conveying assistance to 10 partner countries across Latin America, Africa, and Southeast Asia to increase the transparency and predictability of regulatory systems for medical devices by providing technical assistance on good regulatory practices."

First Medtech-NRA Global Level Curriculum Jointly Approved by Industry and Government

During PY3, following numerous coordination meetings with FDA regarding capacity building activities for the Africa regional and continental trainings in 2023, USFDA approved the Medical Device Technical Assistance Training Curriculum. The curriculum now constitutes the first ever FDA-industry developed "menu" of MD NRA training options from which to develop training sessions aligned with international reference documents and with an emphasis on GRP and use of standards. With inputs from SAHPRA, PPB, Mecomed, FDA, and MDRC, the training curriculum is also the first medtech-NRA global level curriculum jointly approved by industry and government.

The training curriculum builds off curricula that were previously developed beginning with the APEC Core Curriculum but also leverages significant inputs from other sources. Additionally, the curriculum incorporates the principles of the WHO GMRF in acknowledging the "stepwise approach" for NRAs to prioritize and regulate within available regulatory resources, focusing, on NRAs ensuring a proper legal foundation for regulations; emphasizing employment of regulatory reliance as a tool and complement to capacities for reviewing domestic dossiers.

Scott Colburn, USFDA Director - Division of All Hazards Response, Science and Strategic Partnerships (DARSS), Center for Devices and Radiological Health and chair of ISO Technical Committee 210 speaks on the value of international standards for medical device regulatory convergence, reliance, patient access and supply chain resilience at the MDRC- AMDF-FDA capacity building workshop in Nairobi, Kenya, November 2023.

The curriculum is meant to serve as a "menu" of options from which specific Africa (and other) training agendas may be compiled. The curriculum is broken into two worksheets:

01. **Medtech regulatory fundamentals across a set of core areas**

02. **GRP and rulemaking fundamentals**

The curriculum is intended to be introductory, focused on NRA essentials – the absence of which have caused the near totality of global regulatory non-alignments and supply chain bottlenecks. As such, the curriculum does not include more complex subjects such as cybersecurity, AI, SaMD. Rather, the curriculum provides a strong foundation and is coherent across the policy areas of health, medical technologies, international reference documents, trade, standards, conformity assessment, proper legal foundations, and foundational GRP.

The finalization of the curriculum marks a significant MDRC output and a GMTA and IMDRF contribution. It is the hope of MDRC that this curriculum will be repurposed and used by other projects seeking to advance global regulatory harmonization and foundational GRP.

USFDA and AMDF NRA representatives at the MDRC-FDA-AMDF capacity building workshop

COFEPRIS Submits NOM-241 for Revision within the 2024 Regulatory Agenda

Following MDRC's numerous meetings with COFEPRIS and coordination with U.S. government partners as well as the Ministry of Economy (SE) and the Mexican Embassy to the United States, COFEPRIS committed to reviewing NOM-241 and submit corresponding reform within the 2024 regulatory agenda. This commitment marks a significant MDRC outcome in resolving significant trade concerns.

In October 2023, COFEPRIS issued the Strategy for Regulatory Certainty of the Medical Devices Sector which refers to MDRC contributions, the creation of a Committee of GRP as well as the GRP and CA Checklist. Additionally, COFEPRIS confirmed the formal submission of their application to become an affiliate member of MDSAP and commitment to gradually harmonize the national regulation of medical devices with IMDRF, which are major milestones achieved through the joint effort by COFEPRIS, USFDA, and MDRC.

MDRC ECONOMIC OUTCOME

The MDRC generated the following estimates[7] of the costs of medical device market authorization bottlenecks deriving from regulatory, standards and conformity non-alignments in the MDRC countries. These values are estimates only based on aggregated information from MDRC-supporting medical device manufacturers.

Non-Aligned Medical Device Technical Regulatory Requirements and Delays (World):	**50B**
Non-Aligned Medical Device Technical Regulatory Requirements and Delays (MDRC Countries):	**2.35B**
MDRC Policy Change Economization (if Colombia GRP model extended to all MDRC countries)	**1.75B**
MDRC Policy Change Economization (policies implemented to date)	**235M**

numbers in USD

MDRC DEVELOPMENT CONTEXT AND GENDER BALANCE

The Standards Alliance seeks to expand programming to address gender-based issues such as representation in policy making and technical work and to promote gender responsive standards. Under SA2, MDRC advanced this target and prominently featured female leadership to positively influence attitudes and behaviors in the workplace and policy environment. **In particular, the Coalition's Technical Secretariat and MDRC project support team is led by the industry's leading and highly experienced professionals who are also women from a diversity of national and ethnic backgrounds.**

The Coalition establishes a strong example within the medtech sector and with other sectors, advancing the goals of USAID's Gender Equality and Female Empowerment Policy (the Policy) and aligned with the Women's Global Development and Prosperity Initiative (WGDP). More specifically, **the Coalition fully aligns with the Operational Principles of the Policy, including integrating gender equality and female empowerment into USAID's work through the program cycle as well as pursuing an inclusive approach to fostering equality while building partnerships across a wide range of stakeholders.**

In addition, the partnerships built with MDRC stakeholders underscore the leading role that women played in MDRC implementation. The project's success is largely owed to the support of project country government partners, international and regional fora, and the global medtech industry, all of which featured prominent female leadership driving project outputs and outcomes.

[7] A non-exhaustive list of the costs in the estimate can be found in the report annex.

MDRC CORE PROJECT TEAM

Steven Bipes
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MDRC Project - Southeast Asia POC

Joe Lewelling, Association for the Advancement of Medical Instrumentation (AAMI) and Terry Woods, USFDA/CDRH Standards and Conformity Assessment Program (SCAP) address the Optimization of Standards for Regulatory Purposes with the AMDF – 7 November 2023 – Nairobi, Kenya.

Consistent with the MDRC architecture, medical device industry representatives participated in the MDRC training sessions with national regulatory authorities to provide real-world inputs in effective regulatory frameworks. Pictured from left to right: Neil Mafnas (USFDA), Asmaa Awad (Roche Diagnostics), Tammy Steuerwald (Roche Diagnostics), and Fatemeh Razjouyan (Medtronic).

VIII. MDRC Legacy

While the USAID federal contributions to the MDRC under Standards Alliance Phase 2 conclude with the delivery of this final report at the end of 2024, the MDRC has been structured to continue to serve as a legacy resource of information to the public and private sectors for the advancement of medical device regulatory convergence and implementation of foundational good regulatory practices including the use of international standards for medical devices.

At the global level, this takes the form of:

- GMTA/GDA efforts to provide and/or support the ongoing training on IMDRF reference documents
- The availability of the GMTA co-secretariat at AdvaMed, leveraging the GMTA/GDA membership of global medtech associations and companies, to respond to questions and provide information regarding medical device regulatory frameworks, reference documents, standards, conformity assessment and technologies
- Expanded capabilities of the WTO ePing library with medical device sector functionality – facilitating the tracking of medical device notifications

At the regional level, this takes the form of:

- Western Hemisphere:
  - The Inter-American Coalition for Regulatory Convergence – Medical Technology Sector
  - Liaison status to and from ISO TC 210
- Africa:
  - GMTA Africa Working Group
  - Request for AMDF Liaison status to and from ISO TC 210

At the national level, this takes the form of:

- Increased medical device association institutional knowledge of and dedication to the application of foundational GRP and use of standards in support of medical device regulatory development, maintenance and convergence – across all MDRC countries with a particular emphasis on Brazil, Colombia, Mexico, Peru, Kenya, and South Africa

IX. MDRC Recommendations

The MDRC offers the following recommendations to its various partners as a roadmap to continue MDRC-initiated workstreams, fully implementing foundational Good Regulatory Practice policies that support medical device regulatory convergence, reliance and use of international standards across all MDRC countries.

MULTILATERAL ORGANIZATIONS AND INTERNATIONAL FORA

World Health Organization (WHO)

01. Develop WHO guidance documents consistent with the terms of the WHO GRP document, for the inherent benefits to their quality and applicability, but also as a model for NRA document development and maintenance.

02. Provide a minimum 60-day public consultation period on all WHO documents, aligned with the terms of the WTO/TBT Agreement, and allowing for adequate time for translation of documents, technical review and translation of comments made back to the WHO.

03. Emphasize and prioritize with NRAs the need to conduct rulemaking with the proper legal foundations – and avoiding regulating beyond sustainable regulatory capacities – given the health access barriers that can be created.

04. Continue to emphasize NRA use of relevant international standards and IMDRF references, and conformity assessment as core components of GRP and regulatory reliance

05. Prioritize NRA utilization of Reliance for medical devices already reviewed/approved by reference NRAs – freeing up NRA bandwidth to prioritize and attend to local medical device manufacturers.

06. Establish recommendations for the proper training and stability of MD NRA staff.

07. Update the GBT+ to properly assess NRAs maturity level as it pertains to medical device and IVDs.

08. Follow other more detailed MDRC recommendations available here.

International Medical Device Regulators Forum (IMDRF)

01. Establish some type of IMDRF recognition of or "crosswalk" to relevant WHO guidance and WTO obligations applicable to medtech, including but not limited to:
    a. WHO Global Model Regulatory Framework (GMRF)
    b. WHO Good Regulatory Practices (GRP)
    c. WHO Good Reliance Practices (GRelP)
    d. WHO Post-Market Surveillance
    e. WTO/TBT Agreement

02. Consider establishing guidance on regulatory issues that are also trade and supply chain issues, examples including:
    a. IMDRF Recommendations for Medical Device Conformity Assessment
    b. IMDRF Recommendations for Certificates of Foreign Government / Certificates of Free Sale (CFG/CFS)
    c. IMDRF Recommendation / Note of Clarification regarding discrepancies between NRA definitions of Country of Manufacture with Trade and Customs definitions of County of Origin

03. Consider establishing a permanent secretariat, possibly modeled on that of the ICH.

04. Consider requiring demonstrated use of or adherence to IMDRF documents as condition of membership.

05. Consider implementing an IMDRF GRP process for the development of reference documents.

Global Harmonization Working Party (GHWP)

01. Continue seeking alignment with the IMDRF for existing and new documents.

02. Consider implementing a GRP process for the development of reference documents.

World Trade Organization (WTO)

01. Continue to support ePing functional library for medical devices.

02. Expand training to members on best practices for notification of medical device regulations.

03. Establish standing cooperation with the WHO and IMDRF considering joint publications where appropriate, of the benefits and responsibilities of NRA compliance with TBT Agreement as supporting to global medical device regulatory convergence.

World Bank, the Inter-American Development Bank (IDB), other Development Banks and Technical Assistance providers:

01. Incorporate the implementation/adherence to GRP as an essential requirement for the lending process for projects involving regulatory convergence or framework support.

GOVERNMENT

Medical Device NRAs

01. Prioritize implementation of GRP as an essential component of medical device regulatory function.
02. Prioritize the development and implementation of globally aligned regulatory reliance policies.
03. Establish and maintain a quality management system for medical device regulatory function, including a GRP SOP and its related training program, to warrant sustainable compliance with legal obligations.
04. Establish a goal of developing zero (0) medical device technical regulations that are not based on international standards.
05. Establish a staff person with lead responsibilities on standards, monitoring the organizations activities in medical device standards development in SDOs.
06. Train regulatory and standards personnel in concise executive communications so that the importance of their work is readily understood by senior management.
07. Establish institutional crosswalk between regulatory/standards personnel, global and domestic government affairs, legal, and trade functions.
08. Establish a mechanism to systematically track notifications to the WTO on draft and final medical device technical regulations, preferentially providing global industry consensus positions.

Governments in General

01. Consider establishing foundational GRP as a mandatory whole-of-government policy applicable to all ministries, authorities, agencies, bodies.
02. Consider establishing a central regulatory coordination body or structure.

Ministries of Trade

01. Consider codifying GRP as a trade commitment to strengthen local industry, to open export markets and to maximize the conditions to attract foreign direct investment (FDI).

PRIVATE SECTOR

Medical Device Industry Associations and Companies

01. Prioritize advancement of GRP as an essential component of regulatory efforts

02. Establish SOPs within the Quality Management System to include and follow GRP requirements, including appropriate and continuous training to all personnel involved in rule making processes

03. Routinely participate in domestic public consultations on draft technical regulations for medical devices, providing sound science, data and reasoned decision-making including recommendations on the use of international standards as a basis for technical regulations

04. Establish a staff person with lead responsibilities on standards, monitoring the organizations activities in medical device standards development in SDOs.

05. Train regulatory and standards personnel in concise executive communications so that the importance of their work is readily understood by senior management.

06. Establish institutional crosswalk between regulatory/standards personnel, global and domestic government affairs, legal, and trade functions.

07. Establish a mechanism to systematically track notifications to the WTO on draft and final medical device technical regulations, preferentially providing global industry consensus positions.

REGION-SPECIFIC

Latin America

01. Continue strengthening institutionalization of GRPs in the regulatory instrument development process across the region

02. Regional leverage of "state of the art" MDRC GRP procedures developed and implemented by the Colombian MoH, MinCIT and DNP

03. Pursue full implementation of Regulatory Reliance and Recognition Mechanisms as committed to in the Pacific Alliance

04. Expedite regional recognition of MDSAP

05. Timely PAHO translation and endorsement of WHO and IMDRF Reference Documents for Medical Device Regulatory Frameworks:
    a. Global Model Regulatory Framework
    b. Good Regulatory Practices
    c. Good Reliance Practices
    d. Post-Market Surveillance

06 Establishment of a PAHO GRP SOP for the development of its own recommendations aligned with the WHO GRP document

07. Establishment of IDB policy prioritizing GRP implementation as either a prerequisite or preliminary component of IDB regulatory convergence projects

Africa

01. Development of AMDF SOP for GRP / TBT / AfCFTA Compliance of AMDF Documents

02. Development of AMDF Template Policy for member NRAs GRP / TBT Compliance – including liaising with National Standards Bodies (NSBs)

03. Development of AMDF - ARSO MOU, including implementation of GRP, trade agreement compliance, and use of international standards

04. Development of AMDF - AfCFTA MOU, including implementation of GRP, trade agreement compliance, and use of international standards

COUNTRY-SPECIFIC

Brazil

01. INMETRO to issue an SOP incorporating the GRP TR/CA checklists

02. Conformity Assessment of Medical Devices to follow GRP in full compliance with the ATEC Protocol

Colombia

OVERALL

01. Consistent process to update national regulations supported by the implementation of the GRP SOP, enforced by the Ministry of Health, Ministry of Commerce and DNP

02. Continue work on decrees 4725 & 4770. Ex-ante evaluation expected to be completed under revised concept of Technical Regulations by MinCIT, supported by MDRC

03. Support continuous training and auditing to ensure compliance with the GRP SOPs at all relevant agencies across government

INVIMA

01. Continue strengthening the institutionalization of GRPs in the process of developing Colombia's regulatory instruments as supported by INVIMA.
02. Consider developing new reliance mechanisms with different countries of reference for Colombia.
03. Develop actions for Colombia to obtain IMDRF and MDSAP affiliate membership, including both INVIMA and the Ministry of Health and Social Protection.
04. Develop joint actions with the Ministry of Health and Social Protection for the implementation of the lines of action of the Medical Devices Policy.
05. Develop joint actions with the Ministry of Health and Social Protection for the issuance of technical regulations related to good manufacturing practices and good clinical practices for medical devices, as well as to continue working on the implementation of the lines of action of the Medical Devices Policy.
06. Finalize the work updating Decrees 4725 of 2005 and 3770 of 2004.

MinCIT

01. Strengthen the entities in charge of issuing technical regulations through the implementation of a training program on Good Technical Regulation Practices to:
    a. Improve understanding of the definition of technical regulations consistent with the WTO/TBT agreement to avoid possible technical barriers to trade, ensuring that the responsible entities correctly apply the established guidelines. Provide training on regulatory reliance, and on how to implement it.
    b. Provide the officials in charge with the necessary skills and knowledge to develop high quality and effective technical regulations through the correct use of the Regulatory Impact Analysis tool (NIA).
    c. Promote the participation of all key stakeholders in the various stages of the implementation of a technical regulation to generate the necessary information for ex-ante and ex-post evaluation and to ensure that adequate inputs are produced to guide regulatory decisions.

DNP

01. Support the training and implementation of the GRP procedure adopted across the government through the Integrated Planning and Management Model (MIPG).
02. Strengthen the policy on procedures at the national level by revising its definition and aligning the term 'applicable administrative provisions' to be consistent with the WTO/TBT – the absence of which may be generating technical barriers to trade, especially for medical devices.
03. Clarify the policy that determines the application of the ex-ante 'Simple' and 'Complete' Regulatory Impact Analysis and strengthen the "whole-of-government" understanding of the definition of 'technical regulation' as applicable to different regulated sectors.

Mexico

01. Formalize GRP & CA Checklists – SOPs under COFEPRIS GRP Committee
02. Align Mexican Pharmacopeia and MDs Annex and update process to comply with GRPs
03. Pursue IMDRF Membership
04. Update NOM-241 (GMP), NOM-137 (Labeling), and NOM-240 (Technovigilance) in compliance with GRP: TBT & USMCA
05. Develop Implementing Regulation of the National Quality Infrastructure Law

Peru

01. Establishment of a Peruvian government policy applicable minimally to SGP (Tier One) and DIGEMID (Tier Two) that stabilizes the budgetary and managerial organization of the bodies and that can establish stable staffing of the agencies with career personnel that do not rotate with agency leadership changes which are frequent
02. Completion of the update of processes to approve MDs: Elimination of Peru-unique technical regulatory requirements for medical devices – particularly for those requiring resources that exceed DIGEMID's allocation and capacities which is currently most of them, a significant fraction of which currently constitute patient access and supply chain bottlenecks
03. Application of the many GRP recommendations of the PCM-SGP and those supported by Peru in APEC, within SOPs of the Ministry of Health and DIGEMID as they pertain to medical device regulatory processes – with a particular focus on ensuring TBT and standards compliance

Kenya

01. Update MD & IVD regulatory framework to comply with the updated GRP SOP
02. Develop PPB Action Plan to implement MDRC recommendations on applicable GBT+ audit findings
03. Develop inter-agency action plan to redefine PPB and KEBS roles regarding Medical Device CA & Post-market Surveillance
04. Implement MDRC recommendations included in the Updated PPB Strategic Plan

South Africa

01. Implementation of SAHPRA – KEBS MoU

02. Increase participation of SAHPRA and Industry in SABS Standards Technical Committees for MedTech

03. Develop and implement GRP & CA SOP to ensure compliance with legal obligations

04. Update current regulatory framework to include Reliance and ensure compliance with GRP

Indonesia

01. Issue MOH top-level statement of regulatory intent to modify the MOH Medical Device Regulatory SOP incorporating MDRC recommendations, establishing a timeline

02. Develop MOH implementation of the Omnibus Health Law incorporating MDRC recommendations and in alignment with the updated SOP

X. Annex

SPECIAL ACKNOWLEDGEMENTS

United States

Office of the U.S. Trade Representative (USTR), U.S. Food and Drug Administration (USFDA), U.S. Department of Commerce (DOC), U.S. Department of Health and Human Services (HHS), National Institute of Standards and Technology (NIST), U.S. Department of State (DOS)

Global Partners

International Medical Device Regulators Forum (IMDRF), World Health Organization (WHO), World Trade Organization (WTO), Organisation for Economic Development and Cooperation (OECD), Global Medical Technology Alliance (GMTA), Global Diagnostics Alliance (GDA), Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA), Foundation for Innovative New Diagnostics (FIND), London School of Hygiene and Tropical Medicine

Standards Developing Organizations

Association of Advanced Medical Instrumentation (AAMI), ASTM International, Clinical Laboratory Standards Institute (CLSI), International Electrotechnical Commission (IEC), International Organization for Standardization (ISO)

Latin America

Inter-American Coalition for Regulatory Convergence – Medical Technology Sector (IACRC), Latin American Alliance of Medical Device Associations (ALDIMED), Latin American Alliance for the Development of In-Vitro Diagnostics (ALADDIV), Americas Business Dialogue (ABD), Pan American Health Organization (PAHO), Pan American Standards Commission (COPANT)

Brazil

National Health Regulatory Agency (ANVISA), National Institute of Metrology Standardization and Industrial Quality (INMETRO), Ministry of Economy, Ministry of Development, Industry, Trade and Services (MDIC), Secretariat for Competitiveness and Regulatory Policy (SCPR), Secretariat for Economic Monitoring (SEAE), Secretariat of Foreign Trade (SECEX), Foreign Trade Chamber (CAMEX), Brazilian Innovative Health Industry Alliance (ABIIS), Brazilian High-Technology Health Product Industry Association (ABIMED), Brazilian Health Products Importers and Distributors Association (ABRAIDI) Brazilian In-Vitro Diagnostics Chamber (CBDL), Brazilian Association of Technical Standards (ABNT), ABNT Committee of Clinical Analyses and In Vitro Diagnostics (ABNT/CB-36), AmCham Brasil, Brazilian National Confederation of Industry (CNI)

Colombia

Ministry of Commerce, Industry and Tourism (MinCIT), Ministry of Health and Social Protection (MinSalud), National Planning Department (DNP), Administrative Department of the Public Function (DAFP), Colombian National Food and Drug Surveillance Institute (INVIMA), Colombian Institute of Technical Standards and Certification (ICONTEC), National Association of Employers – Medical Device Chamber (ANDI-CDMIS)

Mexico

Mexican Federal Commission for the Protection against Sanitary Risks (COFEPRIS), Pharmacopoeia of the United Mexican States (FEUM), National Commission for Regulatory Improvement (CONAMER), Ministry of Economy, General Directorate of Standards (DGN), Mexican Association of the Innovative Medical Device Industry (AMID), National Chamber of the Pharmaceutical Industry - Medical Device Divisions (CANIFARMA)

Peru

Secretariat of Public Management – Presidency of the Council of Ministers (SGP), National Institute of Quality – Ministry of Production (INACAL), Joint Medical Device Committee – ALAFARPE-AmCham (CDMMAA), Lima Chamber of Commerce – Health Guild (CCL-COMSALUD), National Confederation of Private Business Institutions (CONFIEP)

Africa

AU-NEPAD Africa Medical Devices Forum (AMDF), Africa Centres for Disease Control and Prevention Africa (Africa CDC), Africa Diagnostic Advisory Committee (DAC), African Organisation for Standardisation (ARSO), Medical Technology Association of Middle East and Africa (MECOMED), Global Medical Technology Alliance (GMTA) Africa Task Force

Kenya

Pharmacy and Poisons Board (PPB), Kenya Bureau of Standards (KEBS), Medical Technology Industry Association of Kenya (MEDAK)

South Africa

South African Health Products Regulatory Authority (SAHPRA), South African Bureau of Standards (SABS), South African Medical Technology Industry Association (SAMED), Southern African Laboratory Diagnostics Association (SALDA), Medical Device Manufacturers of South Africa (MDMSA)

Ghana

Ghana Food and Drug Administration (GFDA), Ghana Standards Authority (GSA)

Southeast Asia

ASEAN Medical Device Committee (AMDC)

Indonesia

Ministry of Heath, National Standardization Agency (BSN), Gakeslab Indonesia

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Annex

MDRC Economic Outcome

A non-exhaustive list of the costs in the estimate include:

- Preparing and submitting differing medical device dossiers for different jurisdictions
- Demonstrating compliance with country-unique Good Manufacturing Practice requirements based on neither MDSAP or ISO13485
- Complying with country-unique technical regulations not based on IMDRF reference documents and relevant SDO medical device standards
- Complying with country-unique conformity assessment requirements not aligned with global best practices
- Maintaining separate production lines for country-unique requirements OR lost patient access / market by those devices not being available in that market
- Unique labeling requirements
- Unique UDI and traceability requirements
- Procuring Certificates of Foreign Government / Certificates of Free Sale with Apostilles and Official Translations