Standards Alliance

Regulatory Coherence and Convergence in the Americas

Medical Technology and Beyond

Standards Alliance Initiative

USAID Funding Program

- Capacity-building assistance, specifically related to:
  - Increased understanding of WTO TBT principles
  - Implementation of the Code of Good Practice for the Preparation, Adoption and Application of Standards
  - Improved transparency in the development and/or modification of technical regulations
  - More robust and transparent engagement with the private sector in standards development and use

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USAID Funding Program

- American National Standards Institute (ANSI) is the USAID designated Standards Alliance Administrator
- Initial countries of focus: Colombia, Costa Rica, Mexico, Peru
- Must have demonstrable link to use of international standards

Standards Alliance Initiative

USAID Funding Program

- AdvaMed project approved by USAID and ANSI to support and promote:
  - Tier 1: Good Regulatory Practices (GRP = Regulatory Coherence)
    - Horizontal – Sector Independent
  - Tier 2: Medical Device Regulatory Convergence: Capacity Building, GRP, Model Frameworks, Technical Regulations, Standards, Conformity Assessment requirements
    - Vertical – Medical Technology Specific

Standards Alliance Initiative

USAID Funding Program

- Tier Structure:
  - Phase 1: Identify set of international best practices
  - Phase 2: Conduct GAP analysis
  - Phase 3: Work with individual governments to address/fill gaps
  - Phase 4: Work with interested governments together / regional benchmarking

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Project Progress:

- Tier 1 – Phase 1: 100% Complete
  - GRP Policy / Implementation Guide (English, Spanish, Portuguese)
- Tier 1 – Phase 2: 100% Complete
  - GRP GAP Analysis (Colombia, Costa Rica, Mexico, Peru)
- Tier 1 – Phase 3: 100% Complete (initiation and buy in)
  - Bilateral Cooperation: (CRR, industry: Colombia, Costa Rica, Mexico, Peru)
- Tier 1 – Phase 4: 100% Complete (initiation and buy in)
  - Multilateral Cooperation (CRR, industry: Colombia, Costa Rica, Mexico, Peru)

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Tier 1 – Phase 1: GRP International Benchmark

- Good Regulatory Design Document
  - Core elements: OECD, WTO/TBT, APEC, U.S. OMB-A119
  - GRP Checklist (12 items)
  - RIA Checklist (16 items)
  - Policy Primer
    - Including Central Regulatory Review (4 key functions)
  - Spanish / Portuguese

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Tier 1 – Phase 1: GRP International Benchmark (continued)

- Implementing Good Regulatory Practices
  - Transparency & Stakeholder Engagement
    - Regulatory Forecast
    - National Regulatory Register
    - Opportunity for Public Comment
    - Publication of Evidence / Regulatory Analysis
    - Respond to Stakeholder Input
  - Other
    - Use of Quality Data & Sound Science
    - Risk-Based Approach
    - Regulatory Impact Assessment
    - Assessment of International Impact
    - Use of international standards and conformity assessment
    - Ex-Post Assessments of Regulatory Impacts

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Tier 1 – Phase 1: GRP International Benchmark (continued)

- Central Regulatory Oversight Body

  - Structure
    - Located Close to Important Government Decision Makers
    - Given Formal Authority of Regulatory Oversight
    - Staffed with Experts and Given Independence
    - Given the Necessary Scope of Review to be Effective

  - Functions
    - Establish and Foster Good Regulatory Practices and Principles of Regulation
    - Ensure Forward Planning of Regulatory Activity
    - Review Proposed and Final Regulatory Measures before they are Published
    - Coordinate International Regulatory Cooperation

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Project Progress:

- Tier 2 – Phase 1: 100% Complete
  - MedTech GRP, TR, Standards, Conformity Assessment international benchmark
- Tier 2 – Phase 2: 100% Complete
  - Medtech Technical Regulation, Standards, Conformity Assessment GAP analysis
- Tier 2 – Phase 3: 100% Complete (initiation and buy in)
  - Bilateral cooperation (MD regulators, MOHs, NSBs, industry)
- Tier 2 – Phase 4: 100% Complete (initiation and buy in)
  - Multilateral cooperation (MD regulators, MOHs, NSB, industry)

Standards Alliance Initiative

Proyecto Reglamentos Internacionales y Estándares para Dispositivos Médicos en los países de América Latina

Objetivo

- Realizar un estudio situacional sobre el reconocimiento de las normas internacionales, aplicadas a dispositivos médicos, con fines regulatorios

Metodología

- Conferencia de sensibilización sobre la importancia de los temas abordados en el estudio
- Recolección de datos - cuestionarios electrónicos
- Análisis documental - documentos públicos

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Conferencia de Sensibilización

VII Reunión de Autoridades Reguladoras para el Fortalecimiento de la Capacidad Reguladora de Dispositivos Médicos en la Región de las Américas

Reunión Abierta - Ottawa - Canadá
Septiembre - 2017

Temas
El uso de Dispositivos Médicos en Programas de Salud Pública Rosanna Peeling, IDC / LSHTM
Modelo Global de Marco Regulatorio de la OMS para Dispositivos Médicos Mike Ward – OMS
Asian Harmonization Working Party Playbook Jeong Rim Lee – AHWP / ASEAN
Regulación sobre Dispositivos Médicos en las Américas. La Perspectiva de los Reguladores. La experiencia de COFEPRIS, México y de la DNM, El Salvador COFEPRIS – Norma Morales DNM – José Coto
Regulación sobre Dispositivos Médicos en las Américas. La Perspectiva de los fabricantes. Nicole Taylor Smith – Johnson & Johnson
Uso de normas para fines reglamentarios. La experiencia de EEUU / La experiencia de Cuba Sheron Lapalaning – CDRH – FDA Dulce Maria Martinez – CECMED -CUBA
Encuesta “Standards Alliance” Carlos Gouvêa – ALADDIV

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Recolección de Datos

Los cuestionarios electrónicos contemplaron los siguientes temas:

- I. Autoridad reguladora
- II. Legislación
- III. Capacidad regulatoria
- IV. Establecimientos de dispositivos médicos (fabricantes / importadores / representantes / distribuidores autorizados)
- V. Control de productos
- VI. Normas internacionales

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Recolección de Datos

Colombia

- INVIMA - Dirección De Dispositivos Médicos y Otras Tecnologías
- Cámara De Dispositivos Médicos e Insumos para la Salud – ANDI

Costa Rica

- Ministerio de la Salud
- Costa Rica Biotechnology and Medical Device Business Association – CR BioMed

México

- Sector regulado

Perú

- Documentos públicos disponibles en la web, entre otros, el sitio: http://www.digemid.minsa.gob.pe/ Dirección General de Medicamentos Insumos y Drogas - Autoridad Reguladora Peruana

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Hallazgos Principales

- Participación de las autoridades en foros de cooperación:
  - Grupos de Trabajo Regional de América para Fortalecer la Capacidad Reguladora de Dispositivos Médicos de la Organización Panamericana de la Salud
  - Foro Internacional de Dispositivos Médicos
- Uso de normas técnicas internacionales para fines regulatorios
- Existencia de controles pre y post-mercado

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Hallazgos Principales

- Nuevas regulaciones:
  - Consultas Públicas - plazos variables entre los países y en algunos casos, difieren de los establecidos por la OMC
  - Evaluación de Impacto Regulatorio: aplicado por los 4 países
- Producción local de Dispositivos Médicos:
  - Existe en los 4 países
  - Sistema de Gestión de Calidad
- Control de Producto:
  - Requisitos de autorización previa a la comercialización, en función de la clasificación de riesgo

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Hallazgos Principales

- Utilización de Normas Internacionales:
  - Sensibilización generalizada sobre su uso preferencial
  - Valoración de la normalización como herramienta de apoyo para el proceso de reglamentación
  - Aplicación con fines regulatorios aún en estado embrionario

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Consideraciones Finales

- Heterogeneidad entre los sistemas regulatorios de los países encuestados
- Impacto de infraestructura, recursos humanos y financieros, prioridad política
- Diagnóstico del estadio de los sistemas regulatorios
- Reflexión acerca del impacto de la regulación sobre el acceso a nuevas tecnologías de salud
- Visualizar algunas de las dificultades para la incorporación de normas técnicas reconocidas internacionalmente

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Consideraciones Finales

- Ampliación del debate
- Establecer alianzas
- Transformar los espacios regulatorios
  - Permear la participación de la sociedad y el intercambio de experiencias internacionales
- Necesidad de perfeccionar los instrumentos normativos
- Oportunidades constantes para la innovación
- Optar por la convergencia regulatoria para beneficiar a todos, independientemente del estadio de desarrollo de sus entidades reguladoras

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Consideraciones Finales

- Importancia de la incorporación del concepto de “reliance” como vía para lograr el reconocimiento de las evaluaciones de conformidad entre las autoridades reguladoras
- Es evidente la necesidad de ampliar el universo de países estudiados:
  - Diagnosticar con mayor precisión la realidad en la que está inserto el sector de dispositivos médicos
- Avanzar en el camino prometedor de la convergencia regulatoria

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Tier 2 – Phase 1: Medtech GRP, TR, Standards, CA International Benchmark

1. WHO Global Model Regulatory Framework for Medical Devices Including IVD Medical Devices
2. Asia Harmonization Working Party (AHWP) Playbook for Implementation of Medical Device Regulatory Frameworks
3. International Medical Device Regulators Forum (IMDRF) documents (all), including:
   - IMDRF N47 - "Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices"
   - IMDRF N51 - Standards WG (PD1)/N51 "Optimizing Standards for Regulatory Use"
4. Global Harmonization Task Force (GHTF) Documents
5. ISO 16142-1: 2016 "Medical Device – Recognized essential principles of safety and performance of MDs – Part 1 (non-IVD)"
6. ISO 16142-2: 2017 "Medical Device – Recognized essential principles of safety and performance of MDs – Part 2 (IVD)"

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Project Accomplishments:

Institutional Awareness and Cooperation:

- LatAm Medtech Associations, Standards Bodies and SDOs
- Presidencies, Agencies of Central Regulatory Review, Trade Ministries
- MedTech Regulators and Ministries of Health
- Pan American Health Organization (PAHO)
- Inter-American Development Bank (IDB)
  - Americas Business Dialogue (ABD)
  - Summit of the Americas
- APEC aligned for LatAm economies (Chile, Mexico, Peru)
- Brazil - Government and Industry

Standards Alliance Initiative

Project Accomplishments:

GRP/RIA Implementation

- Colombia, Mexico (Argentina, Brazil, Chile, Peru)

MD GRP Implementation & IMDRF

- Colombia, Mexico (Argentina, Brazil, Colombia)

MD Regulator – Industry – Standards Cooperation

- Colombia, Costa Rica, Mexico, Peru, (Brazil)

Inter American Regulatory Coalition (ALDIMED, ALADDIV, AdvaMed)

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Standards Alliance – PAHO – LatAm MD Regulatory Workshop
Sep 19, 2017 – Ottawa, Canada

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Key Project Benchmarks:

- WHO – Reliance and Stepwise Approach
- OECD – Good Regulatory Practices (GRP)
- WTO – Technical Barriers to Trade (TBT)

2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations…

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Key Project Findings:

- WHO, OECD/GRP and WTO/TBT guidance/commitments clear with:
  - Ministries of Trade
  - Central Regulatory Oversight Bodies
  - Inter-Ministerial Committees
  - GRP/TBT points of contact within Ministries of Health and MD Regulatory Agencies

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Key Project Findings:

- WHO, OECD/GRP and WTO/TBT guidance/commitments not systematically implemented with:
  - Ministries of Health and MD Regulatory Agency teams that develop regulations:
  - Agency-level policies helpful that require:
    - Agency documentation of WHO, OECD, WTO implementation
    - Agency search for relevant international standards as a pre-step to drafting regulation
    - Agency use of relevant international standards
    - Agency participation in (international) standardization
    - Agency Regulatory Impact Assessment / ex-post review
    - Agency publication of standards use
    - Designated agency position responsible for implementation of the above

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Key Project Take-Aways:

- Like medical devices, regulations require a quality control process
- Regulatory convergence means a goal of creating zero country/agency-unique regulations and standards
- If it's not written down, and someone is not put in charge, it won't happen
- One of the largest barriers to medical device regulatory convergence in Latin America is Human Resources

Standards Alliance Initiative

Next Steps:

- Tier 2 Webinar / GAP Analyses Roll Out (Sep/Oct 2019)
- Final Report Submission

Continuing Private Sector Support

- Scheduling of 2019-2021 Capacity Building Meetings
  - Regional: IDB, APEC, PAHO, AHWP
  - Colombia: ICONTEC, ANDI-CDMIS, INVIMA, MOH
  - Costa Rica: INTECO, COGR
  - Mexico: DGN/ANCE, AMID, COFEPRIS, MOH
  - Peru: INACAL, CCL, DIGEMID, MOH
  - (+ Argentina, Chile et al)

Helpful Links

Standards Alliance

https://standardsalliance.ansi.org/Project-for-the-Medical-Device-Sector.aspx

Proyecto de Alianza de Normas – Normas y estándares internacionales de dispositivos médicos en países de América Latina

https://www.aladdiv.org.br/projeto-standards-alliance?lang=es

Contact

Steven Bipes
AVP – Global Strategy & Analysis (LatAm, Global Standards, GRP, TBT)
Advanced Medical Technology Association (AdvaMed)
sbipes@advamed.org
+1.202.400.0853

Leticia Seixas Fonseca
Executive Director
Alianza Latinoamericana para el Desarrollo del Diagnóstico In Vitro (ALADDIV)
leticia.seixas@aladdiv.org.br
+55.61.3033-4402