Inter-American
Coalition for
Regulatory Convergence
MEDICAL TECHNOLOGY SECTOR

Welcome & Overview: Regulatory Coalition and Policy Webinar Series

Sandra Ligia González
Steven Bipes

If you would prefer to join over the telephone in listening mode, please select “Phone Call” in the Audio pane and the dial-in information will be displayed.

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Questions?

Please use the Questions/Chat pane of the GoToWebinar Control Panel

Outline

- Welcome
- Schedule of Policy Webinars
- Coalition Objectives
- Relationships
  - Health
  - Transparency
  - Trade
- Definitions
  - Regulatory Convergence
  - Good Regulatory Practices

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Overview and Schedule of Policy Webinars

- **Tue May 26: 10:00-11:30 ET**
  - Coalition Overview + International Medical Device Benchmarks
- **Tue June 2: 10:00-11:30 ET**
  - GMTA Regulatory Update + Good Regulatory Practices
- **Tue June 9: 10:00-11:30 ET**
  - WTO Technical Barriers to Trade + International Standards & Conformity Assessment + Medical Device Standardization
- **Mon June 15: 10:00-11:30 ET**
  - Policy Session with Regulators: FDA

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Coalition Overview

Sandra Ligia González
Executive Secretary, IACRC - MedTech

Overarching Industry Objectives

- Increase availability of life-saving and life-improving medical technologies to patients:
  - Reduce Barriers to Patient Access
  - Strengthen Regulatory Efficacy
  - Improve Transparency and Administrative Efficiency
  - Optimize Supply Chains
  - Eliminate Technical Barriers to Trade

Coalition Website

http://interamericancoalition-medtech.org/

- In one location, provide relevant and up to date resources to the Coalition Members and all the materially involved stakeholders of the MedTech Sector

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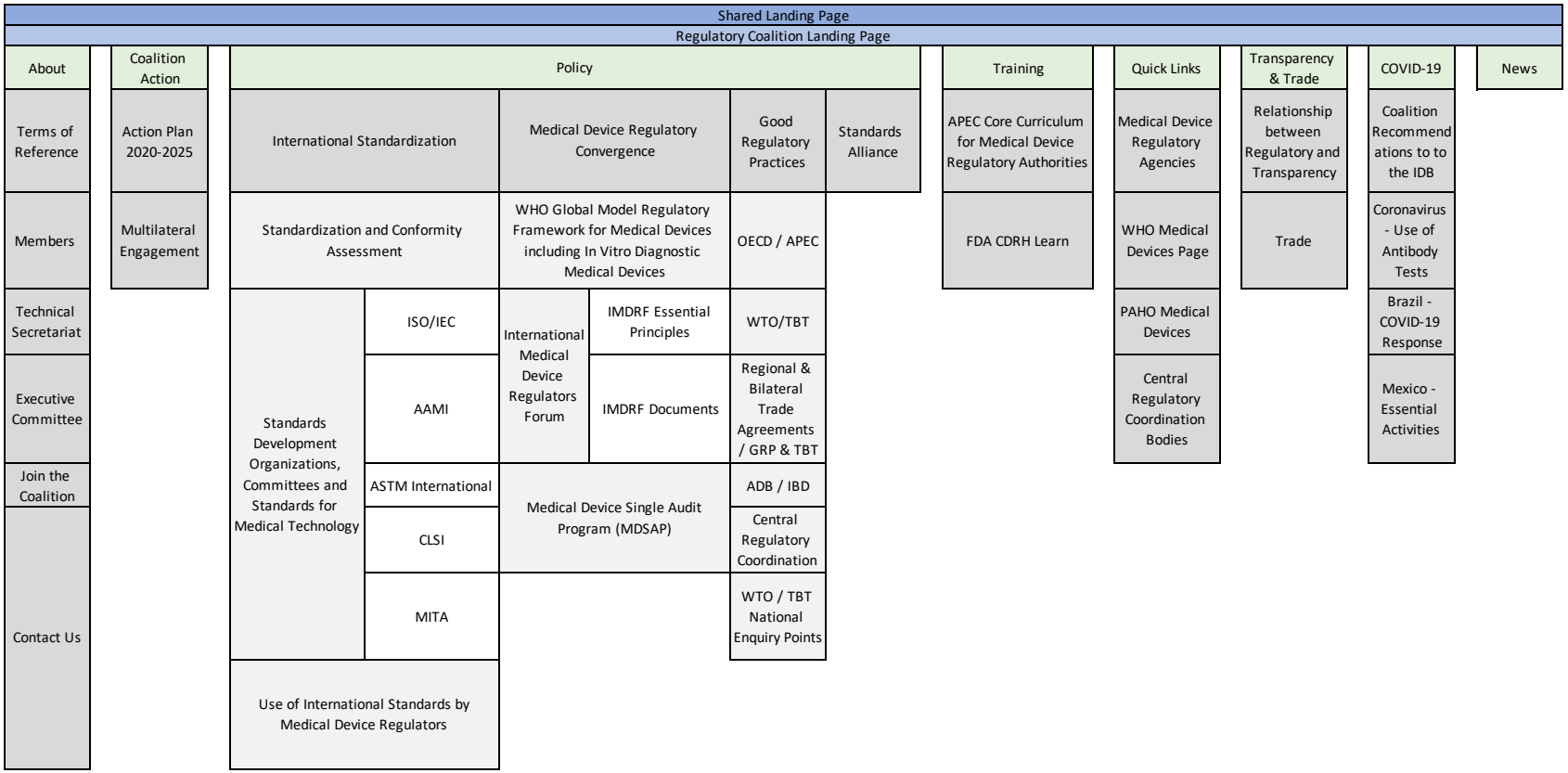
Coalition Website - Structure



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Coalition COVID-19 Response

- The Coalition has prioritized regulatory matters assisting in the combat of COVID-19 within the context of its vision and mission towards regulatory convergence.
- The Coalition is actively working with key government agencies around the region to identify how the industry can help ensure that providers and patients everywhere have access to the medical technologies they need to help diagnose and fight this deadly virus.
- The Coalition has been developing *adhoc* resources, directly and indirectly, to support the specific needs of our members:
  - IVDs: Use of Antibody Tests – Members & GMTA
  - Position papers before IDB and ABD
  - Webinar and resources guidance to prepare for and pass inspections and maintain critical operations as essential industries
    - Manufacturers of medical devices and components in the Mexican border states with the United States
    - 300 attendees: AdvaMed, AMID and Med-Tech cluster associations

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Vision

One standard, one test, accepted everywhere for any medical technology scope. This Vision implies that medical technology regulators across the Western Hemisphere base their national medical device regulations, standards and conformity assessment criteria on the relevant international standards for medical technology.

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Mission

Lead the coordination of all materially affected stakeholders to achieve the Vision. This includes promoting regulatory cooperation across the Western Hemisphere to achieve internationally aligned medical technology regulations, standards and conformity assessment requirements within a continual process of convergence to maximize patient access to innovative, effective, life-saving and life-improving medical technologies.

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International Medical Device Benchmarks

Steven Bipes
Vice President, AdvaMed

Contexts

- Health
- Trade
- Transparency

Context: Health

- WHO Guidance
  - Reliance
  - Stepwise Approach
- Public Health System Prioritization

Context: Trade

- WTO Requirements
  - Treaty Obligations
  - Use of International Standards

- Preventing Barriers to Trade
  - Non-Tariff Barriers
    - Technical Barriers to Trade (TBTs)
      - Regulatory, Standards, Conformity Assessment
      - Customs and Trade Facilitation
  - Tariff-Barriers (Market Access)

Context: Transparency

The longer that it takes any government agency to conduct its function, and the more that it deviates from the use of international standards, the higher the perception – and margin – for unethical conduct.

Colombian Secretary of Transparency
ANDI Medical Device Forum
Bogotá, Colombia – November 2018

Regulatory Convergence

A concerted public-private effort to systematically pursue and maximize alignment of sector-specific technical regulations, standards and conformity assessment criteria to globally harmonized international standards.

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Regulatory Convergence (for Medical Technology)

A concerted public-private effort to systematically pursue and maximize alignment of medical technology sector-specific technical regulations, standards and conformity assessment criteria to globally harmonized international standards for medical technology.

Good Regulatory Practices (GRP)

- 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 of the same purpose.

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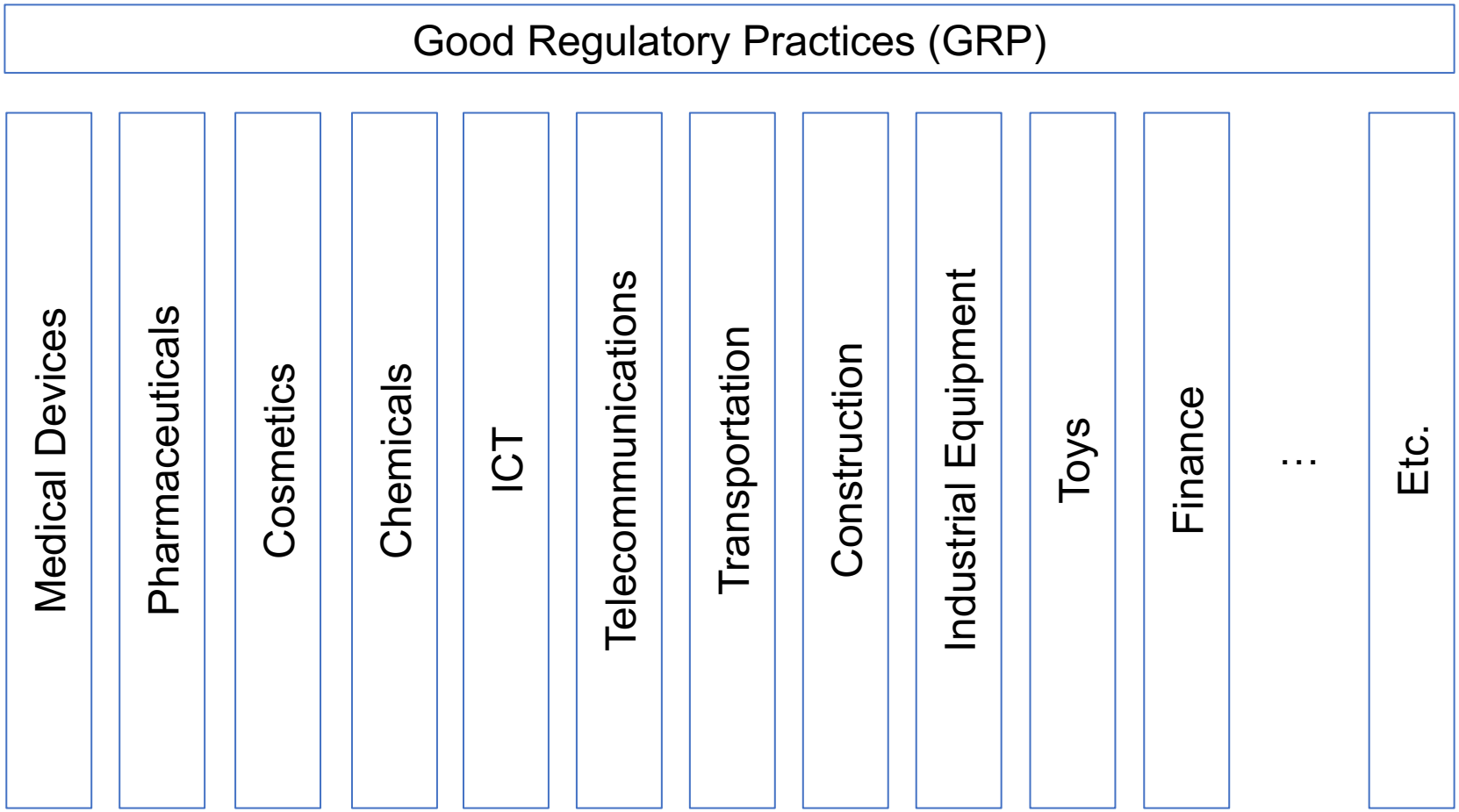

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Inter-American Coalition for Regulatory Convergence
Medical Technology Sector

Public/Private (Industry + SDOs + govs, et al)

	Regulatory Cooperation / Information Sharing / Capacity Building / Training	Trade Obligations, Enforcement / Market Openness
Good Regulatory Practices (GRP) **(Foundational, Cross-Sectoral)** **(Horizontal = Tier 1)**	• OECD, APEC, IDB Central Regulatory Coordination Bodies	• WTO / TBT (2.2, 2.3, 2.4) • Other Trade Agreements • OECD & Accession Executive Office of the Presidencies, Trade & Foreign Ministries
Regulatory Convergence **(Sector-Specific, e.g. Medical Technology)** **(Vertical = Tier 2)**	• WHO (Model Reg Framework) • IMDRF (incl. N47 and N51) • APEC, PAHO • FDA/CDRH Standards and CA Program/Policy MD RAs, MOHs (MD teams) MD RAs, MOHs (Reg process teams)	• WTO / TBT (2.2, 2.3, 2.4) • Other Trade Agreements Trade & Foreign Ministries

Key Overarching Take Aways

- A Technical Regulation is a document with which compliance is mandatory
- A Standard is a document with which compliance is voluntary
- The best mechanism to harmonize cross-border requirements is for regulators to use harmonized international standards (either directly or as a basis for their regulations)

Key Overarching Take Aways

- Standards Developing Organizations (SDOs) have Technical Committees that develop the international standards for medical devices
- SDOs must be open to all materially affected stakeholders
- Every country in the Americas has access to the SDOs

Key Overarching Take Aways

- One of the most expensive activities a government can engage in is rulemaking
- This is particularly the case if the rule is ineffective or if it is overly burdensome given the regulatory purpose
- Governments have the independence to prioritize their health resources
- What is the likelihood that an agency working alone will:
  - Identify a new regulatory issue not yet identified elsewhere globally?
  - Develop a policy that does not conflict with existing policies globally?

Key Overarching Take Aways

- GRP is the QA system for a government's regulatory process
- The WTO TBT Agreement is a GRP and legally binding international treaty obligation
- Countries (and all of their government agencies) are required to use international standards as a basis for their technical regulations
- Not doing so is inconsistent with the TBT Agreement

Key Overarching Take Aways

- The WHO encourages medical device regulators to use international standards

- The WTO requires medical device regulators to use international standards

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Key Overarching Take Aways

- Coalition website is a resource for industry and regulators:

  http://interamericancoalition-medtech.org/

- Coalition is establishing regulatory priorities and position papers by topic and country

- Coalition is dedicated to working with all stakeholders towards 1 standard : 1 test accepted everywhere

Q & A

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Thank you!

Sandra Ligia González

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MedTech Specific Regulatory Convergence and Intl Benchmarks

Leticia Fonseca

Inter-American
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MedTech Specific Regulatory Convergence and International Benchmarks

Leticia Fonseca
Deputy Executive Secretary,
Executive Secretary Brazil, IACRC - MedTech

Index

1. WHO Model Regulatory Framework for Medical Devices and IVDs
2. IMDRF Documents (incl N47 and N51)
3. MDSAP

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World Health Organization

WHA67.20-2014
Regulatory system strengthening
for medical products

"Effective regulatory systems are an essential component of health system strengthening and contribute to better health outcomes"

WHO Model Regulatory Framework for Medical Devices and IVDs

Guidelines that are intended to provide guidance and support for the development and implementation / improvement of regulatory controls of medical devices.

WHO Model Regulatory Framework for Medical Devices and IVDs

It suggests a progressive approach: a step-by-step approach to implementing and enforcing regulatory controls for medical devices, as regulation progresses from a basic level to an expanded one.

WHO Model Regulatory Framework for Medical Devices and IVDs

The model does not offer detailed guidance on regulatory issues but contains references to relevant documents where additional information can be found.

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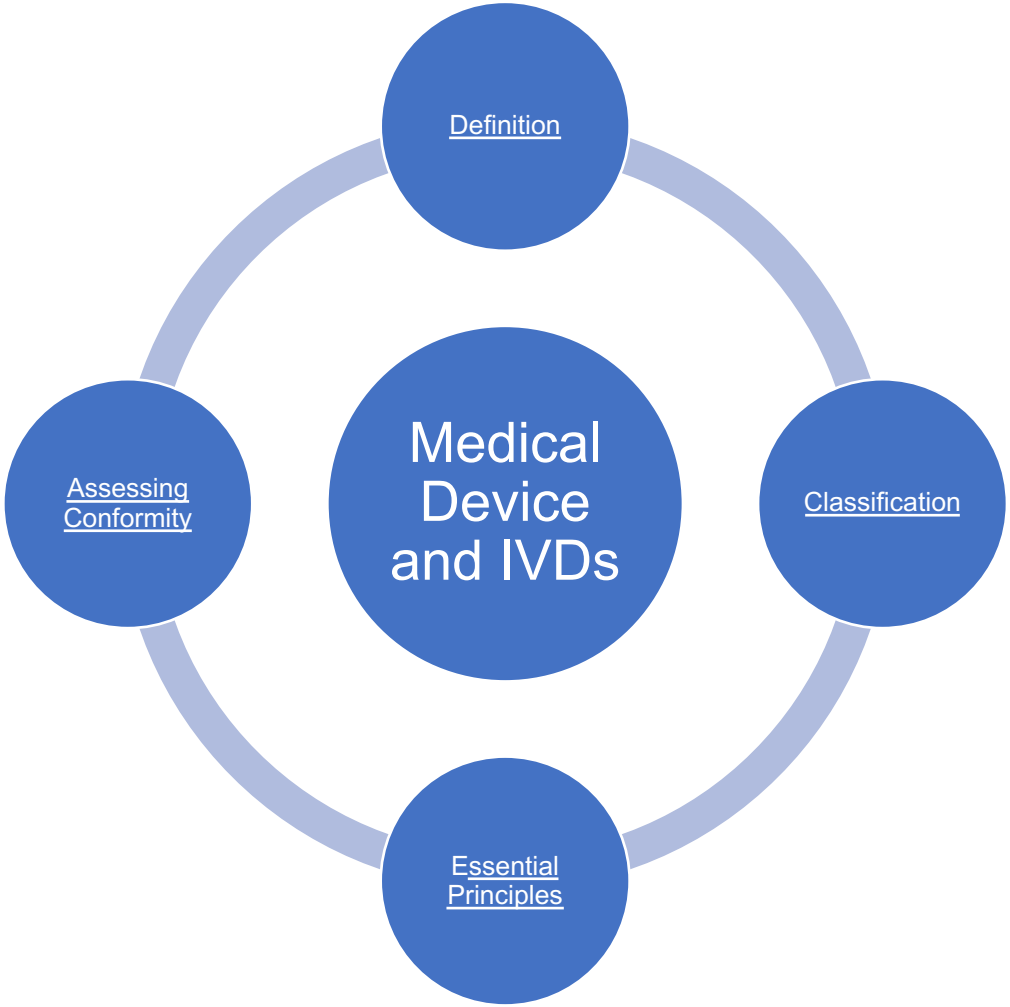
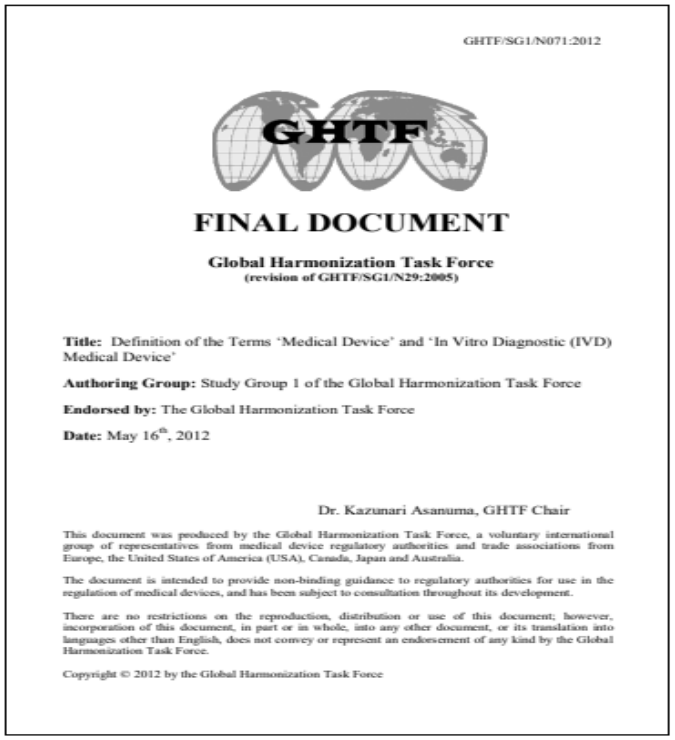
WHO Model Regulatory Framework for Medical Devices and IVDs



Definition



GHTF/SG1/N071:2012

GHTF

FINAL DOCUMENT

Global Harmonization Task Force
(revision of GHTF/SG1/N29:2005)

Title: Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'

Authoring Group: Study Group 1 of the Global Harmonization Task Force

Endorsed by: The Global Harmonization Task Force

Date: May 16th, 2012

Dr. Kazunari Asanuma, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide non-binding guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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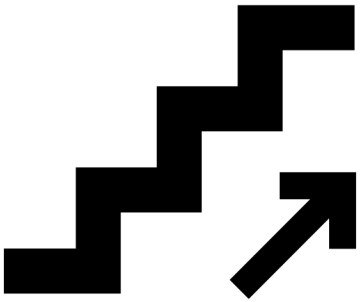
- IMDRF/GRRP WG/N52 FINAL:2019 - Principles of Labelling for Medical Devices and IVD Medical Devices.
- IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices.

Classification

- Resources allocated and imposed controls proportional to the potential for harm associated with medical devices.
- Classification made by applying a set of classification rules.
- IMDRF Proposed Document:

  IMDRF/IVD WG (PD1)/N64 - Principles of In Vitro Diagnostic (IVD) Medical Devices Classification Closes on July 25, 2020.



Essential Principles

- "Products should be safe and perform as intended when placed on the Market.

  Manufactures must be able to demonstrate to the regulatory authority that their product complies with the Essential Principles and has been designed and manufactured to be safe and perform as intended during its lifetime, when used according to the manufacturer's stated intended purpose."

- WHO Model Regulatory Framework for Medical Device and IVDs

Conformity Assessment

Conformity assessment processes as determined by class device

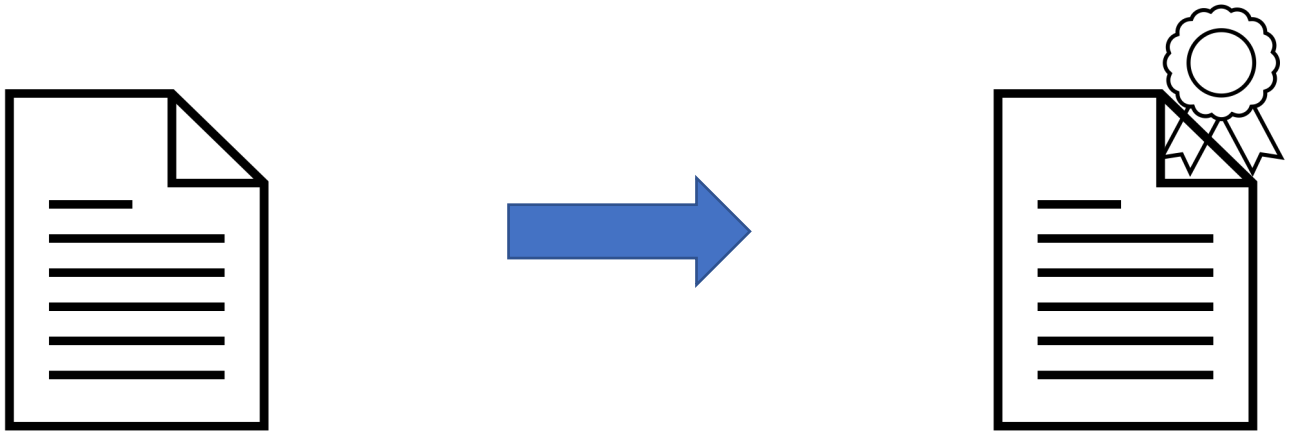
Conformity assessment element	Class A	Class B	Class C	Class D
Quality management system (QMS)	Regulatory audit normally not required, except where assurance of sterility or accuracy of the measuring function is required.	The regulatory authority should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization.	The regulatory authority should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization.	The regulatory authority should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to marketing authorization.
Technical documentation[a]	Premarket submission normally not requested.	Not normally reviewed premarket. The regulatory authority may request and conduct a premarket or postmarketing review sufficient to determine conformity with Essential Principles.	The regulatory authority will undertake a review sufficient to determine conformity with Essential Principles prior to the device being placed on the market.	The regulatory authority will undertake an in-depth review to determine conformity with Essential Principles, prior to the device being placed on the market.
Declaration of conformity	Submission normally not requested.	Review and verify compliance with requirements by the regulatory authority (see footnote to Table A4.1).	Review and verify compliance with requirements by the regulatory authority (see footnote to Table A4.1).	Review and verify compliance with requirements by the regulatory authority (see footnote to Table A4.1).

WHO Model Regulatory Framework for Medical Device and IVDs

Reliance

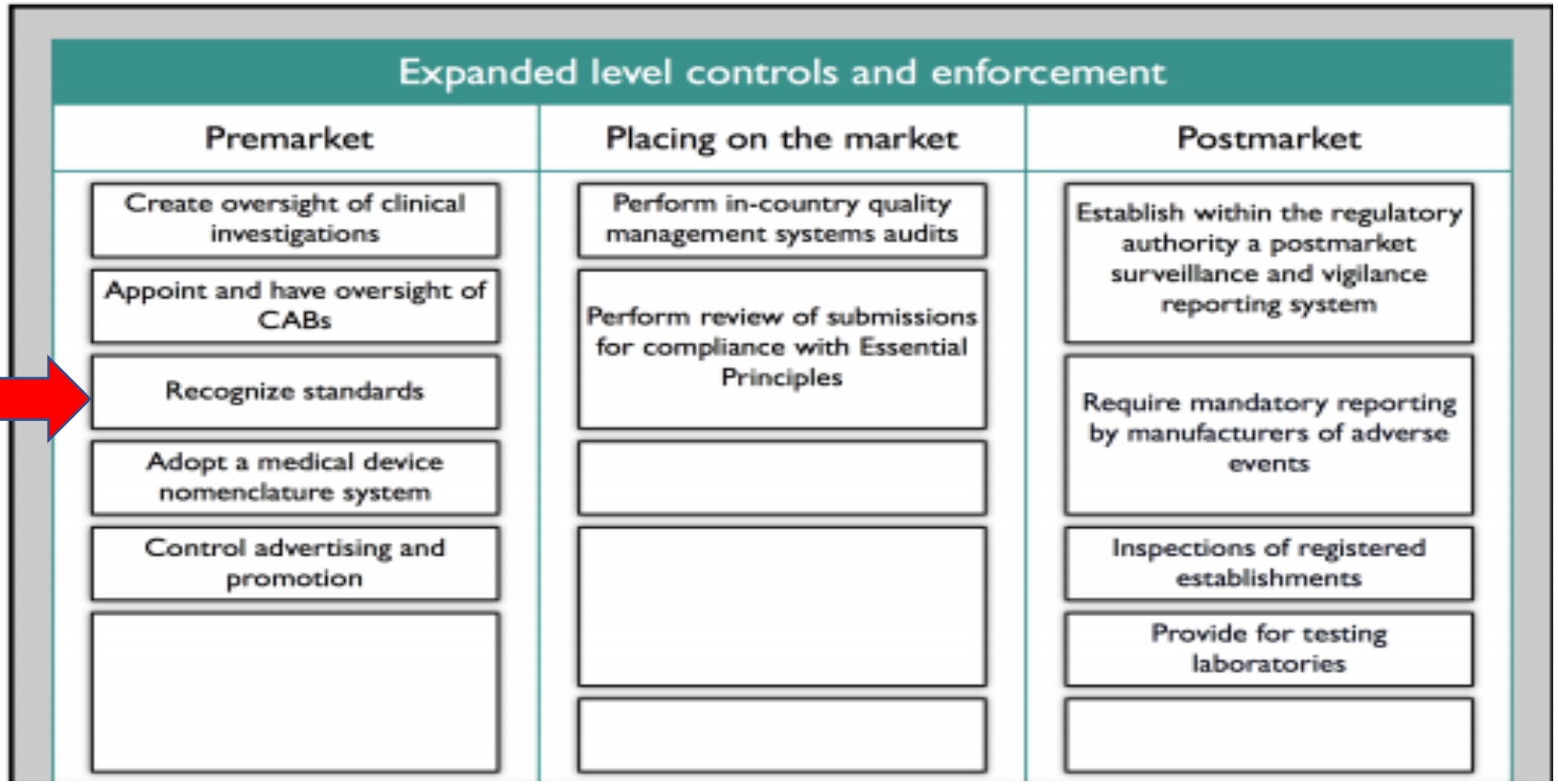
Assessment performed by another Regulatory authority or other trusted institution

Recognition



Basic level controls and enforcement		
Premarket	**Placing on the market**	**Postmarket**
• Publish law, including definition, and regulations with transition period • Establish medical device classification for regulatory purposes • Establish Essential Principles of safety and performance • Establish basis for reliance and recognition • Establish requirements for declaration of conformity • Establish requirement for manufacturers for a QMS • Establish requirements for labels and labelling • Prohibit deceptive, misleading and false advertising • Establish provisions for exceptional premarket situations	• Registration of establishments • Listing of medical devices • Import controls	• Establish a system for vigilance reporting • Require mandatory notification by the manufacturer of field safety corrective actions • Establish a procedure to withdraw unsafe medical devices from the market • Establish procedure to issue safety alerts to users • Undertake market surveillance

WHO Model Regulatory Framework for Medical Device and IVDs



WHO Model Regulatory Framework for Medical Device and IVDs

Recognition of standards

- Conformity with voluntary standards is a means by which the manufacturer may demonstrate that a medical device conforms to one or more of the Essential Principles of safety and performance, consistently throughout its life cycle.

Recognition of standards

- Preference for recognition should be given to international standards (ISO, IEC, regional standards and the national versions of international standards).
- National standards → current version of international standards.
- Adoption of a recognition system of recognizing standards

WHO Model Regulatory Framework for Medical Device and IVDs

Standards

IMDRF/GRRP WG/N47 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices Group

Date: 31 October 2018

Yuan Lin, IMDRF Chair

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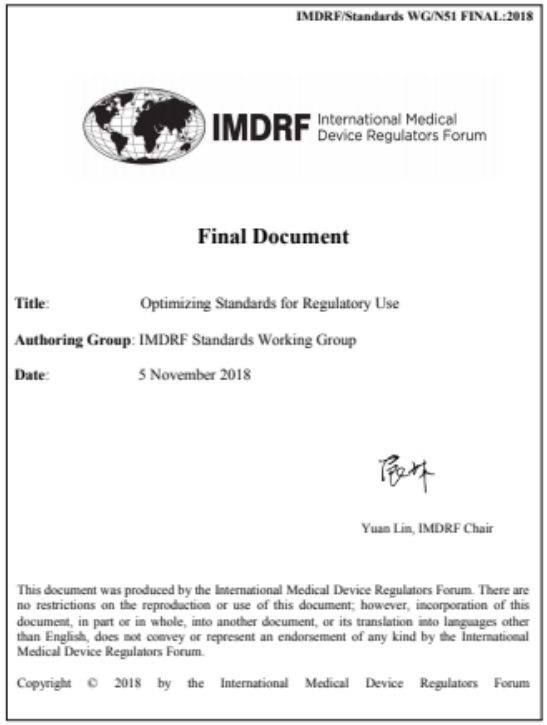

IMDRF/Standards WG/N51 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Optimizing Standards for Regulatory Use

Authoring Group: IMDRF Standards Working Group

Date: 5 November 2018

Yuan Lin, IMDRF Chair

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Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

IMDRF/GRRP WG/N47 FINAL: 2018

- The worldwide adoption of a common set of fundamental design and manufacturing requirements for medical devices that, when met, provide assurance the device is safe and performs as intended, offers significant benefits to, among others, manufacturers, users, patients/consumers, and to Regulatory Authorities.

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

IMDRF/GRRP WG/N47 FINAL: 2018

- Applies to all medical devices and IVD medical devices.
- Identify and describe essential principles of safety and performance which should be considered during the design and manufacturing process.
- When some of the essential principles of safety do not apply, justifications should be provided.

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IMDRF International Medical Device Regulators Forum

Essential Principles of Safety and Performance

Medical Devices and IVD Medical Devices

- General
- Clinical Evaluation
- Chemical, Physical, and Biological Properties
- Sterilization and Microbial Contamination
- Considerations of Environment and Conditions of Use
- Protection against Electrical, Mechanical, and Thermal Risks
- Active Devices and Devices Connected to Them
- Software or SaMD
- Diagnostic or Measuring Function
- Labeling and Instructions for Use
- Protection against Radiation
- Protection against Risks posed by Devices for Use by Lay Persons
- Devices Incorporating Materials of Biological Origin

Medical Devices

- Chemical, Physical, and Biological Properties
- Protection against Radiation
- Requirements for Implantable Medical Devices
- Protection against the Risks Posed to the Patient or User by Medical Devices Supplying Energy or Substances
- Devices Incorporating a Substance Considered to be a Medicinal Product/Drug

IVD Medical Devices

- Performance Characteristics
- Chemical, Physical, and Biological Properties

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IMDRF International Medical Device Regulators Forum

Essential Principles: Relationship with Standards and Guidances

Essential Principle	Guidances	Relevant Standards
5.1	GHTF/SG3/N18:2010 *Quality Management System –Medical Devices – Guidance on Corrective Action and Preventive Action and related QMS Processes* GHTF/SG3/N17:2008 *Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers* GHTF/SG3/N99-10:2004 *Quality Management Systems - Process Validation Guidance* GHTF/SG3/N15R8 *Implementation of Risk Management Principles and Activities within a Quality Management System* ISO 13485:2016 Handbook	ISO 13485 ISO 14971 ISO 23640 ISO 24971 CLSI EP25
5.2	Declaration of Helsinki GHTF/SG5/N1R8:2007 *Clinical Evidence – Key Definitions and Concepts* GHTF/SG5/N2R8:2007 *Clinical Evaluation* GHTF/SG5/N3:2010 *Clinical Investigations* GHTF/SG5/N6:2012 *Clinical Evidence for IVD Medical Devices - Key Definitions and Concepts* GHTF/SG5/N7:2012 *Clinical Evidence for IVD Medical Devices - Scientific Validity Determination and Performance Evaluation.* GHTF/SG5/N8:2012 *Clinical Performance Studies for In Vitro Diagnostic Medical Devices*	ISO 14155

Appendix A: Use of Standards in Meeting Essential Principles

- Consensus standards.
- Voluntary Use.
- Alternative ways to demonstrate the that they meet Essential Principles.

Optimizing Standards for Regulatory Use

IMDRF/Standards WG/N51 Final: 2018

- Directed to RAs, SDOs and those who participate in the standards development process.
- Serve as an educational tool and resource by proposing improvements in the standards writing process.

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Optimizing Standards for Regulatory Use

IMDRF/Standards WG/N51 Final: 2018

- Standards play a significant role in the design, production, post-production and regulation of medical devices throughout their lifecycle.
- The way of Standards frequently are written X Utility in regulatory processes.
- Participation of RA in ISO and IEC committees X Resources

Optimizing Standards for Regulatory Use

IMDRF/Standards WG/N51 Final: 2018

- IMDRF encourages the use of appropriate consensus standards in regulatory regimes and recommends that all RAs assess standards and **publish a list** of recognized or approved standards.

Optimizing Standards for Regulatory Use

IMDRF/Standards WG/N51 Final: 2018

Expectations:

- A commitment to IMDRF's Essential Principles.
- An emphasis on performance over design stipulations in writing standards.
- And the importance of a consensus approach.


State of the Art
Compatibility
Consensus
Fairness
Efficiency
Attributes
Accessibility
Reproducibility
Non-duplication
Consistency
Clarity

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Optimizing Standards for Regulatory Use

IMDRF/Standards WG/N51 Final: 2018

Enhancing Stakeholder Participation:

- International, regional and national level participation: joining the conversation.
- Recommendations for participation: submitting effective comments.

CDRH Learn

Standards

Module 1: Standards Overview
Presentation Printable Slides Transcript

Module 2: Standards Resources and Premarket Use
Presentation Printable Slides Transcript

Module 3: CDRH Standards Recognition Process
Presentation Printable Slides Transcript

Appropriate Use of Voluntary Consensus Standards
Presentation Printable Slides Transcript

Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program: Draft Guidance ***(New module 10/28/19)***
Presentation Printable Slides Transcript

https://www.fda.gov/training-and-continuing-education/cdrh-learn

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Medical Device Single Audit - MDSAP

What is MDSAP?

The Medical Device Single Audit Program allows an MDSAP 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.

Medical Device Single Audit - MDSAP

Why was the MDSAP developed?

- Appropriate regulatory oversight.
- Minimizing regulatory burden on industry.
- Promote more efficient and flexible use of regulatory resources.
- Promote globally alignment of regulatory approaches and technical requirements based on international standards and best practices;

Medical Device Single Audit - MDSAP

- Promote consistency, predictability and transparency of regulatory programs by standardizing:
  - the practices and procedures of participating regulators for the oversight of third party auditing organizations.
  - practices and procedures of participating third party auditing organizations.

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Members	Observers	Affiliate Members
Australia - TGA	Prequalification of In Vitro Diagnostics (IVDs) Programme (WHO)	ANMAT
Brazil - ANVISA	European Union (EU)	South Korea - Ministry of Food and Drug Safety
Canada - Health Canada Agency	Official Observer to the MDSAP Regulatory Authority Council (RAC) and Subject Matter Expert (SME) Work Group	
Japan - Ministry of Health, Labour and Welfare, and PMDA		
U.S. - FDA		

Medical Device Single Audit - MDSAP

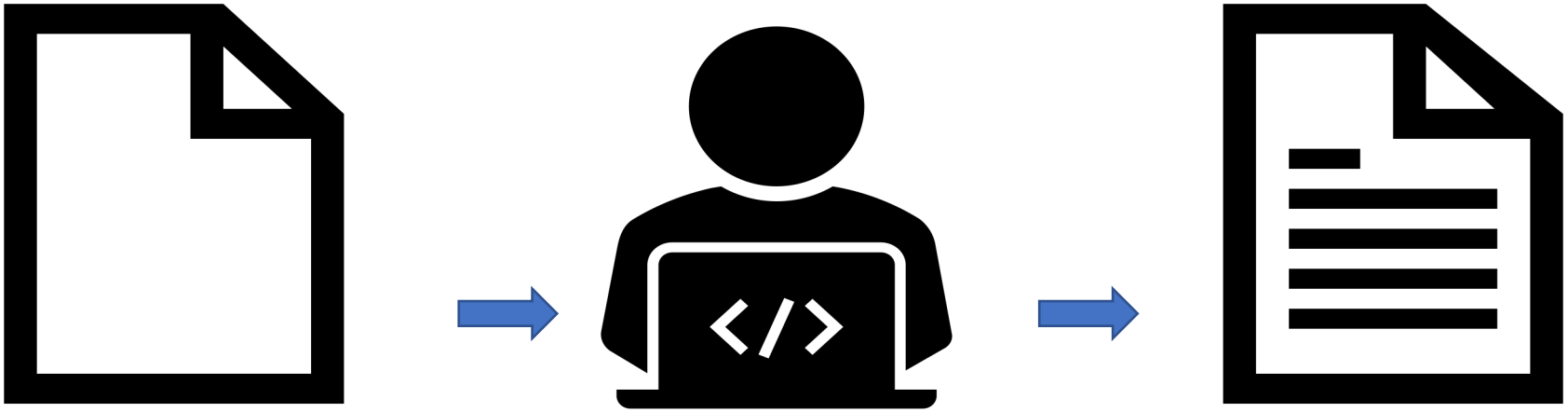
Medical Device Single Audit Program Regulatory Authority Council (RAC):

Representatives from all participating regulatory authorities. Provides direction, oversight, and resources to support the MDSAP development, implementation, maintenance, and expansion.

Medical Device Single Audit - MDSAP

MDSAP Affiliate Member:

A non-participating MDSAP Observer or non-participating MDSAP RAC regulatory authority that **wants to engage** in MDSAP, **demonstrates understanding** of MDSAP and **utilize** MDSAP audit reports and/or MDSAP certificates for evaluating a medical device manufacturer's quality management system.

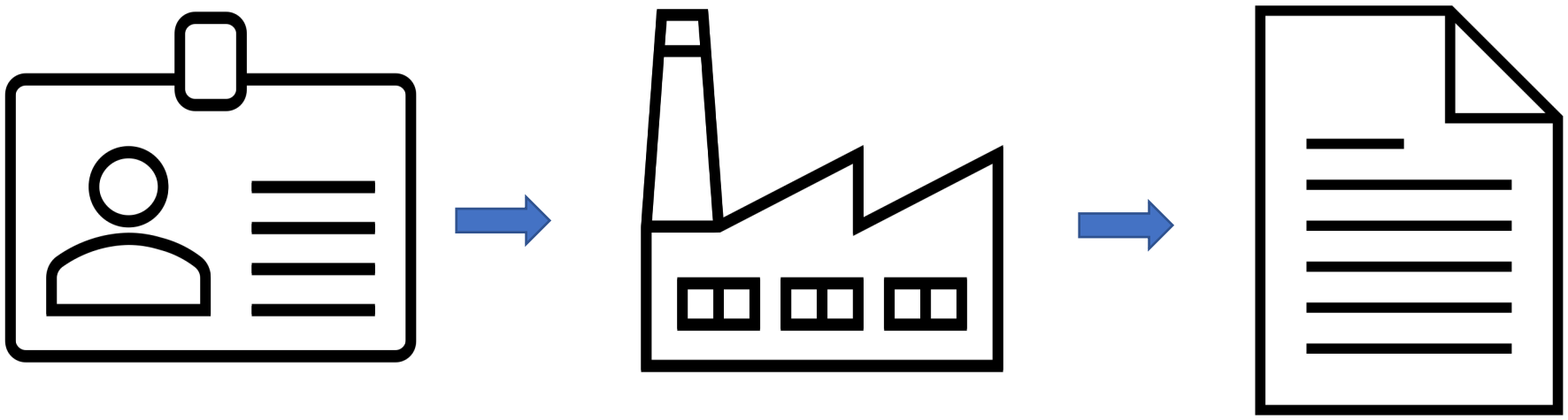


Statement of Intent

Training

Report Annualy

Access to weekly status reports that will contain information on the manufacturer, manufacturing site, audit dates and the recognized auditing organization.



Regulatory Authority

Manufacturer

Report or Certificate

Medical Device Single Audit - MDSAP

MDSAP will coverage the requirements of:

1. Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016);
2. Quality Management System requirements of the Conformity Assessment Procedures – **Australia**;
3. Good Manufacturing Practices (RDC ANVISA 16/2013) – **Brazil**;

Medical Device Single Audit - MDSAP

4. Canadian Medical Device Regulations (CMDR, Part 1) – **Canada**
5. Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (Ministerial Ordinance No. 169) – **Japan**
6. Quality System Regulation (21 CFR Part 820) – **U.S.**;
7. Specific requirements of medical device regulatory authorities participating in the MDSAP program.

Exchange of Medical Device Audit Report

Regulatory Exchange Plataform (REPs):

Virtual platform, hosted by PAHO, that allows to exchange nonpublic regulatory information.

- Module MDSAP: support the MDSAP activities.
- Module RISE: authorities that adhere to REPs through a memorandum of understanding between the NRA and PAHO.

Q & A

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Thank you!

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Deputy Executive Secretary

Executive Secretary, Brazil

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Closing Remarks