GMPs.
Strategies to increase NRAs affiliation to MDSAP

Working Group Update

INTER-AMERICAN COALITION FOR REGULATORY CONVERGENCE

MEDICAL TECHNOLOGY SECTOR

ANNIVERSARY

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Strategy Roadmap Status

Capability Building

Detail: Build capability on MDSAP. Generate expertise on MDSAP guidelines and existing data from MDSAP members.

On Going

NRAs Classification

Detail: Identify, assess and classify NRAs according to the willingness & needs to adopt MDSAP.

Done

MDSAP positioning

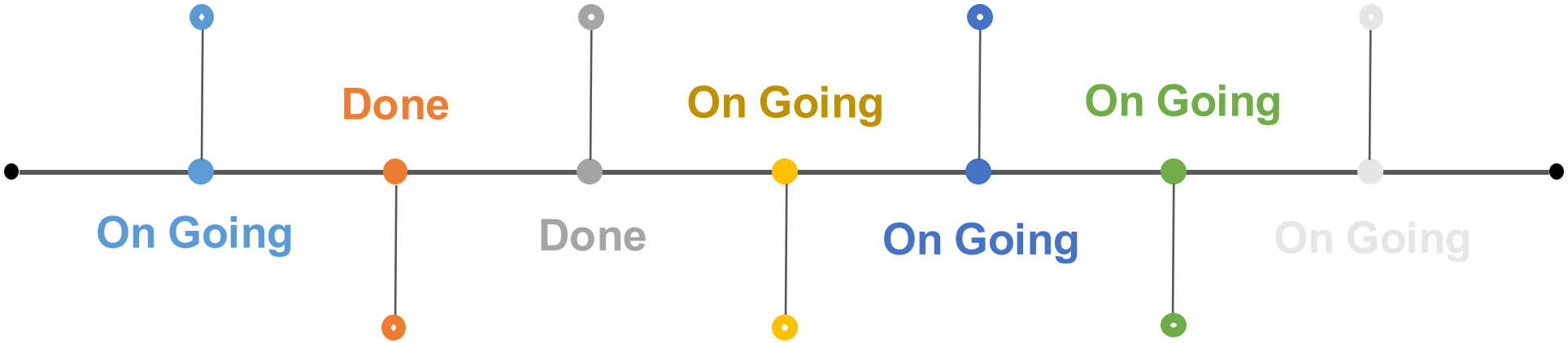
Detail: Tailor the local-strategies, identify pathways and develop proposals to advocate regulators on MDSAP prioritization and adoption.

On Going

Support Implementation

Detail: Cooperate and support HAs and NRAs on local/regional actions required to guarantee the proper implementation of MDSAP adoption and/or acceptance.

On Going



Landscape Mapping

Detail: Map and understand current landscape of GMPs validation processes in the NRAs and MDSAP adoption or acceptance status.

Done

Frameworks Analysis

Detail: Legal & Regulatory Framework deep analysis for jurisdictions and regulators willing to adopt and/or accept MDSAP.

On Going

External Engagement

Detail: Develop engagement plan development and drive the execution with regulators and any related policy/decision makers.

On Going

Capacity Building: Training Package

Webinars

Decks

Guidebook

Virtual Self-Trainig

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Capacity Building: MDSAP Training Guidebook

A Training Guidebook to the Medical Device Single Audit Program (MDSAP)

Summary

The document is a comprehensive guide to the Medical Device Single Audit Program (MDSAP). It explains that basic concept on MDSAP and how MDSAP allows a single audit of a medical device manufacturer's Quality Management System (QMS) to satisfy the requirements of multiple regulatory authorities (RAs).

Key Components included in the Guidebook:

- MDSAP Core Objectives: A single audit to meet multiple jurisdictions' QMS requirements.
- Participating RAs: Full members, Observers and Affiliates
.
- Audit Scope: Focus on the manufacturer's QMS, audits covering ISO 13485 and specific RA regulations.
- Audit Approach: Process-based model, seven key processes.
- Audit Cycle: Three-year cycle including initial, surveillance, and recertification audits. Audit duration.
- Nonconformity Grading: Use of a point-based system.
- Leveraging MDSAP Audits for GMP validation.

Capacity Building: Virtual Self-Training

Medical Device Single Audit Program (MDSAP)

The MDSAP interactive e-learning consists of 3 parts. It is recommended to start with the overview training MDSAP Overview. For more details on the MDSAP audit process, do the MDSAP Audit Process training, to learn more about the content of the audits do the MDSAP Audit Content training.

MDSAP Overview

(15 min)

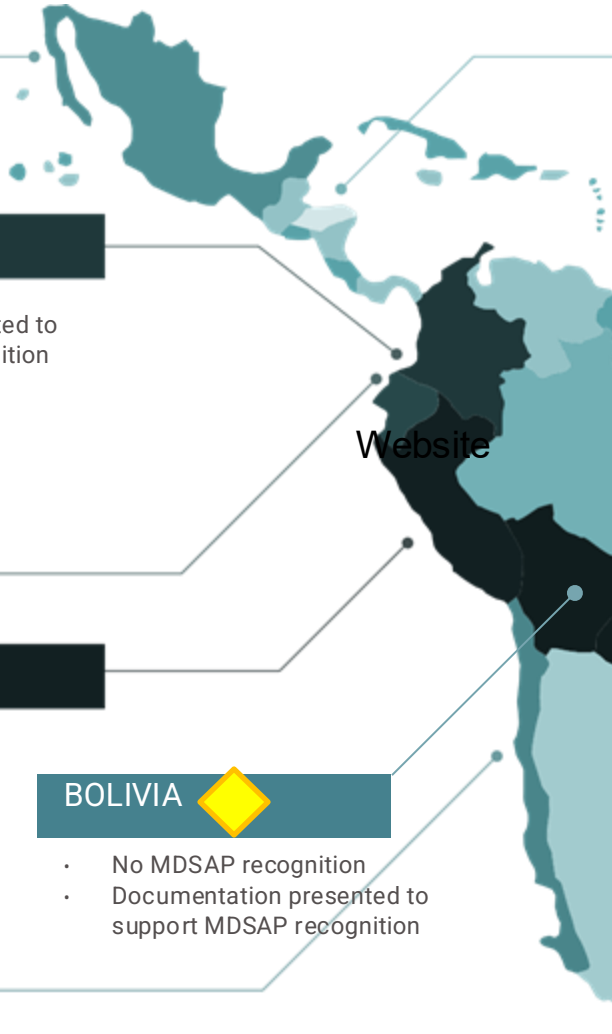
MDSAP Audit Process

(30 min)

MDSAP Audit Content

(30 min)

Landscape Mapping: MDSAP Heatmap



MEXICO

- Affilliate member of MDSAP
- MDSAP mentioned in the regulatory framework
- Agency released a communication accepting MDSAP certificates

COLOMBIA

- No MDSAP recognition
- Documentation presented to support MDSAP recognition

ECUADOR

- No MDSAP recognition

PERU

- No MDSAP recognition

CHILE

- No MDSAP recognition
- Documentation presented to support MDSAP recognition

BOLIVIA

- No MDSAP recognition
- Documentation presented to support MDSAP recognition

BRAZIL

- Member of MDSAP

Central America & Caribbean

Panama

- No MDSAP recognition
- Proposal included in draft regulation.

Rest of countries

- No MDSAP recognition

PARAGUAY

- No MDSAP recognition

URUGUAY

- No MDSAP recognition

ARGENTINA

- Affilliate member of MDSAP
- No GMP validation required for imported products

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Landscape Mapping: NRA Classification

1

- Brazil
- Mexico

2

- Argentina
- Chile
- Colombia
- Peru
- Bolivia
- Panama
- Dominican Republic

3

- Cuba
- El Salvador
- Honduras
- Costa Rica
- Guatemala
- Nicaragua
- Ecuador
- Paraguay
- Uruguay

MDSAP Positioning: IACRC Executive Summary & Position Paper

Medical Device Single Audit Program (MDSAP)

Executive Summary

The Medical Device Single Audit Program (MDSAP) is an international initiative that allows a single audit to satisfy the regulatory requirements of multiple jurisdictions. Developed by the International Medical Device Regulators Forum (IMDRF), MDSAP streamlines compliance for medical device manufacturers operating in multiple markets. The program is currently recognized by five key regulatory authorities:

- **United States (FDA)** – Uses MDSAP audit reports as a substitute for routine FDA inspections (except for For-Cause and Pre-Approval Inspections).
- **Canada (Health Canada)** – Requires MDSAP certification for medical device market access.
- **Australia (TGA)** – Accepts MDSAP reports as part of its conformity assessment process.
- **Brazil (ANVISA)** – Utilizes MDSAP audits to inform its inspection requirements.
- **Japan (PMDA/MHLW)** – Considers MDSAP reports in regulatory decision-making.

Benefits of MDSAP

For Regulators:

- Enhances global oversight and collaboration between participating regulatory agencies.
- Reduces regulatory burden by leveraging a standardized audit approach.
- Allows more efficient allocation of inspection resources to high-risk manufacturers.

For Industry:

- Reduces the number of audits required for market entry, saving time and resources.
- Ensures a consistent audit approach across multiple jurisdictions.
- Facilitates faster market access, particularly in Canada where MDSAP is mandatory.
- Strengthens internal quality systems through rigorous, internationally recognized audit criteria.

For Health Systems and Patients:

- Promotes higher standards of quality and safety for medical devices globally.
- Reduces delays in the availability of compliant medical devices.
- Enhances trust in regulatory oversight and product quality.

Benefits of MDSAP adoption in Latin America:

Inter-American Coalition for Regulatory Convergence of the MedTech Sector Position Paper

1. **Introduction to MDSAP: A Global Framework for Medical Device Regulation**

- 1.1 Overview of the Medical Devices Single Audit Program (MDSAP): Objectives, Scope, and Participating Regulatory Authorities.

The Medical Devices Single Audit Program represents a significant international initiative designed to harmonize the regulatory auditing of medical device manufacturers. This program offers a framework where a single regulatory audit of a medical device manufacturer's quality management system can satisfy the relevant requirements of multiple regulatory jurisdictions[1]. This unified approach aims to enhance the safety and oversight of medical devices on a global scale by establishing a standardized method for auditing and monitoring their manufacturing processes[1]. The core objective is to streamline the regulatory landscape, reducing the need for manufacturers to undergo multiple audits from different authorities, thereby improving efficiency and potentially lowering costs.

The development of MDSAP was spearheaded by the International Medical Device Regulators Forum (IMDRF), recognizing the increasing globalization of the medical device industry and the need for a more coordinated approach to regulation[1]. The IMDRF, through its working group on MDSAP, has established the program's objectives, scope, and operational procedures, fostering a collaborative environment among participating regulatory bodies.

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Next Steps

Planned Actions	Publication of the MDSAP Training Package
	Publication of the IACRC Positioning
	Definition of the Capacity Building Plan
	Definition of the Regulators Engagement Strategy

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THANK YOU

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