



Global Harmonization Working Party

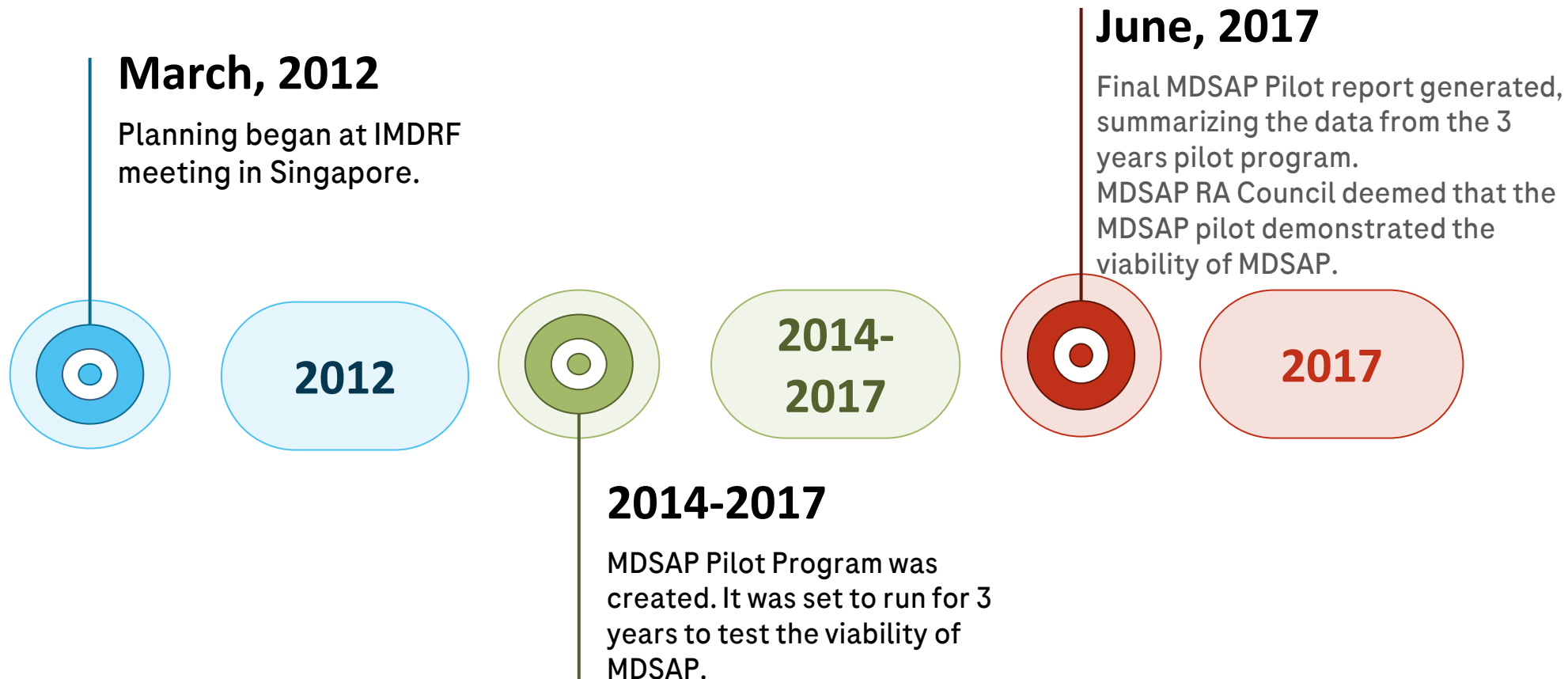
GHWP Towards Medical Device Harmonization



MDSAP_Industry perspective

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Introduction: MDSAP Timelines



What is MDSAP

The medical Device Single Audit Program (MDSAP) is a program that allows the conduct of a single regulatory audit of a medical device manufacturer's Quality Management System(QMS) to satisfy the requirements of multiple regulatory jurisdictions. Audits are conducted by Auditing Organizations designated and authorized by the participating Regulatory Authorities to audit under MDSAP requirements.





MDSAP Objectives:



- **Optimize** the use of regulatory resources through **work-sharing and mutual acceptance** among regulators while respecting the independence of each authority
- Promote **regulatory convergence** on approaches and technical requirements globally based on international standards and best practices,
- Achieve **consistency, predictability and transparency** of regulatory programs by standardizing
- Enable the **appropriate regulatory oversight** of medical device manufacturers' quality management systems while minimizing regulatory burden on industry.

MDSAP Members



MDSAP Official Observers

- European Union (EU)
- United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA)
- The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme
- Singapore's Health Sciences Authority (HSA)



MDSAP Members

- Therapeutic Goods Administration of Australia (TGA)
- Brazil's National Agency of Sanitary Vigilance (ANVISA)
- Health Canada
- Japan's Ministry of Health, Labour and Welfare, the Japanese Pharmaceuticals and Medical Devices Agency (PMDA)
- U.S. Food and Drug Administration (US FDA)

MDSAP Affiliate Members*

- Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT)
- Kenya's Pharmacy and Poisons Board
- Republic of Korea's Ministry of Food and Drug Safety
- Federal Commission for Protection from Sanitary Risks (COFEPRIS) of Mexico
- TFDA - Taiwan Food and Drug Administration
- Ministry of Health of Israel.



MDSAP membership Category_ **Affiliate Members**

- Regulatory requirements of the Affiliate Member are not included in the audit model
- Reports will need to be requested from the medical device manufacturer.

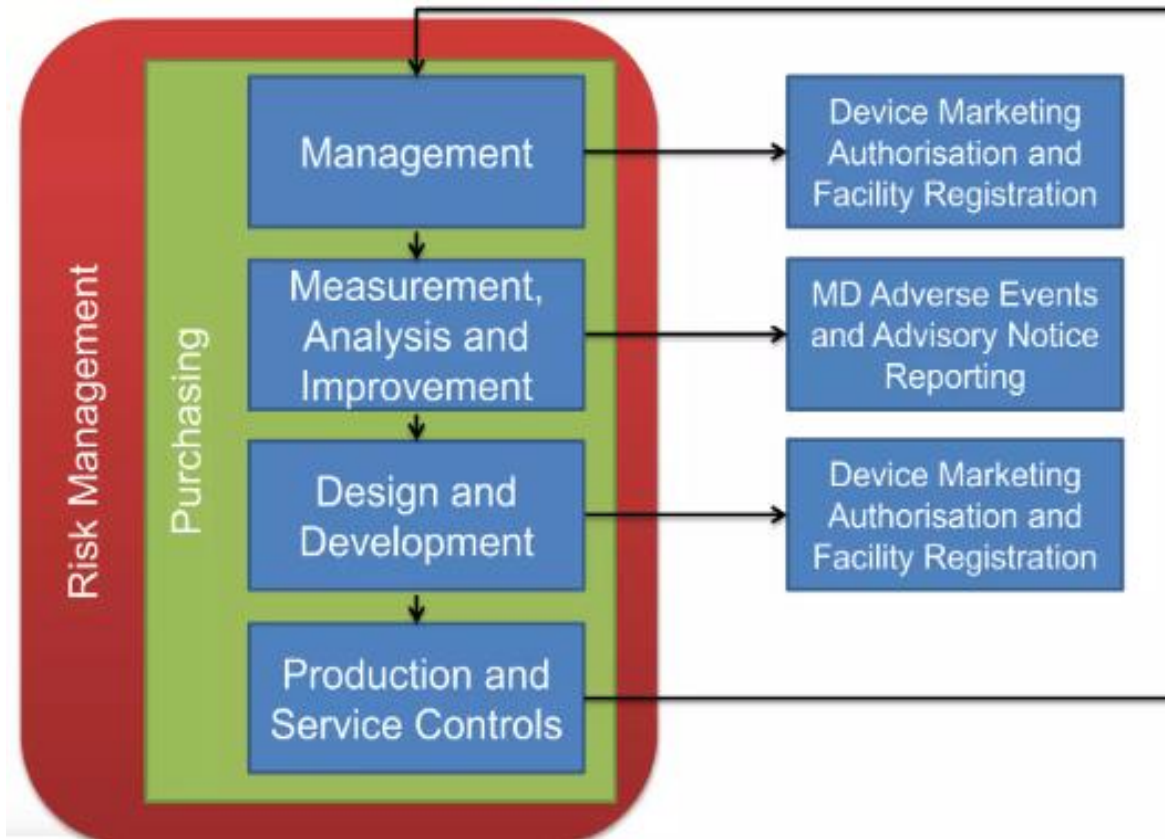
Benefits:

- Training on MDSAP
- Ability to utilize MDSAP reports in the new jurisdiction
- Receive a routine list of MDSAP audits conducted, dates, location, and AO's
- Listed on MDSAP website as an Affiliate Member
- Participate in yearly MDSAP Forum meetings

What to expect in the **MDSAP** audit:

Core processes

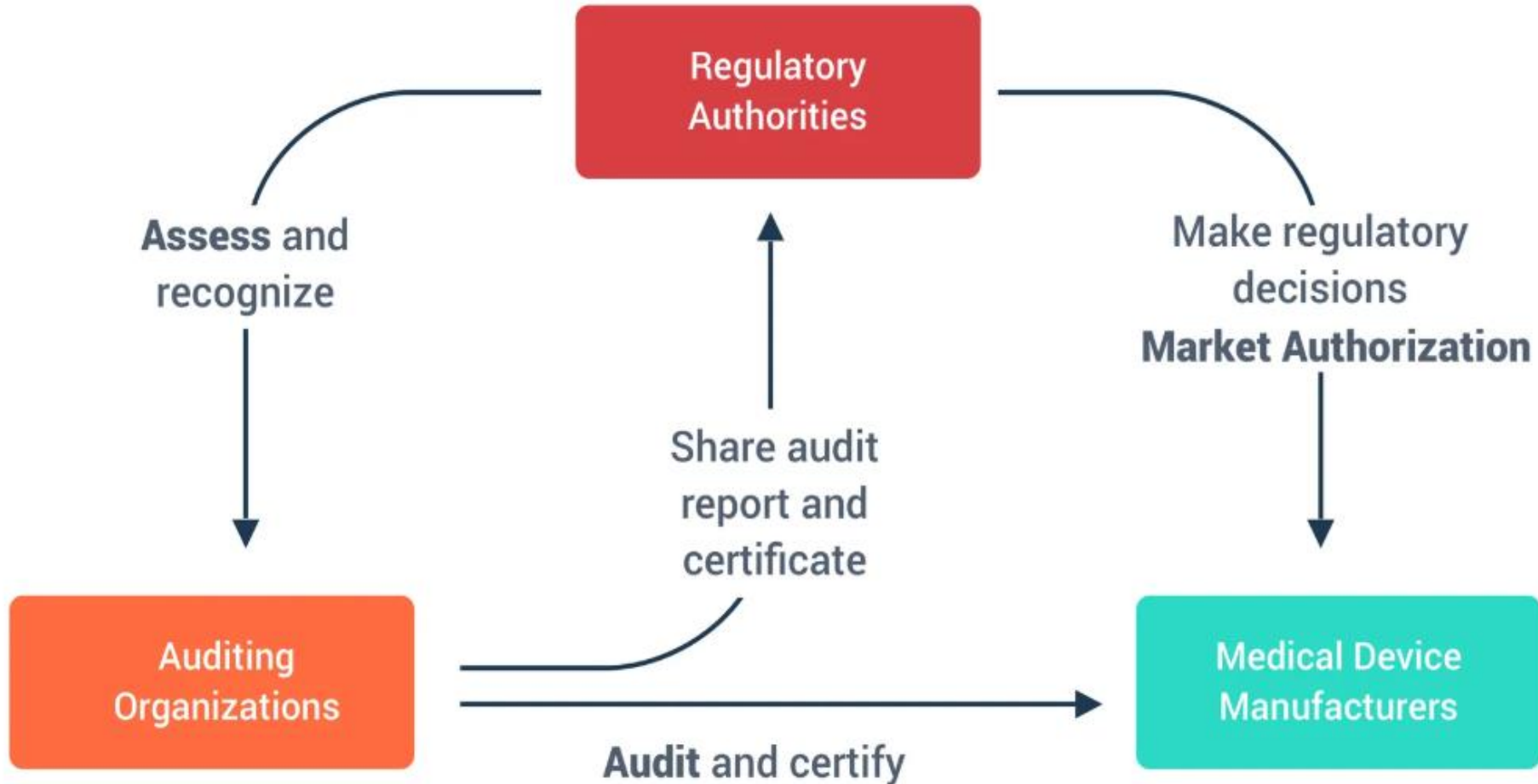
Regulatory output



Manufacturer Steps to Successfully Implement **MDSAP**:

<p>1- Familiarize with the MDSAP Requirements</p> <p>Gain a thorough understanding of MDSAP framework requirements and regulatory guidance</p>	<p>2- Conduct a Gap Analysis</p> <p>Identify discrepancies between current practices and MDSAP requirements to prioritize necessary changes</p>
<p>3- Develop an Implementation Plan</p> <p>Create a detailed plan with actions, timelines, and resources, engaging all relevant stakeholders</p>	<p>4- Train and Educate the Team</p> <p>Equip your team with the necessary knowledge and skills through training sessions and resources</p>
<p>5- Implement Changes to the Quality Management System</p> <p>Update procedures, documentation, and processes to meet MDSAP standards, ensuring thorough documentation and communication</p>	<p>6- Perform Internal Audits</p> <p>Verify implementation effectiveness through independent internal audits and address any identified issues</p>
<p>7- Address Audit Findings</p> <p>Promptly correct any nonconformities identified during the audit, collaborating with the auditing organization to resolve issues</p>	

How Does it Work?



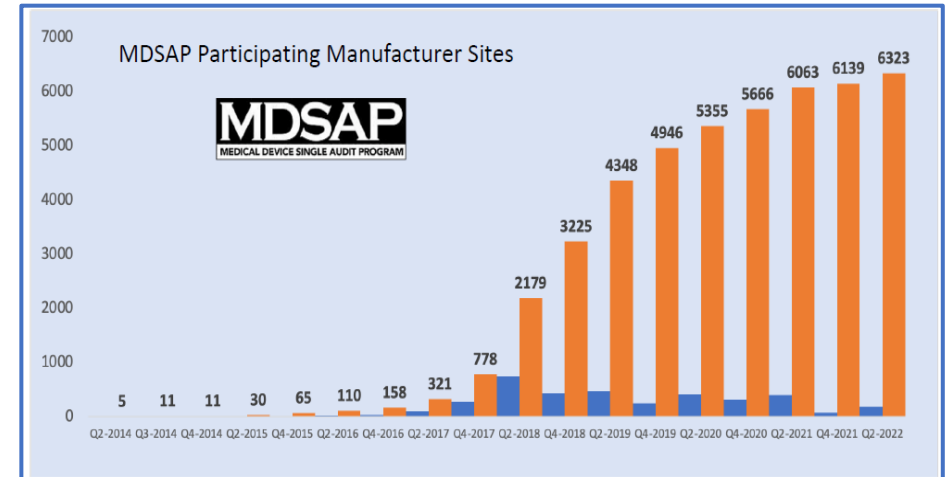
what are the Benefits of MDSAP

Patients	Regulatory Authority	Manufacturers
<p>Accelerating Access while ensuring Patient Safety: Accelerating access to quality assured, safe and effective medical devices and IVDs.</p> <p>Enhance Equitable Access: patients globally will benefit from the same level of safety, quality and effectiveness in medical devices.</p>	<p>Optimized Resource Utilization: Improves efficiency and flexibility</p> <p>Strengthened Oversight: Ensures robust and effective monitoring of medical device manufacturers' Quality Management Systems (QMS).</p> <p>Global Alignment: Enhances global alignment of regulatory approaches and technical requirements with international standards and best practices, fostering global consistency.</p>	<p>Single comprehensive audit: Manufacturers can comply with different regulatory authorities' QMS requirements with single audit, which reduces business disruptions and saves resources.</p> <p>Predicted audit schedules: Manufacturers can clearly plan their timeframes and resources.</p> <p>Commitment to quality: MDSAP certification emphasizes the Manufacturer's commitment to quality and compliance with international high standards.</p>

One Audit, Multiple Markets: MDSAP's Game-Changing Reliance Model

Auditing Organizations	Status
BSI Group America	Recognized
TUV SUD America Inc.	Recognized
Intertek Testing Services	Recognized
UL Medical and regulatory Services of UL, LLC	Recognized
SGS UK Ltd.	Recognized
DEKRA Certification B.V.	Recognized
TUV Rheinland N.A. Inc.	Recognized
LNE G-MED	Recognized
TUV USA Inc.	Recognized
NSAI	Recognized
DQS Med	Recognized
NCC Certificacoes do Brasil Ltd.	Authorized
DNV Presafe	Authorized
DNV Medcert	Authorized

14 Auditing Organizations



≈ 7,000 Participating Manufacturing Sites



> 22,000 Audits performed

MDSAP Remote and Hybrid Auditing Pilot

Adoption of New Audit Modalities:

Over **30%** of MDSAP audits now incorporate remote elements, using either fully remote or hybrid formats.

Pilot Program Duration and Extension:

Original Schedule: The **18-month Pilot**, defined in procedure P0036, was initially set to conclude in September 2024. To facilitate planning and certainty, the Pilot will now continue until **March 31, 2025**.

Post Pilot evaluation:

The Regulatory Authority Council (RAC) will review the Pilot outcomes to determine the conditions for the ongoing use of remote and hybrid audits, and they will publish the requirements for the post-pilot use of remote/hybrid audits in late **2024**.

MDSAP leveraged by WHO prequalification of in vitro diagnostics

The World Health Organization (WHO) is enhancing its reliance on the Medical Devices Single Audit Program (**MDSAP**) for the prequalification (PQ) of in vitro diagnostics. Going forward, **WHO will conduct prequalification inspections based on MDSAP reports through a desk review instead of on-site inspections.** This step aligns with WHO's broader initiative to **enhance reliance and recognition as critical regulatory principles for PQ assessments.**

Documentary evidence of compliance with PQ requirements may still be requested according to relevant PQ procedures. This change was effective starting **May 1, 2024.**



Industry Efforts:

Mecomed is leading efforts within the **GMTA (Africa WG)** to craft a position paper advocating for the adoption of MDSAP and reliance practices to streamline manufacturing site audit requirements.

Focus Areas:

- Highlighting the benefits of MDSAP in enhancing regulatory efficiency, reducing audit duplication, and promoting faster patient access.
- Showcasing reliance as a tool to optimize resources and build confidence in audit processes.

Currently, the draft position paper is under review by the GMTA (Africa Working Group) and other stakeholders for broader input and alignment.



Key Takeaways

- MDSAP unifies regulatory expectations, reducing redundancy and fostering global market access.
- A single, high-quality audit ensures faster regulatory approvals, allowing manufacturers to deliver medical innovations faster to the patients who need them.
- MDSAP's rigorous audit framework ensures safety and performance, building trust among patients, healthcare providers, and regulators.
- By reducing audit duplication, MDSAP enhances operational efficiency for manufacturers and allows regulators to focus resources on other critical areas.



Detailed Guidance and Training Materials

The FDA provides extensive training materials and procedural documents that can help non-participating regulators understand the MDSAP audit process in detail. This includes:

- **Procedures and Forms:** Detailed documentation on various MDSAP procedures, such as audit processes, assessment techniques, and forms used during audits ([FDA](#)) ([FDA](#)) ([FDA](#)).
- **Training Modules:** Specific training materials that outline the scope and methodology of MDSAP audits, helping regulators understand the thoroughness and rigor of the audits ([FDA](#)) ([Accessdata FDA](#)).

IMDRF MDSAP Technical Guidelines

IMDRF/MDSAP WG/N5 [Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations](#) 18 December 2013

IMDRF/MDSAP WG/N22 [MDSAP: Overview of Auditing Organization Assessment and Recognition Decision Related Processes](#) 18 September 2014

IMDRF/MDSAP WG/N24 [Medical Device Regulatory Audit Reports](#) 2 October 2015

IMDRF/MDSAP WG/N8 [Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations](#)

2 October 2015

IMDRF/MDSAP WG/N29 [Clarification of the Term "Legal Entity" for MDSAP Recognition Purposes](#) 2 October 2015

IMDRF/MDSAP WG/N3 [Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition](#) 24 March 2016

IMDRF/MDSAP WG/N4 [Competence and Training Requirements for Auditing Organizations](#) 20 October 2021

IMDRF/MDSAP WG/N6 [Regulatory Authority Assessor Competence and Training Requirements](#) 20 October 2021

IMDRF/MDSAP WG/N11 [MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization](#) 20 October 2021



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