For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

Medical Device Single Audit Program
MDSAP

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What is MDSAP

- **M**edical **D**evices **S**ingle **A**udit **P**rogram
- It allows of a single regulatory audit for the Quality Management system of medical devices manufacturers to satisfy the regulatory requirements of multiple regulatory Jurisdictions
- Audits are conducted by Auditing Organizations (AO's) **authorized** by the participating regulatory authorities to audit according to MDSAP requirements

MDSAP
Medical Device Single Audit Program

A little bit of history…

- 2012 It started as a WG under IMDRF
- 2012 Statement of cooperation AU, BR, CA, USA
- 2014-2016 MDSAP Pilot program
- 2015 Japan becomes participating Regulatory Authority
- 2016 moved from a pilot program into a fully operational program Revision of the model to ISO 13485:2016
- 2017 Full implementation
- 2019 Canada discontinue their own CMDCAS

The MDSAP program has grown significantly since its commencement, now including around 7000 certified medical device manufacturers.

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MDSAP Members

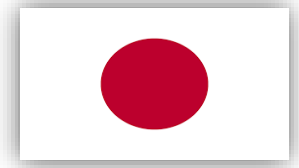
These five RAs form the MDSAP Regulatory Authority Council (RAC), the decision-making body of the MDSAP. The RAC provides direction, oversight, and resources to support the MDSAP development, implementation, maintenance, and expansion.

Health Canada

Agência Nacional de Vigilância Sanitária - Anvisa

FDA U.S. FOOD & DRUG ADMINISTRATION

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration



Pmda 独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

MDSAP
Medical Device Single Audit Program

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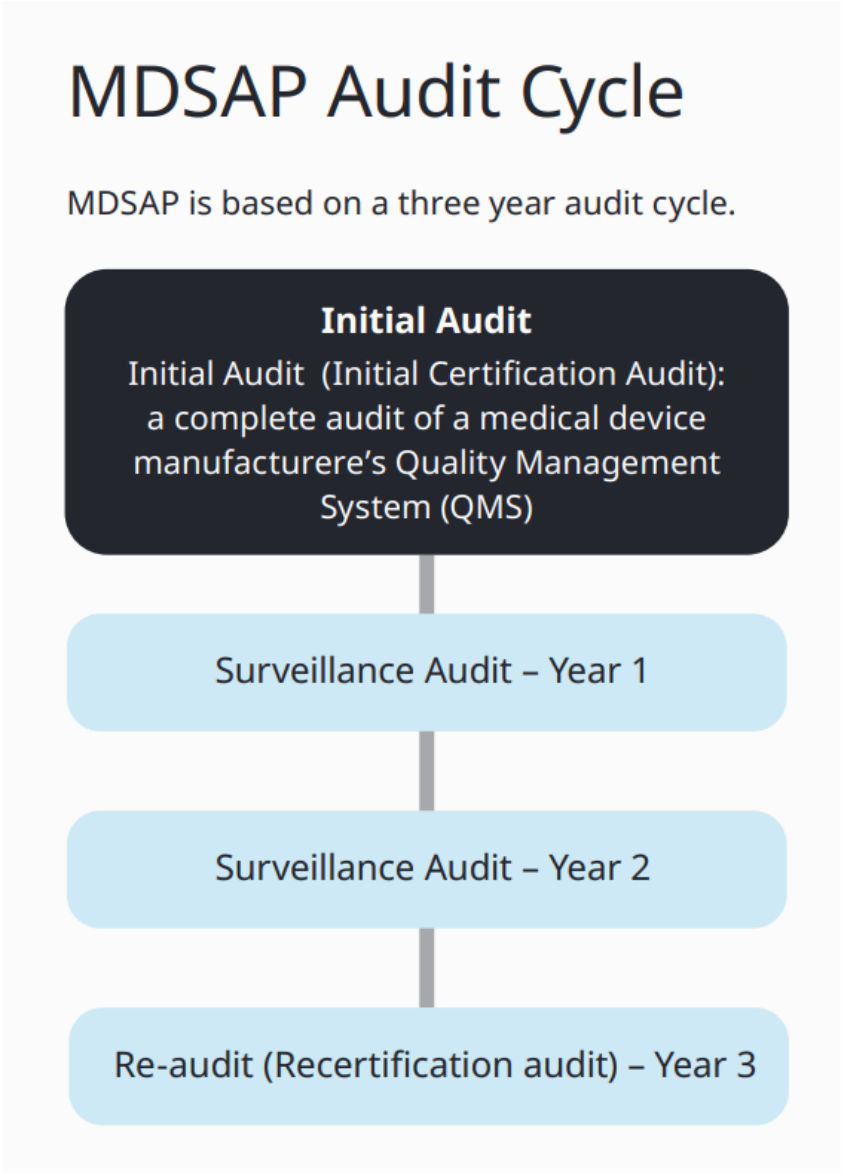
The program is based on *ISO 13485 - Medical devices - Quality management systems - Requirements for regulatory purposes*, with additional guidance provided to AOs on specific RA needs. In accordance with best practices, the MDSAP incorporates a transparent assessment program to oversee the compliance of AOs with MDSAP requirements and ensures appropriate competency and training of RA assessors who undertake the AO recognition process.

At the conclusion of an MDSAP audit, a standardized MDSAP Audit Report is completed that ensures the reporting requirements of all participating RAs are effectively documented. After the successful closure of an audit, the AO will issue a MDSAP certificate to the medical device manufacturer. These certificates are used by many RAs globally and can be verified by reaching out to directly to the issuing MDSAP AO.

The single audit of a medical device manufacturer's quality management system will include the assessment of the quality management system processes including management responsibility, resource management, product realization, measurement, analysis and improvement, and adverse event reporting; as well as compliance with Good Manufacturing Practices (GMPs) or other applicable requirements specific to a participating regulatory authority.



Benefits

MDSAP was developed ***to encourage and support global harmonization*** of regulatory systems, where possible, to ***increase efficiency*** and ***reduce duplication of effort***. It achieves this through ensuring the highest standards of safety for medical devices, whilst minimizing regulatory burden through use of an agreed single audit process.

Specifically, MDSAP aims to:

- Enable appropriate regulatory oversight of medical device manufacturers' Quality Management Systems (QMS) while minimizing regulatory burden on industry
- Promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the sovereignty of each RA
- Promote globally, in the longer term, a greater alignment of regulatory approaches and technical requirements based on international standards and best practices
- Promote consistency, predictability, and transparency of regulatory programs by:

  - standardizing the practices and procedures of participating regulators for the oversight of third-party AOs

  - leveraging, where appropriate, existing requirements and procedures for conformity assessment, and

  - standardizing the practices and procedures of participating third-party AOs.

MDSAP Official Observers

Official Observers observe and/or contribute to RAC activities while not having equal authority with respect to final RAC decisions and deliverables.

MDSAP Official Observers may express suggestions, concerns, and alternatives to RAC decisions and deliverables.

However, the RAC retains final decision authority regarding all MDSAP development, implementation, maintenance, and expansion activities.

European Union (EU)

Singapore's Health Sciences Authority (HSA) (NEW)

United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA)

The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme

Affiliate Members

- ✓ Affiliate Members engage with, but do not participate in the decision-making process of MDSAP.
- ✓ Affiliate Members utilize MDSAP audit reports and/or MDSAP certificates for evaluating compliance with applicable medical device requirements, including a manufacturer's quality management system, under the Affiliate Member's regulatory framework.
- ✓ Affiliate Members report annually on the utilization of MDSAP audit reports and/or MDSAP certificates to the RAC. This report may be presented at the MDSAP Forum by the MDSAP Affiliate Member or the RAC.
- ✓ Affiliate Members have access to a list of participating MDSAP facilities, which contains information on the manufacturer, manufacturing site, audit dates and the responsible AO.
- ✓ Affiliate Members can obtain MDSAP audit reports and/or MDSAP certificates by contacting participating manufacturers.

- *Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT)*
- *Ministry of Health of Israel*
- *Kenya's Pharmacy and Poisons 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*
- *South Africa Health Products Regulatory Authority*
- *Malaysia Medical Device Authority*

Benefits of becoming Affiliate Member

- Affiliate members are Regulatory Authorities that show interest in MDSAP and whish to engage with MDSAP and utilize MDSAP reports to evaluate medical devices manufacturers quality management system compliance, and they will have access to MDSAP deliverables.
- If a medical device manufacturer export to these countries of these regulatory authorities, those authorities will have access to MDSAP audit reports and deliverables of this manufacturer and therefore accelerate the evaluation and have the product in a faster manner.

Non-MDSAP members may also benefit from relying on MDSAP inspections in lieu of performing a local inspection through unilateral reliance. By leveraging MDSAP audits as a replacement for local audits and additional on-site audits.

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WHO

may recognize successful MDSAP - Version 018 2022-08-22 audits as acceptable evidence of QMS compliance with international regulations. This may result in either abbreviated or waived WHO inspection depending on the scope of audit.

Canada

MDSAP replacing CMDCAS

Republic of Korea

When certain manufacturing sites submit MDSAP certificate and audit report during GMP audits, the Ministry of Food and Drug Safety (MFDS) grants exemptions from on-site audit and conducts a document-based review instead.

EU Position

European medical technology industry calls for the EU to join the Medical Device Single Audit Program (MDSAP) as a Full Member

Believing that becoming an MDSAP full member, will reduce regulatory complexity, reduce administrative burden, enhance regulatory harmonization and faster patient access.

https://www.medtecheurope.org/wp-content/uploads/2025/02/20250217_mte-and-cocir_reflection-paper-on-mdsap.pdf

Benefits of adopting/relying on MDSAP (for industry and Authorities)

Industry:

- Minimize medical device manufacturer disruptions due to multiple regulatory audits.
- Reduce time and resources dealing with findings from multiple audits
- Reduce unintended economic consequences associated with increased costs of product site inspections that contribute to a potential barrier to trade and entry into markets, which can have negative impact for healthcare and patient access.

Authorities:

- Only one audit to show compliance with standards and regulatory requirements of up to 5 different regulatory Authorities (Australia, Brazil, Canada, Japan and USA)
- More efficient use of regulatory resources would be granted, fostering a common understanding of safety and effectiveness. This increases also the consistency, predictability and transparency of regulatory programs, without lowering the inspection standards.
- Benefit patient health and patient access with ease of entry to multiple markets.
- Avoid duplication of work and provide a mean for more efficient use of capacity at authorities' level, by focusing on more important tasks like vigilance and PMS

Call to Action:

- MDSAP reliance provide harmonized, transparent and predictable mean for oversight of Medical Device manufacturers' quality management system.
- Members can benefit by having access to deliverables and audit reports.
- Non-members can also benefit by relying on MDSAP certificates in lieu of performing a local inspection through unilateral reliance. By leveraging MDSAP audits as a replacement for local audits and additional on-site audits.

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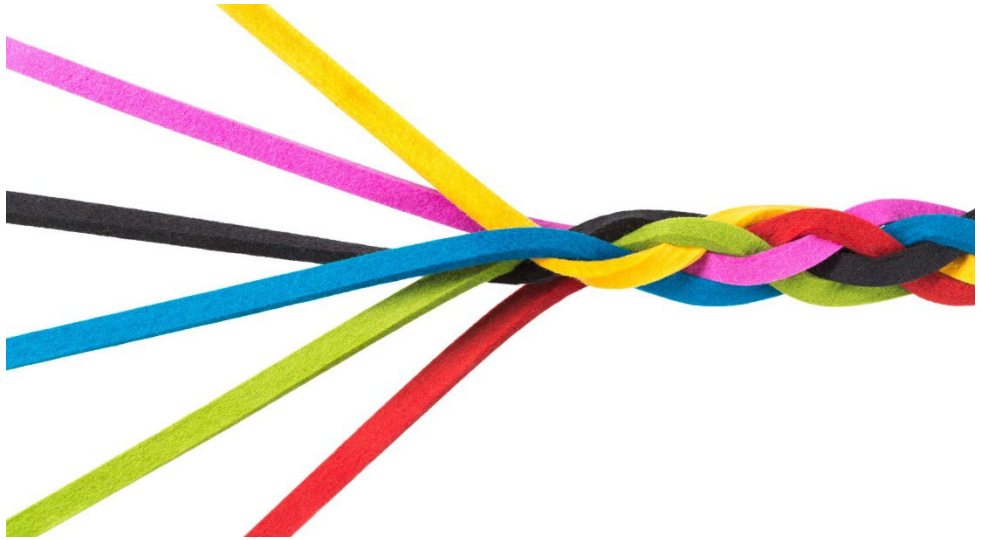
“Success is not about starting over it is about building smarter on what's already been done”



“The best way to move forward is often to pick up where others left off and push further”

References:

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