



Medical Device Single Audit Program (MDSAP) Overview

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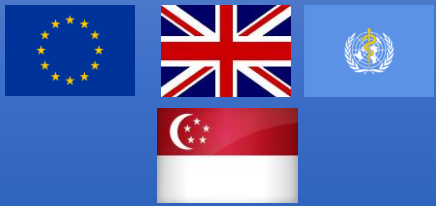


Medical Device Single Audit Program

Global Approach to Auditing Medical Devices

Voluntary program where one inspection is conducted by a 3rd party Auditing Organization to meet the requirements of the 5 participating regulatory authorities.

Official Observers



Participating Regulatory Authorities (RA)



Affiliate Members

- Argentina
- Chinese Taipei
- Israel
- Kenya
- Mexico
- Malaysia
- Republic of Korea
- South Africa

Assess
and
Recognize

Share
Audit
Report

Regulatory
Decisions

Auditing Organizations (AO)
(14 recognized)

Audit and Certify

Manufacturers
(>7600 individual sites worldwide)



MDSAP Vision



- To ensure the highest standards of safety for medical devices, whilst minimizing regulatory burden through use of an agreed single audit process.
- The MDSAP Regulatory Authorities are committed to protecting patient health and wellbeing by continuously improving our audit methodologies, fostering transparency, and upholding the integrity of medical device safety.



MDSAP Goals

- Provide oversight of medical device manufacturer's Quality Management Systems (QMS).
- Let regulators share the workload — pooling resources and accepting each other's findings — while each authority still maintains its own sovereignty.
 - MDSAP regulators may use results differently and add extra requirements if their laws demand it
 - Marketing approval always stays with the local authority
- Bring global requirements into closer alignment, based on international standards and best practices.



MDSAP Benefits

- ✓ Provides for more effective, efficient and less burdensome regulatory oversight of the quality management systems of medical device manufacturers.
- ✓ Encourages and supports global regulatory harmonization.
- ✓ Increases efficiency and reduces duplication of regulatory audits.
- ✓ Ensures the highest standards of safety for medical devices, whilst minimizing regulatory burden through use of an agreed single audit process.



MDSAP Benefits

- ✓ Promotes consistency, predictability, and transparency by:
 - standardizing the practices and procedures of participating regulators for the oversight of Auditing Organizations,
 - leveraging, where appropriate, existing requirements and procedures for conformity assessment, and
 - standardizing the practices and procedures of participating third-party AOs.
- ✓ Demonstrates feasibility of regulatory reliance
- ✓ Increases regulatory confidence



Thank You!

