Save time & reach global markets with the MDSAP

SGS MEDICAL DEVICE SOLUTIONS

Introducing the MDSAP

The Medical Device Single Audit Program (MDSAP) provides a single quality management system (QMS) audit to satisfy all participating regulatory authorities' requirements.

Reach global markets

The goal is to create a coalition of countries that are dedicated to improving medical device manufacturing safety and oversight.

The program is one audit for compliance with the standard and regulatory requirements of:

- Australia
- Brazil
- Canada
- Japan
- The US
- Affiliate jurisdictions that use the MDSAP report, such as South Korea, Argentina, Singapore and others

Key benefits

- Access to multiple markets via a single audit, leading to improved patient health and access
- Minimize business disruptions from multiple audits
- Leverage regulatory resources and save time and costs
- Routine audits scheduled with the auditing organization (AO), such as SGS
- Incorporate ISO 13485 (medical device QMS) assessment
- Greater industry transparency

The audit process & regulatory authorities

The MDSAP is based on a three-year audit cycle.

There is a complete initial audit of your QMS, surveillance audits in years one and two, and a re-audit in year three.

The regulatory authorities (RAs) involved

The MDSAP is perfect for global organizations wishing to export medical devices to the listed countries and affiliates.

The following is what each country's RA says about utilizing MDSAP reports.

AUSTRALIA

The Therapeutic Goods Administration (TGA) uses MDSAP audit reports as part of the evidence that is assessed for compliance with medical device conformity assessment procedures and market authorization requirements. This is unless the device is excluded or exempt from these requirements, or if current policies restrict using MDSAP reports.

BRAZIL

The Agência Nacional de Vigilância Sanitária (ANVISA) utilizes program outcomes, including reports, to constitute important input for its pre- and post-market assessment procedures. ANVISA provides, when applicable, key information that is expected to support regulatory technical evaluation concerning these issues.

CANADA

Health Canada (HC) only accepts the MDSAP for manufacturers that market their devices in Canada. Therefore, manufacturers wishing to place a product in the Canadian market must have MDSAP certification from an AO.

JAPAN

The Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) utilize MDSAP audits in pre- and periodical post-market audits under Japanese regulations.

THE US

The US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) accepts MDSAP audit reports as a substitute for FDA routine inspections.

Inspections conducted "For Cause" or "Compliance Follow-up" by the FDA are not affected by the MDSAP. The MDSAP does not apply to any necessary pre- or post-approval inspections for Pre-Market Approval (PMA) applications or decisions under section 513(f)(5) of the Act (21 U.S.C. 360c(f)(5)) concerning the classification of a device.

WHO & THE EU

The World Health Organization (WHO) prequalification of in vitro diagnostics (IVDs) and European Union (EU) are official MDSAP observers.

An auditing organization

MDSAP audits are conducted by an AO, such as SGS, authorized by the relevant RA under the program's requirements.

One audit from SGS

Our MDSAP audit covers the regulatory requirements of the five member jurisdictions and replaces multiple audits. Our experienced auditors can support you to bring any medical device to the Australian, Brazilian, Canadian, Japanese and/or US markets.

Affiliate participants may examine audit reports provided by the participating manufacturer.

Combining to save time

Our MDSAP audit can also be combined with CE and ISO 13485 assessments.

Medical device training courses

Stay up to date on the latest medical device standards and regulations with SGS Academy's series of training courses.

SGS Academy's training solutions help organizations to improve personal competence and skills, as well as enable sustainable business development and a competitive advantage.

With expert trainers, training moves beyond theory to provide valuable real-world insights.

Medical device training courses

- Introduction to the new MDR – online
- MDR – implementing the changes
- MDR internal auditor
- MDR medical devices auditor/lead auditor training course
- MDR technical documentation training course
- ISO 14971 and ISO 31000 – adopting a product and process risk-based approach
- Medical devices clinical evaluation implementation
- Introduction to the new IVDR – online

SGS medical device solutions

In addition to our MDSAP service, we offer a range of solutions to act as the one-stop shop for all your medical device certification and testing needs.

Certifications

ISO 13485
Medical Devices – Quality Management Systems

MDR
Medical Device Regulation

3P510k
510(k) Third-Party Review

JPAL
Japanese Pharmaceutical Affairs Law

UKCA
UK Conformity Assessed

Training with SGS Academy

ISO 13485 Medical Devices QMS Lead Auditor Training

Build your knowledge, skills and practical toolkit to effectively lead medical device quality management system audit teams to perform audits of ISO 13485, in accordance with ISO 19011 auditing guidance.

Duration: 4 days

ISO 13485 Medical Devices QMS Internal Auditor Training

Build your knowledge, skills, and practical toolkit to perform internal audits of an ISO 13485 medical device quality management system.

Duration: 3 days

ISO 13485 Documenting and Implementation

This course provides knowledge and skills to create and maintain quality management system documentation that meets ISO 13485 requirements.

Duration: 2 days

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WHEN YOU NEED TO BE SURE