Medical Device Single Audit Program (MDSAP)

One audit for multiple market access.

Add value.
Inspire trust.

The Challenges Faced by Medical Device Manufacturers
Medical device manufacturers face rising product development costs and time-to-market challenges as they must register with different regulatory agencies to gain access to individual export markets. A globally consistent approach to auditing and monitoring medical device manufacturing is needed to minimize burdens and eliminate redundancy while ensuring safety and efficacy.

What is the Medical Device Single Audit Program (MDSAP)?
The MDSAP program supports manufacturers in accessing multiple markets via a single audit conducted by a recognized auditing organization. The program promotes an aligned approach to auditing quality regulatory and technical requirements while encouraging consistency and transparency within regulatory programs. This enables MDSAP to streamline the process by allowing a single regulatory audit to meet the varying requirements of multiple jurisdictions.

The MDSAP functional statement defines the policy as

"To jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturer's quality management systems."

MDSAP Regulators
The MDSAP program is supported by the following regulatory authorities:

Five Participating Regulators:
- Australian Therapeutic Goods Administration
- Brazilian National Health Surveillance Agency (ANVISA)
- Health Canada
- Japan Ministry of Health, Labour and Welfare and the Pharmaceuticals and Medical Devices Agency
- U.S. Food and Drug Administration Center for Devices and Radiological Health

Four Official Observers:
- 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) Program

In addition, there are currently **six participating Affiliate Members**:
- Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT)
- Ministry of Health of Israel
- 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
- Taiwan Food and Drug Administration (TFDA)

Nation-Specific Overview:
There are specific aspects that manufacturers selling products in each of the five countries participating in the MDSAP program should consider:

- **Canada:** Since January 1, 2019, Class II, III, and IV medical devices in Canada must follow the MDSAP Program. MDSAP is mandatory for regulatory submission in Canada.
  Note: If you apply for MDSAP in Canada and sell into any other MDSAP-participating countries, these countries must also be included in the scope of the MDSAP Certificate.
- **Australia**: The MDSAP Program accepts combination products and other medical devices. When including a device on the ARTG, the TGA can accept MDSAP certificates as evidence of compliance with the ISO 13485 standard. The regulators use MDSAP Audit Reports as part of a desktop audit to support the TGA Conformity Assessment Certificate application or change application.
- **Brazil**: Initial and Recertification MDSAP reports covering all requirements from RDC n°665/2022 are used as an alternative to an ANVISA inspection for granting ANVISA initial certifications. Since January 2024, under RDC N°850/2024, the validity of ANVISA GMP certificates issued through the use of MDSAP will be extended from 2 to 4 years, conditioned by the manufacturers' continuous participation in the program for the entire duration of the GMP certificate.
- **U.S**: The MDSAP Program can be an alternative to an FDA inspection, except for combination products and PMA inspections. Certification documents issued by the AO (Auditing Organization) must meet applicable U.S. regulations.
- **Japan**: An MDSAP audit report submitted during a pre- or post-market QMS inspection can exempt some manufacturing sites from on-site inspection and/or allow the Manufacturer's Marketing Authorization Holder (MAH) to substitute a significant part of the documents required for the inspection by the MDSAP report.

MDSAP Eligibility and Audit Process
Manufacturers wishing to participate in the MDSAP can be located anywhere worldwide. However, their medical product must fall under the scope of at least one participating Regulatory Authority and be subject to its quality management system requirements. On the other side, a manufacturer participating in the program may not choose which of the five regulatory schemes to include in the audit scope if products are distributed within the jurisdiction and are subject to the quality management system requirements.

The audit must cover ISO 13485 and all country-specific requirements for each market the manufacturer sells to.

Audit Process:

- The audit program for the initial certification includes a two-stage initial audit (Stage 1 and Stage 2)
- Surveillance audits in the first and second years following the certification decision
- Recertification audit in the third year before the expiration of the certificate

Non-Conformities:
For MDSAP, Non-Conformities are graded on a scale of 1 to 5, with grades 4 and 5 indicating the most significant concerns. The grading assignment follows consistent and transparent rules defined within the MDSAP guidance document, available to the public on the program website. If an audit identifies one or more grade 5 non-conformities, more than two grade 4 non-conformities, a public health threat, counterfeit products, or fraudulent activity, the AO is responsible for informing the Regulatory Authorities within five days. It is standard practice for the AO to complete an unannounced visit to verify that the appropriate actions have been taken to correct previously identified issues.

Benefits for Medical Device Manufacturers
MDSAP is a key opportunity for manufacturers as it is designed to cover the existing ISO 13485 standard and applicable country-specific requirements. This means reduced duplication of regulatory effort and costs to manufacturers. Manufacturers will also benefit from the standardization and harmonization within QMS and regulatory submissions, and more, including:

- Global Compliance Simplified: One audit satisfies multiple regulatory requirements.
- **Operational Efficiency**: Streamlined processes and optimized operational costs associated with compliance.
- Efficient **Access to Markets**: Achieve efficient regulatory approvals and seamless product launches to secure a competitive advantage in international markets.
- **Risk Mitigation**: Ensure consistency in audits and compliance, thereby reducing the risk of market delays or rejections

Streamline Your Regulatory Compliance with TÜV SÜD
MDSAP has recognized dedicated Auditing Organizations following a rigorous assessment process to conduct single regulatory audit on their behalf and assist with the program‘s implementation.

TÜV SÜD is a recognized Auditing Organization that can support any medical device manufacturer that sells into at least one of the participating MDSAP markets, regardless of its current Certification Body.

Using the MDSAP Audit Approach, TÜV SÜD will audit the following seven process groups, including four primary and three supporting processes:

Primary:

- Management
- Measurement, analysis, and improvement
- Design and development
- Production and service controls

Supporting:

- Purchasing
- Device marketing authorization and facility registration
- Medical device adverse events and advisory notices reporting

If you are interested in learning more, contact us at medicaldevice@tuvsud.com.

Why Partner with TÜV SÜD
With over 900 dedicated medical device experts in major markets worldwide, TÜV SÜD is one of the largest Auditing Organizations. Our expertise is tailored to specific product needs and regulatory requirements, ensuring a comprehensive approach to compliance. When you partner with us, you are assigned a dedicated point of contact responsible for tracking certifications, managing change notices, and responding quickly to your queries —offering you the support you need. We deliver large-scale, global expertise with a focused team's responsiveness and direct action.

To provide maximum flexibility, TÜV SÜD can combine the MDSAP audit with your already prescheduled annual EU regulatory or (EN) ISO 13485 audits or perform a separate MDSAP audit to avoid disrupting an existing program.

Add value. Inspire trust.
TÜV SÜD is a trusted partner of choice for safety, security and sustainability solutions. It specializes in testing, certification, auditing and advisory services. Through close to 28,000 employees across over 1,000 locations, it adds value to its customers, inspiring trust in a physical and digital world.

Related services

TÜV SÜD provides the following related services:
- ISO 13485
- EU IVDR
- EU MDR
- Medical Device Testing

Learn more about the services we provide for the healthcare and medical device industry.

www.tuvsud.com/en-us/industries/healthcare-and-medical-devices

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