Add value.
Inspire trust.

Medical Device Single Audit Program (MDSAP)

One audit for multiple market access.

Your challenges

Medical device manufacturers are faced with increased product development costs and time-to-market challenges as they must apply for testing and certification with different Certification Bodies to gain access to individual export markets. A globally consistent approach to the auditing and monitoring of medical device manufacturing is needed to minimise burdens and eliminate redundancy, while improving safety and efficacy.

What is the Medical Device Single Audit Program (MDSAP)?

MDSAP promotes the greater alignment of regulatory approaches and technical requirements while simultaneously encouraging consistency and transparency within regulatory programs. The idea is that MDSAP will manage and oversee a single audit program that will allow a single regulatory audit to satisfy the varying requirements in 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 manufacturers' quality management systems.".

MDSAP Regulators

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
- US Food and Drug Administration, Center for Devices and Radiological Health

In addition, there are currently **three participating Affiliate Members**:

- Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT)
- Republic of Korea's Ministry of Food and Drug Safety
- Singapore's Health Sciences Authority (HSA)

MDSAP recognised Auditing Organizations (AO) are able to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulating authorities.

Nation by Nation Overview:
There are specific aspects that manufacturers selling products in each of the five counties involved 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. In contrast to the other partners of the program where participation is voluntary, MDSAP is mandatory for the regulatory submission in Canada.
  Note: If you apply for MDSAP for Canada and sell into any of the other MDSAP participating Countries, then these Countries must also be included within the scope of the MDSAP Certificate.
- **Australia**: Combination products and other medical devices are accepted by the MDSAP Program. The TGA can accept MDSAP certificates as support of evidence for compliance with the ISO 13485 standard, and may request additional documents.
- **Brazil**: The resolution from August 2015 allows MDSAP reports to be used as an alternative to an ANVISA inspection, but only when the previous ANVISA inspection was deemed satisfactory.
- **U.S**: The MDSAP Program can be an alternative to a FDA inspection, excluding combination products and PMA inspections. Certification documents issued by the AO must comply with applicable U.S. regulations.
- **Japan**: An MDSAP audit report submitted at the time of pre- or postmarket QMS inspection can be used as a trial to exempt some manufacturing sites from on-site inspection, and/or to allow the Manufacturer's Marketing Authorization Holder (MAH) to substitute the MDSAP report for a considerable part of documents required for the inspection.

MDSAP eligibility and audit process

Manufacturers who wish to participate in the MDSAP can be located anywhere in the world. However, their medical product must fall under the scope of at least one participating Regulatory Authority and be subject to their quality management system requirements. A manufacturer may not select which of the five regulatory schemes to include in the audit scope. In the audit plan, TÜV SÜD must cover ISO 13485, plus all country specific requirements for each market the manufacturer sells into. To give manufacturers flexibility, TÜV SÜD can combine MDSAP audits with prescheduled annual audits, such as those within the scope of European Directives/ Regulations or as a separate audit dedicated to the MDSAP Audit Model.

Audit process:
The audit programme 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, and a recertification audit in the third year prior to expiration of the certificate.

Non-Conformities:
Under most audit schemes Non-Conformities are typically graded as major and minor however for MDSAP Non-Conformities are graded on a scale of 1 to 5, with the grade 4 and 5 being the more serious gradings. If any audit finds one or more grade 5 non-conformities, two or more grade 4 conformities, a public health threat, or even fraudulent activity, it is the responsibility of the AO to inform the Regulatory Authorities within five days. It is normal practice for the AO to then complete an unannounced visit to verify the appropriate actions have been put in place to correct previous flaws.

Why is MDSAP important for your business?

The MDSAP program provides manufacturers access to multiple markets via a single audit conducted by an authorised auditing organisation. Increased consistency among the auditing organisations will save your business money and minimise administrative overheads. In particular, a reduced number of annual audits will save significant amounts of time, helping you to enter markets faster.

Our MDSAP services

TÜV SÜD is an authorised auditing organisation, which can support any medical device manufacturer that sells into at least one of the participating MDSAP markets, regardless of their current Certification Body. If you are interested in participating, email medicaldevice@tuv-sud.com.

Using the MDSAP Model, TÜV SÜD will audit the following seven process groups, including four main and three supporting processes:

- Management
- Measurement, analysis and improvement
- Design and development
- Production and service controls
- Purchasing
- Device marketing authorisation and facility registration
- Medical device adverse events and advisory notices reporting

Your business benefits

MDSAP is a key opportunity for manufacturers as it is designed to cover the existing ISO 13485 standard and applicable country specification. This means manufacturers complying with MDSAP will automatically find they are in-line with local regulations and ISO 13485. Manufacturers will also benefit from the standardization and harmonization within QMS and in other regulatory submissions.

Although the initial stages of implementation appear challenging, the benefits MDSAP will provide supersedes its constraints as the time and effort required to prepare for and respond to audits and inspections from various markets and jurisdictions will contract.

- **Save time and money** – by gaining access to multiple markets with a single audit program that satisfies the needs of multiple regulatory authorities.
- **Reduce FDA routine inspections** – and minimise manufacturing plant and personnel disruptions.
- **Increase speed to market in Brazil** – by avoiding the three-year backlog of companies awaiting ANVISA inspection. Alternatively, use MDSAP, which is accepted for initial audits with the exception of certain higher risk devices.

Why choose TÜV SÜD?

With over 600 dedicated medical device experts situated in major markets worldwide, TÜV SÜD is one of the largest Notified Bodies in the world. Our expertise is tailored to specific product requirements and regulatory contexts. For maximum accountability, we assign a dedicated point of contact to you, who is responsible for tracking certifications, managing change notices, and delivering a rapid response to your queries. We deliver large-scale, global expertise, with the responsiveness and direct action of a small team.

Choose certainty. Add value.

TÜV SÜD is a premium quality, safety, and sustainability solutions provider specialising in testing, inspection, auditing, certification, training, and knowledge services. Represented by more than 24,000 employees, 1,000 locations worldwide, TÜV SÜD's service portfolio adds value to businesses, consumers and the environment.

Related services

TÜV SÜD provides the following related services:

- EN ISO 13485
- ISO 13485
- EN ISO 9001
- EC Certification
- Medical Device Testing

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