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)?

The Medical Device Single Audit Program (MDSAP) allows authorised auditing organisations to conduct a single audit of a manufacturer's quality management systems that will satisfy some requirements of the regulatory authorities of each participating country. For example, the US Food and Drug Administration will now accept the MDSAP audit report as a substitute for its own routine inspections. The MDSAP Pilot Program started in 2014 and ended on December 2016, with the implementation of an official program in January 2017.

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

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 or as a separate audit dedicated to the MDSAP Audit Model.

Why is MDSAP important for your business?

Participation in the MDSAP pilot 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.

At the end of 2015, Health Canada announced that it will terminate the current Canadian Medical Devices Conformity Assessment System (CMDCAS) program on December 31, 2018. It will then be replaced by the implementation of MDSAP as the sole mechanism for manufacturers to demonstrate compliance with the quality management system requirements of the Medical Devices Regulations (the Regulations). If manufacturers intend to market their medical devices in Canada in the future, they must apply for MDSAP certification.

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
- Production and service controls
- Purchasing
- Device marketing authorisation and facility registration
- Medical device adverse events and advisory notices reporting

Your business benefits

- **Continued accessibility in the Canadian market beyond 2018** - Beginning on January 1, 2019, manufacturers must have a MDSAP certificate if they want to maintain or apply medical device licenses.
- **Save time and money** – by gaining access to multiple markets with a single audit program that satisfies the needs of multiple regulatory authorities.
- **Avoid 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 experts' on-site technical file review gives you immediate access to information, helping you to understand any noncompliance issues. This strict technical accuracy is complemented by expertise tailored to specific product requirements and regulatory contexts. For maximum accountability, we assign one lead auditor 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.

Add value. Inspire trust.

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:

- ISO 13485
- EC certification
- Medical device testing

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