GMED LNE GROUP Newsletter

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MDSAP PROGRAM: PRINCIPLES, IMPLEMENTATION AND ADVANTAGES

The Medical Device Single Audit Program (MDSAP) is an initiative started in 2012. This young program has been accepted by several countries. The growing company adoption demonstrates the interest for companies and regulators across the world.
With the MDSAP certification, medical device manufacturers can undertake a single audit that will be considered when selling devices in different markets. MDSAP program is based on QMS requirements according to ISO 13485 with consideration of regulatory requirements related to each of the participating countries. The application of country's regulations requirement depends where the manufacturer sells or wants to sell devices.
As of today, the countries which are using the MDSAP reports and certificates are Australia, Brazil, Canada, Japan, and the USA.

A MDSAP RECOGNITION

Before MDSAP, there were multiple attempts to combine audits across different countries. Only MDSAP has succeeded to get significant traction across multiple jurisdictions. There are a clear fast growing number of audited facilities.
In 2020, 55.4% of the Brazilian GMP (Good Manufacturing Practices) certificates (which are compulsory for registration of Risk Class III and IV devices) have been issued by ANVISA based on Medical Device Single Audit Program (MDSAP) reports. As a result, ANVISA on-site international inspections have significantly decreased from 238 inspections in 2017 to 84 inspections in 2019. (1)

Health Canada has placed MDSAP certification as cornerstone of the regulation for medical devices in Canada.
By contrast, the other countries of the program (United States of America, Japan, Brazil and Australia) did not make MDSAP mandatory. However, when a manufacturer is selling medical devices in Canada and other jurisdictions, MDSAP audits have to include all the applicable country specific requirements.
The recognition of the MDSAP reports/certificates of the different member of the consortium is as followed:

- **Health Canada:** Starting January 1st, 2019, MDSAP certificate is required for registration of Class II, III, and IV devices in Canada. Early 2019, some accommodations were implemented to ensure transition between the CMDCAS program and the MDSAP program.

(1) Information from MDSAP 2019 Forum

- **Food and Drug Administration (FDA):** American authority is accepting the results of MDSAP audit reports as a substitute for FDA routine inspections. However, inspections conducted by the US FDA such as for Cause, Pre/ Post approval (PMA), Compliance Follow ups and Compliance with Electronic Product Radiation Control Regulations still apply.
- **Agencia Nacional de Vigilancia Sanitária (ANVISA):** Brazilian authority is taking into account MDSAP audit reports for initial and renewal GMP certification. ANVISA will take care of MDSAP reports with particular attention with grading of non-conformances identified (if any) and their closure status. Depending on that, ANVISA will consider appropriate actions to conduct (contact with Auditing Organization (AO), inspection...). ANVISA may also investigate information reported on 5-day notice related with possible risks to patient or public health.
- **Ministry of Health, Labour and Welfare (MHLW):** Japan announced its participation to MDSAP program in June 2015. Japanese authorities are accepting MDSAP audit reports and may perform off-site inspection instead of on-site inspection or reduce documents for off-site inspection. MDSAP reports are taken into account as part of pre-market and post-market activities. PMDA (Pharmaceuticals and Medical Devices Agency) has accepted more than 352 QMS inspection applications which utilize MDSAP audit reports (as of September 2019).
- **Therapeutics Goods Administration (TGA):** Australian authorities use MDSAP certification for both pre-market and post-market conformity assessment certification decisions and also to support marketing authorization. End of 2019, over 400 medical devices have been included on the ARTG (Australian Register of Therapeutic Goods) using MDSAP certificates as evidence and approximately 70% of manufacturer's holding a TGA certificate have entered the MDSAP. MDSAP Audit Reports can be provided as a form of evidence to demonstrate a manufacturer's QMS meets requirements (for all conformity assessment routes and device classes). QMS assessment may be abridged if the MDSAP audit report contains sufficient evidence of compliance.

Recently South Korea (Ministry of Food and Drug Safety) and Argentina (ANMAT) have joined the MDSAP program as affiliate members. MDSAP affiliate member is a special status that allows the country to use MDSAP audit report or certificate to evaluate a medical device manufacturer's QMS under their under its own regulation.
MDSAP affiliate members have access to weekly status reports containing information on the manufacturer, manufacturing site, audit dates and the recognized auditing organization (AOs).
Because MDSAP affiliate members do not have access to the MDSAP database on the Regulatory Exchange Platform secure (REPs), hosted on the secured web portal, they will have to contact participating manufacturers to access MDSAP audit report(s) and/or MDSAP certificate(s).

B HOW DOES MDSAP WORK?

As for a regular ISO 13485 QMS certification, MDSAP audits consist of an Initial Certification Audit (organized in two stages), followed by two annual Surveillance Audits, and a Recertification Audit to be done before the MDSAP certificate end of validity . The MDSAP certification is therefore valid for a maximum period of 3 years.
The GMED MDSAP audit can be combined with assessment in view of ISO 13485 certification and for certification under European regulations (Medical Device Directives and Medical Device Regulation).
Applicable products, activities and locations covered by the certification scope have to be audited and a separate report per site will be established unless the locations covered are part of a campus.
The MDSAP audit is performed following the MDSAP audit approach document which is organized in seven processes being audited in a specific sequence: Management, Market authorization and registration, Measurement analysis and improvement, adverse events and advisory notices, Design and development, Production and services controls, Purchasing. The MDSAP audit is therefore conducted following a consistent method across all Auditing Organizations as well as in a logical and efficient way with a focus on the interactions between those processes.
The audit duration is based on applicable tasks and processes implemented by the audited facility (number of sites, activities of each site, number of applicable jurisdictions, numbers of devices families and risks).

C MDSAP BENEFITS

Clarity and Transparency

The MDSAP consortium has created library of documentation for Manufacturers and Auditing Organizations. Also, the MDSAP audit and audit duration is based on comprehensible process that make MDSAP audit consistent across the Auditing Organizations.

Time saving and Efficiency

MDSAP allows the applicant to gain access to multiple markets with a single audit program satisfying the needs for five regulatory authorities and more if the MDSAP audit is combined with other audits (i.e. CE). Additionally, the MDSAP incorporates ISO 13485 assessment.
MDSAP audit minimizes manufacturer disruptions due to multiple regulatory audits and reduce time and resources allocated to post audit activities.

Predictability

The MDSAP is based on the ISO 13485 requirements. Also, there are additional country specific requirements depending where the manufacturer is selling Medical Devices.

The non-conformity grading depends on its QMS impact with escalation criteria (repeated findings, lack of required procedure and release of NC product).

Conclusion

The adoption rate of companies joining the MDSAP program is continually growing. This program provides benefits for medical device manufacturers interested by international markets.
In the near future, new Regulatory Authorities (RAs) may decide to recognize this MDSAP program as part of their own regulation. South Korea and Argentina recently joined the program as affiliate members, EU and World Health Organization are observers.

To go further

TRAINING FOR NORTH AMERICA REGION

Medical Device Single Audit Program (MDSAP) for Manufacturers
2-day training session | February 25-26 | June 3-4 | September 27-28

- Acquire the knowledge and develop the skills required to be prepared to support an efficient and successful MDSAP audit within your organization;
- Understand how the MDSAP program works and how it is different from the ISO 13485 through its country-specific regulatory audit approach, the grading and handling of the nonconformities, and the handling of the audit report;
- Understand MDSAP Audit Model and Audit Trail;
- Help your organization to assess and adapt your QMS processes with the MDSAP requirements for the jurisdictions where your products are marketed, to be prepared to support an efficient and successful MDSAP audit.

→ CHECK OUT THE PROGRAM

TRAINING FOR EUROPE AND OTHER PART OF THE WORLD (EXCL. US)

To be prepared for a MDSAP audit
2 day-training session | On demand
→ CONTACT GMED TRAINING CENTER

CHOOSE GMED TO TAKE ADVANTAGE OF THE MDSAP

- GMED is recognized as an Auditing Organization by the MDSAP Regulatory Authority Council (RAC). It has participated in the program since it was launched by authorities, and has been conducting MDSAP audits since April 2015;
- Most of GMED auditors are qualified to conduct both Quality Management System audits (MDSAP and ISO) and regulatory audits (CE marking), an added benefit for medical device manufacturers wishing to combine their certification programs;
- When you combine your certification processes, you can rest assured that GMED, as your Auditing Organization, will provide you with optimized planning, reducing the time your company's resources have to devote to the audit cycle.

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