Pathway to MDSAP Certification

Transitioning to Medical Device Single Audit Program Compliance

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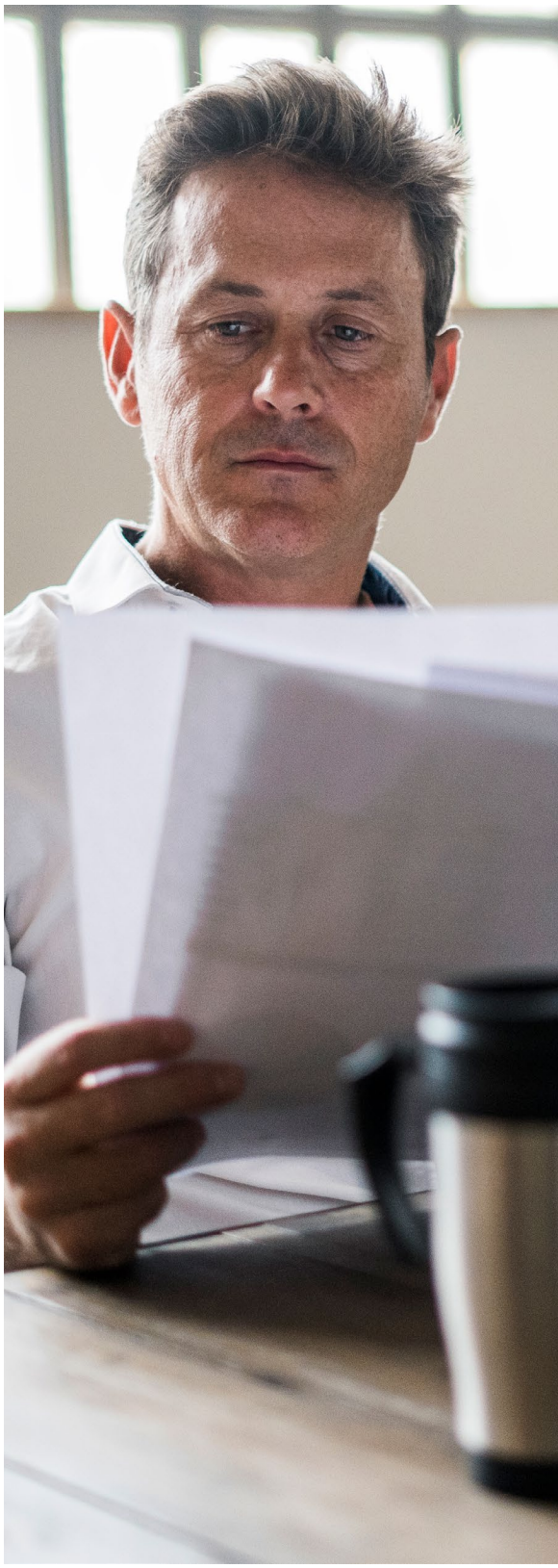
WHITE PAPER

Steps in the MDSAP transition process

The Medical Device Single Audit Program (MDSAP) allows a single regulatory audit of a medical device manufacturer's quality management system (QMS) to satisfy the needs of multiple regulatory jurisdictions, which currently include the United States (U.S.), Canada, Brazil, Australia and Japan. The single audit of a medical device manufacturer's quality management system will include the assessment of the quality management system processes including management responsibility, resource management, product realization, measurement, analysis and improvement, and adverse event reporting; as well as compliance with Good Manufacturing Practices (GMPs) or other applicable requirements as outlined in the **MDSAP audit approach**.

This white paper assumes you are aware of the MDSAP's history and background and outlines the broad steps for medical device manufacturers to consider in their transition to MDSAP certification and their interactions with recognized Auditing Organizations (AOs).

The pathway for an ISO 13485-registered company to transition to MDSAP certification is similar to that when adopting a QMS for compliance with any country-specific regulatory requirements. It can be broken into the following 10 stages:



1 Pre-implementation management review

Management reviews should always include an assessment of changes that may impact an organization's QMS and serve as an opportunity for senior management to determine the resources (financial, human and infrastructure) necessary to support such changes. The MDSAP has been operational since early 2017; therefore, manufacturers in participating countries (the U.S., Canada, Brazil, Australia and Japan) should have already considered and discussed the implications of MDSAP during management reviews. While it's possible that a manufacturer may decide that there is currently no benefit or need to participate in MDSAP, this should be continually assessed by an organization as it expands globally.

Other markets such as the European Union (EU) and the U.K. are official observers of the MDSAP program and regulators including South Korea's Ministry of Food and Drug Safety (MFDS) and Singapore's Health Sciences Authority (HSA) are affiliate members. Official observers are not members of the Regulatory Authority Council (RAC); however, they observe and/or contribute to RAC activities as deemed adequate. Affiliate members are also not members of the RAC; however, they engage in MDSAP, demonstrate understanding of MDSAP and utilize MDSAP audit reports and/or MDSAP certificates for evaluating compliance with applicable medical device requirements, including a manufacturer's quality management system, under the Affiliate Member's regulatory framework.

The International Medical Device Regulators Forum (IMDRF) continually assesses the expansion of the program to markets beyond the current five participants as part of the organization's harmonization efforts. That said, all manufacturers holding medical device licenses (MDL) in Canada are required to participate in the MDSAP program. The transition to the MDSAP was initially announced in December 2015 and was completed in 2019. Manufacturers without MDSAP certification will be unable to obtain a medical device license and unable to market devices in Canada.

2 Identify MDSAP certification scope

While five countries currently participate in MDSAP, manufacturers only need to apply for MDSAP certification in those countries where they currently, or plan to, market their devices. This is an important consideration as subsequent expansion to other MDSAP member markets will require QMS changes to add supportive documentation, as well as re-certification by the AO. Additionally, as MDSAP certification is site-specific, manufacturers that use multiple sites should assess the scope of activities performed at each site and the impact on the certification process.

MDSAP gap analysis and training

3 Gap analysis and action plan development/implementation

Manufacturers should use their CAPA and change control processes to identify and address any gaps in their QMS and implement actions necessary for compliance with applicable MDSAP requirements including, but not limited to:

- Training requirements;
- Country-specific regulatory procedures addressing regulatory roles, facility registration, device classification, market clearance and change notification;
- Post-market surveillance/adverse event reporting and field action/recall/advisory notice procedures in line with region-specific requirements;
- Agreements in place with the regulatory representatives for the markets of interest;
- Country-specific design requirements (e.g., standalone AU Essential Principles Checklist vs. EU Essential Requirements (ER)/General Safety and Performance Requirements (GSPR) Checklist, labeling);
- Maintaining copies of facility and marketing authorizations/approvals;
- Internal audits to verify compliance with MDSAP requirements and the effectiveness of the implemented changes.

Manufacturers may have to take additional actions, as well. For example, while already required for FDA registration, each site or facility undergoing MDSAP certification must also have a D-U-N-S® number, which AOs use to identify each unique establishment or site. (In the future, D-U-N-S® numbers will be replaced by REPS RA data exchange platform numbers.)

4 Training

One of the outputs of management review is the determination of human resources necessary to support changes to the QMS. For MDSAP, this will include training sessions run throughout the pathway to certification, including training in new or revised procedures, but beginning with formal training in MDSAP requirements including:

- MDSAP objectives
- Role of AOs
- Planning and preparation for MDSAP audits
- MDSAP audit requirements, nonconformity grading system and report content
- The seven MDSAP processes and specific task requirements
- Country-specific QMS/regulatory requirements
- Post-audit activities and timeframes

Personnel should become familiar with the MDSAP audit approach, the main auditing tool employed by AO auditors during MDSAP audits. Internal auditors should be trained in all applicable QMS/regulatory requirements and appropriate training records should be maintained.

Selecting an Auditing Organization (AO)

5 Contracting an AO

Companies already familiar with the CE marking process know that not all Notified Bodies (NBs) are created equal, and while the MDSAP AO requirements apply equally to all AOs, each AO and their auditors may have their own approach to how to comply with these requirements. The same care taken in selecting an NB should be taken when selecting an AO. The **FDA** MDSAP and **ANVISA MDSAP** websites list AO-recognized or authorized to conduct MDSAP audits. Furthermore, as AOs are service providers, they are subject to QMS purchasing controls. Therefore, appropriate supplier qualification records should be maintained.

Each AO will obtain information from the manufacturer necessary for providing a quote and audit planning purposes. This information includes:

- Facility details (name, address, contact, D-U-N-S® number, scope of activities)
- MDSAP jurisdiction details (manufacturers cannot exclude any MDSAP jurisdiction to which their devices are being supplied)
- Device registration numbers and classification
- Inspection status with Regulatory Authorities (e.g., any open non-conformities)
- Applicability of MDSAP processes and tasks (scope of QMS)
- Identification of product categories/specialties
- Incorporation of specific technology in products (e.g., tissues/cells of human/animal origin, nanotechnology, medicinal substances, etc.)
- Any special processes, e.g., sterilization methods (and details of any contract sterilizers)

Due to the limited availability of qualified auditors and the resource constraints currently placed on AOs (AOs may also be NBs), a wait of at least six (6) to twelve (12) months is normal to schedule the on-site audit, depending on the region.

Internal audits and management reviews

6 Internal audit

Once all of the changes necessary for MDSAP compliance have been implemented, internal auditors should be used to verify the efficacy of these changes as part of the CAPA or change control process.

A critical consideration during internal audits is the identification of repeat findings, as these can escalate a nonconformity grading during the actual AO audit. Manufacturers should assess all CAPA based on earlier findings for efficacy. The efficacy of any CAPA implemented as a result of this internal MDSAP audit is equally important for the same reason.

For manufacturing facilities that produce various types of devices, internal auditors should use a risk-based approach when selecting device records for assessment, as AOs use this same approach. However, if devices are limited to specific MDSAP countries, then this should also be considered by the auditing team and aligned with AO communications in relation to audit scope.

Procedure **MDSAP AU P0008** Audit Time Determination specifies how to determine the on-site audit duration in man-days. AOs decide how many auditors will compose the audit team. For instance, a six-man-day audit could be completed in three days by a two-auditor team. AOs are also required to take into account the competency of the audit team for the type of audit and the scope of products that are produced under the control of the manufacturer's QMS. Manufacturers can use this same guidance in estimating appropriate amounts of time for the execution of internal MDSAP audits. This allows the manufacturer to have a similar experience prior to an AO initial certification audit.

7 Post-implementation management review

Following full implementation of the changes necessary for MDSAP compliance, the manufacturer should discuss the results of the change during its next scheduled management review and document the results of these discussions. This review should ideally be held, or at least planned, before the AO MDSAP audit, as the AO will request to review related records.

What to expect from an MDSAP audit

8 MDSAP audit realization

The MDSAP audit sequence allows for a logical, focused and efficient performance of the audit, covering four primary processes (purchasing is a support process) in addition to two supporting processes (Device Marketing Authorization and Facility Registration and Medical Device Adverse Events and Advisory Notices Reporting). Figure 1 represents the sequence in which these processes are audited during a typical MDSAP audit.

It will be customary for AOs to send two auditors for on-site audits. However, in the event that more than one auditor is on-site, they can only audit a single process concurrently prior to moving to the next sequential element in the audit sequence. For example, they may audit Management and Device Marketing Authorizations and Facility Registration concurrently, but not Management and Design and Development.

Notably, as MDSAP is still a fairly new program, many AO auditors still rely on the **MDSAP audit approach document** and will refer to this during the realization of their audits. Manufacturers should be well-versed in the audit approach document and have copies available for their staff during AO MDSAP audits.

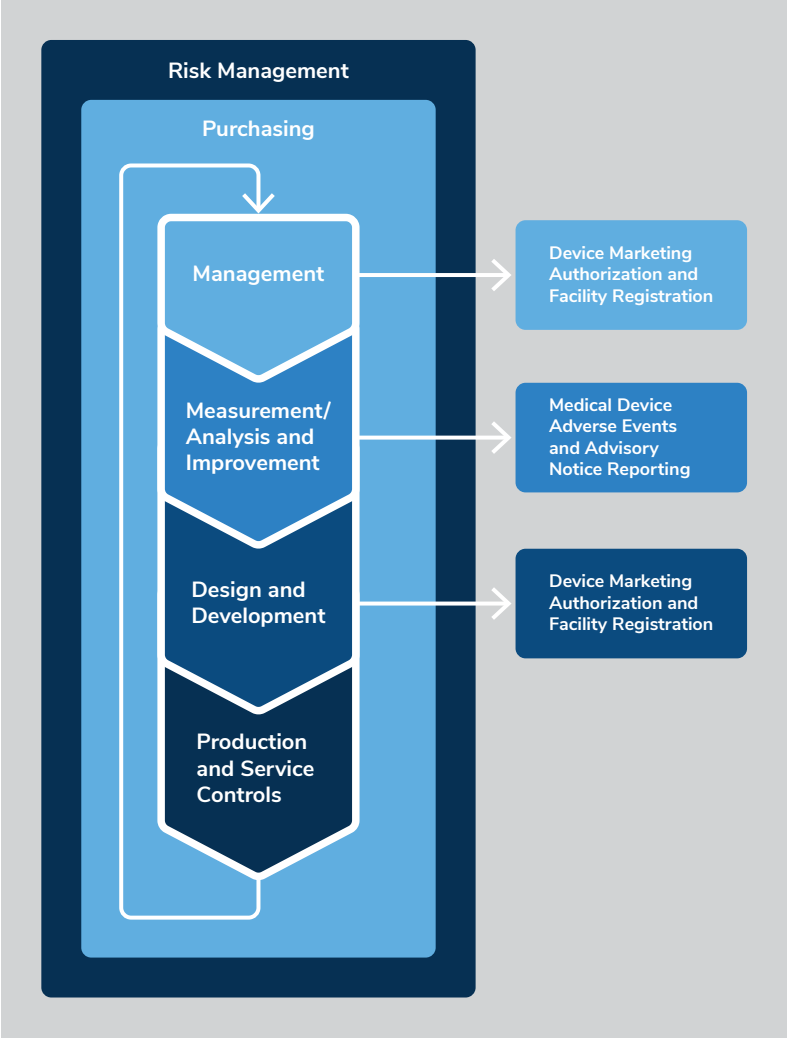


Figure 1: MDSAP Audit Sequence Source: MDSAP AU P0002.008

MDSAP Certification and Ongoing Compliance

9 Post-audit activities and MDSAP certification

Upon conclusion of the final on-site audit, the clock starts for the post-audit activities and depends on the observations noted by the AO auditors during the execution of the on-site audit. Figure 2 represents the applicable post-audit timeframes.

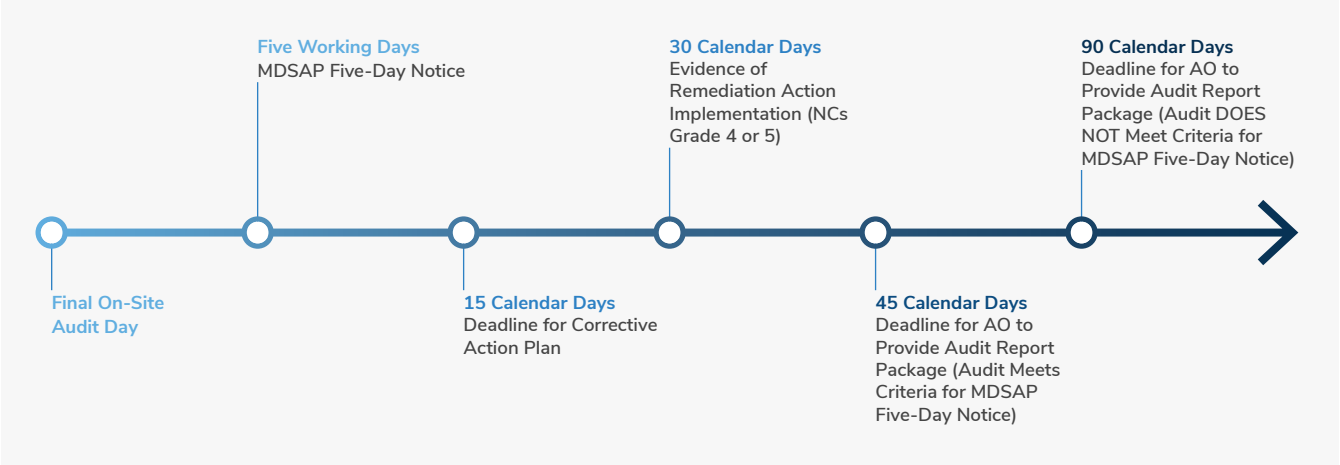


Figure 2: Post-Audit Timeframes Source: Emergo

In the event that any one of the following occurs, an MDSAP Five-Day Notice will apply:

- Greater than or equal to one grade five nonconformity
- Public health threat
- Greater than two grade four nonconformities
- Fraudulent activity
- Counterfeit product

Additionally, regulatory authorities will review audit reports and may request changes or updates as a result of these reviews, particularly where there are discrepancies in the registration information on file for the manufacturer and the details in the audit report (such as the number of manufacturing facilities).

If no MDSAP Five-day Notice is applicable, the complete audit report package (including the MDSAP certificate) will be issued within 90 calendar days following the final on-site audit.

10 Ongoing compliance

Having successfully obtained MDSAP certification, manufacturers must ensure continued QMS compliance. Changes in regulatory requirements for the markets of interest and changes that require regulatory authority notification or authorization before implementation should receive close attention. ANVISA, in particular, is known to frequently make significant regulatory changes, so manufacturers should ensure they have processes in place to maintain their regulatory intelligence.

Summary: High hopes for MDSAP expansion

Feedback about the benefits of MDSAP has been overwhelmingly positive. The most significant ones:

- **Continued accessibility in the Canadian market** – Since Jan. 1, 2019, manufacturers must have an MDSAP certificate if they want to apply for or maintain 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.
- **Reduce FDA routine inspections** – Minimize manufacturing plant and personnel disruptions.
- **Faster market access in Brazil** – The MDSAP helps you to demonstrate that your devices comply with the quality management and regulatory requirements that are applicable to place your device on the market in Brazil. Many manufacturers must wait up to one year — in certain cases even longer — for inspection by the Brazilian registration authority, ANVISA. Except for some high-risk products, ANVISA accepts the MDSAP certification audit report as a basis for the preparation of a Brazilian Good Manufacturing Practice (BGMP) certificate, which you need to register your class III and class IV medical devices in Brazil. There is a consultation to extend the validity of a BGMP certificate based on an MDSAP certificate to four years.

Potential disadvantages/considerations for MDSAP implementation include:

- Having to change/update processes and upgrade QMS to comply with MDSAP requirements
- Manufacturers can't opt out of a market if they sell there under the MDSAP program.
- Cost of MDSAP certification can vary between $35,000 and $80,000 (USD), depending on the size of the company, the number of products and the countries in scope, as well as the AO used.

Many regulatory authorities beyond those actively participating in MDSAP are paying careful attention to its progress and there is a general expectation that it will expand beyond the current five participants, particularly as AOs gain more experience.

A well-structured, planned approach to compliance with MDSAP requirements will help overcome many of the difficulties encountered by manufacturers and ensure that organizations are prepared for certification, as well as continued compliance as the program evolves.

Learn more

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About the author

Luana Zerafa is located in the U.K. and has over 15 years of industry experience, working with medical devices and applicable regulations in all classes, including implantable devices, ophthalmic products and medication delivery products. Zerafa specializes in quality engineering and has extensive knowledge of quality system implementation and improvement, as well as compliance with many international standards. As Program Manager for audits globally within Emergo by UL, Zerafa manages the audit activities internally to support auditors with the necessary tools and adequate training and confirm that Emergo by UL customers get the best-in-class audit deliverables.

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