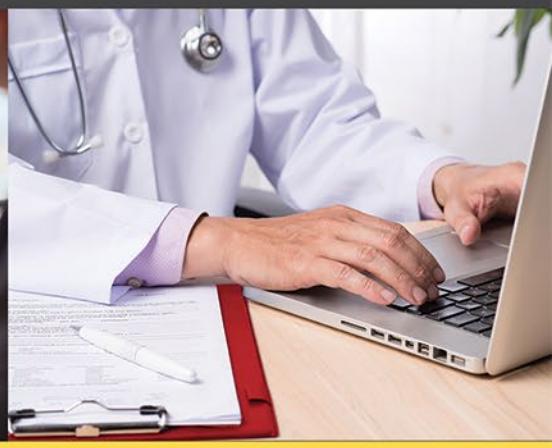
Pathway to MDSAP Certification

Transitioning to Medical Device Single Audit Program Compliance





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Steps in the MDSAP Transition Process

As the first year of its operational phase ends, the Medical Device Single Audit Program (MDSAP) is finally gaining traction among medical device manufacturers. Emergo has observed a marked increase in the number of companies requiring assistance with MDSAP certification. We expect more manufacturers will participate in MDSAP in 2018, particularly as Health Canada's compliance deadline of January 2019 approaches.

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 quality management system (QMS) for compliance with any country-specific regulatory requirements. It can be broken into the following ten 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 US, 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 South Korea have expressed interest in participating in MDSAP. 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, manufacturers who currently market devices in Canada must consider MDSAP implementation given the deadline for MDSAP certification of January 2019. Failure to do so will directly impact their Medical Device Licenses (MDL) and ability to continue marketing 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.

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 QMSs 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 Checklist, labelling);
   - Maintaining copies of facility and marketing authorizations / approvals;
   - Internal audits to verify compliance with MDSAP requirements and 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 from 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 Companion Document, 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.

5. Contracting an AO

Companies already familiar with the CE Mark 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 AOs 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, DUNS 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 three to six months is normal to schedule the on-site audit, depending on the region.

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.

   Additionally, MDSAP guidance indicates the amount of time that is estimated as necessary for AOs to perform on-site audit activities. 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.

8. MDSAP Audit Realization

As indicated in current MDSAP guidance, the MDSAP audit sequence allows for 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 & Medical Device Adverse Events and Advisory Notices Reporting). Figure 1 represents the sequence in which these processes are audited during a typical MDSAP audit.

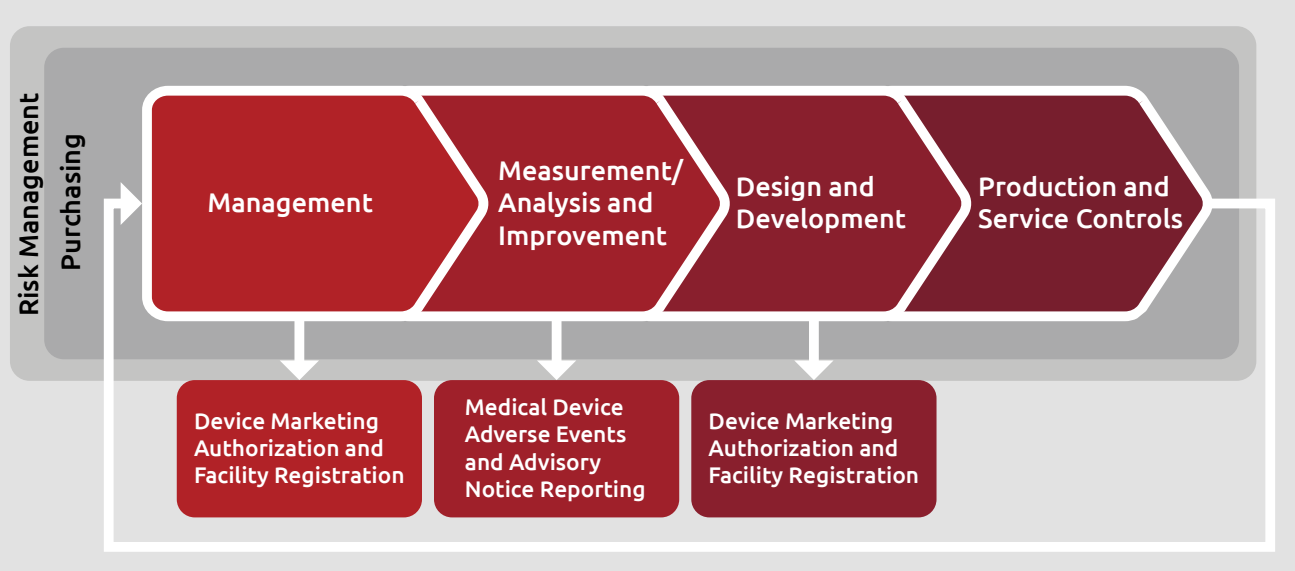

Figure 1: *MDSAP Audit Sequence* ***Source:*** *MDSAP Audit Model*

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 in its first operational year, many AO auditors also still rely on the MDSAP companion document and will refer to this document during the realization of their audits. Manufacturers should be well versed in the companion document and have copies available for their staff during AO MDSAP audits.

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 5-Day Notice will apply:

- ≥ 1 grade 5 nonconformity;
- > 2 grade 4 nonconformities;
- Public health threat;
- 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 5-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 prior to 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

Despite initial reluctance from manufacturers to participate in MDSAP during its pilot and initial operational phases, 2017 saw increased interest in participation with an expectation that this will surge in 2018.

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 over time.

Learn more about QMS compliance

If you enjoyed this white paper, you might find our video about major changes in ISO 13485:2016 useful. We address how the new standard will affect your company and major QMS changes you need to consider to prepare for your recertification audit.

WATCH VIDEO

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About the Author

Michael Dun is the Australia Country Manager and Director at Emergo. He has more than 13 years of experience in quality systems, auditing, regulatory affairs, and research and development across the biotechnology, IVD, and medical device manufacturing and services industries. His areas of expertise include QMS implementation and audits, risk management, and device registration and documentation in the US, EU, Brazil, and Australia.