

Introduction

The clock is ticking for medical device manufacturers worldwide. Manufacturers that want to continue selling products in Canada's \$6.7 billion medical device market should be preparing and planning for the international Medical Device Single Audit Program (MDSAP) by now. Canada is the first market to require the MDSAP audit as part of its medical device licensing scheme, beginning Jan. 1, 2019. On that date, companies selling Class II, III, and IV medical devices and IVDs must have an MDSAP Certificate on file with Health Canada to maintain their Canadian Device Licenses. Companies that aren't already prepared for MDSAP, can get started by following four steps.

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1. Learn about MDSAP

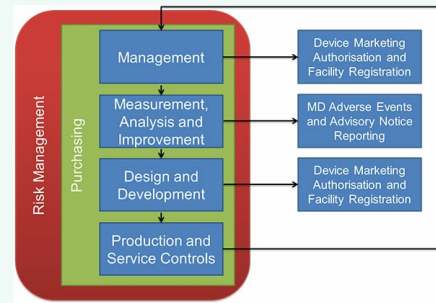
Enter "MDSAP" into any search engine for general information. Each of the five jurisdictions' regulatory authority websites provide helpful information—the FDA site as well as Australia's Therapeutic Goods Administration, Brazil's ANVISA, Canada's Health Canada, and Japan's Pharmaceutical and Medical Devices Agency. The FDA website, which is the Regulatory Consortium's official site, offers a comprehensive overview of the program while NSF.org highlights essential components and important details, including the MDSAP audit structure.

2. Conduct a Gap Analysis.

Also known as a needs assessment, a gap analysis is used to determine what an organization must do to move from its current state—in this case, meeting existing medical device certification requirements—to a future standard (i.e. compliance with ISO 13485:2016 and any specific country requirements). MDSAP tools such as the Audit Model provide a process map to verify the inclusion/implementation of regulatory requirements following ISO 13485:2016.

The Audit Model and the Audit Model Companion Guidance document should not be relied upon for exact regulatory requirements because slight discrepancies exist. Instead, the model and guidance document should be used as a reference and an audit preparation tool. It is essential to read the regulations of the five jurisdictions for specifics on each. The FDA website includes an MDSAP Frequently Asked Questions document which is also quite useful.

MDSAP Audits



3. Take Action Based on the Gap Analysis

Prioritize actions to address areas of greatest urgency first.

- Understand the regulatory requirements thoroughly to avoid mistakenly placed resources and insufficient implementation.
- Perform a proper root cause analysis wherever discrepancies exist to understand what and/or why something happened.
- Fix any problems and implement corrective actions to ensure they don't recur.
- Use the "verification of effectiveness" process to ensure successful implementation. This process is widely misunderstood and often incorrectly performed, but it's an essential step in analyzing QMS health.
- Acquire, leverage, and approve needed resources while ensuring that management understands the costs (time and money) needed to implement the requirements.
- Acquire necessary training for responsible parties.
- Assume ownership (along with top management) of the QMS.

4. Choose an authorized Auditing Organization

The FDA website includes a list of all AOs authorized to conduct MDSAP audits. Be sure to consider factors such as expertise, cost, availability, and experience. Schedule the audit no later than September 2018 in order to ensure ample time to utilize that audit for Health Canada Licensing purposes.