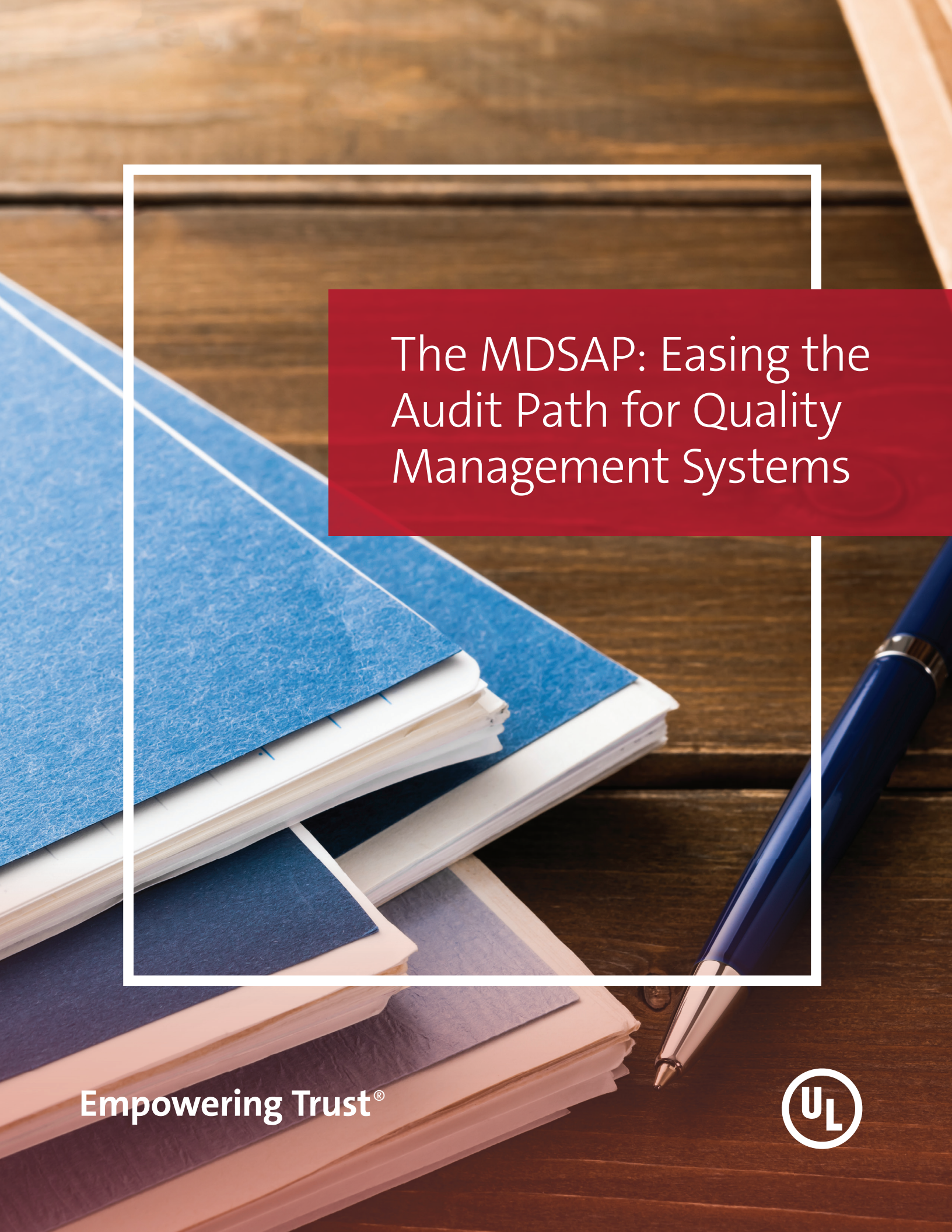

The MDSAP: Easing the Audit Path for Quality Management Systems

Empowering Trust®

Executive summary

Initiated in 2012 by the International Medical Devices Regulators Forum (IMDRF), the Medical Device Single Audit Program (MDSAP) offers medical device manufacturers a mechanism to significantly streamline the process of pre- and post-market audits required by regulatory authorities in jurisdictions around the world. Under the MDSAP, a single audit performed by an authorized auditing organization (AO) is deemed sufficient to assess compliance with the quality management system requirements of regulatory agencies in multiple major medical device markets, including the U.S., Canada, Japan, Brazil and Australia. This single audit approach reduces the need for duplicate quality management audits, helping device manufacturers better manage costs and easing market access.

This white paper provides an overview of the MDSAP and discusses how the single audit approach can benefit medical device manufacturers. Beginning with a brief history of the formation of the MDSAP, the paper then describes the audit process prescribed under the program and concludes with recommendations on how device manufacturers can take advantage of the MDSAP program.

Global cooperation

Although growing global interest in advance medical technologies offers significant market potential for medical device manufacturers, the process of obtaining regulatory approval remains a complex one. This is especially true when it comes to pre- and post-market audits of a device manufacturer's quality management system (QMS). Even in cases in which auditing requirements are substantially similar, independent regulatory authorities in key jurisdictions often decline to accept audit reports that address requirements of other regulators or regions. The absence of a mutual recognition scheme for QMS audits results in a significant added expense for device manufacturers selling in multiple economic areas as well as longer lead times for market acceptance.

The IMDRF, a voluntary consortium of national regulators from major markets around the world, was established in 2011, building on the work of the former Global Harmonization Task Force on Medical Devices (GHTF).

The IMDRF management committee membership includes representatives from the national regulatory authorities in 10 major medical device markets: Australia, Brazil, Canada, China, the European Union (EU), Japan, Russia, Singapore, South Korea and the United States. The World Health Organization (WHO) is an official observer. The Asian Harmonization Working Party (AHWP), Pan American Health Organization (PAHO) and APEC LSIF Regulatory Harmonization Steering Committee are IMDRF affiliate organizations.

The origins of the MDSAP

The MDSAP began with the formation of a working group in 2012, charged with developing a common set of requirements for entities responsible for conducting regulatory audits of manufacturers' quality systems. As part of that effort, the working group launched an initial three-year pilot study to evaluate how a proposed single audit program structure would work under real-world conditions. The MDSAP pilot program was conducted from January 2014 through December 2016 and was subsequently approved for implementation.

Regulatory members in the MDSAP program include:

- U.S. Food and Drug Administration (FDA)
- Health Canada
- Australia's Therapeutic Goods Administration (TGA)
- Brazil's National Health Surveillance Agency (ANVISA)
- Japan's Ministry of Health, Labour and Welfare (MHLW)
- Japanese Pharmaceuticals and Medical Devices Agency (PMDA)

Under the terms of the program, the participating regulatory authorities agree to accept QMS audit reports prepared by recognized (or authorized) auditing organizations (AOs) based on audits conducted in accordance with the requirements of ISO 13485. Additional MDSAP audit requirements also include country specific provisions defined in the audit approach (MDSAP AU P0002).

The MDSAP currently has two official observers: the WHO Prequalification of In Vitro Diagnostics (IVDs) Programme and the EU.

The program also has two affiliate members: Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT) and the Republic of Korea's Ministry of Food and Drug Safety (MFDS, formerly known as the KFDA). Affiliate members utilize MDSAP audit reports and/or MDSAP certificates for evaluating a medical device manufacturer's QMS.

The auditing organizations started the transition of medical device manufacturers to the MDSAP in 2017, with the majority of the registrations occurring in 2018. This was because of Health Canada's decision to replace the Canadian Medical Devices Conformity Assessment System (CMDCAS) program with the MDSAP effective Jan. 1, 2019. MDSAP is the only mechanism by which manufacturers can demonstrate their compliance with Canada's QMS requirements under that country's medical device regulations. The application of the MDSAP requirements apply even to those manufacturers who intend to sell or distribute their medical devices solely and exclusively in Canada.

The FDA recognizes MDSAP audit reports as a substitute for FDA Establishment Inspection Reports (EIRs). Manufacturers with activities related to the Electronic Product Radiation Control (EPRC) provisions of the Act will continue to be subject to FDA inspections for the EPRC activities. Australia's TGA uses the MDSAP for both pre-market and post market conformity assessment certification decisions and to support marketing authorization. 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). Brazil uses MDSAP audit reports in order to issue GMP certification in lieu of onsite inspections by ANVISA. Japan uses MDSAP audit reports in order to switch inspection to off-site inspections and/or abbreviated off-site inspections in lieu of onsite PMDA inspections.

MDSAP auditing specifics and considerations

As noted earlier, the MDSAP audit has been designed to meet the requirements of ISO 13485. The audit specifically addresses five primary processes, including:

- Management
- Measurement, analysis and improvement
- Design and development
- Production and service controls
- Purchasing

In addition, the MDSAP audit process includes two additional supporting processes intended to address specific requirements of participating MDSAP regulatory authorities.

These processes are:

- Device marketing authorization and facility registration
- Medical device adverse events and advisory notices reporting

Similar to other management system audit programs, the MDSAP audit program is based on a three-year audit cycle that includes the following auditing activities:

- Initial certification audit: The initial certification audit is a complete audit of a manufacturer's QMS and consists of two separate stages conducted in accordance with the requirements of ISO/IEC 17021. Audit activities in Stage 1 are chiefly intended to evaluate available QMS documentation and the extent of a manufacturer's preparedness to undergo Stage 2 audit activities. Stage 2 audit activities evaluate the actual compliance of the QMS with the requirements of ISO 13485 and other requirements of MDSAP-participating regulatory authorities.
- Surveillance audits: In each of the two years following the initial MDSAP certification audit, a surveillance audit is conducted to assess ongoing compliance with MDSAP QMS requirements. Annual surveillance audits do not include the Stage 1 review activities that are part of an initial certification audit and do not need to address all MDSAP requirements that are part of Stage 2 activities. However, surveillance audits are expected to assess any changes in the manufacturer's products or QMS processes since the initial certification audit.
- Recertification audit: Conducted in the third year following the initial certification audit, the recertification audit is intended to evaluate a manufacturer's QMS for its continued suitability and effectiveness in meeting QMS requirements under the MDSAP. Through more selective and focused sampling, recertification audits typically take less time than initial certification audits.

In addition to the audit activities conducted under the scope of the three-year audit cycle, device manufacturers may also be subject to special audits or audits conducted by regulatory authorities, as well as unannounced audits.

Benefits for device manufacturers

For the medical device industry, the MDSAP has transformed the approach used to conduct pre- and post-market QMS audits and significantly reduced the audit compliance challenges facing device manufacturers. Specific benefits of the MDSAP include:

- Harmonization of auditing requirements: MDSAP pre- and post-market auditing requirements are based on ISO 13485, the internationally accepted standard for QMS, and have been harmonized to address specific concerns of national regulatory agencies participating in the IMDRF.
- Broader acceptance of audit reports: MDSAP audit reports are accepted by MDSAP regulatory members in lieu of current report requirements. Additionally, affiliate members are also accepting MDSAP audit reports.
- Reduced overall auditing time and expense: The broad application of one set of audit requirements means that manufacturers will spend less time and expense preparing for and meeting QMS audit requirements of individual jurisdictions, expediting the approval process and allowing for the reallocation of critical resources.
- Reduced time responding to findings: Since MDSAP audit requirements are harmonized, any findings of noncompliance are more likely to be consistent from audit to audit and more quickly and easily addressed by device manufacturers.
- Wider choice of third-party audit organizations: Medical device manufacturers have access to a wider selection of AOs who are authorized to conduct QMS audits under the MDSAP. Competition among AOs should lead to an increase in the overall quality and value of audit services.
- More transparent and consistent oversight by regulators: A single, harmonized set of pre- and post-market QMS audit requirements helps ensure more regular and consistent oversight by regulatory authorities. Coordination between regulators also helps facilitate the evaluation of facilities based outside of individual jurisdictions.

Ultimately, these and other benefits of the MDSAP reduce the complexity of a critical aspect of the medical device approval process, thereby removing many current barriers to market entry and allowing device manufacturers to bring new and innovative medical devices to global markets more quickly and efficiently.

Summary and conclusion

The MDSAP offers a harmonized set of pre- and post-market QMS audit requirements that will significantly ease the compliance process for medical device manufacturers and help them achieve access to major medical device markets around the world. The MDSAP model also offers a potential pathway for the harmonization of other medical device requirements and the promise of more widespread access to advanced technologies that can improve the health and well-being of people around the world.

UL is a recognized AO in the MDSAP and can provide medical device manufacturers with QMS pre- and post-market auditing services in all MDSAP jurisdictions.

For additional information about UL's MDSAP service offerings, contact Medical.inquiry@ul.com or go to www.UL.com/services/medical-device-single-audit-program-mdsap.

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