REGULATORY DEMANDS

FDA Migration from QSR to ISO 13485 and QSIT to MDSAP

ISO 13485:16 and MDSAP: Is Your QMS Ready for New Regulatory Demands?

The push for medical device innovation is reaching a high point, as manufacturers seek to meet needs around the rising prevalence of chronic conditions and an aging population. These scientific innovations demand new, more flexible regulatory approaches to help speed products safely to market.

In an effort to keep pace with innovation and ease regulatory burden and compliance, significant, broad regulatory overhaul is taking place around the world. Two of those changes are the U.S. Food and Drug Administration's proposal to harmonize and modernize its Quality System Regulation (QSR) for medical devices and the Medical Device Single Audit Program (MDSAP), which allows a single audit of a medical device manufacturer's QMS, satisfying the requirements of multiple regulatory jurisdictions around the world.

Introduction

This paper breaks down these two changes to give manufacturers the guidance they need to ready their quality management systems (QMS) for what lies ahead.

Moving Toward QMS Harmonization and Modernization

In early 2018, the FDA announced its intention to harmonize the FDA Quality System Regulation (21 CFR Part 820) with the international quality management system standard ISO 13485:2016 for medical devices. The intent of the shift is to reduce compliance and record keeping burdens on device manufacturers.

ISO 13485 is a voluntary international standard that provides a framework for manufacturers and suppliers to meet common regulatory requirements worldwide, and serves as a strong foundation to meet FDA Part 820 requirements, as well as the requirements of other regulatory bodies around the world.

ISO 13485 has continued to gain recognition globally outside the U.S. Because the FDA participated in the development of the most recent version of ISO 13485, it is now very much in sync with 21 CFR Part 820. FDA full adoption of ISO 13485:2016 would further cement global regulatory harmonization efforts. If finalized, the FDA's new rule would make it more efficient for device manufacturers seeking to sell products globally and would continue to ensure manufacturers adhere to high, internationally accepted quality standards.

This change will also modernize the regulations. ISO 13485 was originally published for use in 1996 and revised a few times since, with the most recent version published in 2016. FDA 21 CFR Part 820, in contrast, is the quality system regulation that any company marketing/selling a medical device product in the U.S. has followed since 1996. The FDA wants the new regulations to reflect the many changes that have occurred in the medical device industry since the QSR took effect more than 20 years ago.

Implications for Medical Device Manufacturers

What impact will the transition from QSR to ISO 13485 have on medical device manufacturers? The FDA has indicated they intend to roll out its revised quality system regulation by April 2019. In an attempt to ease concerns among attendees at a MedTech Conference in Philadelphia in Fall 2018, William Maisel, chief medical officer at FDA's Center for Devices and Radiological Health (CDRH), stressed that there will be a public comment period after each step in the process to adopt the rule proposed in May 2018.[1] Device manufacturers that are already ISO-certified would see little impact from this change and would likely benefit from easier U.S. market access without having to implement FDA QSR processes.

Companies that only market devices in the U.S will have to make the shift from 21 CFR Part 820 to ISO 13485:16, though both systems contain many of the same requirements. Smaller manufacturers may struggle to pull together the resources and knowledge to incorporate the necessary changes into their quality systems and practices.

FDA QMS Harmonization Key Points:

- The FDA is adopting ISO 13485:2016 quality system requirements for medical device manufacturers.
- ISO 13485 would replace the FDA Quality System Regulation (QSR) for Medical Device Manufacturing companies.
- FDA alignment to ISO 13485 would align the U.S. market more closely to other major medical device markets.

Transitioning Toward a Single Audit Program

In addition to the FDA's plan to harmonize its Quality System Regulation, medical device manufacturer regulatory teams have another upcoming challenge: The International Medical Device Regulators Forum's Medical Device Single Audit Program (MDSAP).

Medical device manufacturers were slow to adopt the MDSAP in its pilot days. However, the initiative has gained traction since the CDRH name it an official program in 2017, with full implementation set for 2019.

The MDSAP allows a single audit of a medical device manufacturer's QMS, which satisfies the requirements of multiple regulatory jurisdictions. The international partners participating in the MDSAP include the Therapeutic Goods Administration (TGA) of Australia, Brazil's Agencia Nacional de Vigilancia Sanitaria (ANVISA), Health Canada, Japan's Ministry of Health and Labour and Welfare (MHLW), and the FDA. MDSAP-recognized auditing organizations are able to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of all the participating regulating authorities.

A single audit system provides a host of benefits, including time and cost savings, less business disruption related to multiple regulatory audits, and ease of entry to multiple markets. MDSAP provides

sufficient regulatory oversight, while having minimal burden on the industry, and it helps promote consistency, predictability and transparency of regulatory programs through standardization.[2] The MDSAP is quickly becoming the model to follow for most medical device manufacturers selling internationally.

The MDSAP program uses third-party auditors to conduct these audits. MDSAP's audit model covers the requirements of ISO 13485 plus Good Manufacturing Practice (GMP) requirements for each applicable regulatory authority. For example, it covers 21 CFR Part 820 for the U.S. and ANVISA RDC 16/2013 for Brazil. During an MDSAP audit, the auditors will audit only the country-specific regulatory requirements for the MDSAP participant countries in which an organization sells devices.

MDSAP: A Series of Audits

An MDSAP audit is actually a series of three audits conducted over a revolving three-year period. These are:

1. **Initial certification audit**: This is a complete audit of an organization's QMS conducted in accordance with the requirements of ISO/IEC 17021 in two stages:

   Stage 1 audit activities evaluate QMS documentation and preparedness to undergo a Stage 2 audit.

   Stage 2 audits assess actual compliance of the QMS with the requirements of ISO 13485 and other stipulations of the MDSAP-participating regulatory authorities.

2. **Surveillance Audit:** In the two years following an initial MDSAP certification audit, a surveillance audit is conducted to determine compliance with MDSAP QMS requirements. This audit does not include the review activities that are part of an initial certification audit and does not need to address all MDSAP requirements that are part of Stage 2 activities. A surveillance audit should assess any changes in the manufacturer's products or QMS processes since the initial certification audit was performed.
3. **Recertification audit:** A recertification audit is conducted in the third year following the initial certification audit. This audit is intended to evaluate a manufacturer's QMS for continued suitability and ability to meet QMS requirements under the MDSAP. A certification audit employs more precise sampling and typically takes less time than the initial certification audit. [3]

What are the benefits of MDSAP?

A single audit would:

- Minimize disruptions to manufacturers due to multiple regulatory audits
- Provide predictable audit schedules
- Streamline manufacturer entry to multiple markets, improving patient access to treatment and patient health.
- Leverage regulatory resources
- Incorporate ISO 13485 assessment
- Reduce time and resources devoted to dealing with findings from multiple audits
- Reduce cost of audits compared to independent audits
- Improve industry transparency [4]

How an MDSAP Audit Works

The MDSAP audit follows the process approach: It moves in a top-down direction and is conducted in a structured and logical manner. The audit begins with a review of all standard operating procedures and continues through a series of step-by-step questions. The questions are taken from an audit checklist and do not vary.

The audit sequence covers four primary processes:

1. Management
2. Measurement, Analysis and Improvement
3. Design and Development
4. Production and Service Controls

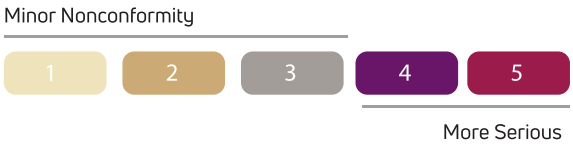
It also covers three supporting processes:

1. Purchasing
2. Device Marketing Authorization and Facility Registration
3. Medical Device Events and Advisory Notices Reporting

Unlike an ISO audit that remains focused on one specific set of procedures, an MDSAP audit follows links to related processes. As such, it is important to have regulatory team members readily available during an MDSAP audit. The FDA Companion Document is a helpful resource that shows examples of these links. During an audit, manufacturers can also expect a heavy focus on risk management activities as they relate to all QMS processes.

The MDSAP Grading System

The FDA Quality System Inspection Technique and other audit grading approaches use terminology such as "major finding," "minor finding" and "opportunity for improvement." Unlike those approaches, the MDSAP has established objective criteria to characterize the significance of findings that can be easily shared among participating regulatory authorities.



The MDSAP uses a 5-point rating scale: 1 (least critical) to 5 (most critical). A grade of 1, 2 or 3 is considered a minor nonconformity, and grades 4 and 5 are more serious

The MDSAP audit process ensures a single audit provides efficient, thorough coverage of QMS requirements covering:

- ISO 13485
- Brazilian Good Manufacturing Practices (ANVISA RDC 16)
- Japanese requirements (MHLW MO 169)
- FDA's Quality System Regulation (21 CFR Part 820)
- Country-specific registration and licensing requirements
- Country-specific adverse event reporting requirements
- Other country-specific requirements beyond QMS

Preparation Begins Now

Many reasons exist for medical device manufacturers to transition to ISO 13485:16 and MDSAP. For example, as of Dec. 31, 2018, any company that sells medical devices to Canada will either need to hold an MDSAP certificate or show proof that they are on track to be MDSAP-certified.[5]

Manufacturers that aren't already prepared for ISO 13485:16 and MDSAP can get started by doing the following:

1. **Learn about ISO 13485 and MDSAP.** A good place to start is by gathering general information online. The FDA website, including the MDSAP Companion Document, as well as the other four jurisdictions' regulatory authority websites all provide useful information.
2. **Conduct a readiness assessment.** Understand what the organization must do to transition from meeting current medical device certification requirements to meeting the requirements of ISO 13485 and MDSAP. If the organization is not ready, where are the gaps?
3. **Develop a transition plan to ensure compliance with the new requirements.** Actions may include:
   - Thoroughly understanding the new regulatory requirements
   - Including needed resources and budget during strategic planning process
   - Coordinating training for the appropriate staff
4. **Update the quality management system.** Companies not currently ISO 13485 certified must create a quality management system that meets the requirements and begin the process of certification with an accredited certification body.
5. **Select a QMS software partner.** Find a partner that offers a solutions-based, best practices approach to compliance software that exceeds GMP standards and improves compliance and quality for the organization. It's important, too, that the software offer enough flexibility and configurability that it can map precisely to the customer's current work flows and processes, with minimal effort.

In an increasingly global regulatory environment, these new regulations present challenges, but also offer the opportunity to streamline quality management processes, improve operational efficiencies and, most importantly, improve patient outcomes. Manufacturers that begin preparing for FDA alignment to ISO 13485 and MDSAP audits now will position themselves for compliance in the rapidly changing regulatory landscape.

Sources

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