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Stay Current with Upcoming Regulatory Changes

Healthcare Market

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The United States Food and Drug Administration (FDA) remains focused on advancing and continually improving the quality, safety, and effectiveness of medical devices to meet patient needs. In an effort to achieve continuous improvement, the FDA has recently announced a proposal to harmonize key areas of the Quality Management System (QMS) requirements for medical device manufacturers to more closely align with the requirements implemented by other global regulatory authorities.

On March 2, 2022, the FDA held a public advisory committee meeting of the Device Good Manufacturing Practice Advisory Committee to review the latest proposal and discuss the requirements and potential impact of amending the requirements of the QMS regulations[1]. The goal is to align the FDA standard more closely with the standard used for medical devices used by other international regulatory systems around the world.

The proposed rule changes included incorporating ISO 13485 standards into 21 CFR (Code of Federal Regulations) Part 820, the Quality System Regulation. If finalized, the proposed regulation will incorporate the requirements of ISO 13485:2016 as the foundational QMS for 21 CFR part 820 requirements.

Global Alignment

Requirements[2] for three foundational global sub-systems are in flux and are expected to have an impact on the U.S. medical device industry in the next few years:

1. **Medical Device Single Audit Program** - sets standards for the auditing processes used by organizations to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program[3]. *(being adopted by U.S., Canada, Japan, Brazil, and Australia)*

2. **ISO 13485:2016** – governs Quality Management Systems of international medical device manufacturers.

3. **EU Medical Device Regulations** - European equivalent of U.S. FDA standards.

The anticipated regulatory changes are likely to alter the competitive landscape of the medical device industry and have far reaching international implications[4]. Global players will now need to develop and implement plans to ensure these new medical device regulatory compliance requirements are captured in their standard operating procedures. The organizations that best embrace and become early adopters of these changes may be able to position themselves to enjoy competitive advantages and enable them to reap economic benefits.

Considering these anticipated changes, it behooves global device specification developers and manufacturing entities to align, to familiarize themselves with the new FDA guidance and to prepare themselves for the inevitable global competitive pressure that will arise. Typical medical device development cycles can range from one-to-three years depending upon the 21 CFR category and device classification. A new device

submission initiated today may need to compete in a very different business environment at a later point in its Total Product Life Cycle.

Be Prepared

When implemented, these dynamic regulatory changes will require careful strategic considerations. The world gets smaller every day, so it is more important than ever to ensure your medical device business goals and manufacturing practices are aligned to help you be more competitive on the global stage.

Nexeo Plastics has a dedicated team of healthcare professionals and an extensive technical team who can help you navigate this changing landscape. Partner with Nexeo Plastics for the Total Product Life Cycle of your medical device products, and we can help you embrace the future from a position of strength and knowledge.

SOURCES

1. Center for Devices and Radiological Health. (2022, February 23). *Proposed rule: Quality system regulation amendments – faqs.* U.S. Food and Drug Administration. Retrieved April 8, 2022, from https://www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices/proposed-rule-quality-system-regulation-amendments-frequently-asked-questions

2. Deloitte. (2018, March 28). *Compliance with medical device regulatory changes:* Deloitte Us. Deloitte United States. Retrieved April 8, 2022, from https://www2.deloitte.com/us/en/pages/advisory/articles/medical-technology-regulation-change-implications.html

3. Center for Devices and Radiological Health. (n.d.). *Medical device single audit program (MDSAP).* U.S. Food and Drug Administration. Retrieved April 8, 2022, from https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap

4. Deloitte. (2018, March 28). *Compliance with medical device regulatory changes:* Deloitte Us. Deloitte United States. Retrieved April 8, 2022, from https://www2.deloitte.com/us/en/pages/advisory/articles/medical-technology-regulation-change-implications.htmlchange-implications.html

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