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Marching to March 2019 – ISO 13485:2016 Update Overview

March 2019 is a significant target for firms operating under ISO 13485 – Medical Devices – Quality Management System Requirements for Regulatory Purposes. ISO 13485 is the standard used to demonstrate consumer and regulatory compliance. It is based on a system of processes used to interrelate and interact internally and can be used with external suppliers. The overall goal is to ensure devices are safe, effective and are manufactured according to the highest standards.

The new standard was released in March of 2016 and there is a three-year transition period. Organizations currently using version 2003 have until March 2019 to fully transition to the new version. After March 2019, existing 2003 certifications will no longer be valid. During the interim period, both versions will coexist. Those seeking accreditation for ISO 13485 can be accredited for either the 2003 or 2016 version through the first two years. After the second year, only accreditation for 2016 will be given.

The revisions to the new version include updates to these key clauses:

- Scope
- Terms and Definitions
- Quality Management System
- Documentation Requirements
- Management Review
- Human Resources
- Infrastructure
- Work Environment and Contamination Control
- Product Realization
- Customer-related Processes
- Design and Development
- Purchasing
- Servicing
- Validation
- Identification
- Complaint Handling
- Regulatory Reporting
- Monitoring of Product
- Nonconforming Product
- Data Analysis
- Corrective and Preventive Action

In many instances, the 2016 revision focuses on adding requirements for key areas due to development of technology and device use. A few of the big areas of impact are reflected in the update to the use of risk-based methodology beyond product realization, the use of the standard for organizations throughout the supply chain and life-cycle of the device, the reporting requirements for complaint handling and effective implementation of corrective and preventive actions without delay.

As with all changes to guidance documents, regulations and other key standards, we must evaluate the changes that impact our business. To quote William Pollard, “Learning and innovation go hand in hand. The arrogance of success is to think that what you did yesterday will be sufficient for tomorrow.”

With the timeline established, let’s get to work and learn more about this revision – March 2019 is approaching!

ABOUT THE AUTHOR: Collis Laton-Floyd has over fifteen years’ experience in FDA Regulated Life Science Industries. She has worked with training development, training design, training delivery, Quality Systems, Lean Principles, technical writing, communications and project management. For the last ten years, Collis has used her expertise to design and implement compliance and training initiatives with success. Collis has a Bachelor of Science in Business Administration and a Master of Arts in English, concentration in Technical and Professional Writing.