Requirements of ISO 13485:2016

Student's Guide

Requirements of ISO 13485:2016

In the following slides, the ISO 13485 Standard is paraphrased for instructional purposes. Please refer to the standard for the actual text.

Questions we will cover today:

- What is ISO 13485:2016?
- Steps to registration
- Benefits of registration
- The Process Model/Process Approach
- What are the requirements of ISO 13485?
  - Section 4 – General Requirements
  - Section 5 – Management Responsibility
  - Section 6 – Resource Management
  - Section 7 – Product Realization
  - Section 8 - Measurement, Analysis and Improvement
- Appendix – Key Requirements

What is ISO 13485?

- ISO 13485:2016 is a standard that represents the requirements of a comprehensive quality management system for the design and development, production, storage, distribution, installation and servicing of medical devices.
- The ISO 13485:2016 standard was designed by representatives from many different countries.
- These elements are good business practice.

Find the Requirement:

	Clause:
1. Establish a Quality policy that is applicable to the purpose of the organization and includes the commitment to comply with requirements and to maintain an effective Quality Management System (QMS).	
2. Determine the processes needed for the QMS and the application of these processes taking into consideration the roles undertaken by the organization.	
3. Document in a quality manual, the scope of the QMS including details of, and justification for, any clause 6, 7 or 8 exclusions.	
4. Address any applicable statutory and regulatory requirements when determining the requirements for products and services offered to customers.	
5. Top management demonstrates commitment with respect to the QMS and to customer focus.	
6. Documented procedures and records required by the QMS and by the ISO standard are controlled to ensure effective planning, operation, and control of processes.	
7. Verify that corrective action does not adversely affect the ability to meet regulatory requirements or the safety and performance of medical devices.	
8. Control documents to ensure that the latest version is identified and available at points of use.	
9. Establish an internal communication process for quality matters regarding the effectiveness of the QMS.	
10. Apply a risk based approach to the control of processes needed for the QMS and document one or more processes for risk management.	
11. Determine and implement a process to gather and monitor information and feedback relating to meeting customer requirements and the timely handling of complaints.	
12. Ensure that persons whose work affects product quality are competent on the basis of education, training, skills or experience.	
13. Plan and document arrangements for the control of contaminated product in order to prevent contamination of the work environment.	
14. Define and implement methods to protect confidential health information contained in records.	
15. Personnel must be aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives.	
16. Determine and provide monitoring and measuring resources needed to provide evidence that product conform to requirements.	
17. Ensure that outsourced processes, and purchased products and services conform to requirements.	