



Contrast of ISO 13485: 2003 and ISO 9001:2008

As summarized below, ISO 13485 builds on ISO 9001 compliance. ISO 13485 requires significantly more documented procedures, documentation requirements, and records.

There are two concepts in ISO 9001:2008 that did not carry over to ISO 13485:

1. The requirement to measure customer satisfaction.
2. The requirement for continuous improvement.

Apparently, the developers of ISO 13485 did not view these requirements as appropriate for the regulated medical industry. In place of the two concepts listed above the following two concepts are dominant:

1. Meeting customer requirements, and
2. Maintaining effectiveness of the quality management system.

Everyone's Involvement:

Like ISO 9001, ISO 13485 requires a commitment from everyone in the company. There are processes that touch every area.

There are also numerous new specific requirements for medical devices (summarized below with some overlapping with ISO 9001):

1. Product specifications and quality system requirements must exist for each type/model of medical device, including the complete manufacturing process
2. Defined record retention periods must exist to assure that key documents are available for the lifetime of the medical device, or at least two years
3. Top management must establish the interrelation of all personnel involved with quality, and assure the independence and authority to perform the required tasks
4. Top management must promote the awareness of regulatory requirements
5. Regulatory requirements must be considered in the input phase of product design
6. Documented procedures must be written for periodic maintenance of manufacturing and measurement equipment
7. Health, cleanliness, and clothing of personnel must be controlled if contact between the personnel or work environment could adversely affect the product
8. Environmental controls must be established in manufacturing if environmental conditions can adversely affect the product



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9. Training requirements must be designated for temporary workers
10. Documented processes must exist for risk management throughout the product design, manufacturing, and delivery processes, including the use of ISO 14971, a guidance standard specific to risk management
11. Procedures must be established for issuance of advisory notices (information provided to customers of delivered devices with information and/or recommended actions related to the use, modification, return/recall, or destruction of a device) including appropriate design transfer activities in the product development process
12. Specific consideration of safety requirements during the product development process
13. The inclusion of specialists during the design review phase of product development
14. The requirement to perform clinical evaluations and/or evaluation of medical device performance in accordance with national or regional regulations
15. Retention of purchasing documents to assure traceability
16. Creating verified and authorized batch records to include quantity manufactured and quantity released for distribution
17. Documenting requirements for product cleanliness
18. Documenting processes for medical device installation
19. Documenting processes for product servicing
20. For sterile products, lot traceable records that include sterilization process parameters
21. Validation of software used in manufacturing or the device itself
22. Validation of sterilization processes
23. Segregation of products returned by customers
24. Systems to provide traceability
25. For implantable devices, special documentation requirements for traceability, distribution, and receiving customers
26. The identification of product status throughout the manufacturing process and supply chain to assure that only properly released product is available to customers
27. The management of used product to avoid contamination, if applicable



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28. Early warning feedback systems for identification and correction of quality problems
29. The identification of personnel performing any inspection or testing
30. Acceptance by concession (deviation) only if regulatory requirements are met
31. Formalized rework processes, including the determination of any adverse effect of the rework on product quality
32. Managing of customer complaints
33. Reporting of adverse events to regulatory authorities, if applicable
34. Formal evaluation of the effectiveness of implemented corrective and preventive actions

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