Kerri Williams was asked to make a presentation about upgrading an existing ISO 9001 management System to ISO 13485.

She kindly allows us to display her presentation. With her agreement we have modified the content to remove background and benefit information about Platinum Registration.

ISO 13485

Upgrading and Certifying an Existing QMS

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Overview

- Purpose of ISO 13485
- Significant differences between ISO 9001:2000/8 and ISO 13485
- Things to Consider BEFORE Upgrade
- Upgrading the QMS to Meet Requirements

ISO 13485

ISO 13485

1. Is based upon ISO 9001:2000
2. Adds additional requirements and clarifications for organizations that need to demonstrate their ability to provide medical devices and related services that meet customer requirements and regulatory requirements.
3. Big focus on regulations (documents, management review, awareness, resources required to meet them), defined processes and records to demonstrate conformance.

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ISO 13485

Significant Additions to ISO 9001:2000

4.2 Documentation requirements

1. Adds regulatory documents as part of the system documentation
2. Requires a file containing or identifying documents defining product specifications and QMS requirements for the complete manufacturing process. (Device master record)

4.2 Documentation requirements concluded

3. Changes must be reviewed and approved by the original approving function or another designated individual who has adequate background information
4. Period for keeping obsolete documents must be defined. (Product lifetime not less than record retention time or time specified by regulations)

6.4 Infrastructure

1. Establish documented requirements for maintenance activities, including their frequency, when such activities (or lack thereof) can affect product quality
2. Records of maintenance are required to be maintained

6.4 Work environment

3. Documented requirements required for health, cleanliness and clothing of personnel if contact between personnel and products or the work environment will adversely affect the quality of product
4. Documented requirements required for monitoring and controlling the work environment if these conditions can affect product quality
5. Control of contaminated and potentially contaminated product, if appropriate to prevent contamination of other product, the work environment or personnel

7.1 Planning of product realization

1. Establish documented requirements for risk management throughout product realization.
2. Maintain risk management records.

7.2.3 Customer Communication

1. Determine and implement effective communication arrangements regarding advisory notices.

7.3 Design and development

1. Lots of changes here – but it is excluded from your management system

7.3 Purchasing

1. Documented procedures for purchasing is required
2. Relevant purchasing information (i.e., documents and records) is required to be maintained as needed for traceability
3. Records must be maintained for verified product

7.5 Production

1. Documented procedures, documented requirements, work instructions, reference materials and reference measurement procedures must be **available** to personnel as part of document control
2. Defined operations for labeling and packaging must be implemented

7.5 Production - continued

3. A record for each batch of medical devices must be established and maintained that provides traceability and identifies the amount manufactured and amount approved for distribution. Each batch record must be verified and approved. (Device History Record)
4. Documented requirements for the cleanliness of product are a required if the product is cleaned by the organization prior to sterilization and/or use (or is subject to cleaning/sterilization prior to use, if cleanliness is of significance during use, process agents are to be removed during manufacture.

7.5 Production - continued

5. Documented requirements for the installing and verifying the installation of the medical device, if appropriate.
6. If installation is allowed to be performed by other organizations (than the manufacturing organization or its authorized agent), documented requirements for installation and verification must be provided.
7. Records of installation and verification must be maintained

7.5 Production - continued

8. If servicing is a requirement, documented procedures, work instructions, reference materials and reference measurement procedures must be developed and maintained.
9. Records of service activities must be maintained
10. Documented procedures for the validation of the application of computer software (and changes to such software and/ir its application) for production and service provision that affect the ability of the product to conform to specified requirements must be implemented and maintained.
11. Records of validation must be maintained

7.5 Production - continued

12. Specific requirements for sterilization, but these are probably excluded from your system
13. Product must be identified my suitable means throughout the product realization process. The process for identifying product must be defined in documented procedures.
14. Documented procedures must be implemented and maintained to ensure that returned medical devices are identified and distinguished from conforming product.

7.5 Production - continued

15. Documented procedures for traceability and the required records to demonstrate traceability must be established and maintained
16. Requirements for active implantable devices…but these are probably excluded from your system
17. The identification of product status must be maintained throughout the processes for production, storage, installation and servicing to ensure that only product that has passed inspections and tests is dispatched, used or installed.

7.5 Production - concluded

18. Documented procedures or work instructions for preserving the conformity of product during internal processing and delivery must be implemented.
19. Documented procedures or work instructions for the control of product with limited shelf life or that requires special storage conditions must be implemented. Special storage conditions must be controlled and recorded

7.6 Control of monitoring and measuring devices

1. Documented procedures to ensure that monitoring and measurement can be carried out in a manner that is consistent with the monitoring and measuring requirements

8.2.1 Feedback

1. Documented procedure for a feedback system to provide early warning of quality problems and for input to the corrective and preventive action processes.
2. Where national regulations require the organization to gain experience from the post production phase, the review of this experience must be part of the feedback system.

8.2.4 Monitoring and measuring of product

1. Must monitor and measure the characteristics of the product at appropriate stages to verify that it meets requirements in accordance with planned arrangements and documented procedures
2. Product release and delivery must not proceed unless requirements have been met

8.3 Control of nonconforming product

1. Nonconforming product may only be accepted only if regulatory requirements are met. Records of the identify of person(s) authorizing the concession must be maintained.
2. The organization must document the rework processes in a work instruction that has undergone the same authorization and approval as the original instruction. Prior to the approval of the instruction, a determination of any adverse effect of the rework on the product must be made and documented.

8.4 Analysis of data

1. Documented procedures must be established to determine, collect and analyze data (including feedback) to demonstrate the suitability and effectiveness of the QMS and to identify opportunities to improve the QMS.
2. Records of the results of the analysis must be maintained.

8.5 Improvement

1. Must identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the QMS. (Must do improvement as well to demonstrate conformance to ISO 9001:2008)
2. Documented procedures for the issue and implementation of advisory notices must be established and maintained.
3. If a customer complaint is not followed by corrective and/or preventive action, a reason shall be authorized and recorded
4. Documented procedures that define the process for notifying authorities of adverse events must be established and maintained.

8.5.2 and 8.5.3 Corrective and Preventive Action

1. Specific requirements for records of investigations and of the actions taken

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Considerations

- Is certification a requirement for potential or on-going customer relationships?
- Are you/do you plan to market the company as a medical device manufacturer/assembly house?
- Will this certification help you manage production of devices for an existing customer more than the ISO 9001 certification does?
- Costs of implementation and maintenance – more requirements for documentation and records….more internal audits…
- Costs of certification

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Upgrading Your QMS to Meet ISO 13485

- How is your system defined? Process-based or standards based?
- Set goals
- Develop a timeline for implementation/certification working backwards (Date of certification, 30 days for corrective action, Stage 2, 30 days before – Stage 1, perform management review, perform internal audits, modify documentation, perform gap analysis)
  - Perform a gap analysis
  - Revise the Quality Manual and existing system where possible (simplify and look for adjustments in processes that give you more bang for the buck)
  - Develop new procedures, work instructions and forms, where needed

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