ISO 9001:2015 QMS to ISO 13485:2016 Upgrade Instructions/Checklist

These instructions allow you to upgrade your ISO 9001:2015 Quality Management System to include ISO 13485:2016 requirements for the medical devices industry.

The above Quality Management Systems are compatible with each other and have common requirements.

In ISO 9001:2015, the requirements are described in:

- Clause 4 Context of the organization
- Clause 5 Leadership
- Clause 6 Planning
- Clause 7 Support
- Clause 8 Operation
- Clause 9 Performance evaluation
- Clause 10 Improvement

In ISO 13485:2016, the requirements are described in:

- Clause 4 Quality management system
- Clause 5 Management responsibility
- Clause 6 Resource management
- Clause 7 Product Realization
- Clause 8 Measurement, analysis and improvement

You have the 9001:2015 version in place and now have the objective of upgrading the system to include the 13485:2016 version. The good news is that since you are familiar with formal management systems, this initiative will be relatively straightforward.

Essentially, the documentation package for the management system will contain:

- One condensed Manual to introduce the documented information required for ISO 9001:2015 and ISO 13485:2016.
- A work instruction needed for the documented information and systems.

The documentation will need to be reviewed, upgraded, and implemented. The first step is to assign a person responsible for the QMS, such as with a Management Representative, to become familiar with the changes for 2016 version of the ISO 13485:2016 standard. Visit http://13485store.com and http://the9000store.com/ for training materials, resources, and information on QMS requirements.

The following table with detailed instructions focuses on the areas of the documentation required to cover both the ISO 9001:2015 and ISO 13485:2016 quality management systems. Please note that in the left-hand column of the instructions, the ISO 9001:2015 clauses shown in **bold numbers** have key changes for ISO 13485:2016. The intent of the main ISO 9001 clauses is shown in **blue font** and the text in ***italics*** indicates where requirements are included in ISO 13485:2016 and the ISO corresponding clauses are highlighted in yellow.

Use copies of the ISO 9001:2015 and ISO 13485:2016 standards along with this instruction to pinpoint for your organization the areas that need attention. You may want to make notes and add comments in the space available to the right and the left of the column for reference documentation. Use the upgrade checklist section on the right side of the table to assign the responsibility for the upgrade and to follow up on its completion.

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ISO 9001: 2015 Clause	Changes to the existing ISO 9001:2015 Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
All	The international standard ISO 9001:2015 contains 10 sections 1 through 10. The international standard ISO 13485:2016 contains 8 sections 1 thru 8.	ISO 9001:2015 ISO 13485:2016	The ISO 9001 requirement clauses of the standard are the Clause 4 through Clause 10. The ISO 13485 requirement clauses of the standard are the Clause 4 through Clause 8. Your company needs to become familiar with the two structures and subsequently upgrade the Quality Management System (QMS). Take advantage of this integration project to review and improve your existing QMS.		
All	As you initiate the upgrade of your QMS to include both ISO 9001:2015 and ISO 13485:2016, here are a few **Short, Quick, and To-the-Point Productivity Tips.** 9000Store . 13485Store		• An important first tip is to assign a responsible person, such as a Quality Team Leader or the Management Representative, who will be the project manager for the transition project. • You will need copies of the ISO 9001:2015 and ISO 13485:2016 standards. Buy the standards at https://standards-stores.com/iso-standards/ • As you include ISO 13485 in your ISO 9001 system, keep your employees informed by issuing 'Employee Newsletters'. For a complete set, refer to http://13485store.com/13485-2016-employee-newsletters/ • Make use of the 'Implementation Plan'. Refer to http://13485store.com/steps-to-13485/. • Get your free Quick Start Kit at http://13485store.com/iso-13485-quick-start-kit/ • As required in clause 9.2, your QMS will need to be audited and your internal auditors properly trained to do this. For a complete auditor training package, refer to http://13485store.com/-internal-auditor-training/		

	device type or device family is in par 4.2.3				
5	This clause requires that your top management demonstrates leadership and commitment with respect to the QMS and to customer focus. This section also asks top management to establish, review and maintain a quality policy that is appropriate to your company and to ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood.				
5	In ISO 9001:2015, clause 5: Leadership corresponds to clause 5: Management Responsibility in ISO 13485:2016.	Procedure	Review / rework your existing document P-500 Leadership and include reference to your medical devices.		
5.1	While there are similarities in the clauses, note that the appointment of a specific management representative is not a requirement in ISO 9001:2015. *However, in ISO 13485:2016, the appointment of a management representative is in par 5.5.2.*		To demonstrate leadership and commitment, assign the responsibility and authority to ensure that the QMS conforms to the requirements of the ISO standard to a member of the management team and appoint the management representative and include the specific responsibilities per 5.5.2: a) Ensuring that QMS processes are documented. b) Reporting to top management on the performance of the QMS and the need for improvement. c) Ensuring the promotion of awareness of regulatory and QMS requirements.		
5.1.1	*In ISO 13485:2016, the requirement for management commitment is in 5.1.*		Include the actions to demonstrate the leadership and commitment to the QMS.		
5.1.2	*In ISO 13485:2016, the requirement for customer focus is included in par 5.2.*		Include the actions to demonstrate the leadership and commitment to customer focus.		
5.2	*In ISO 13485:2016, the requirement for quality policy is included in par 5.3.*		Include the process for developing, communicating, and reviewing the quality policy.		
5.3	*In ISO 13485:2016, the requirement for responsibility and authority is in 5.5.1.* *In ISO 13485:2016, the requirement to document the roles undertaken by the organization under the regulatory requirements is in par 4.1.1.*	Organization chart	Include the system for ensuring that the responsibilities and authorities for relevant roles are assigned and communicated. Ensure that the interaction of personnel whose work affects quality is documented.		
6	This clause talks about the planning for the QMS, where your company needs to consider the internal and external issues (of clause 4) that are relevant to the QMS and determine the risks and opportunities that need to be addressed. In addition, this section covers the quality objectives that will need to be established for the relevant functions and the plans to achieve them determined. You will also need to carry out changes in a planned and systematic manner when it is determined that change to the QMS is required.				
6	In ISO 9001:2015, clause 6 corresponds to clause 5.4 Planning of ISO 13485:2016 and focuses on the planning for the	Procedure	Review / rework the information (in a document P-600) to outline the process for planning for the QMS is carried out to meet the requirements for your		