ISO 13485:2003 to ISO 13485:2016 QMS Upgrade Instructions / Checklist

This instruction / checklist is intended for use in upgrading your Quality Management System for the transition from the ISO 13485:2003 version to the ISO 13485:2016 version for Quality management systems used by organizations involved in the medical devices industry.

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

In both versions, 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 2003 version in place and now have the objective of upgrading the system to the 2016 version. The good news is that since you are familiar with formal management systems, this initiative will be relatively straightforward where documented information for the QMS sets the stage for an understanding of the requirements and of the international standard as a whole.

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

- One Manual with updates to the documented information required for ISO 13485:2016.
- A group of procedure/system documents in your QMS with updates to reflect a document numbering system related to the new clause numbers and to incorporate the upgrades for ISO 13485:2016 requirements,
- A group of forms and attachments needed for the procedures 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/ for training materials, resources and information on quality management systems requirements.

The following table with detailed instructions focuses on the areas of the documentation required for the ISO 13485:2016 quality management system. As you undertake the task of upgrading your quality management system from the 2003 version to the 2016 version, note that in the left hand column of the instructions, the ISO 13485:2016 clauses shown in **bold numbers** have changes from 2003 to 2016. The intent of the main clauses is shown in blue font and the text in *italics* indicates where requirements were included in previous ISO 13485:2003.

Use a copy of the ISO 13485:2016 standard 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 13485:2003 to ISO 13485:2016 QMS Upgrade Instructions / Checklist

ISO 13485: 2016 Clause	Changes to the existing ISO 13485:2003 Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
All	The international standard for Medical Devices - ISO 13485:2016 is updated and contains 8 sections or clause 1 through clause 8.	ISO 13485:2016	The requirements for the revised standard are described in Clause 4 through Clause 8. Your company needs to become familiar with the changes and subsequently upgrade the Quality Management System (QMS).		
All	----	ISO 13485:2016	A project manager or the appointed management representative (per clause 5.5.2) will be integral in setting the stage for an understanding of the requirements and the upgrade of the QMS.		
All	----	Manual	Make use of the information provided with this QMS Upgrade Instructions / Checklist to rework your existing QMS documentation and include the new and revised requirements of ISO 13485:2016.		
All	----	Manual	Begin by revising the cover page of the Manual to specify ISO 13485:2016		
1	*In ISO 13485:2003, justifiable exclusions were only permitted in clause 7.*	Manual	In the scope section of the manual, add a note to say that requirements in clauses 6, 7 or 8 that do not apply to your organization are excluded from the QMS. Document any justifications for the exclusion of requirements.		
2	*In ISO 13485:2003, the standard ISO 9000:2000 is a normative reference.*	Manual	In the normative references section of the manual, update the QMS – fundamentals and vocabulary standard to ISO 9000:2015.		
3	*In ISO 13485:2003, a total of (8) definitions are listed*	Manual	For the definition section of the manual, review the (20) definitions included in section 3 of the standard and identify and record the ones that apply to your organization.		
4	This first clause of the standard deals with the Quality Management System in general and requires that you identify your role as an organization and how management applies a risk based approach to achieve the efficient control of processes and an effective quality system. The scope of the QMS and the QMS processes along with their applicability and interactions need to be determined. In addition, documentation requirements need to be addressed via a Quality Manual, medical device files, and procedures for control of documents and control of records.				

The intent of the main clauses is shown in blue font

ISO 13485: 2016 Clause	Changes to the existing ISO 13485:2003 Quality System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
7.2.3	*In ISO 13485:2003, the arrangements for communicating are determined and implemented.*	Procedure	Ensure that arrangements for communication with customers are planned and documented.		
7.3	*In ISO13485:2003, the requirement for design and development was also in clause 7.3.*	Procedure	When your role as a company includes the design and development of medical devices, document the information (in a procedure P-730) to outline the process for the design and development.		
7.3.1	*In ISO 13485:2003, the requirements for design and development were outlined in par 7.3.1 through 7.3.7.*	Manual	If you are a designer or developer or inventor of medical devices, review section 7 of the manual and update it to agree with the structure for clauses 7.3.1 through 7.3.10. Add new sections for clause 7.3.8		
7.3.2	*In ISO 13485:2003, the requirement for design and development planning was in par 7.3.1 and (3) items listed for planning.*	Procedure	Specify (in a procedure P-730) that planning documents are maintained and updated as the design and development progresses. Review the (6) items required to be documented for design and development planning.		
7.3.3	*In ISO 13485:2003, the requirement for design and development inputs was in par 7.3.2.*	Procedure	Include the requirement that inputs need to be able to be verified or validated.		
7.3.4	*In ISO 13485:2003, the requirement for design and development outputs was in par 7.3.3.*	Procedure	Review the items required as design and development outputs.		
7.3.5	*In ISO 13485:2003, the requirement for design and development review was in par 7.3.4.*	Procedure	Review the items required for design and development review.		
7.3.6	*In ISO 13485:2003, the requirement for design and development verification was in par 7.3.5.*	Procedure	Review the items required for design and development verification. Include the new requirement that verification plans with methods, acceptance criteria and statistical techniques are documented. Include the new requirement that when medical devices are connected or are interfaced with other devices, verification includes confirmation that design outputs meet design inputs.		

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The text in *italics indicates where requirements were included in previous ISO 13485:2003*