QMS Upgrade Instructions for FDA Compliance in ISO 13485:2016

This instruction / checklist is intended for use in upgrading your Quality Management System and integrating the FDA.QSR (21 CFR 820) regulations 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 ISO 13485:2016, the requirements are described in (4) main clauses:

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

In QSR (21 CFR 820), the requirements are described in (15) main parts; Subpart A through Subpart O, covering General provisions to Statistical techniques. CFR Title 21, Part 820 (e-CFR May 26, 2016), represents the US (FDA) Food and Drug Administration's current good manufacturing practices (CGMP) and it is not fully harmonized with ISO 13485. This document provides instructions on how to customize your ISO 13485 QMS to meet these requirements.

You have the 2016 version in place and now have the objective of upgrading the system to the FDA-QSR 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.

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 versions of the FDA regulations and of the ISO 13485:2016 standard. Visit the 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 integrated quality management system. As you undertake the task of upgrading your quality management system, note that in the left hand column of the instructions, all the ISO 13485:2016 clauses are shown and in the 4th column of the table, corresponding, or related requirements, or no correspondence in QSR (21 CFR 820), are indicated in ***Italics.***

The table outlines the changes to your ISO13485 QMS documentation to align it with the Quality System Regulation, 21 CFR 820, as current with the e-CFR data of May 26, 2016.

The applicable parts of the regulation that result in additions or revisions for the QSR are highlighted in yellow.

- Use copies of the ISO13485 standard & the (21 CFR 820) regulation to pinpoint the areas that need attention. Make notes in the space 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 and to follow up.

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

- One Manual with updates to the documented information required to cover both the ISO 13485:2016 requirements and Part 820 of the QSR (21 CFR 820) regulations.
- A group of procedure/system documents in your QMS with updates to reflect both the ISO 13485 requirements and the regulations of Part 820 of the QSR (21 CFR 820).
- A group of forms and attachments needed for the procedures and systems.
- Several relevant Procedures & Forms cover new requirements:
  - P-722, Risk management and related forms F-722-001 and F-722-002
  - P-751, Production and process controls and typical routing sheets forms F-750-001 & F-750-002
  - P-756, Validation of processes for product realization and example form F-756-001
  - P-820, Post production feedback and related customer survey form F-821-001
  - P-833, Advisory notices and product recall (standard medical devices reporting forms)

ISO 13485 Clause	Changes for FDA compliance in the existing ISO 13485:2016 Quality Manual	Reference document	Changes in other existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
4.2.4	Control of documents	--	*In (21 CFR 820), a corresponding requirement is in part 820.40 Document control.* *Related requirements are in parts:* *820.181 Device master record, and* *820.30 j Design history file – see also 7.3.10.*		
4.2.4	---	Procedure	In your existing procedure such as P-424 for Control of Documents (4.2.4), include the requirement for Medical device files and consider the related requirements for 820.30 j design history file and 820.181, device master record.		
4.2.4	---	Procedure	In your procedure P-424 for Control of Documents and for 820.40 b, include the requirement that approved changes are communicated to the affected personnel in a timely manner.		
4.2.4	---	Procedure	In procedure P-424 for Control of Documents and for 820.40, add the requirement that records of changes include a description of the change, identification of the affected documents, the signature of the approving person(s), the approval date, and when the changes become effective.		
4.2.5	Control of records	--	*In (21 CFR 820), a corresponding requirement is in part 820.180 General requirements.* *Related requirements are in parts:* *820.181 Device master record,* *820.184 Device history record,* *820.186 Quality system record, and* *820.30 j Design history file – see also 7.3.10.*		
4.2.5	In the control of records section 4.2.5 of the manual and for 820.180, add a note to say that communication with FDA is required and records are accessible to responsible officials of the company and to employees of FDA.	Manual and Procedure	In your existing procedure such as P-425 for Control of Records (4.2.5) and for 820.180, include the requirement that all relevant records are maintained at the company location or other location that is accessible to responsible officials of the company and to employees of FDA designated to perform inspections.		

7.3.7	---	Procedure	In P-730 and for 820.30.g, describe the method(s) used to ensure that results of validation include identification of the design, method(s), the date, and the individual(s) performing the validation, and are documented in the DHF- see 7.3.10.		
7.3.8	---	Procedure	In P-730 and for 820.30.h, describe the method(s) that ensure that the results of a design review, correctly translate and transfer the medical device design into production specifications.		
7.3.9	---	Procedure	In P-730 and for 820.30.i, describe the method(s) for the identification, documentation, validation, verification, review and approval of design changes.		
7.3.10	In section 7.3.2 and for 820.30.j, add a sentence to say that a design history file (DHF) is established and maintained for each type of device.	Manual and Procedure	In your procedure P-730 and for 820.30.j, describe the method used to establish and maintain the DHF and to ensure that the requirements for the DHF contain or reference the records necessary to demonstrate that the design was developed according to the approved design plan.		
7.4	Purchasing	--	*In (21 CFR 820), a corresponding requirement is in part 820.50, Purchasing controls.*		
7.4.1	In section 7.4.1 of the manual and for 820.50, add a sentence to say that your company established a documented procedure for purchasing, to ensure that products and services purchased from suppliers, contractors, and consultants conform to specified requirements.	Manual and Procedure	In your existing procedure P-740 for purchasing (7.4) and for 820.50.a describe the process by which potential suppliers, contractors, and consultants are evaluated and selected on the basis of their ability to meet specified requirements, including quality requirements.		
7.4.2	---	Procedure	In your purchasing procedure P-740 and for 820.50.b describe the process that ensure that purchasing documents include an agreement that the suppliers, contractors, and consultants agree to notify the company of changes in the product or service, to determine whether the changes may affect the quality of a finished device. Specify in your process that purchasing data is approved prior to issue.		
7.5	Production and service provision.	--	*In (21 CFR 820), a corresponding requirement is in part 820.70, Production and process controls.*		
7.5	In section 7.5 of the manual and for 820.70, add a section for Production and process control to ensure that your company plans, and carries out, production and processes under controlled conditions.	Manual	Address the requirement for production and process control (7.5.1) with the procedure P-751 and take into consideration regulation 820.70 item a through item i.		