Quality Systems Handbook for Medical Devices

by Anna Lundén

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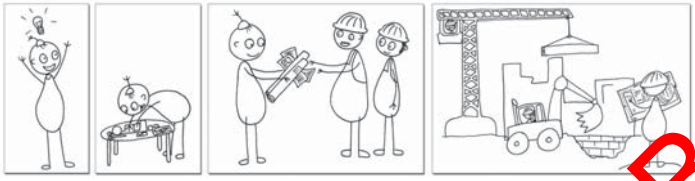
Contents

4. Design of Medical Devices



The majority of the requirements and regulations that we cover in this book are related to that part of business operations where we manufacture medical devices for commercial use. Naturally, the phase of operations involving development of the product is also regulated.

Design procedures
820.30(a)
7.3

Terminology

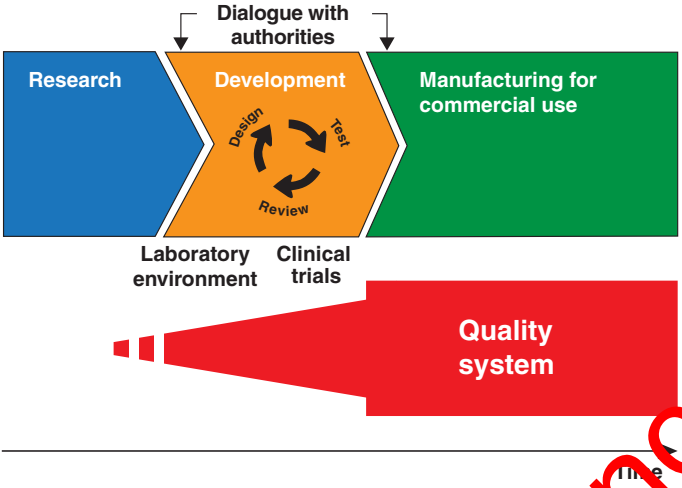
ISO	Design and development
QSReg	Design Control

Design history file
820.30(j)
7.3.10

There are also certain other regulations which are related and which affect the company throughout the development phase. For example, there are rules on how to deal with possible experiments on animals done in order to evaluate the product's safety before completely new products are tested on human beings. There are also rules for how clinical trials or assessments should be performed.

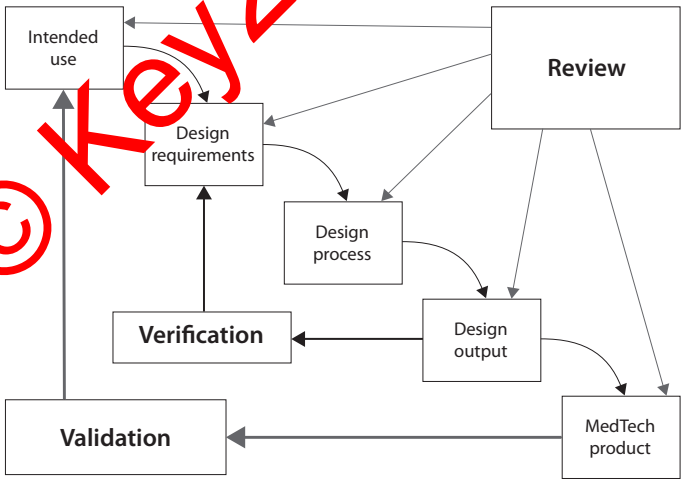
GLP, Good Laboratory Practice
Good Laboratory Practice (rules for tests that are done on animals, for example, in order to show that materials intended for implantation are adequately safe)

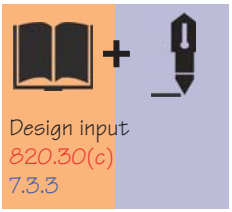
GCP, Good Clinical Practice
Good Clinical Practice (rules for handling patients and documentation during clinical trials/evaluation)



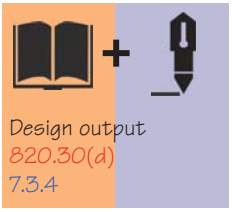
When an idea starts being developed in order that it can be of benefit to the customer, it is also time to start thinking about the quality management system

We are expected to have a plan for each development project; one that clearly defines the areas of responsibility and indicates how we should test and evaluate prototypes and products as the development process proceeds. These plans should also be kept current so that we update and adjust the plan if something changes.

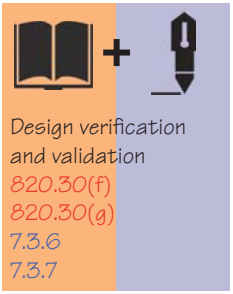




An extremely important part of the rules and regulations that cover the actual development of the product has to do with clearly defining and documenting what the product is supposed to be used for, who will use it and how it should be used – everything seen from the perspective of the user and/or the patient. With this as a starting point, we then create the more technical requirements of the product. These are called design input.



The design input is then used as the basis for developing the product. This is normally done in stages and it is rare to have complete success on the first attempt. Often, several cycles are performed, where different variables are tested and evaluated, until a technical solution that meets the design input is found.



The tests that are done in order to assess a proposed design from a purely technical standpoint are, in this context, called "verification." These verifications are performed according to established test protocols and the results are then documented. When a technical solution that meets the requirements is finally established, it is called the design output.

It is not enough merely to perform workbench tests and laboratory experiments but rather the fully developed product should also be assessed by the user and/or the patient. This is called product validation / design validation."

It is vital to obtain this feedback to ensure that we perceived user and patient needs correctly and that we developed a product that can be used safely and effectively, i.e. a product that provides the intended benefit.

During the course of development, we are also required to perform formal reviews, where we go through any difficulties we encountered and examine the project critically to ensure that we have not missed any critical details.

Once we feel we have a finished product that meets our requirements and has been developed following these principles, we then transfer the documentation from the development function to the manufacturing function of the company. In certain companies, production is outsourced to another party.

Design transfer
820.30(h)
7.3.8

Regardless of which procedure is chosen, all the product specifications, drawings and other documentation that we produced during the development phase are now converted into purchase specifications and manufacturing methods. It is also at this point that we normally ensure that the manufacturing process is reliable and can produce the product with the proper level of quality. This is called process validation. Read more about process validation in Chapter 13.

If, over time, it becomes necessary to make a change in a product, you should always refer to the development documentation in order to judge what the change will entail. Minor changes perhaps only involve updating of the documentation. If there are major changes, it may be necessary to repeat both the verifications and the validations. If changes are made to the design, we should also always determine whether the change means that we must communicate with the government agencies or the Notified Body,

Design changes
820.30(i)
7.3.9

Appendix 1. Requirements for procedures and records in QSReg (21 CFR 820)

	Procedures	Ch.		Records	Ch.
Subpart A					
820.5	Quality system	3			
Subpart B					
820.20(a)	Quality policy	2			
820.20(b)	Organizational structure	3	820.20(b)	Organizational structure	3
820.20(b)(1)	Responsibility, authority, and interrelation of all personnel in the organisation	3			
820.20(b)(3)	Management representative for quality	3			
820.20(c)	Management review		820.20(c)	Management review	
820.20(d)	Quality plan	3			
820.20(e)	Quality system procedures and instructions	3			
820.22	Quality audits	12	820.22	Quality audits	12
820.25(b)	Identifying training needs	3	820.25(b)	Training	3
Subpart C					
820.30(a)	Design controls	4			
820.30(b)	Design and development planning	4			
820.30(c)	Design requirements appropriate and related to intended use	4	820.30(c)	Design requirements	4

Appendix 2. Requirements for procedures and records in ISO 13485

	Procedures	Ch.		Records	Ch.
4.1.1	Quality management system	3	4.1.3(e)	Quality management system	
4.1.5	Quality agreements for outsourced processes				
4.1.6	Validation of software used in the quality management system		4.1.6	Validation of software used in the quality management system	
4.2.1(a)	Quality policy and quality objectives	2			
4.2.1(b)	Quality manual	3			
4.2.2	Quality manual	3			
4.2.3	Product specifications				
4.2.4	Control of documents	14			
4.2.5	Control of records	14			
5.5.1	Responsibility and authority incl. Management representative	3			
5.6.1	Planned quality management system review		5.6.1	Management review	
6.2	Determine necessary training	3	6.2	Training	3
6.3	Infrastructure requirements				
6.3	Maintenance	5	6.3	Maintenance	5
6.4.1	Health, cleanliness and clothing	3			
6.4.1	Environment conditions	5,8, 10			

Appendix 3. List of selected terms

Term	ISO 13485	QSReg (21 CFR 820)
Customer complaint	Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the mark.	Complaint – means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.
Component	-	Means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.
Control number	-	Means any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished devices can be determined.
Establish	-	Means define, document (in writing or electronically), and implement.
Lot	-	Means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.