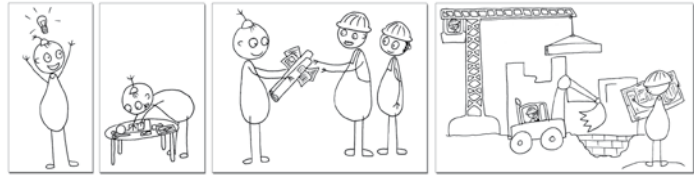


4. Design of Medical Devices



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.



Terminology

ISO Design and development

QS Design Control

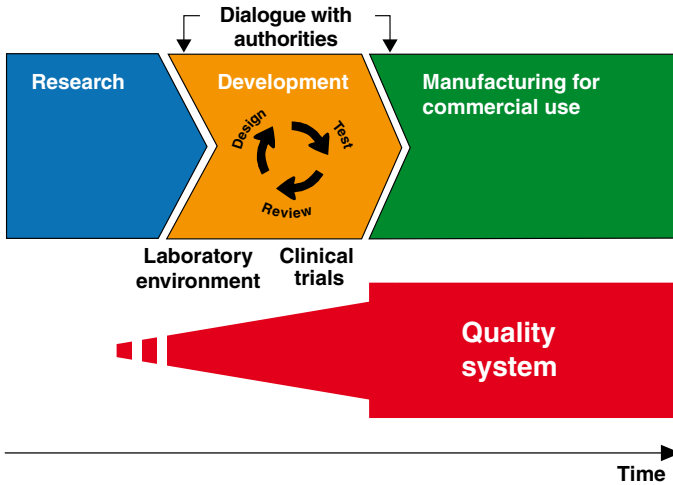
There are also certain other regulations which are related and which affect the company throughout the development phase. For example, there are rules of how to perform possible experiments on animals done in order to evaluate the product's safety before completely new products are tested on human beings. 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)

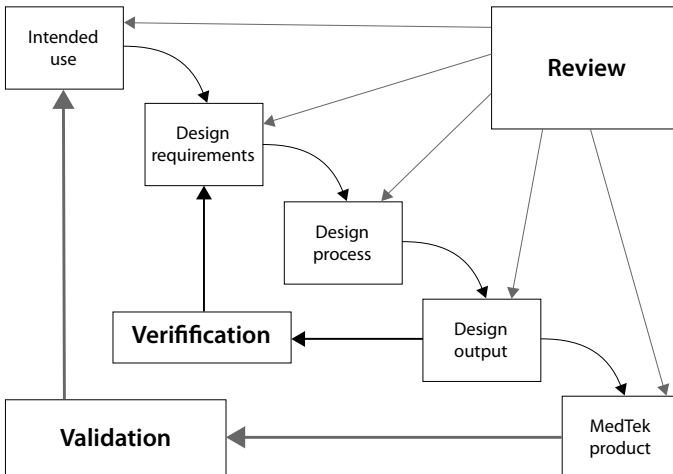
GCP, Good Clinical Practice

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



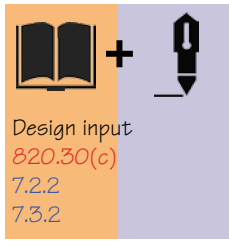
When an idea starts being developed in order that it can be of benefit to the customer, it is also time to start thinking about the quality management system

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 in the development process/procedure. This plan should also be kept current so that we update and adjust the plan if something changes.

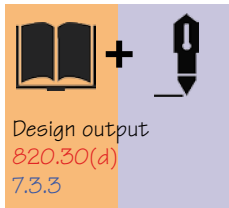


Design and development planning
820.30(b)
7.3.1

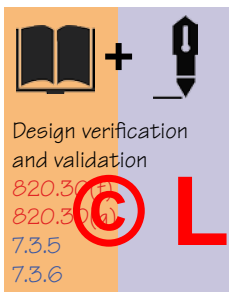
Design input
820.30(c)
7.2.2
7.3.2



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 requirements.



The design requirements are 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 repetitions are performed, where different variables are tested and evaluated, until a technical solution that meets the design requirements is found.



The tests that are done in order to assess a proposed design from a purely technical standpoint are, in this context, called verifications. The verifications are performed according to test based 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.

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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)

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 15.

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)
7.3.7

