

PART 1: DESIGN MODEL

GET A BETTER OVERVIEW AND SAVE TIME
IMPLICITLY COVER STANDARD REQUIREMENTS
GET READY FOR AUTOMATION

Approach

It is important to follow the approach that Requirement Engineering is more than an isolated capture of single attributes. Think of the requirements as a design process that gradually becomes more detailed.

Remember that requirements are connected to each other and in the end will define the product architecture.

Do not use requirement categories like Mechanical, Hardware, Software or even names of your product components. This will be the result of the design process and must not be defined upfront.

Multi-stage design process

The design process for medical devices (MD) is not linear, but a multi-stage process that extends from the idea to the finished product.

The product is developed step by step.

Use three levels of requirements or more when the complexity of your product requires this. This way you follow an approach that implements the requirements of IEC 62366-x (Usability), IEC 62304 (Software development for MD) and ISO 14971 (Risk Management for MD) in a practical way.

Change of perspective

The development process involves different levels of observation in different levels of detail, similar to a change of perspective. This involves switching from a holistic problem solution to detailed design requirements for production.

For the first level of perspective imagine the framework of clinical application. For example, the treatment steps performed by the doctor, and gradually go down into more detail in each level.

Down to the design level imagine the technical component that implements the part of a function.

In complex systems, this can even be a specific electrical component, such as a single I2C EEPROM storage.

