

Requirements Management

Setting up and managing the requirements for the product to be developed is the first step in the development phase. Without requirements, testing the product is useless. Requirements should be implementation free (describing the “what” not the “how”), complete, consistent, unambiguous, verifiable, achievable, necessary, correct, and uniquely identifiable throughout the system. The following requirements documents need to be made, reviewed and approved (between [] are references to other chapters in this guideline):

- On User level
[intended use](#), [clinical claims](#), claimed performance, stakeholder requirements, [Privacy](#), [Security](#) and user training requirements
- On System level
functional, physical, performance, [safety](#), [Usability](#) , interfaces, design, service and [regulatory requirements](#), [Interoperability](#) , scalability
- On Software level
functional & capability, interfaces, alarms & messages, user interface, data definition & database and security requirements.

For a software only system, the system and software level documents are combined.