

Design Input

development of complete and unambiguous Design Inputs is the single most. The PL/HE or designee completes the User Requirements and Product Requirements.

7.2 Design Input - User Requirements

The PL/HE or designee completes the User Requirements as part of the overall design and development plan.

The Design Inputs phase ensures that the User requirements are addressed:

- User requirements - those interface requirements critical to compatibility between the user, patient, and other personnel and external systems

7.3 Design Input - Product Requirements

The PL/HE or designee completes the Product Requirements as part of the overall design and development.

The Design Inputs phase ensures that the Product Requirements are addressed:

Product requirements are those requirements that specify what the Product does, including operational capabilities of the Product and performance requirements such as:

- Accuracy, reliability, and safety. These requirements shall be capable of being verified by an objective method of analysis, inspection, or testing.
- Product Requirements Specification (PRS)
- Product Requirements will evolve as the project progresses from “black box” (understanding only what goes in and what goes out) to “grey box” (understanding the product functions and behaviours) to “white box” (understanding exactly how the product works).
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- The Product Requirements Specification (PRS) Form provides the document structure with an explanation of the contents for each section. Following completion and approval of the PRS, each requirement is assigned to hardware or software. This is done early in the Design Outputs phase.

7.4 Approving Design Input Documents

- The PL/HE schedule a DRC meeting, in accordance with the respective SOP to review and approve the Design Inputs.
- The DRC assures that the Design Inputs are complete and that any incomplete, ambiguous and/or conflicting issues are corrected, as necessary.
- The approved User Requirements document and Product Requirements document are included in the DHF.



7.5 Product Requirements Form (PRS)

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