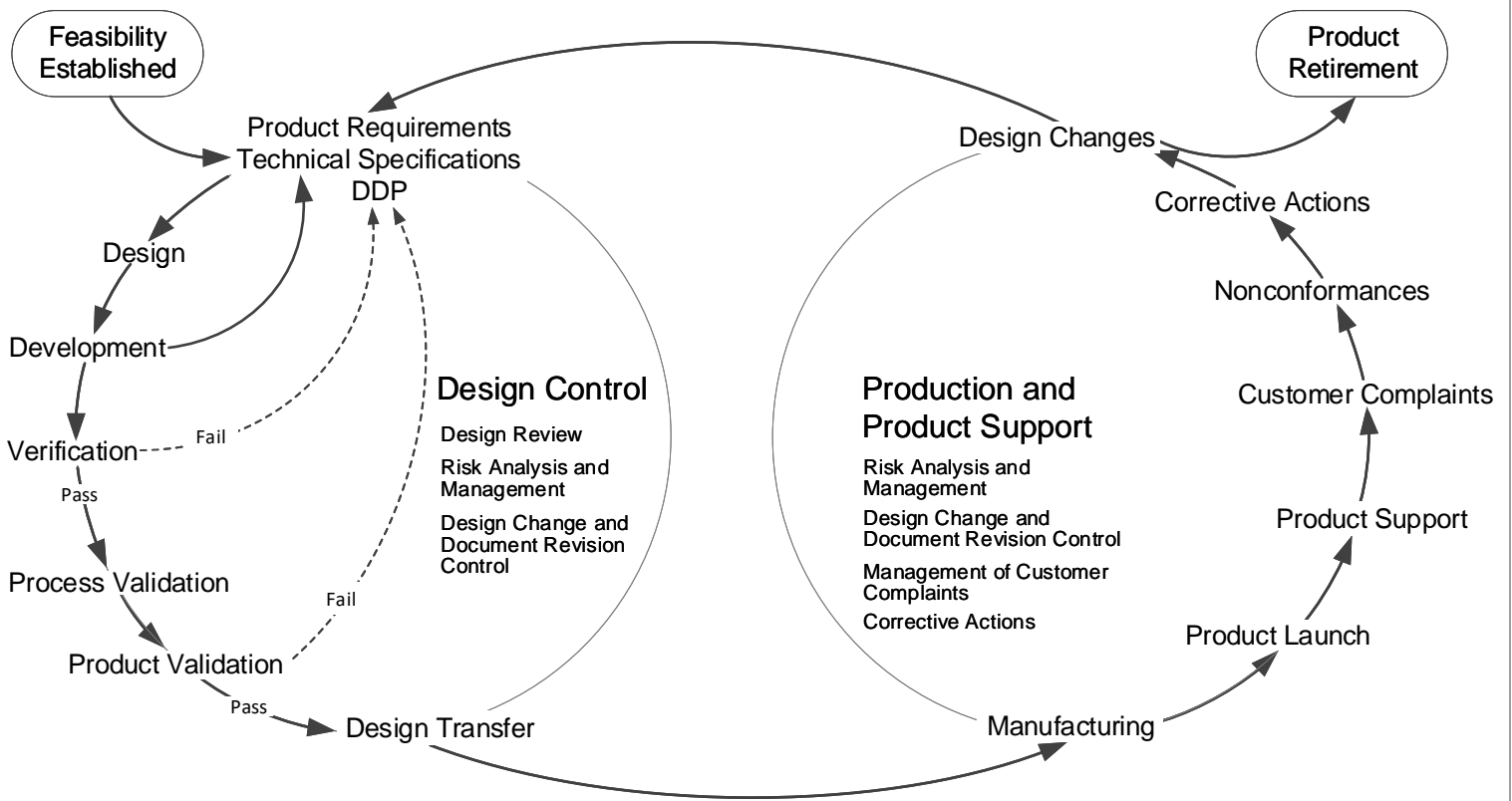


Purpose: This document presents two overview illustrations of design control requirements. Design controls are the regulated activities used to ensure that the design input requirements are adequately defined, and the design output documentation provides objective evidence that the design input requirements were correctly translated to a labeled product that fulfills user needs and intended uses.

The first page's illustration is that of a product's lifecycle from feasibility to retirement. The second page's illustration depicts how the design controls interact and overlap each other. It also provides an index to the relevant QMS-SOPs.

**Product Life Cycle
From Feasibility to Retirement**

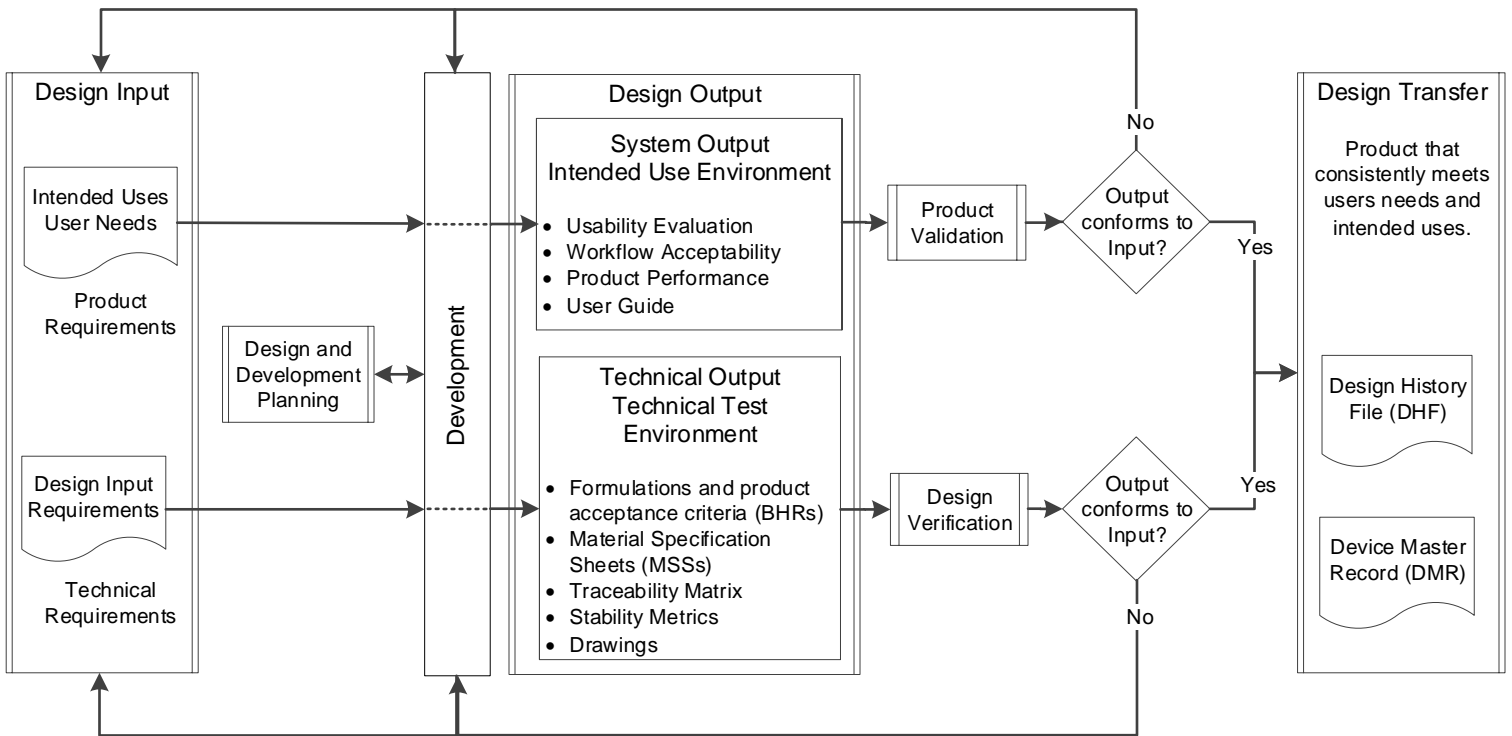


Overview of Design Controls: The design inputs are the user needs, intended uses, and the technical characteristics required to realize the user needs and intended uses. After successful verification and validation that the design outputs meet the design inputs, product transfer to production can proceed. Design output is the product itself, the labeling, and the specifications and procedures required to make and QC the product. The Project Team is responsible for the application of the design controls.

The set of specifications and procedures required to make and QC the product is the device master record (DMR). The set of records that provide evidence that the design and development activities were conducted as required is the design history file (DHF).

Perform Risk Management - Human Safety

Apply Design Change and Document Revision Control



Conduct Design Reviews

Establish Design History File (DHF)

Develop Design Master Record (DMR)