

# How to Optimize Effective Design Control in Medical Device Manufacturing

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Blog

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Design control is not a new concept, or even a new requirement, but a longstanding tradition in medical device manufacturing. Since 1990, the FDA has demanded medical device manufacturers comply with the criteria outlined in [21 CFR 820.30](#). These requirements aim to ensure medical devices marketed in the U.S. meet applicable standards and address the needs of patients and other users.

## Reviewing The Regulatory Landscape

The FDA is not the only regulatory authority requesting compliance. The [EU MDR's Second Annex](#) (plus that of the IVDR) also require medical device manufacturers to establish and maintain design control procedures. Companies must provide evidence the procedures are followed in the form of complete, up-to-date design and manufacturing information. The documentation must be thorough and enable a clear understanding of the various design stages applied to each device. The international standard ISO 13485 also covers design and development at section 7.3.

## SmartSolve's Design Control Module

Enter SmartSolve's design control solution, which enables manufacturers to manage the process for all design phases. From design planning to recording inputs and outputs, through verification and validation, to transferring the design to manufacturing, the solution delivers task management functions that accommodate and promote cross-departmental collaboration. This enables subject experts to record all design evidence and comments.

## Consistent Results with Policy-Driven Processes

As with other SmartSolve modules, the design control process is policy-driven and based on setup, enabling it to deliver consistent system results. The module offers a gated workflow process, by default, ensuring each design phase is approved before the next begins. However, the workflow provides a project owner flexibility to override and initiate parallel phases as needed. Automated and ad-hoc Design Reviews are an integral step in the workflow. These are initiated as each phase's requirements are complete.

## Superior Design Control Functionality

SmartSolve's Design Control module enables manufacturers to optimize operations with multiple useful functions. These include providing quick design evidence and comments.

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SmartSolve's Design Control module enables manufacturers to optimize operations with multiple useful functions. These include providing quick access to the design history as well as dashboards and global search

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