

DATASHEET

# Design Control

AssurX Design Control solution ensures medical devices that are designed and manufactured meet specified compliance requirements and that necessary design control phases are addressed according to the intended use and purpose.

**AssurX Design Control software is a product lifecycle management solution. The capabilities allow users to:**

- Perform comprehensive risk analysis activities, including risk prioritization and mitigation, facilitating efficient and proactive management of design processes
- Track tasks and streamline project management
- Simplify your design process -- centralize planning, inputs, outputs, reviews, verification, validation, transfer, and changes in one location for easy viewing and seamless management'

Phase	Sample Documents and Records
Design and Development Planning	Includes phase flow diagrams or Gantt charts
Design Input	Proper functioning of the device including software functional specifications, intended use information, performance characteristics, and environmental limitations.
Design Output	Includes device, its packaging and labeling, and the Device Master Record. Also, device assembly drawings, quality assurance specifications, and manufacturing procedures.
Design Review	Confirms the design is ready to progress to the next phase of development.
Design Verification (Confirmation to specifications)	Confirms the design outputs meet the design input requirements. Includes performance tests, bioburden tests, visual inspection, laboratory tests, and safety tests.
Design Validation (Confirmation of User needs and intended uses)	Establishes that device specifications conform with user needs and intended use. Includes simulated use testing, clinical/non-clinical evaluations, and historical evidence and performance.
Design Transfer	Knowledge transfer related to assembly drawings, test/inspection specifications, training materials, and manufacturing specifications and procedures.
Design Changes	Includes changes of approved design inputs, approved design outputs, device, and packaging & labeling.