

Design control and risk management processes

Automates design control documentation, risk assessment workflows, and regulatory compliance tracking throughout medical device development. Ensures systematic risk management integration with design controls while maintaining audit trails and regulatory submission readiness.

Download PDF

Get Your Blueprint



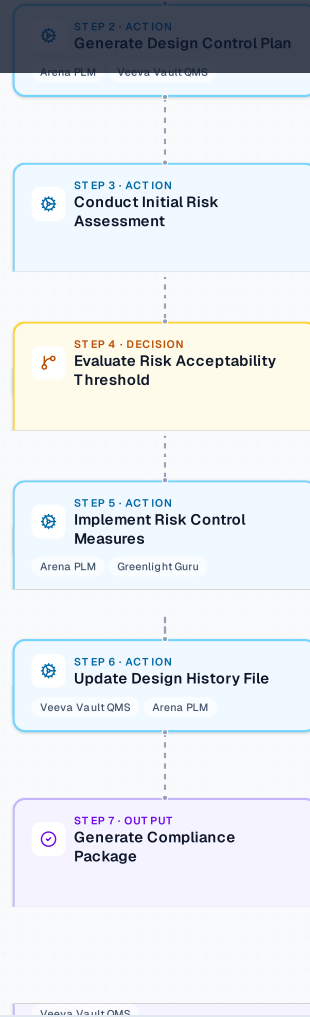
WORKFLOW TRIGGER

New medical device design project initiated in PLM system

Visual Flow

Each node represents an automated step. Connections show how data and decisions move through the workflow.





Step-by-Step Breakdown

Detailed explanation of each automated stage in the workflow.

1

⚡ TRIGGER

Detect New Design Project

Monitors Arena PLM for new medical device projects and automatically extracts project specifications, intended use, and device classification.

Initiates the design control workflow based on project parameters.

AI Business OS

Arena PLM

2

 ACTION

Generate Design Control Plan

Creates standardized design control documentation including design inputs, outputs, verification protocols, and validation requirements. Automatically populates templates based on device type and risk classification.

Arena PLM

Veeva Vault QMS

3

 ACTION

Conduct Initial Risk Assessment

Performs automated risk analysis using device specifications and historical data to identify potential hazards. Generates preliminary risk management file with hazard identification and risk estimation matrices.

Greenlight Guru

Veeva Vault QMS

4

 DECISION

Evaluate Risk Acceptability Threshold

Analyzes calculated risk levels against predefined acceptability criteria and regulatory thresholds. Routes high-risk items for additional controls or design modifications.

Greenlight Guru

5

 ACTION

Implement Risk Control Measures

AI Business OS

Automatically assigns risk mitigation tasks to design teams and updates design specifications with required safety controls. Tracks implementation status and residual risk calculations.

Arena PLM

Greenlight Guru

Sparta Systems TrackWise

6

 ACTION

Update Design History File

Consolidates all design control documents, risk management records, and verification/validation evidence into the master design history file. Ensures traceability and regulatory compliance documentation.

Veeva Vault QMS

Arena PLM

7

 OUTPUT

Generate Compliance Package

Produces complete regulatory submission package including design controls documentation, risk management file, and compliance matrices. Creates audit-ready documentation with electronic signatures and version control.

Veeva Vault QMS



Outputs

AI Business OS

- Complete Design History File
- Risk Management File
- Regulatory Submission Package



Key Metrics

- Design Control Cycle Time
- Risk Assessment Completion Rate
- Regulatory Submission Readiness Score



Tools & Integrations

- Arena PLM
- Veeva Vault QMS
- Greenlight Guru
- Sparta Systems TrackWise

AI Business OS

Actionable AI implementation strategies for business leaders ready to transform their operations.

COMPANY

[About](#)

[Industries](#)

CONNECT

[MVP.dev](#)

[LinkedIn](#)

RESOURCES

[Articles](#)