← Back to Medical Devices

MEDICAL DEVICES · WORKFLOW

Product lifecycle management and change control

This workflow automates the end-to-end product lifecycle management and change control process for medical devices, ensuring regulatory compliance and quality standards while accelerating product development timelines.

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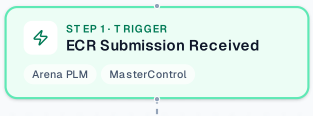
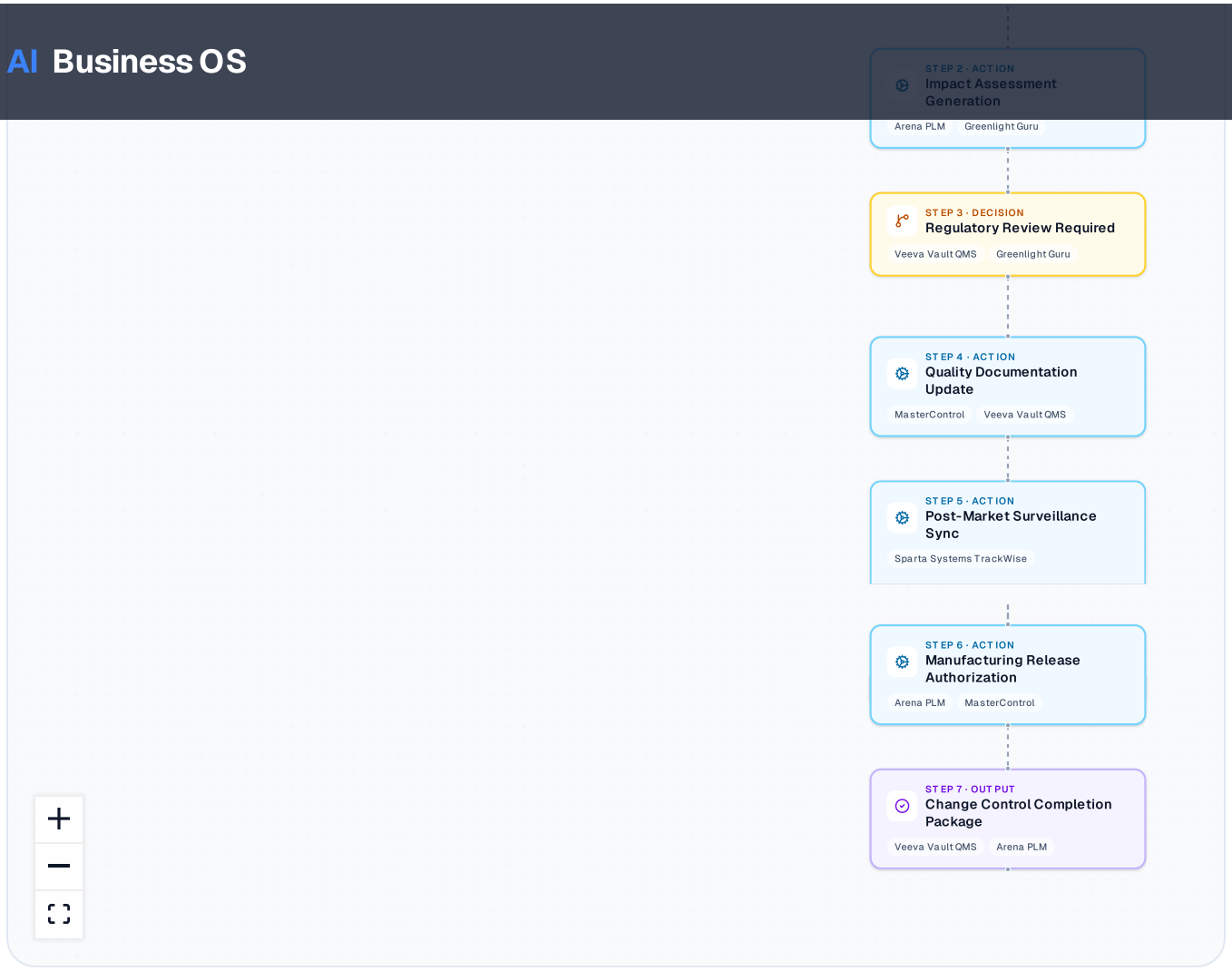
WORKFLOW TRIGGER

Engineering change request (ECR) is submitted for an existing medical device product

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

ECR Submission Received

An engineering change request is automatically captured and validated for completeness. Initial routing to appropriate stakeholders begins based on

device classification and change scope.

Arena PLM MasterControl

2

ACTION

Impact Assessment Generation

Automated analysis evaluates the change impact across regulatory, quality, manufacturing, and clinical domains. Risk scoring algorithms determine required approval levels and documentation needs.

Arena PLM Greenlight Guru

3

DECISION

Regulatory Review Required

Decision point determines if the change requires FDA submission, CE marking updates, or other regulatory notifications based on predefined classification rules.

Veeva Vault QMS Greenlight Guru

4

ACTION

Quality Documentation Update

Automatically updates Design History Files, Device Master Records, and quality procedures. Version control ensures all stakeholders access current documentation.

MasterControl Veeva Vault QMS

5

ACTION

Post-Market Surveillance Sync

Updates post-market surveillance protocols and complaint handling procedures to reflect product changes. Historical performance data is analyzed for trending.

Sparta Systems TrackWise | Medidata Clinical Cloud

6

ACTION

Manufacturing Release Authorization

Generates updated manufacturing instructions, validates supplier requirements, and releases approved changes to production systems with full traceability.

Arena PLM | MasterControl

7

OUTPUT

Change Control Completion Package

Delivers comprehensive change documentation package including regulatory submissions, updated quality records, and manufacturing authorization with full audit trail.

Veeva Vault QMS | Arena PLM

Outputs

- Updated Device Master Record with version control

- Regulatory submission package (510k/CE marking)
- Manufacturing change authorization with traceability
- Post-market surveillance protocol updates

Key Metrics

- Change control cycle time
- Regulatory submission accuracy rate
- Manufacturing deviation incidents post-change

Tools & Integrations

- Arena PLM
- MasterControl
- Veeva Vault QMS
- Greenlight Guru
- Sparta Systems TrackWise
- Medidata Clinical Cloud

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