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MEDICAL DEVICES · WORKFLOW

# Quality management system documentation

Automates the creation, review, approval, and distribution of quality management system documentation across medical device development lifecycle. Ensures regulatory compliance and maintains centralized document control with real-time stakeholder notifications.

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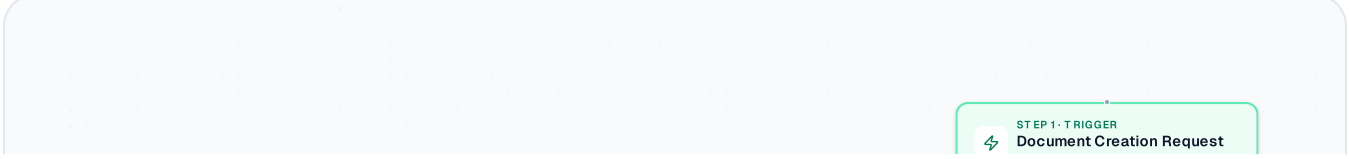
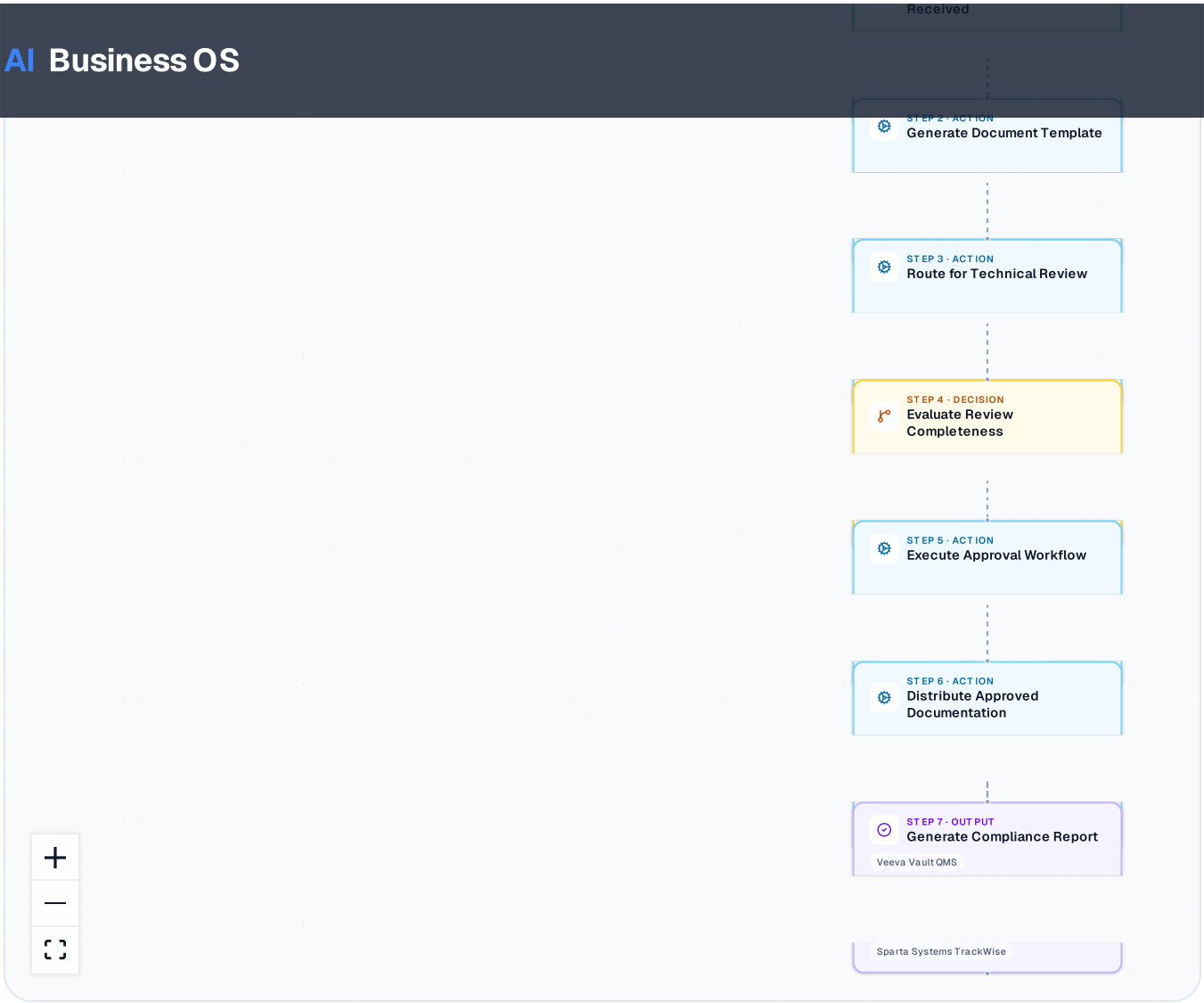
WORKFLOW TRIGGER

New product development milestone is reached or existing QMS document requires revision

## 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

## Document Creation Request Received

System detects new document requirement from Arena PLM milestone or receives manual revision request. Automatically extracts product specifications and regulatory requirements.

Arena PLM

2

ACTION

## Generate Document Template

Creates appropriate QMS document template based on device classification and regulatory pathway. Populates standard fields with product data from PLM system.

Arena PLM | Veeva Vault QMS

3

ACTION

## Route for Technical Review

Assigns document to appropriate subject matter experts based on device type and regulatory requirements. Sends automated notifications with review deadlines.

Veeva Vault QMS | MasterControl

4

DECISION

## Evaluate Review Completeness

Checks if all required reviewers have completed their assessments and resolved comments. Routes back for additional review if deficiencies found or proceeds to approval workflow.

Veeva Vault QMS

5

ACTION

### Execute Approval Workflow

Routes document through quality assurance and regulatory approval chain based on document risk classification. Tracks approval status and escalates overdue items.

Veeva Vault QMS | MasterControl

6

ACTION

### Distribute Approved Documentation

Automatically publishes approved documents to appropriate stakeholders and training systems. Updates document control registers and version histories.

Veeva Vault QMS | Sparta Systems TrackWise

7

OUTPUT

### Generate Compliance Report

Creates summary report of document approval status, training assignments, and regulatory compliance metrics. Archives all workflow activities for audit trail.

Veeva Vault QMS | Sparta Systems TrackWise

## Outputs

- Approved QMS documents
- Document control registers
- Compliance audit trail
- Training assignment notifications

## Key Metrics

- Document approval cycle time
- Review completion rate
- Regulatory compliance score
- Document revision frequency

## Tools & Integrations

- Arena PLM
- Veeva Vault QMS
- MasterControl
- Sparta Systems TrackWise

AI Business OS