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Quality control and batch testing

Automates pharmaceutical quality control testing and batch release processes by collecting test data, analyzing results against specifications, and generating compliance documentation for regulatory approval.

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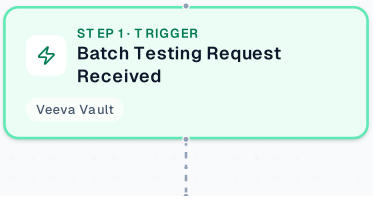
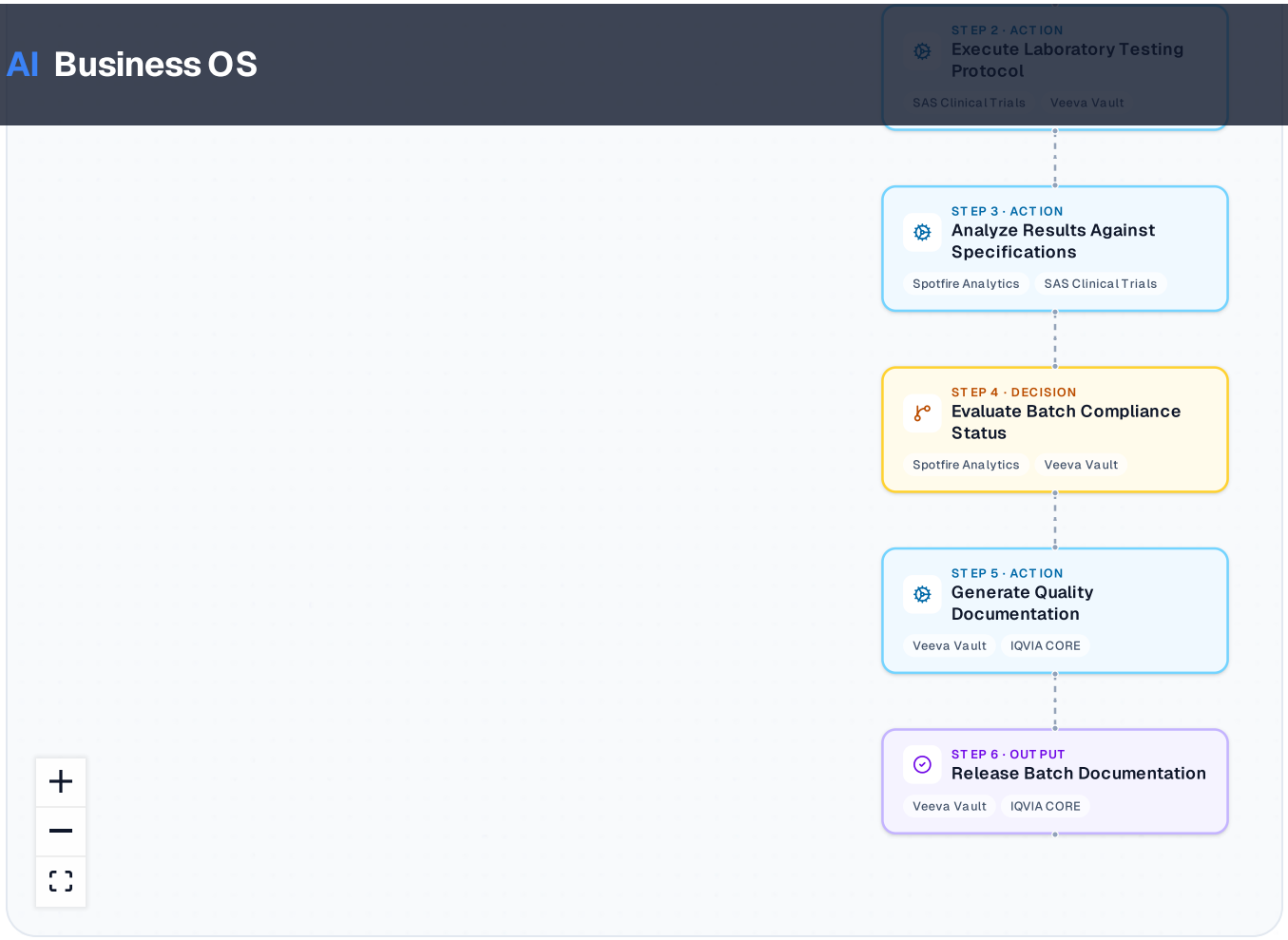
WORKFLOW TRIGGER

Manufacturing batch completes production and enters quality control testing phase

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

Batch Testing Request Received

Manufacturing system triggers quality control workflow when a new pharmaceutical batch is ready for testing. Batch metadata including lot number, product specifications, and testing requirements are captured.

2

ACTION

Execute Laboratory Testing Protocol

Automated laboratory instruments perform required tests including potency, purity, dissolution, and microbial testing according to predefined protocols. Test results are collected and standardized.

SAS Clinical Trials | Veeva Vault

3

ACTION

Analyze Results Against Specifications

Statistical analysis engine compares all test results against approved product specifications and regulatory requirements. Generates detailed analytical reports with trend analysis.

Spotfire Analytics | SAS Clinical Trials

4

DECISION

Evaluate Batch Compliance Status

Decision engine determines if batch meets all quality specifications and regulatory requirements. Routes to approval or investigation pathway based on results.

Spotfire Analytics | Veeva Vault

5

ACTION

Generate Quality Documentation

Automatically creates batch release documentation including Certificate of Analysis, quality summary reports, and regulatory filing documents. Digital signatures are applied per compliance requirements.

Veeva Vault IQVIA CORE

6

OUT PUT

Release Batch Documentation

Final quality documentation is distributed to manufacturing, supply chain, and regulatory teams. Batch status is updated in enterprise systems for release or hold.

Veeva Vault IQVIA CORE

Outputs

- Certificate of Analysis
- Batch release authorization
- Quality trend reports

Key Metrics

- Batch release cycle time

- First-pass quality rate
- Testing accuracy percentage

Tools & Integrations

- Veeva Vault
- SAS Clinical Trials
- Spotfire Analytics
- IQVIA CORE

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