

# Manufacturing quality control and batch records

Automates manufacturing quality control processes by monitoring batch production data, validating compliance against specifications, and generating complete batch records for regulatory submission. Ensures consistent product quality while reducing manual documentation errors and accelerating batch release cycles.

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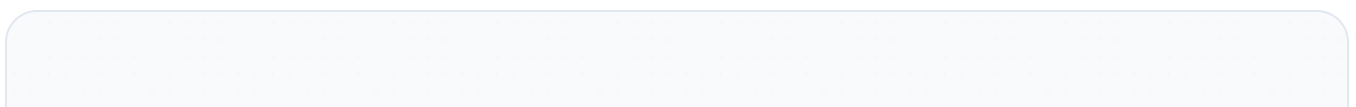
## WORKFLOW TRIGGER

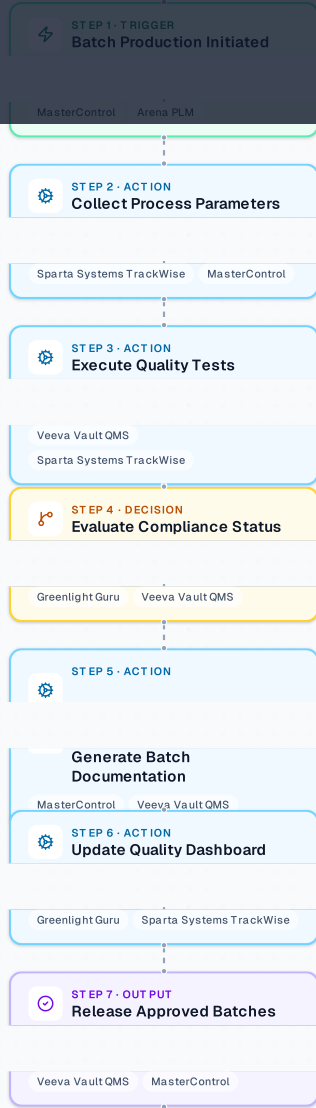


Manufacturing batch production is initiated and batch ID is generated in the production system.

## 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

Batch Production Initiated

Manufacturing execution system generates new batch ID and begins production tracking. Real-time data collection starts for all critical process parameters.

MasterControl

Arena PLM

2

 ACTION

## Collect Process Parameters

Automated sensors and production equipment continuously capture critical quality attributes including temperature, pressure, timing, and material specifications. Data is validated against predetermined control limits.

Sparta Systems TrackWise

MasterControl

3

 ACTION

## Execute Quality Tests

Initiates automated quality control testing protocols based on device specifications. Laboratory equipment performs dimensional, functional, and safety tests according to validated procedures.

Veeva Vault QMS

Sparta Systems TrackWise

4

 DECISION

## Evaluate Compliance Status

AI system analyzes all collected data against FDA specifications and internal quality standards. Determines if batch meets acceptance criteria or requires investigation.

Greenlight Guru

Veeva Vault QMS

5

### Generate Batch Documentation

Automatically compiles comprehensive batch records including all test results, process parameters, operator signatures, and deviation reports. Documents are formatted for regulatory submission.

MasterControl

Veeva Vault QMS

6

 ACTION

### Update Quality Dashboard

Real-time quality metrics and batch status are pushed to centralized quality management dashboard. Stakeholders receive automated notifications of batch completion and compliance status.

Greenlight Guru

Sparta Systems TrackWise

7

 OUTPUT

### Release Approved Batches

Compliant batches receive automated approval and release authorization. Complete batch records are archived in validated document management system for regulatory access.

Veeva Vault QMS

MasterControl



## Outputs

- FDA-compliant batch records
- Quality control test certificates
- Batch release authorizations



## Key Metrics

- Batch cycle time reduction
- First-pass quality rate
- Documentation accuracy percentage



## Tools & Integrations

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

## AI Business OS

## AI Business OS

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

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