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Post-market surveillance and adverse event reporting

Automates the collection, analysis, and reporting of adverse events from medical devices to regulatory authorities while updating quality management systems. Ensures compliance with FDA and international reporting requirements within mandated timeframes.

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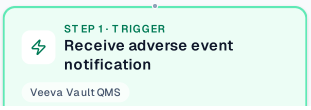
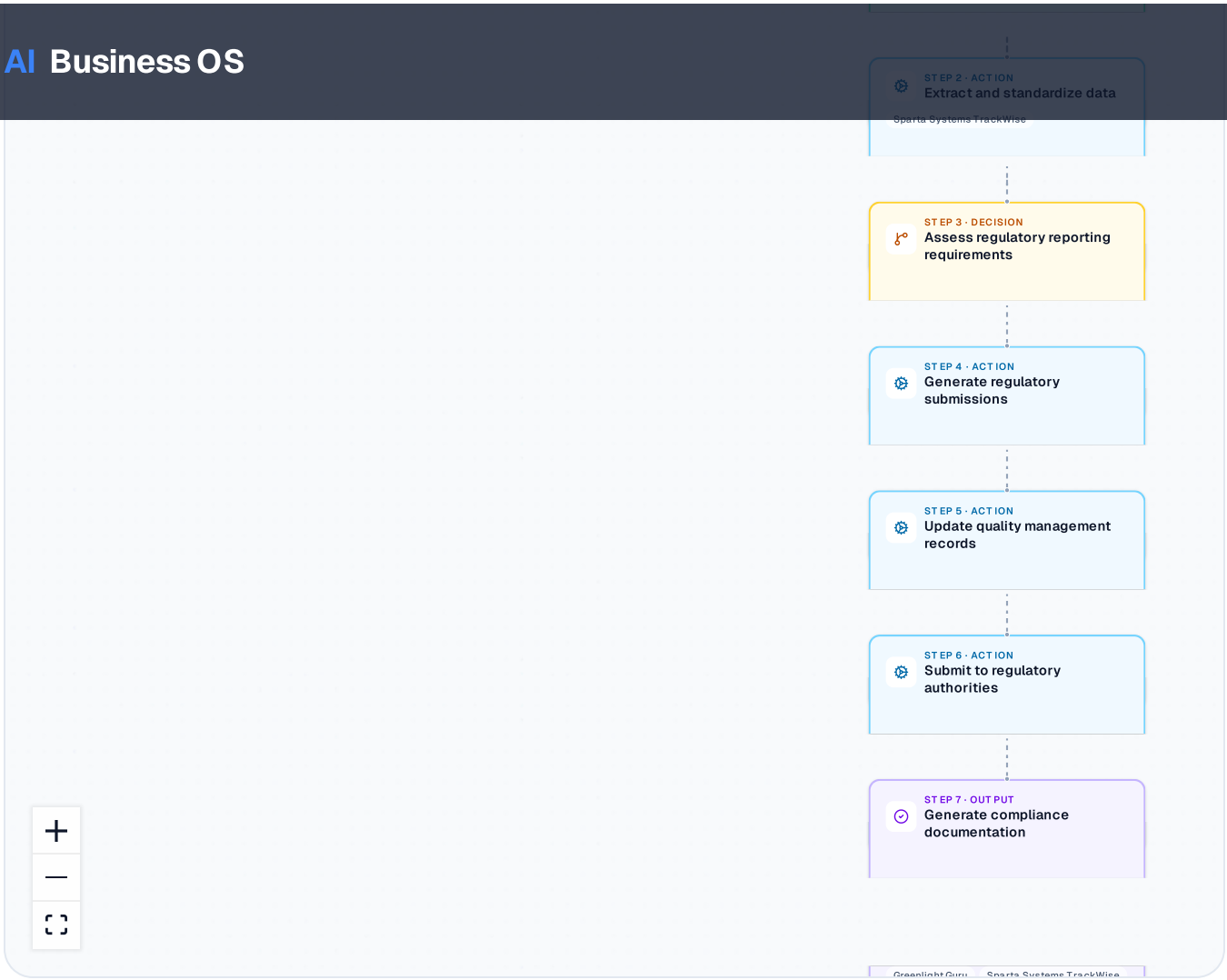
WORKFLOW TRIGGER

Adverse event report received from healthcare provider, patient, or internal source

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

Receive adverse event notification

System captures adverse event data from multiple sources including customer complaints, clinical reports, or regulatory submissions. Initial

data validation and case creation occurs automatically.

Veeva Vault QMS | Sparta Systems TrackWise

2

ACTION

Extract and standardize data

AI processes unstructured adverse event information and maps it to MedDRA coding standards. Missing required fields are flagged for manual completion.

Sparta Systems TrackWise | Veeva Vault QMS

3

DECISION

Assess regulatory reporting requirements

System evaluates event severity, device classification, and jurisdiction to determine if FDA MDR, EU EUDAMED, or other regulatory reporting is required. Timeline and priority levels are automatically assigned.

Veeva Vault QMS | Greenlight Guru

4

ACTION

Generate regulatory submissions

Automated creation of FDA Form 3500A, EUDAMED reports, or other jurisdiction-specific submissions. Documents are populated with standardized adverse event data and device information.

Veeva Vault QMS | MasterControl

5

ACTION

Update quality management records

Case information flows into CAPA systems and risk management databases. Trending analysis is performed to identify potential systematic issues requiring corrective action.

Sparta Systems TrackWise | Greenlight Guru

6

ACTION

Submit to regulatory authorities

Completed reports are electronically transmitted to FDA, notified bodies, and international regulators within required timeframes. Submission confirmations are tracked and stored.

Veeva Vault QMS | MasterControl

7

OUTPUT

Generate compliance documentation

System produces audit trails, submission receipts, and management dashboards showing adverse event trends and regulatory compliance status. Stakeholders receive automated notifications of completed submissions.

Greenlight Guru | Sparta Systems TrackWise

Outputs

- FDA MDR and international regulatory submissions
- Updated CAPA and risk management records
- Adverse event trending and compliance dashboard

Key Metrics

- Regulatory submission timeliness (% within required deadlines)
- Adverse event case processing time
- Post-market surveillance compliance rate

Tools & Integrations

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

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