QMS wrapper™

CAPTURE EVENT

Automate Data Flow Between Forms and Processes for Greater Efficiency

2025

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1. Introduction to Capture Event

Capture Event is a powerful feature within qmsWrapper that enables seamless tracking and management of key quality events. This functionality allows users to document and manage various events using predefined forms that trigger corresponding processes, risk assessments, or additional forms automatically. By reducing repetitive data entry, Capture Event enhances efficiency and ensures compliance with quality management standards.

1.1 What is a Event Form?

Event or **qmsEvent** Form is a structured form within qmsWrapper that captures and categorizes essential quality events. It serves as the starting point for various quality-related actions, ensuring that data flows efficiently between different processes without manual duplication.

1.2 Types of Event Forms

qmsWrapper includes predefined forms for the most common quality events:

- **Change Form:** Logs modifications that impact quality processes
- **Nonconformity Form:** Records deviations from quality requirements
- **Deviation Form:** Captures deviations from established expected behavior.
- **Feedback Form:** Collects user input for continuous improvement

1.3 Key Benefits of Capture Event

- **Eliminates redundant data entry** by automatically transferring information between forms and processes
- **Ensures compliance** with quality management standards
- **Reduces manual errors** through predefined structured forms
- **Enhances traceability** by linking related events seamlessly

2. How it works?

All mandatory forms and processes related to these events will be **automatically approved and activated** within qmsWrapper.

These predefined forms and processes will be used for managing events.

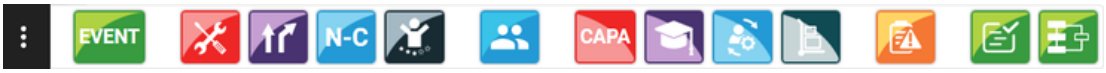
- List of mandatory forms
  - **Event Form**
  - **Change Form**
  - **Deviation Form**
  - **Feedback Form**
  - **Nonconformity Form**
  - **Supplier or Manufacturer Evaluation Form**
  - **Training Form**
  - **Training analysis Form**

- List of related processes
  - **Change significance**
  - **Deviation significance**
  - **Feedback significance**
  - **P-850 13485-2016 CAPA-1**
  - **Document Change Request process**
  - **P-739 Change Request Process**
  - **P-823 13485-2016 Adverse Event Classification**
  - **P-740 Supplier Evaluation**

Reminder: The expiry date for all processes and forms is 1 year; after this period, they must be re-approved in order to continue working with events.

In the **Risk module**, a **Risk Matrix** called "**Hazard Log**" will be created, where all necessary risks triggered by events will be automatically initiated and tracked.

Start form by clicking 3 dots and choosing the Event button.



Based on the selected event type, the system automatically triggers the next steps. This may include initiating a new form, updating an existing Risk Matrix, or launching a corrective action process. This automation eliminates redundancy and ensures a streamlined quality management workflow.

3. Detailed Overview of Predefined Forms

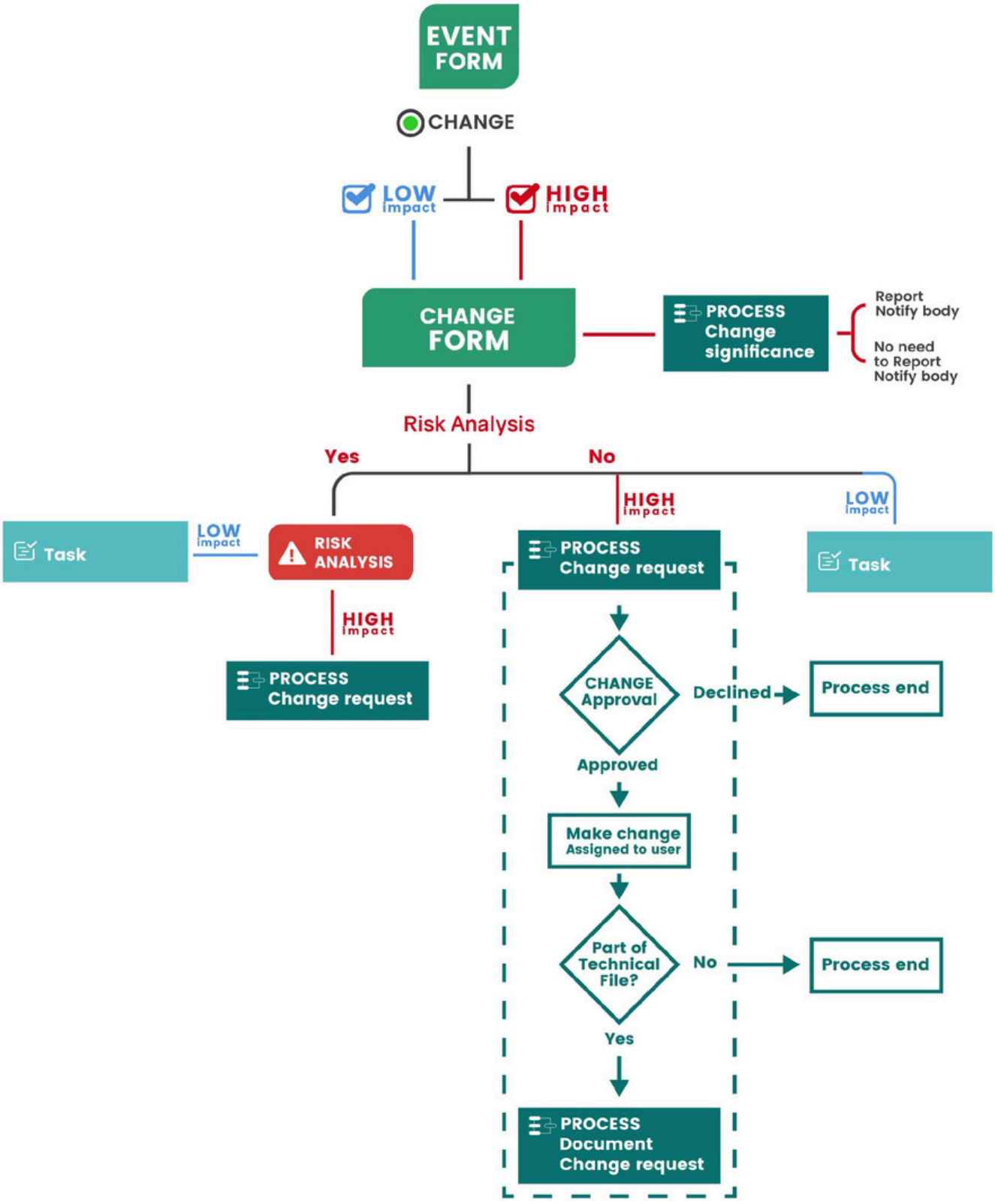
Start Event form by clicking 3 dot button, and choosing Event form button. Fill up required filleds:

- Reference name (recommended to change)
- Event details
- Origin (not required)
- Type of Event
- Impact Level (shows when you choose the Type of event)
- Project

Depending on the selected Event Type, additional fields may appear for completion.

The next steps in the process will vary depending on the type of Event you choose.

3.1 Change Event Form



The behavior of the workflow depends on whether the Change is marked as High Impact or Low Impact in the Event Form.

High Impact Change

- When a **Change is classified as High Impact**, two processes are automatically triggered:
  a. **Change Significance process**
  b. **Change Request process**
- If a **Risk analysis** is required, it will be initiated before the Change Request process begins.

Low Impact Change

- When a **Change is classified as Low Impact**, a **single task** is created and assigned to the person who initiated the form.
- If a Risk analysis is required, it will be initiated before this task is created.

Workflow Start

After filling out the Event Form with **Change + High Impact,** the system automatically triggers the **Change Form**.

Change Form

- **Assigned to:** The user who started the Event
- **QMS Type:** Change
- **Action:** Open the task and complete the required fields.

After completing the **Change Form**, the **Change Significance process** is automatically triggered, as it is a **High Impact** event:

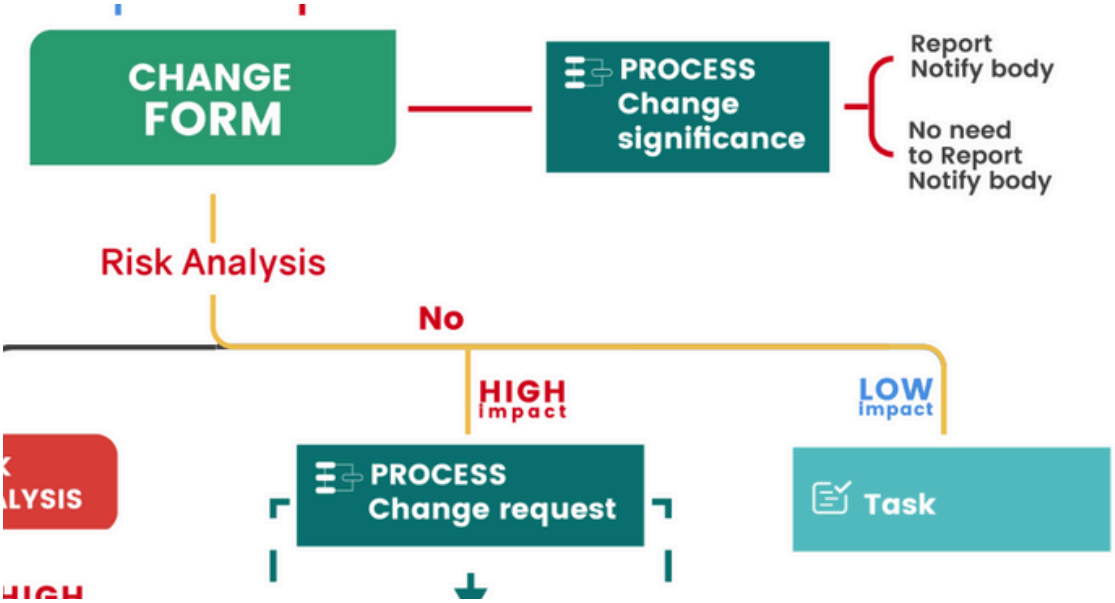
Change Significance Process

- **Assigned to:** QMS Manager
- **QMS Type:** Change
- **Action:** Complete all steps of the process.

Based on the data entered in the **Change Form**, there are two possible next steps:

1. If Risk Analysis is Not required

In cases where **risk analysis is not required** in the Change form, the system will **trigger a process for High Impact** Changes or a **task for Low Impact** Changes.



P-739 Change Request Process

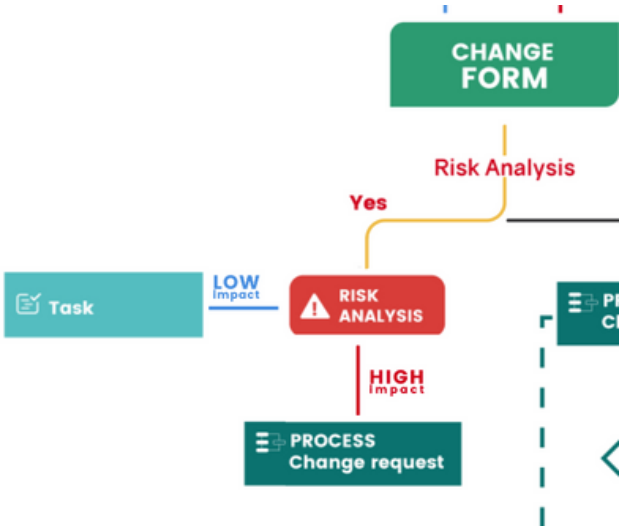
- **Assigned to:** QMS Manager
- **QMS Type:** Change
- **Action:** Complete all steps of the process.

Task

- **Assigned to:** The user who started the Event.
- **QMS Type:** Not QMS-related.
- **Action:** Open the task and complete the required fields.

2. If Risk Analysis is required

If a **risk analysis is required**, it is performed first, **followed by** the automatic triggering of either a **process or a task**, depending on whether the Change is marked as High or Low Impact.



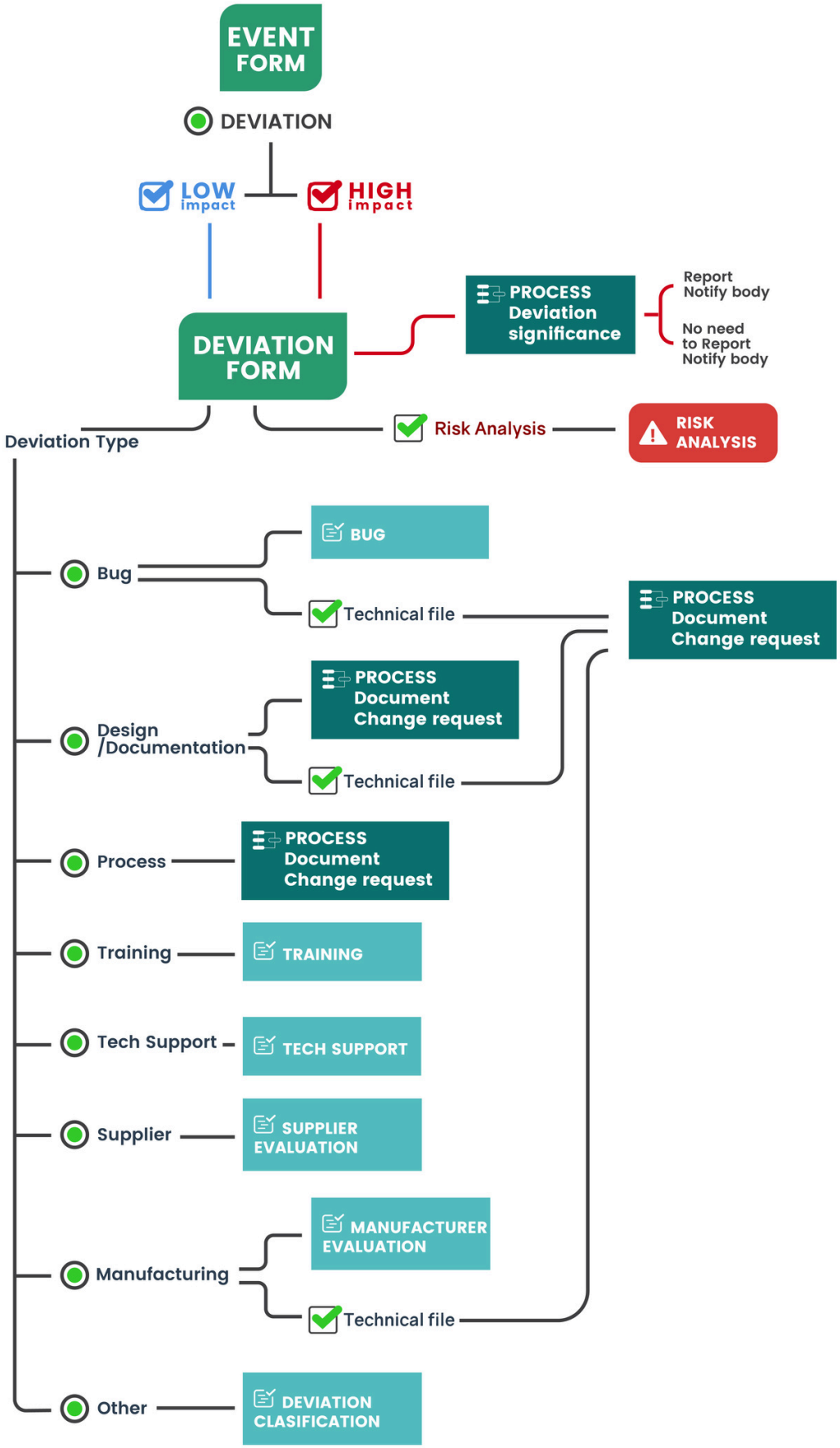
A Risk will be automatically created (+ Risk Task)

- **Assigned to:** QMS Manager.
- **Action:** Complete the risk and close the task.

Important Notes

- Some data from the **Change Form** will be included in the Risk Analysis.
- The **Change Form** will be attached to all processes within this workflow.

3.2 Deviation Event Form



The **Low Impact** and **High Impact** flows differ in only one process: the **Deviation Significance** process, which is triggered when you select **Deviation + High Impact** in the Event Form.

All other steps remain the same, so we will explain the Deviation event example with **High Impact**.

Workflow Start

After filling out the Event Form with **Deviation + High Impact**, the system automatically triggers the **Deviation Form.**

Deviation Form

- **Assigned to:** The user who started the Event
- **QMS Type:** Deviation
- **Action:** Open the task and complete the required fields.

After completing the **Deviation Form**, the **Deviation Significance process** is automatically triggered, as it is a **High Impact** event:

Deviation Significance Process

- **Assigned to:** QMS Manager
- **QMS Type:** Deviation
- **Action:** Complete all steps of the process.

The **Deviation Form** contains fields that will trigger various actions based on your input:

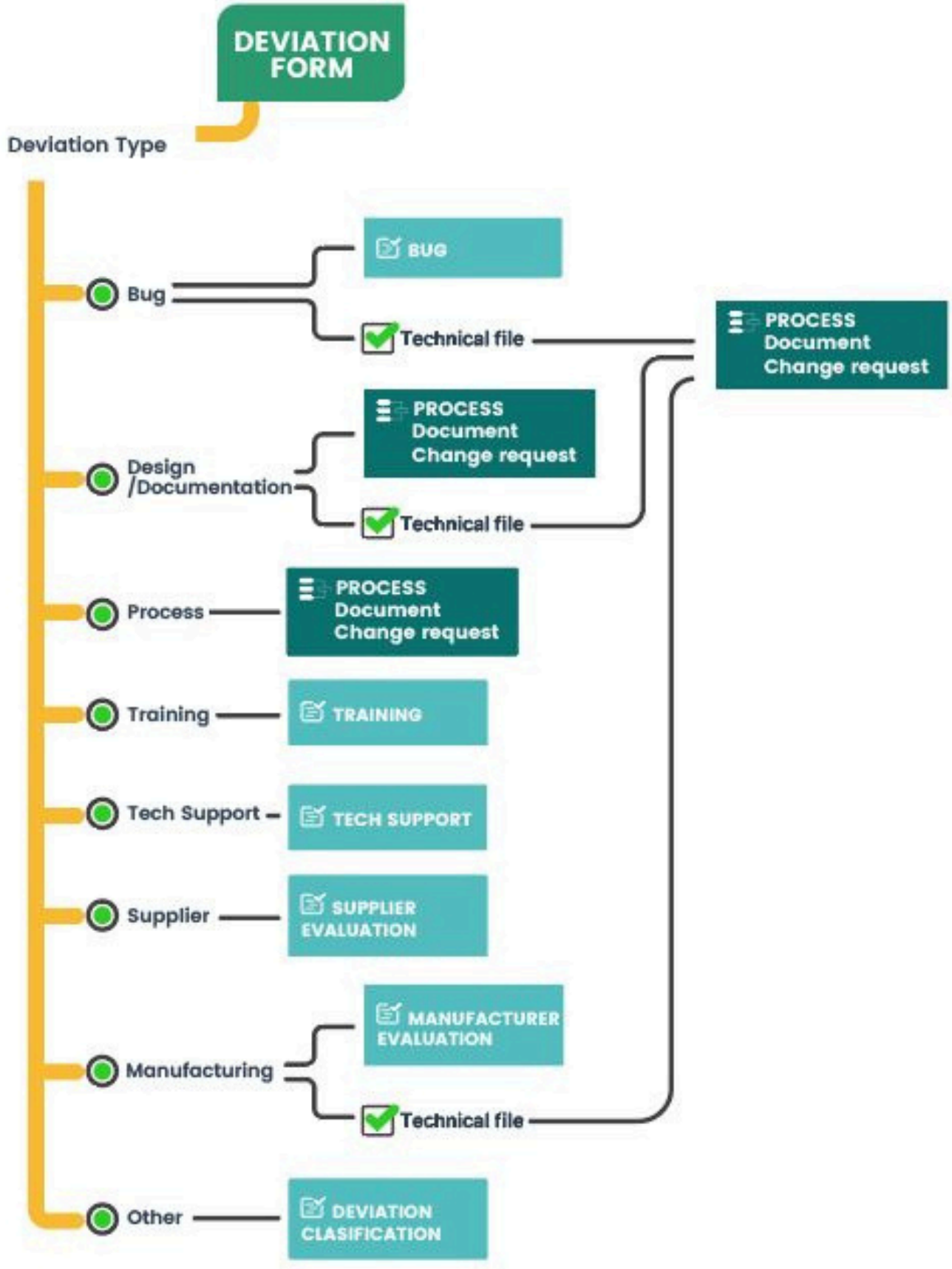
1. If Risk Analysis is required

A Risk will be automatically created

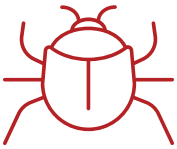
- **Assigned to:** QMS Manager.
- **Action:** Complete the risk and close the task.

2. Next Steps Based on Deviation Type

Depending on the selected **Deviation Type**, the system will generate the corresponding action item:



a) Bug



Bug task

- **Assigned to:** The user who initiated the Event
- **QMS Type:** Not QMS-related by default.
- **Action:** Open the Bug and complete the necessary fields.

b) Design or Documentation

Document Change Request process

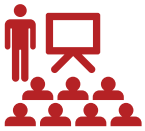
- **Assigned to:** QMS Manager.
- **QMS Type:** Change Management.
- **Action:** Complete all steps of the process.

c) Process

Document Change Request process

- **Assigned to:** QMS Manager.
- **QMS Type:** Change Management.
- **Action:** Complete all steps of the process.

d) Training



Training form

- **Assigned to:** The user who initiated the Event.
- **QMS Type:** Training.
- **Action:** Open the Form and complete the necessary fields.

Training analysis form

- **Assigned to:** The user who started the Event
- **QMS Type:** Training.
- **Action:** Open the Form and complete the necessary fields.

e) Tech Support

Task

- **Assigned to:** Customer Service
- **QMS Type:** Not QMS-related.
- **Action:** Open the Bug and complete the necessary fields.

f) Supplier

Supplier or Manufacturer Evaluation Form

- **Assigned to:** The user who initiated the Event.
- **QMS Type:** Supplier.
- **Action:** Open the form and complete the necessary fields.

g) Manufacturing

Supplier or Manufacturer Evaluation Form

- **Assigned to:** The user who initiated the Event.
- **QMS Type:** Supplier.
- **Action:** Open the form and complete the necessary fields.

h) Other

Task

- **Assigned to:** The user who started the Event.
- **QMS Type:** Not QMS-related.
- **Action:** Open the task and complete the required fields.

By selecting the Deviation type: **Bug**, **Design**, **Documentation**, or **Manufacturing**, an additional option will appear—whether the event is related to the **Technical File**.

If the event is marked as part of the Technical File, the **Document Change Request process** will be triggered automatically.

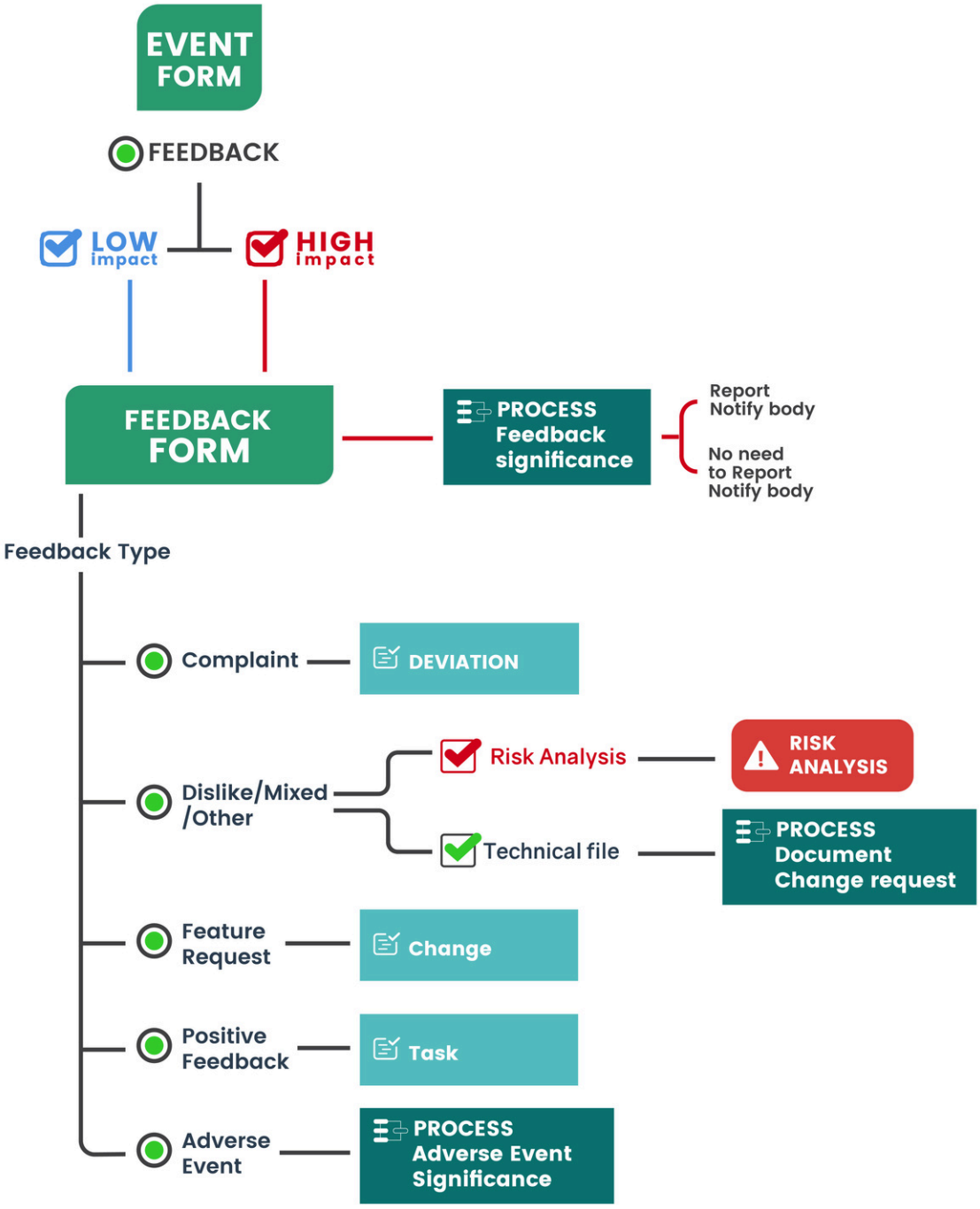
Document Change request process

- **Assigned to: QMS Manager.**
- **QMS Type:** Change Management.
- **Action:** Complete all steps of the process.

Important Notes

- Some data from the **Deviation Form** will be included in the Risk Analysis.
- The **Deviation Form** will be attached to all processes within this workflow.

3.3 Fedback Event Form



The **Low Impact** and **High Impact** flows differ in only one process: the **Feedback Significance** process, which is triggered when you select **Feedback + High Impact** in the Event Form.

All other steps remain the same, so we will explain the Feedback event example with **High Impact**.

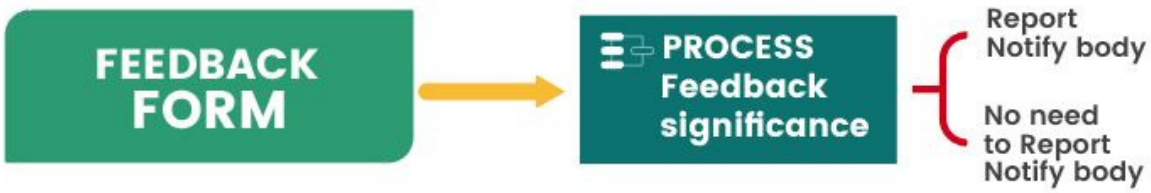
Workflow Start

After filling out the Event Form with **Feedback + High Impact**, the system automatically triggers the **Feedback Form.**

Feedback Form

- **Assigned to:** The user who started the Event
- **QMS Type:** Feedback
- **Action:** Open the task and complete the required fields.

After completing the **Feedback Form**, the **Feedback Significance process** is automatically triggered, as it is a **High Impact** event:

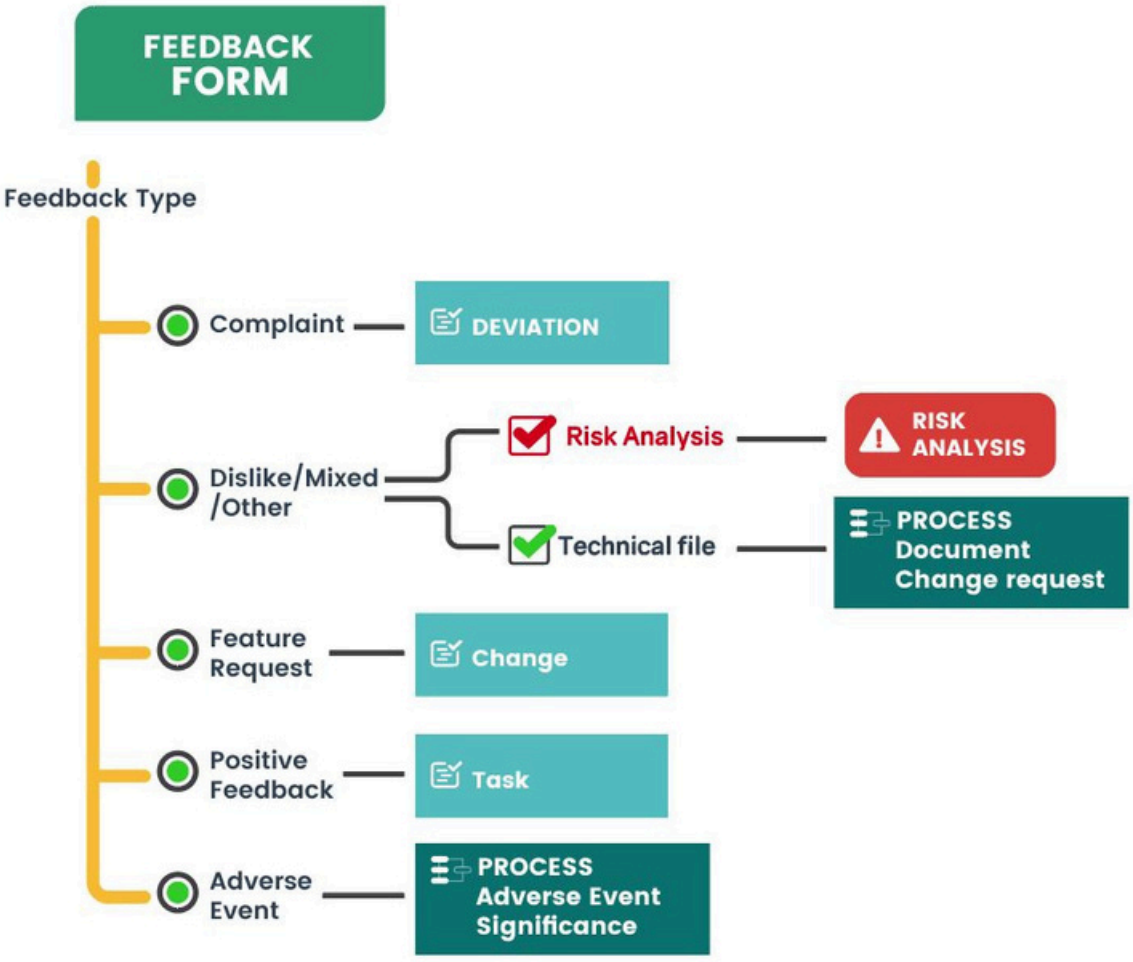


Feedback Significance Process

- **Assigned to:** QMS Manager
- **QMS Type:** Feedback
- **Action:** Complete all steps of the process.

Next Steps Based on Feedback Type

Depending on the selected **Feedback Type** in Feedback Form, the system will generate the corresponding action item:



a) Compliant

Deviation form

- **Assigned to:** QMS Manager
- **QMS Type:** Deviation.
- **Action:** Open the Bug and complete the necessary fields.

b) Feature Request

Change Form

- **Assigned to:** QMS Manager
- **QMS Type:** Change
- **Action:** Open the task and complete the required fields.

c) Positive Feedback

Task

- **Assigned to:** Customer Service
- **QMS Type:** Not QMS-related by default.
- **Action:** Open the task and complete the required fields.

d) Adverse Event

P-823 13485-2016 Adverse Event Classification process

- **Assigned to:** QMS Manager
- **QMS Type:** Feedback
- **Action:** Complete all steps of the process.

e) Dislike, Mixed or Other

By selecting one of the three options—**Dislike**, **Mixed**, or **Other**—two additional options will appear: whether a **Risk Analysis** is required and whether it is part of the **Technical File**.

A Risk will be automatically created

- **Action:** Open the Risk (Feedback Form gets a Risk Relation) and complete all steps.

Document Change request process

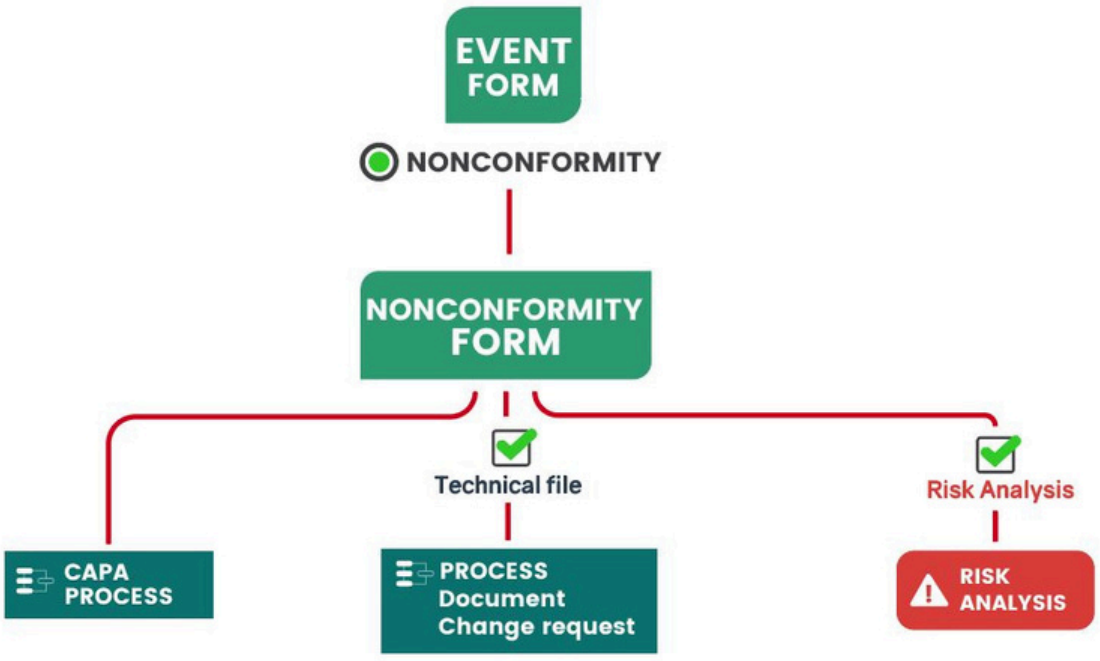
- **Assigned to:** QMS Manager.
- **QMS Type:** Change Management.
- **Action:** Complete all steps of the process.

Important Notes

- Some data from the **Feedback Form** will be included in the Risk Analysis.
- The **Feedback Form** will be attached to all processes within this workflow.

3.4 Nonconformity Event Form

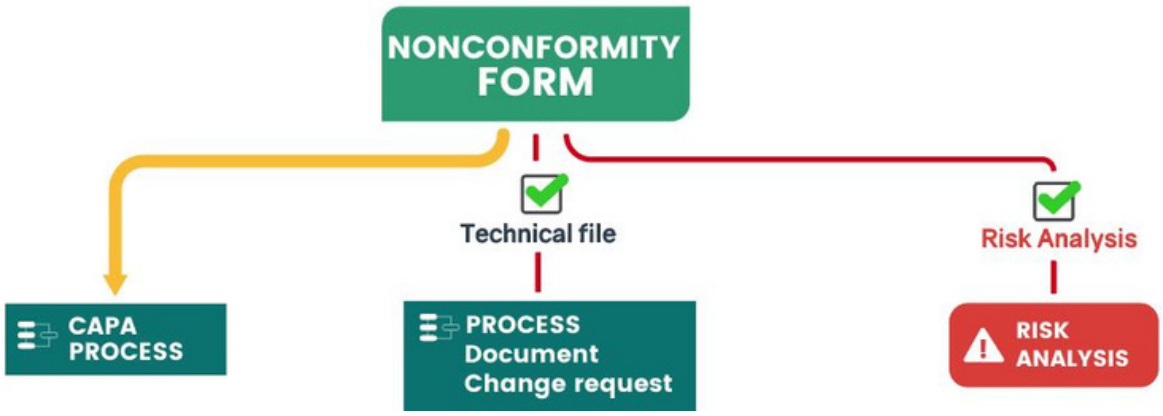
To record a Nonconformity Event, start by selecting **Nonconformity** as the event type in the **Event Form**. This will automatically generate a **Nonconformity Form**, which you need to complete.



Workflow Start

Nonconformity Form

- **Assigned to:** The user who started the Event
- **QMS Type:** Nonconformity
- **Action:** Open the task and complete the required fields.

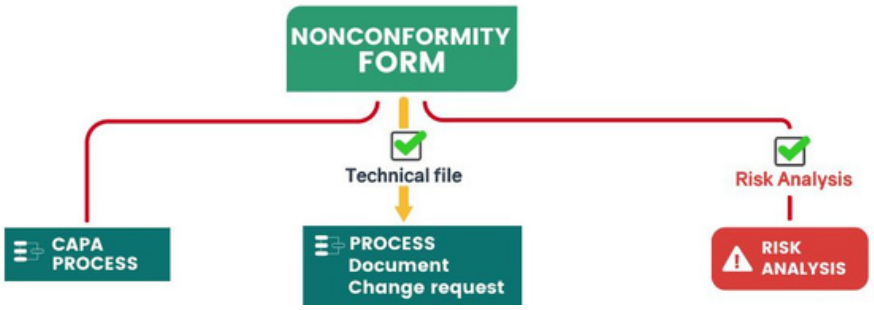


Once the form is submitted, the **CAPA process** will be triggered automatically.

P-850 13485-2016 CAPA-1 Process

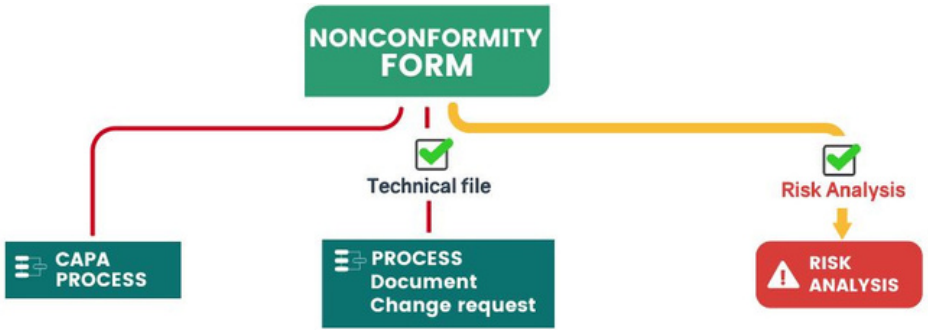
- **Assigned to:** QMS Manager
- **QMS Type:** Capa
- **Action:** Complete all steps of the process.

Within the Nonconformity Form, you can also specify whether a **Risk Analysis** is required and whether the event is part of the **Technical File.**



Document Change request process

- **Assigned to:** QMS Manager.
- **QMS Type:** Change Management.
- **Action:** Complete all steps of the process.



A Risk will be automatically created

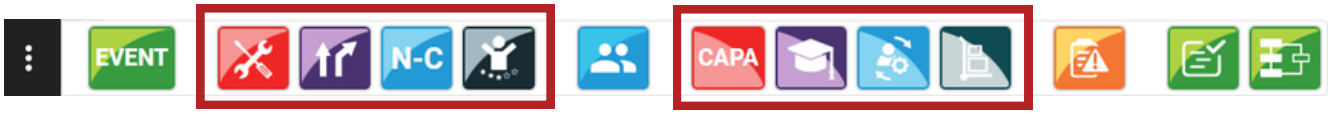
- **Action:** Open the Risk (Nonconformtiy Form gets a Risk Relation) and complete all steps.

Important Notes

- Some data from the **Nonconformity Form** will be included in the Risk Analysis.
- The **Nonconformity Form** will be attached to all processes within this workflow.

4. Tracking Event Outcomes

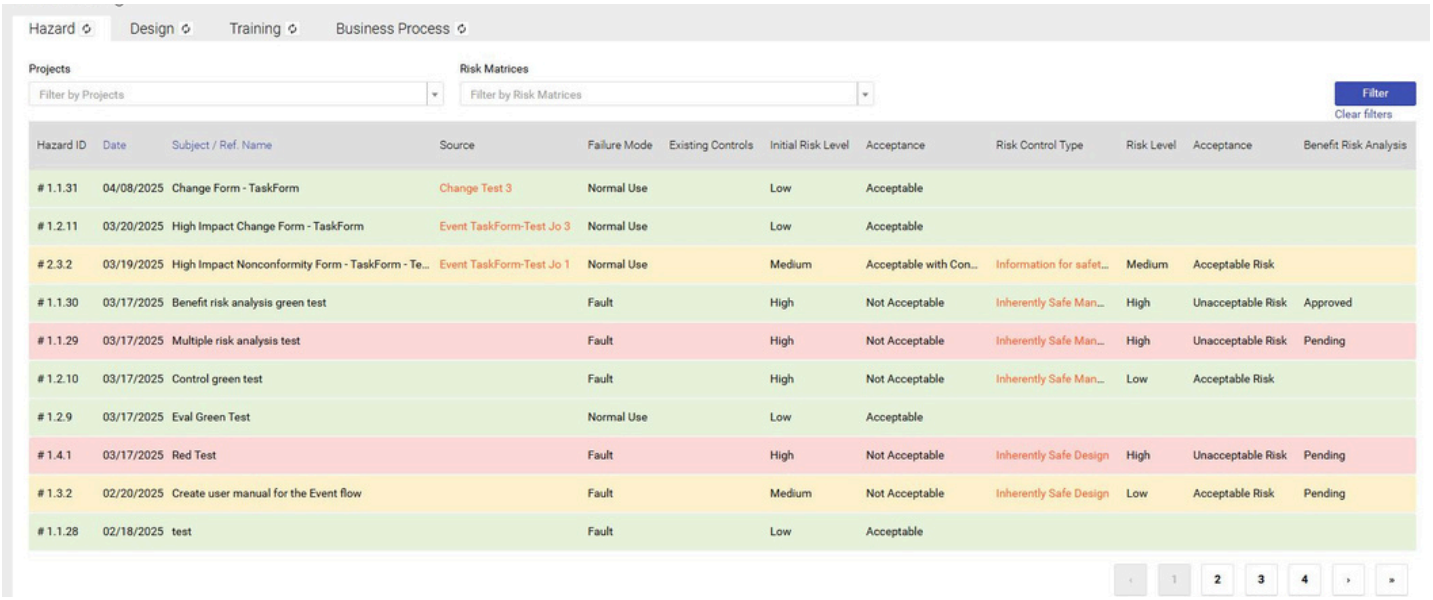
All **Forms/Tasks** associated with a specific **QMS type** can be monitored within the respective **QMS dashboards**. To access them, click the **three-dot button** and select one of the following categories: **Change, Deviation, Nonconformity, Feedback, CAPA, Training**, **Change Management** or **Supplier**.



All ongoing processes can be tracked in the **QMS module > Started Processes.** Since most processes are QMS-related, you can also filter them by **QMS type**.

4.1 Hazard Log

All **Hazards** can be monitored in the **Hazard Log Dashboard**, accessible via the **three-dot button > Hazard Log**. The first tab, **"Hazard,"** displays a list of all hazards, while the remaining three tabs categorize them into **Design, Training,** and **Business Process.**



Hazard ID	Date	Subject / Ref. Name	Source	Failure Mode	Existing Controls	Initial Risk Level	Acceptance	Risk Control Type	Risk Level	Acceptance	Benefit Risk Analysis
# 1.1.31	04/08/2025	Change Form - TaskForm	Change Test 3	Normal Use		Low	Acceptable				
# 1.2.11	03/20/2025	High Impact Change Form - TaskForm	Event TaskForm-Test Jo 3	Normal Use		Low	Acceptable				
# 2.3.2	03/19/2025	High Impact Nonconformity Form - TaskForm - Te...	Event TaskForm-Test Jo 1	Normal Use		Medium	Acceptable with Con...	Information for safet...	Medium	Acceptable Risk	
# 1.1.30	03/17/2025	Benefit risk analysis green test		Fault		High	Not Acceptable	Inherently Safe Man...	High	Unacceptable Risk	Approved
# 1.1.29	03/17/2025	Multiple risk analysis test		Fault		High	Not Acceptable	Inherently Safe Man...	High	Unacceptable Risk	Pending
# 1.2.10	03/17/2025	Control green test		Fault		High	Not Acceptable	Inherently Safe Man...	Low	Acceptable Risk	
# 1.2.9	03/17/2025	Eval Green Test		Normal Use		Low	Acceptable				
# 1.4.1	03/17/2025	Red Test		Fault		High	Not Acceptable	Inherently Safe Design	High	Unacceptable Risk	Pending
# 1.3.2	02/20/2025	Create user manual for the Event flow		Fault		Medium	Not Acceptable	Inherently Safe Design	Low	Acceptable Risk	Pending
# 1.1.28	02/18/2025	test		Fault		Low	Acceptable				

Improved Risk Tracking

Risk tracking is now more intuitive, with color-coded indicators representing the current stage of each risk:

Green risk – No hazard, Risk Evaluation – Acceptable, Risk Control – Acceptable, Benefit-Risk Analysis Approved.
Yellow risk – Risk Analysis is pending or completed but not yet approved.
Red risk – Risk is not acceptable and requires further action.

Smarter Event Tracking,

STRONGER QUALITY

Capture Event significantly improves the efficiency of quality management by automating event tracking and linking relevant processes seamlessly.

By ensuring compliance and reducing manual workload, it empowers teams to focus on continuous quality improvement.

If you need a demo or further clarification,
feel free to schedule a video call with our team
at contact@qmswrapper.com.

qmsWrapper Team