

# Quality Event

#11.1 — Last update: Jan 24, 2024

Interfacing Technologies Corporation

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# 1. User Manual for Quality Event Application

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The objective of this manual is to assist users with the usage of the **Quality Event** application. As its name suggests, the **Quality Event** application enables users to create, examine, and manage quality events. These events include unplanned audit findings, complaints, deviations, incidents, non-conformities, etc.

\* Users can use this application to investigate quality events, create action items, and/or escalate to CAPA. For more details on the CAPA application, [click here](#).

## 2. Technical Support

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For help and technical advice, please contact the Interfacing Technical Support department. In North America, the department is open Monday-Friday from 7:00 AM to 5:00PM, Eastern Time.

**Phone:** +1 514 737 7333

**Email:** [support@interfacing.com](mailto:support@interfacing.com)

**Live Chat:** [interfacing.com](https://www.interfacing.com)

Online technical support and worldwide contact information are available at [www.interfacing.com](https://www.interfacing.com)

## 3. Legal Notices

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## 4. Release Notes 11.1

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In our latest release of the **Quality Event** application, we have introduced new features, improved existing ones, and fixed bugs.

Product	Version	Date
Quality Event Application	11.1	2023/06/14

In these notes, you will find:

1. [Feature Improvements](#)
2. [Fixed Issues](#)



It is worth mentioning that the **Quality Event** application is designed to work in synergy with the **Action Items** application. To stay informed about the latest feature additions and improvements implemented in the **Action Items** application, we recommend referring to the dedicated [release notes](#) for that manual.

## 4.1. Feature Improvements

---



With this latest release, we have implemented the following improvements:

1. [Performance Improvements](#)
2. [Comprehensive Visibility of Audit Observations in Linked/Triggered Quality Events](#)
3. [General UX & UI Enhancements](#)

## 4.1.1. Performance Improvements

This release brings significant improvements to the performance and speed of **QMS** applications.

### 1. Improved Form Loading Time

- Backend optimizations have resulted in faster form loading times.
- Users can expect a more efficient and responsive experience.

### 2. Mass User Training Assignment Time

- The time taken for mass user training assignments has been dramatically reduced, moving from several hours to just minutes.
- Administrators can now efficiently manage and assign trainings for large groups of users.

**New Training**

Training Name  
Provide a short description of the training

— Define Details

Objective/Purpose

Paragraph

Activation Date

Length (Hours)

Deadline (Days)

Status

Priority

Applicability

Assessment Method

Training Definition Reviewer

Training Execution Reviewer

Trainings consist of up to 4 phases. Select phases that will apply to this training and then define each phase in the sections that appear below.

☐ Include pre-assessment

☐ Include documentation to read

☐ Include training course(s) to execute

☐ Include post-assessment

+ Select Trainees

Submit form Save Form

## 4.1.2. Comprehensive Visibility of Audit Observations in Linked/Triggered Quality Events

When a quality event is triggered from the **Audit** application or linked back to an audit plan, users will now benefit from a consolidated view of all relevant audit findings and observations within the forms comprising the [Quality Event](#) workflow. This comprehensive display encompasses general findings, non-conformities, minor observations, and major observations, conveniently presented within the [Observation\(s\)](#) grid.

Audit Information

Cause - Audit Plan ?

	Plan ID	Name
	<input type="text"/>	<input type="text"/>
	AP-00020	Laboratory External Audit - Montreal

Observation(s) of the Audit Plan associated to this Quality Event

	Type	Notes	Requirement ID	Name	Observation ID
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	General Findings	The laboratory's document management and control system	4	Laboratory Document Control	AF-00016
	Major Observation	The laboratory does not have a backup or disaster recovery plan for	4	Laboratory Document Control	AF-00017
	Minor Observation	Some laboratory personnel are not consistently following the	4	Laboratory Document Control	AF-00018
	Non-conformity	The laboratory fails to maintain a comprehensive and up-to-date list	4	Laboratory Document Control	AF-00019

✿ By ensuring the prominent display of related audit findings and observations, this improvement serves to enhance visibility and facilitate a comprehensive understanding of the factors contributing to a quality event.

! If the quality event is eventually escalated to the **CAPA** application, these associated findings and observations will be seamlessly transferred and displayed in the corresponding

CAPA grid. For more information on this matter, [click here](#).



## 4.1.3. General UX & UI Enhancements

In our ongoing commitment to optimizing the user experience with the **Quality Event** application, we have implemented a series of enhancements aimed at elevating its interface.

Changes in this latest release include:

### 1. Streamlined Navigation & Structure

To enhance user experience, we have streamlined navigation to the **Quality Event** application, simplifying the overall platform structure. Now, although the **Quality Event** application remains a part of the **QMS** application suite, it is no longer nested under the **QMS** category. This change has reduced the number of steps needed to access the application and its modules.

#### Previous Navigation Path

Home Page / Quality Management System / Quality Event

### 2. Enhanced Iconography

We have also updated the icons used to represent the **Quality Event** application and its modules, achieving three key objectives:

- **Distinct Application Identity:** We have changed the **Quality Event** application's icon to make it more distinguishable and align it better with its intended purpose.

#### Previous Icon



Quality Event

- **Consistent Icon Styles:** To create a more cohesive visual experience both within the application and across the **QMS** suite, we have standardized icon styles for modules with similar functions.
  - For example, modules presenting lists, such as Quality Event List, now share the same **List** icon. Modules for creating new items, such as New Quality Event, use the same **Add** icon.

### Previous Icon Styles



New Quality  
Event



Quality Event List

- **Modern Design:** As part of our design evolution, demonstrated in the above graphics, we have adopted a thinner icon style, embracing a sleeker and more modern aesthetic.

### 3. Improved Form Design & Layout

We have redesigned our forms to make them more intuitive and space-efficient. This includes reordering fields to ensure a logical flow, improving field labels for clarity and comprehension, and removing unnecessary elements to simplify and declutter the interface.

We have also transitioned from tabs to accordions, a change which not only enhances aesthetics and readability but also enables a more focused interaction with content. Users can now smoothly navigate through forms, progressively revealing information as needed.

New Quality Event

Quality Event Name

Provide a short description of the issue

Quality Event ID

QE-00001

Event Type

Select... ▾

Severity

Select... ▾

Quality Event Reviewer ?

Select... ▾

Additional Details

Business Division ?

▾

Business Line ?

▾

Category

Select... ▾

Source

Select... ▾

Reason

Select... ▾

Site(s)

▾

Issue Statement

Paragraph ▾

A ▾ AI ▾ A ▾ A ▾ B I U S ≡ ▾ ≡ ▾ ≡ ▾ ≡ ▾

Attach any relevant document(s)

Max 100 files, 2000MB each

No data

+ Quality Event Related To (Optional)

Submit form

Save Form

✿ In the forms comprising the Quality Event workflow, accordions, much like the tabs before them, are dynamically shown or hidden based on relevance, ensuring that the interface remains clean and user-centric.

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## 4.2. Fixed Issues

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### What's Been Fixed?

With this latest release, we have resolved the following issue:

- **Grid View – Incorrect Title Displayed in Rich Text Pop-up**

In grids that utilize the pop-up window option to display rich text fields, there was an issue where the title occasionally included the full attribute name. We have successfully resolved this issue in our latest release.

## 5. General Application Functionalities

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To enhance understanding and utilization of the application, users are encouraged to familiarize themselves with the following key features and options:

- [Field Behavior](#): Learn how disabled, enabled, and mandatory fields appear and behave in the application.
- [Dropdown Controls](#): Learn how to effectively use single-select and multi-select dropdown fields for efficient and accurate data selection.
- [Rich Textbox Controls](#): Learn how to utilize rich textbox controls to add formatting, images, links, and more to your content.
- [Comment Controls](#): Learn how to add, edit, reply to, or delete comments.
- [Templates](#): Learn how to access and utilize pre-designed document templates.



By default, in the **DBP** web application, sessions time out after 20 minutes of inactivity. To access the latest version of content, users will need to refresh the page.

# 5.1. Field Behavior

To distinguish between different fields in the interface, specific visual cues are employed. By default, disabled fields, which cannot be modified, are presented with a dark background color.\* Mandatory fields, on the other hand, which must be filled out, are highlighted with a light-blue background color.\*\* Enabled fields, in contrast, do not have any background color, appearing transparent.

CAPA ID	CAPA Name	Business Division
CAPA-00009		

\* In the settings of either the Designer program or the **DBP** web application, users can set the background of disabled fields as transparent. In this mode, disabled fields nonetheless remain distinguishable from enabled fields in that they cannot be manipulated by the user in any way.

\*\* In the **DBP** web application, users have the ability to customize the color of mandatory fields according to their preference.

## 5.2. Dropdown Controls

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There are two types of dropdown fields that are commonly used in forms:

1. [Single-Select Dropdown Fields](#)
2. [Multi-Select Dropdown Fields](#)

## 5.2.1. Single-Select Dropdown Fields


---

A single-select dropdown field allows users to select only one value at a time from a predetermined list of options.

### Frequency



There are two ways to select an item from the dropdown:

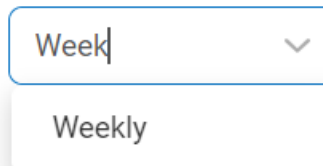
1. Click on the  icon. It will release the list of values. Users can then scroll through the options and make their selection.

### Frequency



2. Search for the value in the dropdown by inputting its name or keywords relating to it. Any items that match the search will be retrieved. Users can then click on the desired value to finalize their selection.

### Frequency






## 5.2.1.1. Single-Select Dropdown Field with Modal Window

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Although most single-select fields release a dropdown menu, there are some that instead open a modal window.

\* A modal window is a pop-up window that disables the main form, requiring users to interact with it before they can regain access. Users can interact with a modal typically by either completing the set task or exiting the window.

To use a single-select dropdown field linked to a modal window, follow these steps:

1. Click on the  icon. It will open a modal window containing the options available to choose from.
2. Navigate through the options and select the desired one by double-clicking on it.
  - Users will then be returned to the main form where they will find the field now populated with their selection.
3. Otherwise, to return to the main form without making a selection, click on the **Exit (X)** button.

In the example below, the modal window contains a tree view control to help users navigate through a hierarchical structure of options.

\* Users can determine the contents of the modal window by creating the form and linking the corresponding form behavior to the control.

**Folder**

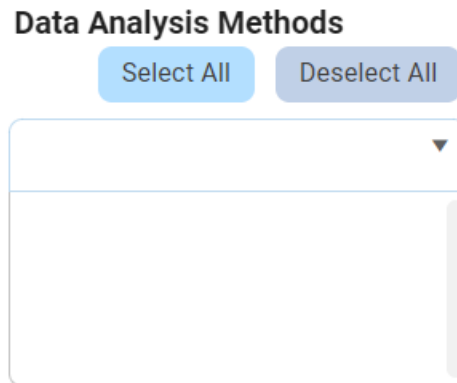
Select...

---



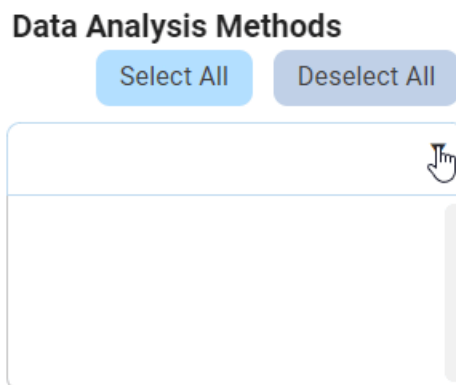
## 5.2.2. Multi-Select Dropdown Fields

A multi-select dropdown field allows users to select multiple values at a time from a predetermined list of options.



There are two ways to select items from the dropdown:

1. Click on the ▼ icon. It will release the list of values. Users can then scroll through the options and make their selection.



2. Search for the value in the dropdown by inputting its name or keywords relating to it. Any values that match the search will be retrieved. Users can then click on the desired value to finalize their selection.

### Data Analysis Methods

[Select All](#)[Deselect All](#)

Des

×

▼

After selecting items, users can remove them from the dropdown by clicking on the **X** button.

### Data Analysis Methods

[Select All](#)[Deselect All](#)

▼

Descriptive Analysis

×

Exploratory Analysis

×

Content Analysis

×



To automatically select all items in the list, click on the **Select All** button. To automatically deselect all items in the list, click on the **Deselect All** button.

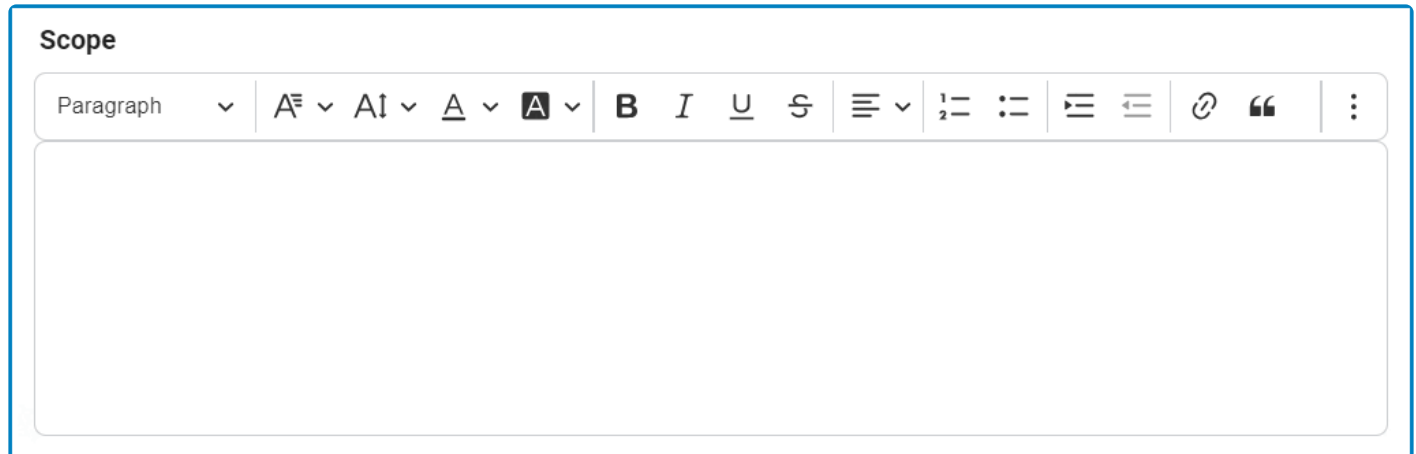
## 5.3. Rich Textbox Controls

In certain forms, users are provided access to rich text fields, also known as rich textbox controls.

For those unfamiliar with using these fields, here are some key features to consider:

### 1. Text Formatting

Users have access to various formatting options in the rich textbox control, including:

A screenshot of a rich text editor interface. At the top, there is a title bar labeled "Scope". Below the title bar is a toolbar containing various formatting options: a dropdown menu for "Paragraph", followed by font size (A), font color (A), font background color (A), bold (B), italic (I), underline (U), strikethrough (S), text alignment (left, center, right, justified), bulleted list, numbered list, link, quote, and a more options menu (three dots). Below the toolbar is a large, empty text area for editing.

- **Heading Style:** This field allows users to choose a heading style from a dropdown menu.
- **Font Family:** This field allows users to choose the font family from a dropdown menu.
- **Font Size:** This field allows users to choose the font size from a dropdown menu.
- **Font Color:** This field allows users to choose the font color from a dropdown menu.
- **Font Background Color:** This field allows users to choose the font background color from a dropdown menu.
- **Bold:** This button allows users to apply a bold effect to the selected text.
- **Italic:** This button allows users to apply an italic or slanted effect to the selected text.
- **Underline:** This button allows users to apply an underline effect to the selected text.
- **Strikethrough:** This button allows users to apply a strikeout effect to the selected text.
- **Text Alignment:** This field allows users to choose the alignment of the text from a dropdown menu.
- **Numbered List:** This button allows users to apply a numbered list format to selected text.
  - Users can create nested lists by using the **Indent** button, either in the rich text editor or on their keyboard.
- **Bulleted List:** This button allows users to apply a bulleted list format to selected text.
  - Users can create nested lists by using the **Indent** button, either in the rich text editor or on their keyboard.
- **Increase / Decrease Indent:** These buttons allow users to adjust the indentation level of the selected text.
- **Block Quote:** This button allows users to apply a block quote format to the selected text.

- ✱ To undo any text formatting, users can either click on the **Undo** button or unselect the formatting option.

## 2. **Hyperlinks**

Users can insert hyperlinks to external web pages within the rich textbox control.

**Scope**

Paragraph ▾ | A<sup>Ⓐ</sup> ▾ | A<sub>Ⓐ</sub> ▾ | A ▾ | **B** | *I* | U | ~~S~~ | ≡ ▾ | ½= | := | ≡ | ≡ | 🔗 | “” | ⋮

## 3. **Media Support**

Users can embed various types of media into the rich textbox control, either by uploading them from their computer or by providing a URL to online media content.

**Scope**

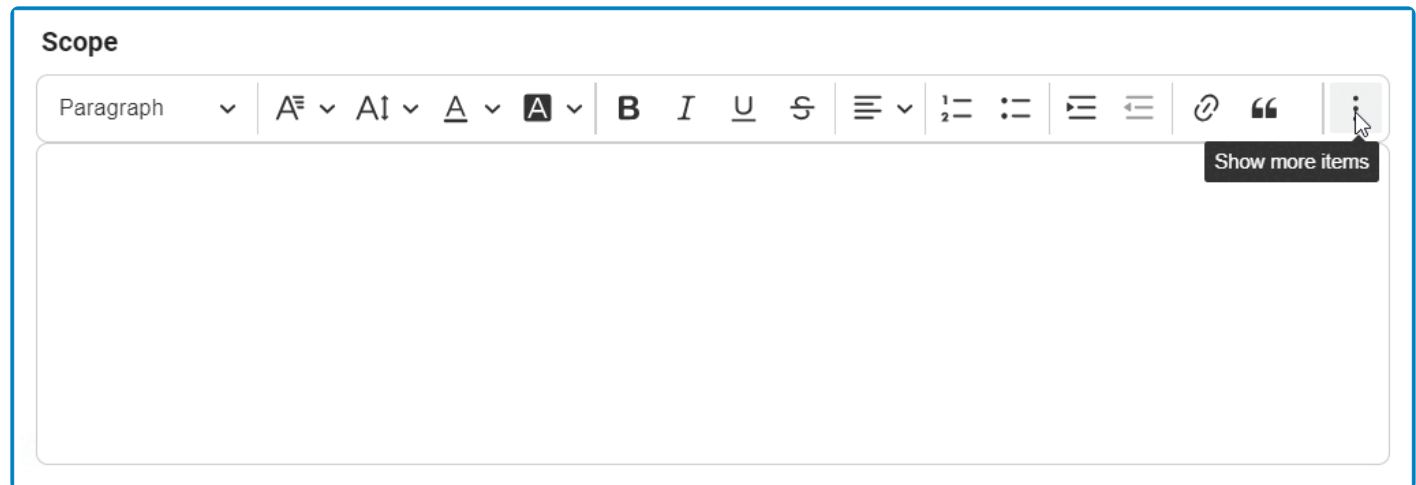
Paragraph ▾ | A<sup>Ⓐ</sup> ▾ | A<sub>Ⓐ</sub> ▾ | A ▾ | **B** | *I* | U | ~~S~~ | ≡ ▾ | ½= | := | ≡ | ≡ | 🔗 | “” | ⋮

Show more items

- ✱ Once an image has been inserted into the control, users can adjust its alignment, resize it, and add alternative text if needed.

## 4. **Table Support**

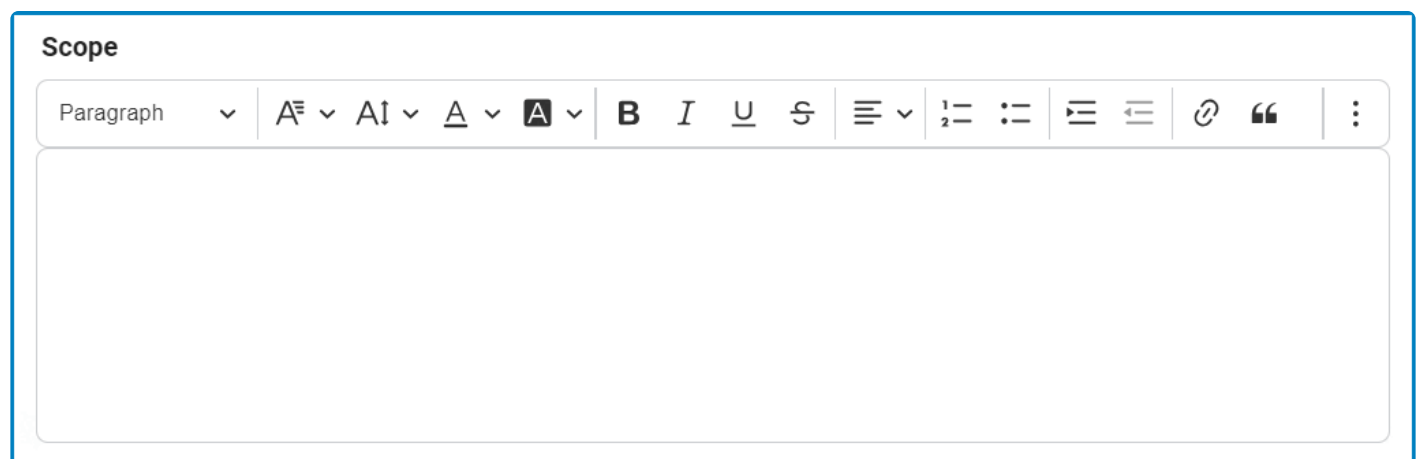
Users can add, edit, and format tables in the rich textbox control.



- ✿ Once a table has been inserted into the control, users can modify the column and row properties, merge or split cells, and adjust various table properties like border, background color, dimensions, and alignment. The control also enables users to modify individual cell properties for complete control over their table design.

## 5. Undo / Redo

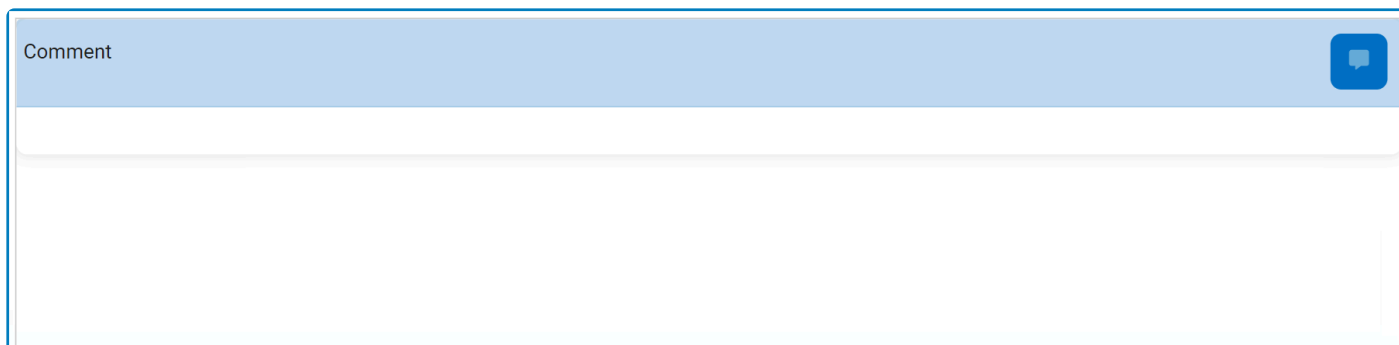
Users can undo or redo a previous action in the rich textbox control.




- ✿ Depending on the amount of text entered, a vertical scrollbar may appear on the side of the rich textbox to allow users to scroll through the contents. Additionally, users can resize this textbox by dragging at its bottom right corner.

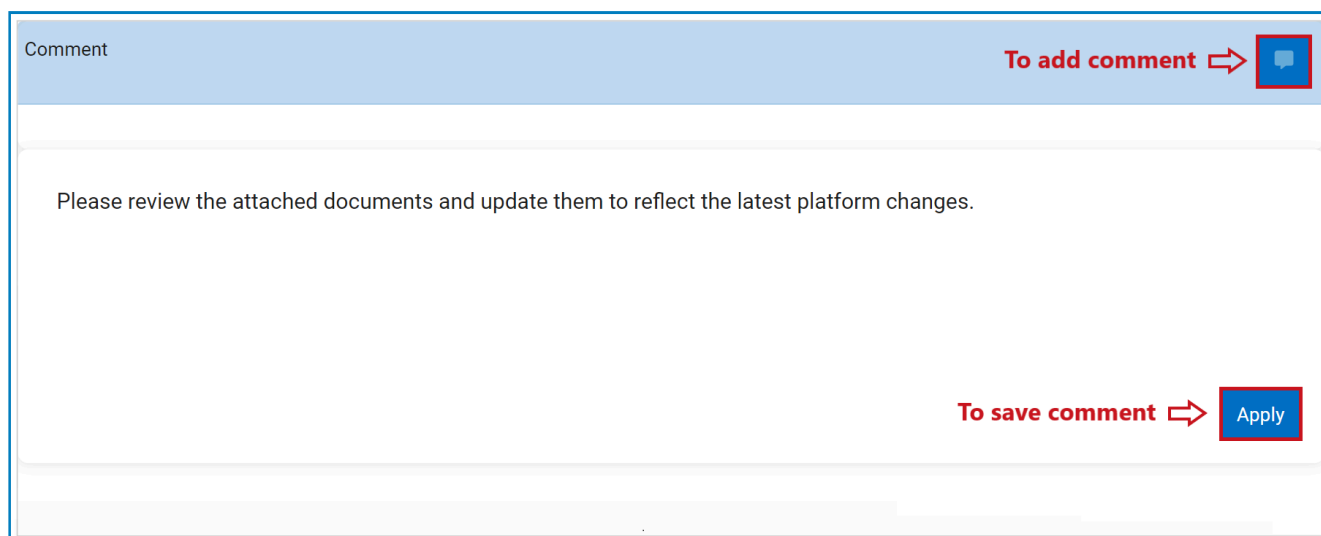
## 5.4. Comment Controls


In certain forms, users are provided access to comment controls, which enable them to input any relevant comments they may have regarding a given task,

A screenshot of a comment box interface. It features a light blue header bar with the word "Comment" on the left and a blue speech bubble icon on the right. Below the header is a large, empty white text area for input.

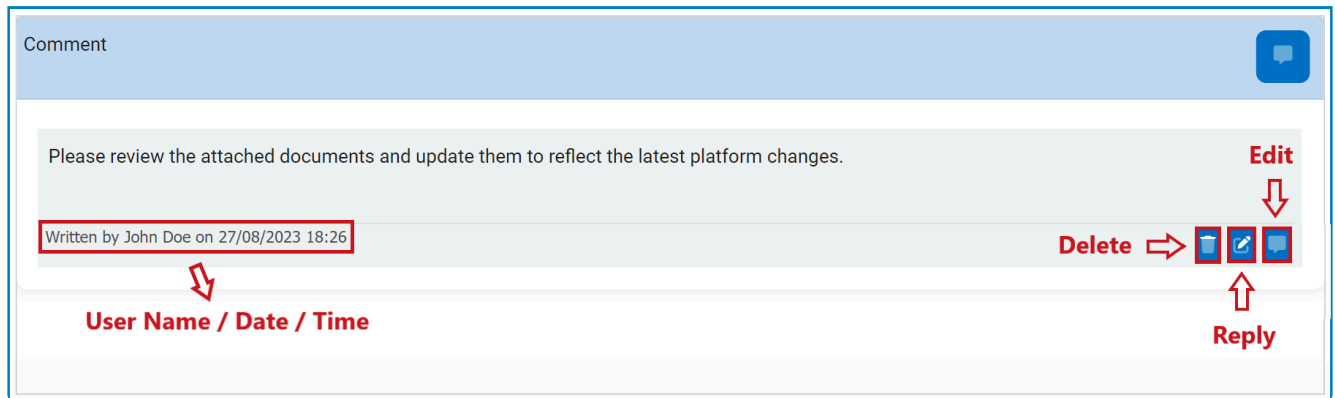
To use this function, follow the instructions below:


1. To add a comment, click on the  icon in the top right corner, input your comment(s) in the text field, and then click on the **Apply** button to save your work.

A screenshot of a comment box interface showing a comment and its controls. The header bar is light blue with "Comment" on the left. On the right, there is a red speech bubble icon with a red arrow pointing to it, labeled "To add comment". Below the header is a large white text area containing the text "Please review the attached documents and update them to reflect the latest platform changes." At the bottom right of the text area, there is a red arrow pointing to a blue button labeled "Apply", with the text "To save comment" above it.


2. To edit a comment, click on the  icon in the bottom right corner, make changes as desired to the original comment, and then click on the **Apply** button to save your work.

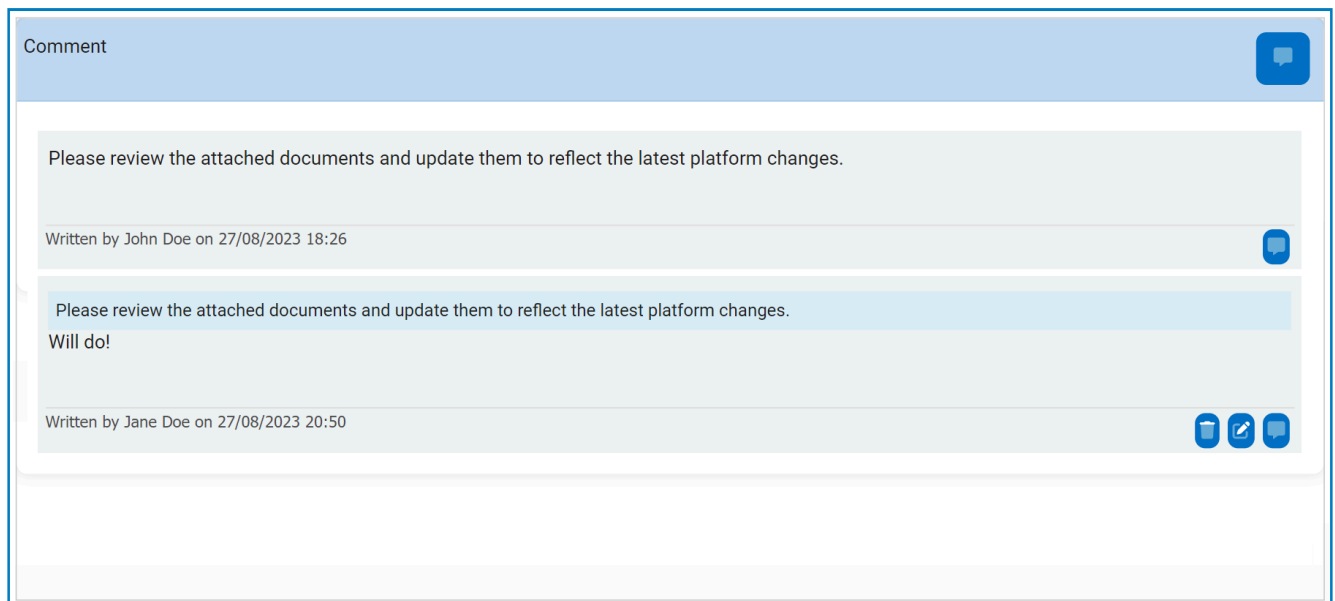




3. To delete a comment, click on the  icon in the bottom left corner.
- If selected, users will be alerted of the action with the following confirmation message:

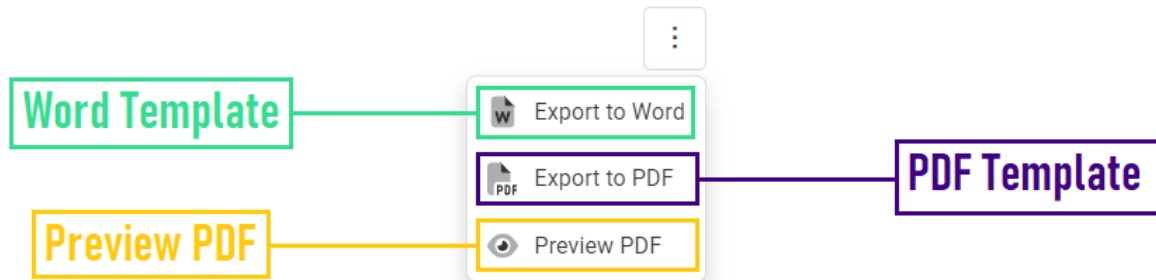
Are you sure you want to delete?

- Click on either the **Submit** button to confirm the deletion or the **Cancel** button to cancel it.
4. To reply to a comment, click on the  icon in the bottom right corner, input your reply, and then click on the **Apply** button again to save your work.



## 5.5. Templates

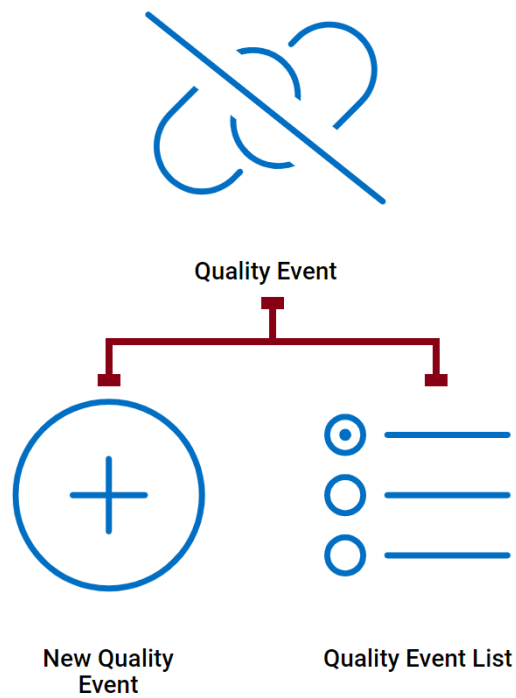
When enabled, templates can be accessed using the kebab (or three dots) menu located in the rightmost corner of the form.



As outlined in the above image, using the available options in the menu, users can download a Word template, download a PDF template, or preview a PDF template.

## 6. Quality Event Application Overview

---



## 6.1. Accessing the Quality Event Application

The **Quality Event** application is part of the larger **Quality Management System (QMS)** application suite.

1. From the Home Page, click on **Quality Event**.



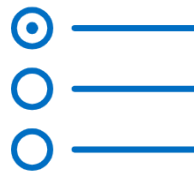
Quality Event

2. Selecting **Quality Event** directs users to the following subcategories:

- [New Quality Event](#)
- [Quality Event List](#)



New Quality  
Event



Quality Event List

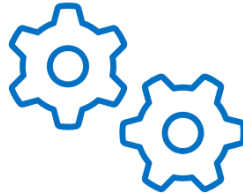
\* For a list of the action items created in the **Quality Event** application, users will need to access the [Action Item List](#). This module is located in the **Action Items** application.

## 7. Settings

In the **QMS Settings** section of the **QMS** application suite, users can configure the settings for the **Quality Event** application.

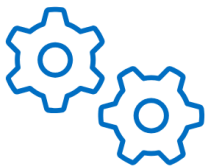
To access **QMS Settings**, use the following steps:

1. From the Home Page, click on **QMS Settings (Admin)**.



QMS Settings  
(Admin)

2. Selecting **QMS Settings (Admin)** directs users to the following subcategories:



General Settings



Audit Settings



Quality Event  
Settings



Action Item  
Setting



CAPA Setting



Training Settings



Management  
Review Setting



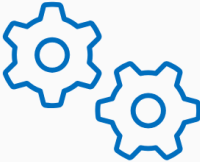
Product &  
Supplier Setting




Risk Setting

3. There are three modules from this list that are relevant to the **Quality Event** application:


- [General Settings](#)
- [Quality Event Settings](#)
- [Action Item Settings](#)




General Settings




Audit Settings




Quality Event Settings




Action Item Setting




CAPA Setting




Training Settings



Management Review Setting



Product & Supplier Setting

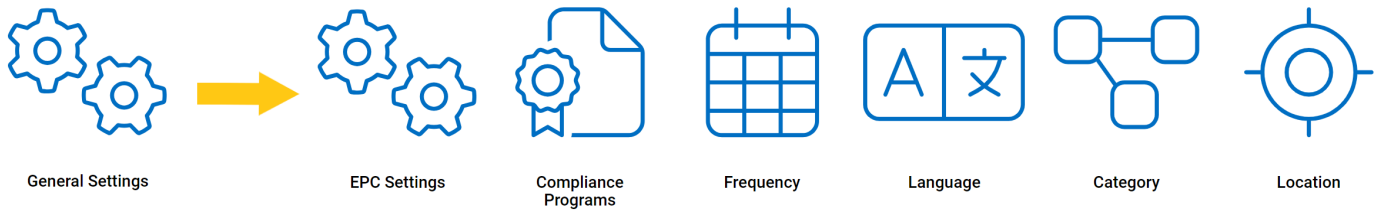


Risk Setting

## 7.1. General Settings

---

Selecting **General Settings** directs users to the following subcategories:

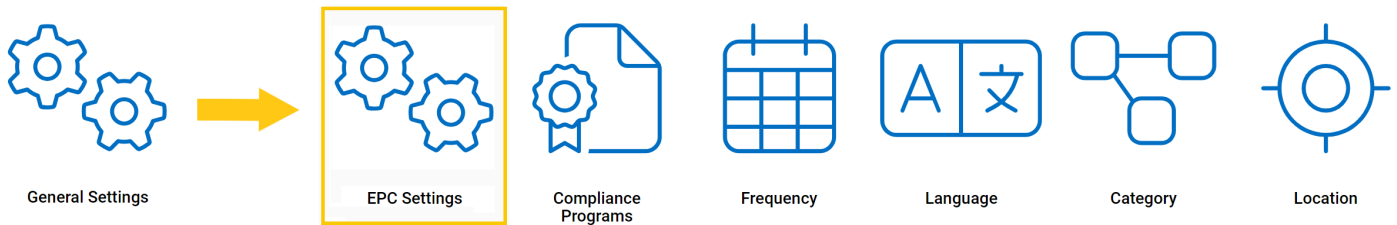


From this list, there are four modules that are relevant to the **Quality Event** Application.

1. [EPC Settings](#)
2. [Compliance Types List](#)
3. [Frequency](#)
4. [Category](#)
5. [Location](#)

## 7.1.1. EPC Settings

In this section, users can set the EPC environment from which they want data to be pulled.




### Setting EPC Environment

### EPC Settings

---

#### Enter an EPC administrator's credentials

Base URL 

The server's timezone offset in 00:00:00

https://epc-qa-mut.interfacing.com/

Username

epcadmin

Password

.....

☒ Skip Certificate Validation

Fetch Environments

#### Select the environment from which all EPC data will be pulled

Environment

Aerospace and Defense

Submit form

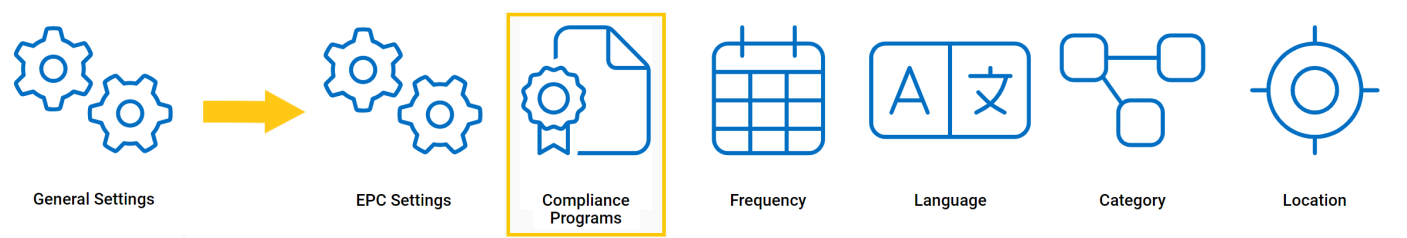
1. **Base URL:** This is a text field that allows users to input the base URL of the EPC server. It is a **mandatory** field.
2. **Username:** This is a text field that allows users to input the username.
3. **Password:** This is a text field that allows users to input the password.



4. ***Skip Certification Validation:*** This is a checkbox that, when selected, allows users to skip certification validation.
5. ***Fetch Environments:*** This button allows users to fetch the list of environments from the selected EPC server.
6. ***Environment:*** This is a single-select dropdown field that retrieves the list of environments from EPC. It allows users to select only one value from the dropdown.
7. ***Submit Form:*** This button allows users to submit the form.

# 7.1.2. Compliance Types List

In this section, users can create, edit, and delete the compliance types displayed in the **Compliance Program** dropdown. This dropdown is found in the [Add Action Item to Quality Event](#) form.



## Defining Compliance Types

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### Compliance Types List

Create, edit, and/or delete the compliance types that are to be used in QMS ?

Add

Discard changes

Save changes

#		Active	Compliance Type	French Title	Arabic Title	German Title	Prefix
		(All) ▾	🔍	🔍	🔍	🔍	🔍
1	🗑	☑	ISO 27001				ISO27001
2	🗑	☑	ISO 9001				ISO9001
3	🗑	☑	ISO 17025				ISO17025
4	🗑	☑	ISO 45001				ISO45001
5	🗑	☑	ISO 14001				ISO14001

- 1. **Add:** This button allows users to add a new compliance type.

#	Active	Compliance Type	French Title	Arabic Title	German Title	Prefix
	(All) ▼	🔍	🔍	🔍	🔍	🔍
🗑️	<input type="checkbox"/>					

- **Title:** This is a text field that allows users to input the title(s) of the compliance type (in English [default], Arabic, German, or French). It is a **mandatory** field.
  - **Prefix:** This is a text field that allows users to input the prefix associated with the compliance type.
  - **Active:** This is a checkbox that, when selected, allows for the compliance type to be displayed in the **Compliance Program** dropdown.
    - This checkbox is automatically unselected when a new compliance type is added; however, if users want the compliance type to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete (🗑️):** This button allows users to delete a compliance type.

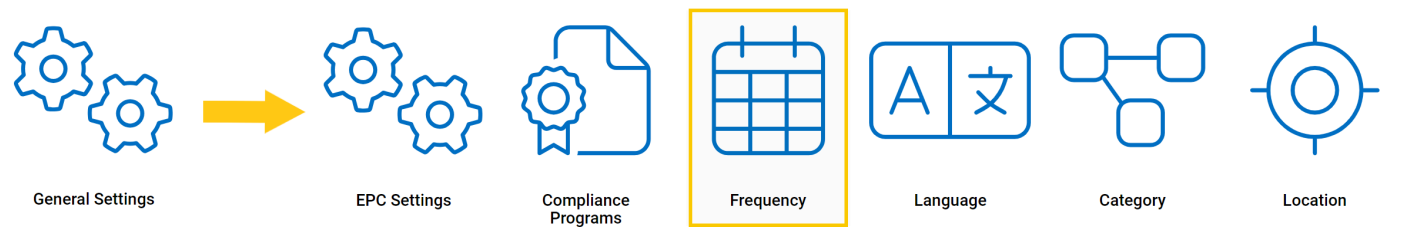
✳ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo (↶)** icon.

✳ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

! If a compliance type is in use, users cannot delete it without first deleting all instances of its use.

# 7.1.3. Frequency

In this section, users can create, edit, and delete the frequency options displayed in the **Frequency** dropdown. This dropdown is found in the [Add Action Item to Quality Event](#) form.



## Defining Frequency Options

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### Frequency

Create, edit, and/or delete the frequency options that are to be used in QMS

Add

Discard changes

Save changes

#		Active	Frequency	French Title	Arabic Title	German Title	Day Count
		(All) ▾	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1		<input checked="" type="checkbox"/>	Daily				1
2		<input checked="" type="checkbox"/>	Weekly				7
3		<input checked="" type="checkbox"/>	Monthly				30
4		<input checked="" type="checkbox"/>	Biweekly				14
5		<input checked="" type="checkbox"/>	Quarterly				90

- 1. **Add:** This button allows users to add a new frequency option.

<div> Add Discard changes Save changes </div> <div>⋮</div>						
#	Active	Frequency	French Title	Arabic Title	German Title	Day Count
	(All) ▾	🔍	🔍	🔍	🔍	🔍
🗑️	<input type="checkbox"/>					

- **Frequency/Title:** This is a text field that allows users to input the title(s) of the frequency option (in English [default], French, Arabic, or German). It is a **mandatory** field.
  - **Day Count:** This is a numeric field that allows users to input the day count. It is a **mandatory** field.
  - **Active:** This is a checkbox that, when selected, allows for the frequency option to be displayed in the **Frequency** dropdown.
    - This checkbox is automatically unselected when a new frequency option is added; however, if users want the frequency option to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete (🗑️):** This button allows users to delete a frequency option.

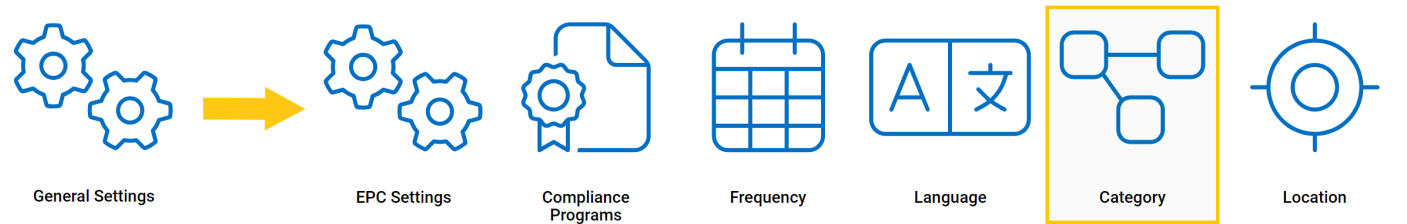
✳ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo (↶)** icon.

✳ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

! If a frequency option is in use, users cannot delete it without first deleting all instances of its use.

# 7.1.4. Category

In this section, users can create, edit, and delete the categories displayed in the **Category** dropdown. This dropdown is found in both the [New Quality Event](#) and the [Add Action Item to Quality Event](#) forms.



## Defining Categories

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

Category

Create, edit, and/or delete the categories that are to be used in QMS

Add

Discard changes

Save changes

#		Active	Category	French Title	Arabic Title	German Title
		(All) ▾	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1		<input checked="" type="checkbox"/>	QMS			
2		<input checked="" type="checkbox"/>	BCM			
3		<input checked="" type="checkbox"/>	OHS			
4		<input checked="" type="checkbox"/>	IT			
5		<input checked="" type="checkbox"/>	ISMS			

- 1. **Add:** This button allows users to add a new category.

<div> Add Discard changes Save changes </div> <div>⋮</div>					
#	Active	Category	French Title	Arabic Title	German Title
	(All) ▾	🔍	🔍	🔍	🔍
🗑️	<input type="checkbox"/>				

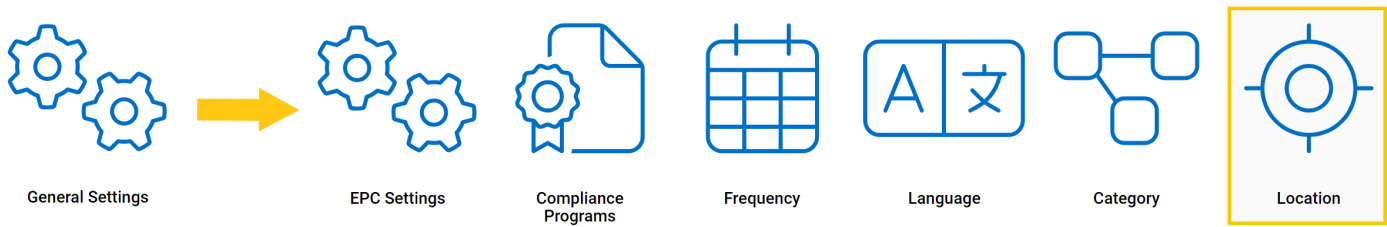
- **Category/Title:** This is a text field that allows users to input the title(s) of the category (in English [default], French, Arabic, or German). It is a **mandatory** field.
  - **Active:** This is a checkbox that, when selected, allows for the category to be displayed in the **Category** dropdown.
    - This checkbox is automatically unselected when a new category is added; however, if users want the category to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete** (🗑️): This button allows users to delete a category.

✿ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (↶) icon.

✿ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

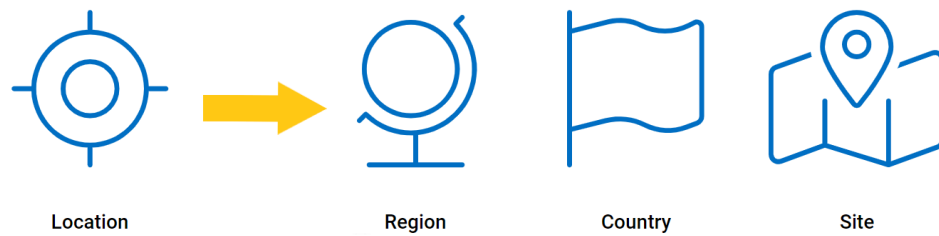
## 7.1.5. Location

In this section, users can set up the list of locations.



Selecting **Location** directs users to the following subcategories:

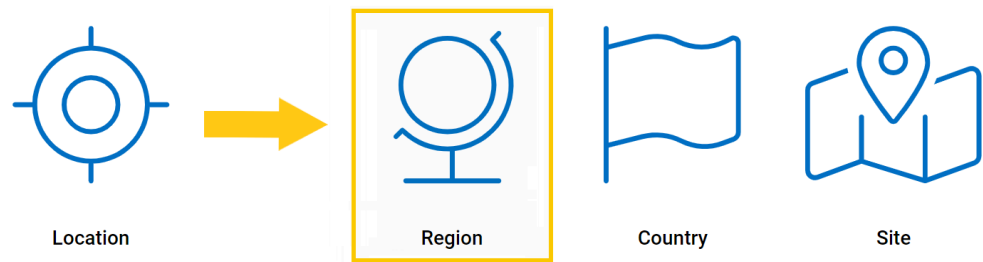
1. [Region](#)
2. [Country](#)
3. [Site](#)





# 7.1.5.1. Region

In this section, users can create, edit, and delete the region options displayed in the **Region** dropdown. This dropdown is found in the [New Site](#) form.



## Defining Region Options

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

Region

Create, edit, or delete Regions ?

Add

Discard changes

Save changes

#		Active	Name
		(All) ▾	🔍
1	🗑️	<input checked="" type="checkbox"/>	South America
2	🗑️	<input checked="" type="checkbox"/>	North America
3	🗑️	<input checked="" type="checkbox"/>	Europe
4	🗑️	<input checked="" type="checkbox"/>	Asia
5	🗑️	<input checked="" type="checkbox"/>	Oceania

- 1. **Add:** This button allows users to add a new region option.

- **Name:** This is a text field that allows users to input the name of the region option. It is a mandatory field.
  - **Active:** This is a checkbox that, when selected, allows for the region option to be displayed in the **Region** dropdown.
    - This checkbox is automatically unselected when a new region option is added; however, if users want the region option to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete** ( ): This button allows users to delete a region option.

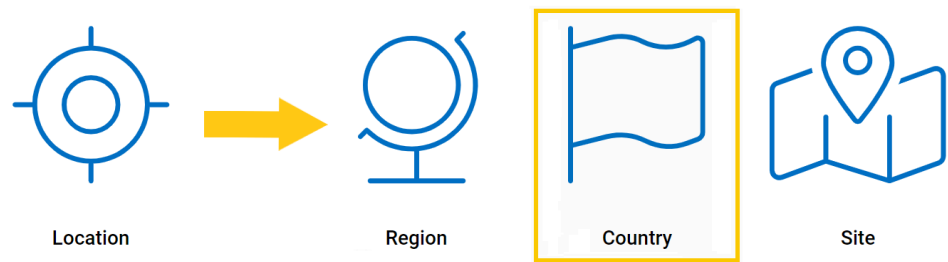
✿ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** ( ) icon.

✿ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu ( ) located in the upper rightmost corner.

! If a region option is in use, users cannot delete it without first deleting all instances of its use.

# 7.1.5.2. Country

In this section, users can create, edit, and delete the country options displayed in the **Country** dropdown. This dropdown is found in the [New Site](#) form.



## Defining Country Options

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### Country

Create, edit, or delete Countries ?

Add

Discard changes

Save changes

#		Active	Country	Region
		(All) ▾	🔍	
1	🗑️	<input checked="" type="checkbox"/>	Canada	North America
2	🗑️	<input checked="" type="checkbox"/>	Japan	Asia
3	🗑️	<input checked="" type="checkbox"/>	France	Europe
4	🗑️	<input checked="" type="checkbox"/>	Germany	Europe
5	🗑️	<input checked="" type="checkbox"/>	Australia	Oceania

- 1. **Add:** This button allows users to add a new country option.

#	Active	Country	Region
	(All) ▼	🔍	
🗑️	<input type="checkbox"/>		

- **Name:** This is a text field that allows users to input the name of the country option. It is a mandatory field.
  - **Region:** This is a single-select dropdown field that retrieves the list of predefined regions. It allows users to select only one value at a time from the dropdown.
  - **Active:** This is a checkbox that, when selected, allows for the country option to be displayed in the **Country** dropdown.
    - This checkbox is automatically unselected when a new country option is added; however, if users want the country option to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete** (🗑️): This button allows users to delete a country option.

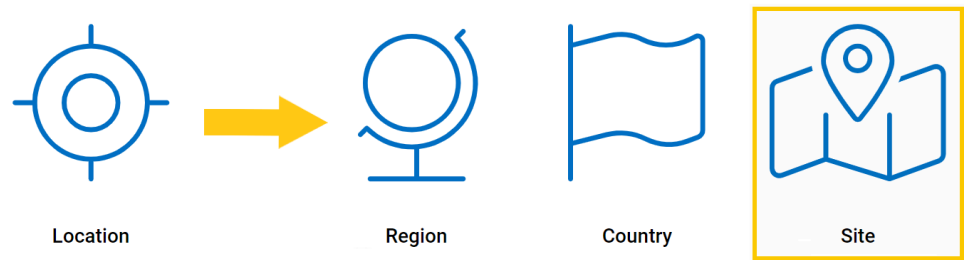
✳ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (↶) icon.

✳ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

! If a country option is in use, users cannot delete it without first deleting all instances of its use.

# 7.1.5.3. Site

In this section, users can create, edit, and delete the site options displayed in the **Site** dropdown. This dropdown is found in the [New Quality Event](#) form.



## Defining Site Options

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Add/Edit** functions. For more details on this type of grid and its features, [click here](#).

Site

Create, edit, or delete Sites

Add

Discard changes

Save changes

	Active	Site	Region	Country	Site Manager	GEO Location	French Title	Arabic Title	German Title
	(. ▾	🔍				🔍	🔍	🔍	🔍
	<input checked="" type="checkbox"/>	Montreal	North America	Canada	John.Doe				
	<input checked="" type="checkbox"/>	Paris	Europe	France	Jane.Doe				
	<input checked="" type="checkbox"/>	Tokyo	Asia	Japan	John.Doe				
	<input checked="" type="checkbox"/>	Sydney	Oceania	Australia	Richard.Roe				
	<input checked="" type="checkbox"/>	Berlin	Europe	Germany	Max.Mustermann				

- 1. **Add:** This button allows users to add a new site option.
  - If selected, it will display the [New Site](#) form.

New Site

Region

Select... ▼

Country

Select... ▼

GEO Location

Title

Arabic Title

German Title

French Title

Site Manager


Select... ▼

☐ Active

Save and Return

Save and New

- **Region:** This is a single-select dropdown field that retrieves the list of predefined regions (from the [Region List](#)).
- **Country:** This is a single-select dropdown field that retrieves the list of predefined countries (from the [Country List](#)).
- **GEO Location:** This is a text field that allows users to input the GEO location of the site option.
- **Title:** This is a text field that allows users to input the title of the site option (in English [default]). It is a **mandatory** field.
- **Arabic Title:** This is a text field that allows users to input the Arabic title of the site option.
- **German Title:** This is a text field that allows users to input the German title of the site option.
- **French Title:** This is a text field that allows users to input the French title of the site option.
- **Site Manager:** This is a text field that single-select dropdown field that retrieves the list of users. It is a **mandatory** field.
  - The user selected will be assigned as manager of the site.
- **Active:** This is a checkbox that, when selected, allows for the site option to be displayed in the **Site** dropdown.
  - This checkbox is automatically unselected when a new site option is added; however, if users want the site option to be displayed, they can still manually select the checkbox.
- **Save and Return:** This button allows users to save the site option and return to the main form.
- **Save and New:** This button allows users to save the site option and open a new form to create another site option.

2. **Delete** (  ): This button allows users to delete a country option.

- ✿ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (↶) icon.

3. **Edit** (✎): This button allows users to edit an existing site option.

- ✿ To edit, users can also simply double-click on the respective entry in the grid.

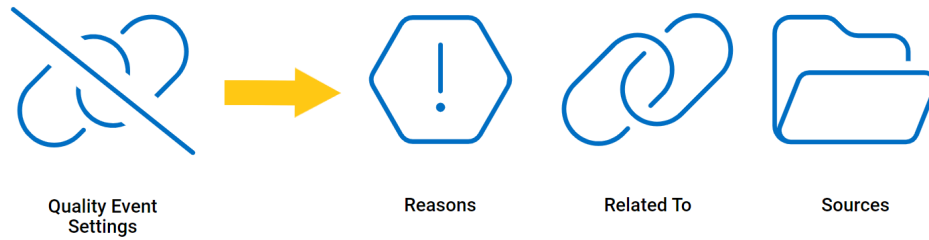
- ✿ To access additional options or perform actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

! If a site option is in use, users cannot delete it without first deleting all instances of its use.

## 7.2. Quality Event Settings

---

Selecting **Quality Event Settings** directs users to the following subcategories:

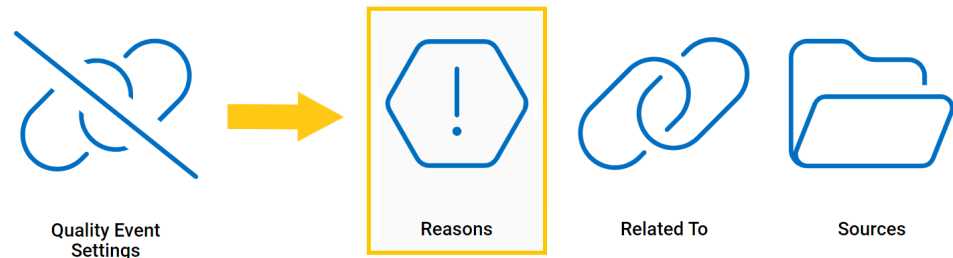


1. [Reasons](#)
2. [Related To](#)
3. [Sources](#)



# 7.2.1. Reasons

In this section, users can create, edit, and delete the reasons displayed in the **Reasons** dropdown. This dropdown is found in the [New Quality Event](#) form.



## Defining Reasons

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### Quality Event Reasons

Create, edit, and/or delete the quality event reasons that are to be used in QMS

AddDiscard changesSave changes

#		Active	Reason	French Title	Arabic Title	German Title
		(All) ▾	🔍	🔍	🔍	🔍
1	🗑️	<input checked="" type="checkbox"/>	Defective Product or Supplies			
2	🗑️	<input checked="" type="checkbox"/>	Procedural Gap			
3	🗑️	<input checked="" type="checkbox"/>	Procedural Inconsistency			
4	🗑️	<input checked="" type="checkbox"/>	Unauthorized Data Access			
5	🗑️	<input checked="" type="checkbox"/>	Uncontrolled Documents			

- 1. **Add:** This button allows users to add a new reason.

Add		Discard changes		Save changes					
#		Active	Reason	French Title	Arabic Title	German Title			
		(All) ▼	🔍	🔍	🔍	🔍			
🗑️		<input type="checkbox"/>							

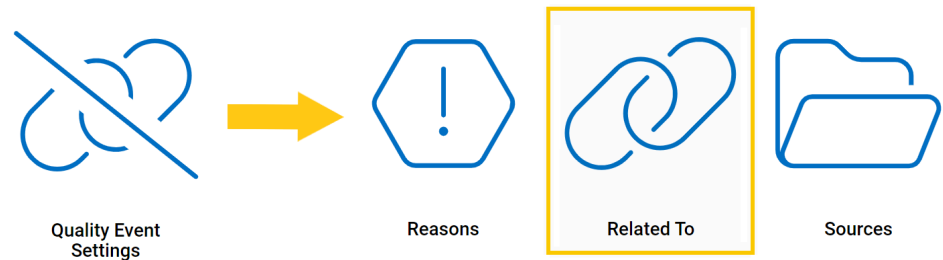
- **Reason/Title:** This is a text field that allows users to input the title(s) of the reason (in English [default], French, Arabic, or German). It is a mandatory field.
  - **Active:** This is a checkbox that, when selected, allows for the reason to be displayed in the **Reason** dropdown.
    - This checkbox is automatically unselected when a new reason is added; however, if users want the reason to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete (🗑️):** This button allows users to delete a reason.

✳ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo (↶)** icon.

✳ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

## 7.2.2. Related To

In this section, users can create, edit, and delete the quality event relations displayed in the **Quality Event Related To** dropdown. This dropdown is found in the [New Quality Event](#) form.



### Defining Quality Event Relations

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### Quality Event Related To List

Create, edit, and/or delete the items to which a quality event can be related ?

Add

Discard changes

Save changes

#		Active	Item	French Title	Arabic Title	German Title
		(All) ▾	🔍	🔍	🔍	🔍
1	🗑	<input checked="" type="checkbox"/>	Process			
2	🗑	<input checked="" type="checkbox"/>	Product			
3	🗑	<input checked="" type="checkbox"/>	Service			


1. **Add:** This button allows users to add a new quality event relation.


Add


Discard changes

Save changes

#		Active	Item	French Title	Arabic Title	German Title
		(All) ▾	🔍	🔍	🔍	🔍
	🗑	<input type="checkbox"/>	<input type="text"/>			

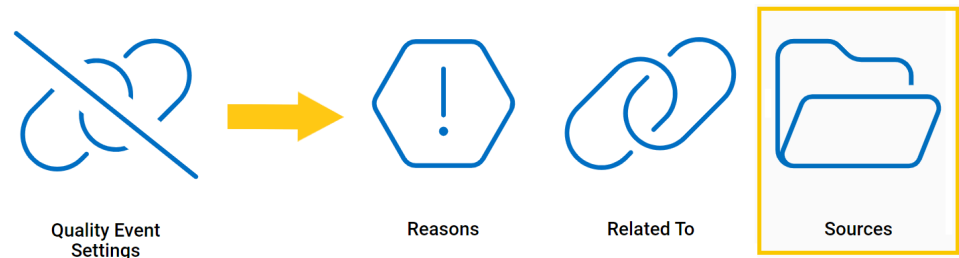
- **Item/Title:** This is a text field that allows users to input the title(s) of the quality event relation (in English [default], French, Arabic, or German). It is a **mandatory** field.
  - **Active:** This is a checkbox that, when selected, allows for the relation to be displayed in the **Related To** dropdown.
    - This checkbox is automatically unselected when a new relation is added; however, if users want the relation to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete** (  ): This button allows users to delete a quality event relation.

\* To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.

\* To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

# 7.2.3. Sources

In this section, users can create, edit, and delete the sources displayed in the **Source** dropdown. This dropdown is found in the [New Quality Event](#) form.



## Defining Sources

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### Quality Event Sources

Create, edit, and/or delete the quality event sources

Add

Discard changes

Save changes

#		Active	Source	French Title	Arabic Title	German Title
		(All) ▾	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1		<input checked="" type="checkbox"/>	QMS			
2		<input checked="" type="checkbox"/>	BCM			
3		<input checked="" type="checkbox"/>	Regulatory Finding			
4		<input checked="" type="checkbox"/>	Employee Report			
5		<input checked="" type="checkbox"/>	IT			

- 1. **Add:** This button allows users to add a new source.

Add		Discard changes		Save changes					
#		Active	Source	French Title	Arabic Title	German Title			
		(All) ▼	🔍	🔍	🔍	🔍			
🗑️		<input type="checkbox"/>							

- **Source/Title:** This is a text field that allows users to input the title(s) of the source (in English [default], French, Arabic, or German). It is a mandatory field.
  - **Active:** This is a checkbox that, when selected, allows for the source to be displayed in the **Source** dropdown.
    - This checkbox is automatically unselected when a new source is added; however, if users want the source to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete (🗑️):** This button allows users to delete a source.

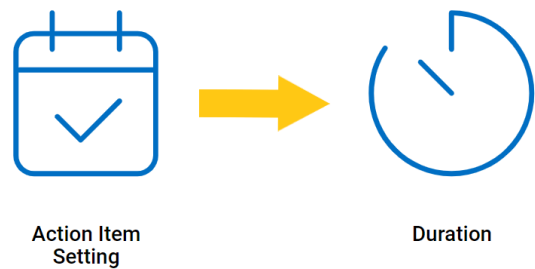
✳ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo (↶)** icon.

✳ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

! If a source is in use, users cannot delete it without first deleting all instances of its use.

## 7.3. Action Items Setting

In this section, users can access the [Duration](#) module, which allows users to define the items in the **Effectiveness Check Duration** dropdown. This dropdown is found in the [Add Action Item to Quality Event](#) form.



### Defining Durations

In this form, users can create and edit the durations used for action items. Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

Duration

Create, edit, or disable the action item durations

Add

Discard changes

Save changes

#		Active	Duration	French Title	Arabic Title	German Title
		(All) ▾	🔍	🔍	🔍	🔍
1	🗑️	<input checked="" type="checkbox"/>	All Day			
2	🗑️	<input checked="" type="checkbox"/>	One Month			
3	🗑️	<input checked="" type="checkbox"/>	One Week			
4	🗑️	<input checked="" type="checkbox"/>	Two Weeks			
5	🗑️	<input checked="" type="checkbox"/>	Three Months			

1. **Add:** This button allows users to add a new duration.

Add		Discard changes		Save changes						⋮	
#		Active	Duration	French Title	Arabic Title	German Title					
		(All) ▼	🔍	🔍	🔍	🔍					
		<input type="checkbox"/>									

- **Duration/Title:** This is a text field that allows users to input the title(s) of the duration (in English [default], French, Arabic, or German). It is a **mandatory** field.
  - **Active:** This is a checkbox that, when selected, allows for the duration to be displayed in the **Effectiveness Check Duration** dropdown.
    - This checkbox is automatically unselected when a new duration is added; however, if users want the duration to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.

✿ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu ( ⋮ ) located in the upper rightmost corner.



## 8. Quality Event Application Forms and Workflow

In the sections of the manual that follow, we will be delving into the forms and workflows of the **Quality Event** application.

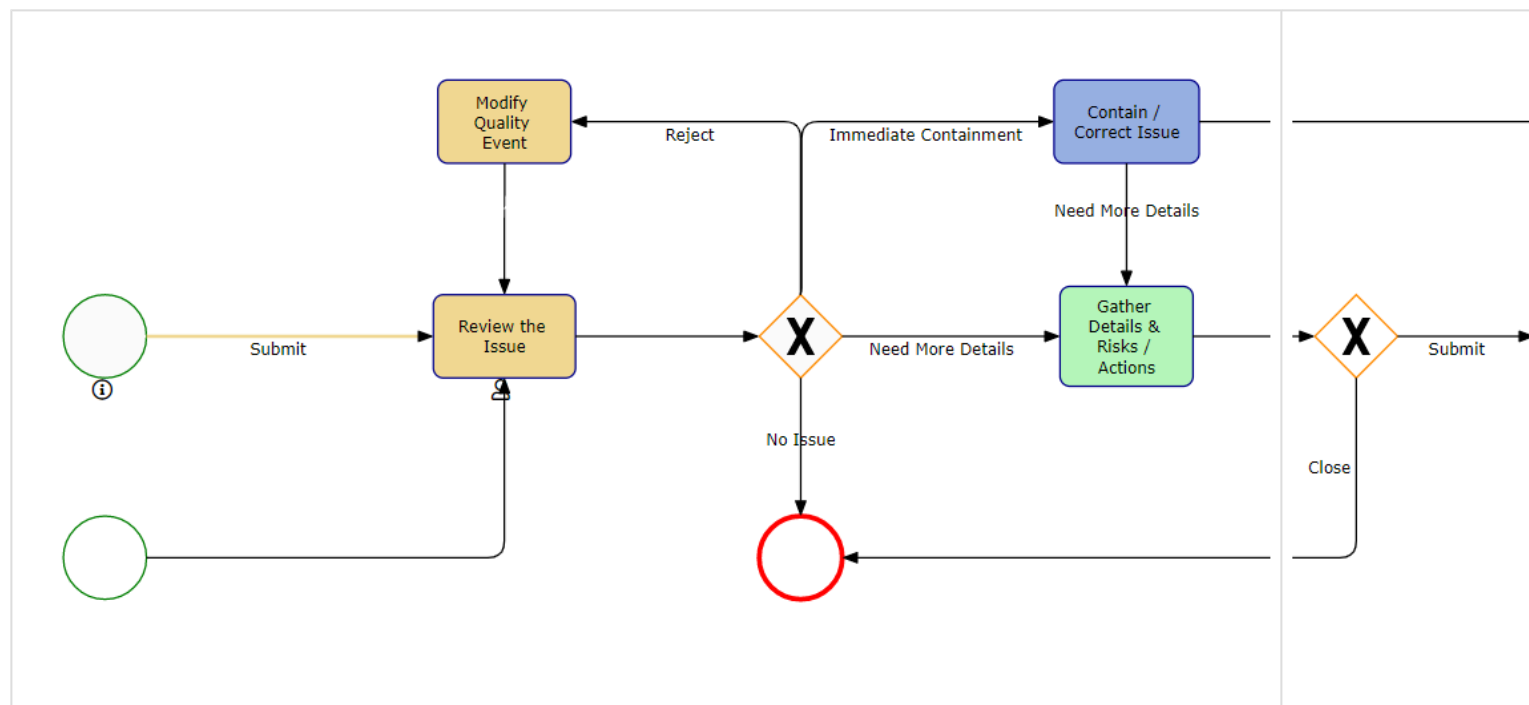
The **Quality Event** application is comprised of one central workflow.

- **Quality Event**

This workflow consists of seven primary stages: [New Quality Event](#), [Review the Issue](#), [Modify Quality Event](#), [Contain/Correct Issue](#), [Gather Details](#), [Review the Issue – Needs CAPA](#), [Correct the Issue with Actions](#), and [Check Issue Correction](#).



A quality event can be triggered either independently or via the **Audit** application. When triggered from the **Audit** application, the first step of the Quality Events workflow is [Review the Issue](#).



\*\* Although the **Modify Quality Event** form is part of the workflow, it is only issued if the quality event is rejected by the reviewer.

\*\* Likewise, although the **Contain/Correct Issue** form is part of the workflow, it is only issued if the quality event is immediately contained upon first review.

- \* If the quality event is sent to the **CAPA** application at the Review the Issue – Needs CAPA stage, it will trigger the CAPA workflow. The assigned user will be tasked with completing the root cause analysis (RCA). For more details on the CAPA workflow, see the [User Manual for the CAPA Application](#).

## 9. New Quality Event

---

In this module, users can create a new quality event. Upon submission, it will trigger the [Quality Event](#) workflow. Users will be guided on how to navigate this workflow throughout the **New Quality Event** portion of this manual.

For the purposes of ease and clarity, the New Quality Event form has been divided into several subsections within this manual.

- For more details on the contents of this form, [click here](#).

# 9.1. New Quality Event Instance

In the New Quality Event form, users can create and customize the quality event to align with their specific needs and preferences.

New Quality Event

Quality Event Name

Provide a short description of the issue

Quality Event ID

QE-00001

Event Type

Select...v

Severity

Select...v


Quality Event Reviewer

Select...v?

+ Additional Details

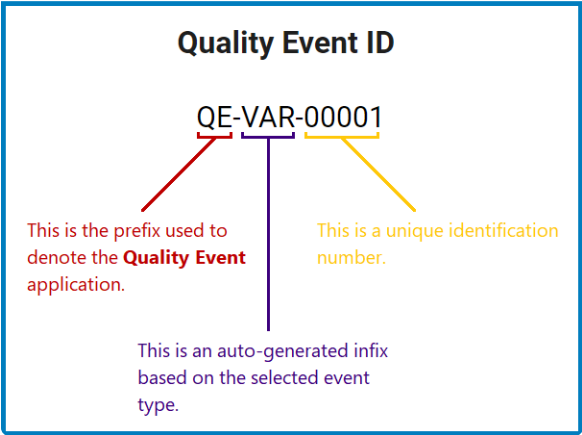
Submit form

Save Form

 For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Quality Event Name:** This is a text field that allows users to input a name for the quality event.

2. **Quality Event ID:** This field is automatically populated with a unique identifier when a new quality event is created. Users cannot modify the field.
  - When an event type is selected, the quality event ID will dynamically update to incorporate the appropriate infix.
    - For example, if Variance is selected as an event type, the quality event ID undergoes the following modification:



3. **Event Type:** This is a single-select dropdown field that displays the list of event types. It is a **mandatory** field. It allows users to categorize the nature of the quality event.

- **Event Types:** Audit Finding (Internal/External), Complaint, Deviation, Incident, Inspection Finding, Non-Conformity, Out-of-Spec, Serious Breach, Variance.
- If Audit Finding (Internal) is selected, it will reveal the following field:

<b>Event Type</b>	<b>Severity</b>	<b>Quality Event Reviewer ?</b>	<b>Audit Plan (Internal) ?</b>
Audit Finding (Internal) ▼	Select... ▼	Select... ▼	Select... ▼

- **Audit Plan ID (Internal):** This is a single-select dropdown field that retrieves the list of internal audit plan IDs. It is a **mandatory** field. It allows users to associate the quality event with a specific internal audit plan.
  - Internal audit plans are retrieved from the [Completed Audit Plans](#) module of the **Audit** application.



This field essentially allows users to manually create a quality event for an internal audit plan, as opposed to triggering the quality event directly from the **Audit** application. For more information on triggering a quality event directly from the **Audit** application, [click here](#).

- When an audit plan is linked to the quality event, a new accordion labeled **Audit Information** will appear in the form, containing the relevant details.

— Audit Information

Cause - Audit Plan ?

Plan ID	Name
AP-00020	Laboratory External Audit - Montreal

Observation(s) of the Audit Plan associated to this Quality Event

Type	Notes	Requirement ID	Name	Observation ID
General Findings	The laboratory's document management and control system	4	Laboratory Document Control	AF-00016
Major Observation	The laboratory does not have a backup or disaster recovery plan for	4	Laboratory Document Control	AF-00017
Minor Observation	Some laboratory personnel are not consistently following the	4	Laboratory Document Control	AF-00018
Non-conformity	The laboratory fails to maintain a comprehensive and up-to-date list	4	Laboratory Document Control	AF-00019

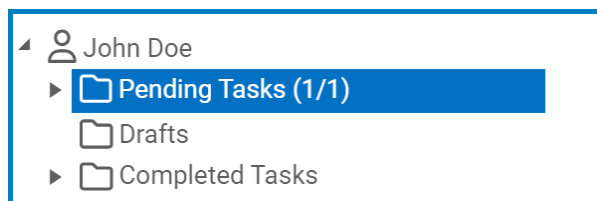
- If Audit Finding (External) is selected, it will reveal the following field:


Event Type Audit Finding (Internal) ▼	Severity Select... ▼	Quality Event Reviewer ? Select... ▼	Audit Plan (External) <input type="text"/>
--	-------------------------	---	---

- **Audit Plan ID (External):** This is a text field that allows users to input the unique identifier of the external audit plan. It is a **mandatory** field. It allows users to associate the quality event with a specific external audit plan.
- If Inspection Finding is selected, it will reveal the following field:

Event Type Audit Finding (Internal) ▼	Severity Select... ▼	Quality Event Reviewer ? Select... ▼	Inspection ID (External) <input type="text"/>
--	-------------------------	---	--

- **Inspection ID (External):** This is a text field that allows users to input the unique identifier of the inspection. It is a **mandatory** field. It allows users to associate the quality event with a specific external inspection.
4. **Severity:** This is a single-select dropdown field that displays the list of severity levels. It allows users to specify the severity of the quality event.
    - Severity Levels: Critical, Major, Minor.
  5. **Quality Event Reviewer:** This is a single-select dropdown field that retrieves the list of users, roles, and groups in the system. It is a **mandatory** field. It allows for the selection of the user, role, or group responsible for [reviewing the quality event](#).
  6. **Accordion:** The form includes a collapsible section, known as an accordion, which allows for the provision of additional information on the quality event.
    - [Additional Details](#)
  7. **Submit Form:** This button allows users to submit the completed form.
    - Once the New Quality Event form has been submitted, the assigned user will be tasked with [reviewing the issue](#).
  8. **Save Form:** This button allows users to save the form.
    - If saved, this form can be found in the **Drafts** folder (shown in the image below).
      - A saved form can be found in the **Drafts** folder if it is the first step in a given workflow. If it is a task assigned in the middle of a workflow, the saved form will remain in the **Pending Tasks** folder.



✱ To access additional options or perform actions related to the form, please utilize the kebab menu (  ) located in the upper rightmost corner.

### 9.1.1. Additional Details

In this section of the New Quality Event form, users can provide additional details about the quality event.

— Additional Details

Business Division ?

Business Line ?

Category

Select...

Source

Select...

Reason

Select...

Site(s)

Issue Statement

Paragraph

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A<sup>ⓐ</sup>

A<sub>Ⓐ</sub>

A<sub>ⓐ</sub>

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Attach any relevant document(s)

📎

Max 100 files, 2000MB each

🔄

No data

— Quality Event Related To (Optional)

Link this Quality Event to EPC Processes, Services or Products using the fields below.

Related To

Select...

EPC Process(es)

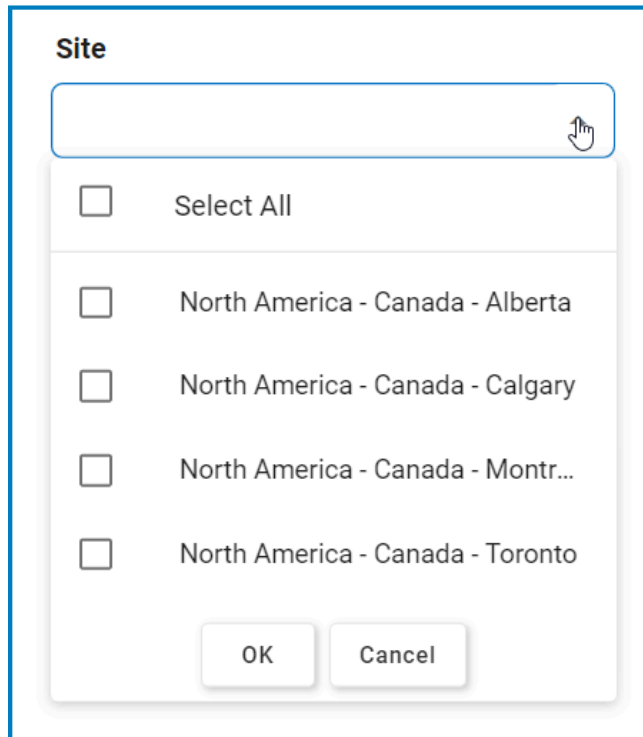
EPC Service(s)

Product(s)

✿ For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Business Division:** This is a single-select dropdown field that retrieves the list of business divisions or departments. It allows users to specify the relevant business division for the quality event.
  - Once a parent department is selected from this field, it will filter the items in the **Business Line** dropdown.
2. **Business Line:** This is a single-select dropdown field that retrieves the list of business lines associated with the selected business division. It allows users to specify the relevant business line for the quality event.
  - All child departments of the selected parent department will be displayed in this list.

3. **Category:** This is a single-select dropdown field that retrieves the list of predefined categories. It allows users to specify the category to which the quality event belongs.
  - Categories are created in the [Category](#) section of **General Settings**.
4. **Source:** This is a single-select dropdown field that retrieves the list of predefined quality event sources. It allows users to specify the source of the quality event.
  - Sources are created in the [Sources](#) section of **Quality Event Settings**.
5. **Reason:** This is a single-select dropdown field that retrieves the list of predefined quality event reasons. It allows users to specify the reason for the quality event.
  - Reasons are created in the [Reasons](#) section of **Quality Event Settings**.
6. **Site:** This is a multi-select dropdown field that retrieves the list of predefined location sites. It allows users to specify the site associated with the quality event.
  - Site options in this dropdown adhere to the following template: [Region] – [Country] – [Site].

The image shows a 'Site' multi-select dropdown menu. At the top, there is a search bar with a magnifying glass icon. Below the search bar, there is a list of site options, each preceded by a checkbox. The options are: 'Select All', 'North America - Canada - Alberta', 'North America - Canada - Calgary', 'North America - Canada - Montr...', and 'North America - Canada - Toronto'. At the bottom of the menu, there are 'OK' and 'Cancel' buttons.

**Site**

☐ Select All

☐ North America - Canada - Alberta

☐ North America - Canada - Calgary

☐ North America - Canada - Montr...

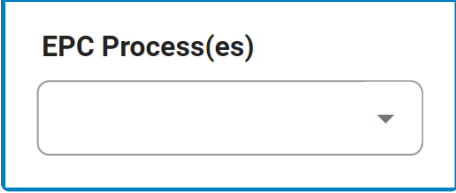
☐ North America - Canada - Toronto

OK Cancel

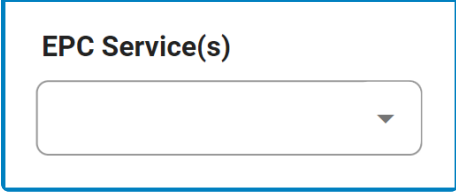
- Site options are created in the [Site](#) form. To properly set up a site, however, users will need to first set up the corresponding region in the [Region](#) form and the corresponding country in the [Country](#) form.
    - For example, to establish Montreal as the site for the quality event, users will first need to set up North America as a region and Canada as a country in the associated forms.
      - These forms are all found in the [Location](#) section of **General Settings**.
7. **Issue Statement:** This is a rich text field that allows users to provide a statement regarding the issue at hand.
  8. **Attach Any Relevant Document(s):** This is an attachment field that allows users to upload any documents relevant to the quality event.
  9. **Related To:** This is a multi-select dropdown field that retrieves the list of predefined quality event relations. It allows users to define their quality event as specific to certain processes, products, services, etc.
    - Quality Event Relations (Standard): Process, Service, Product.



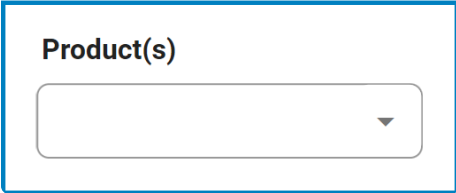
- If Process is selected, it will enable the **EPC Process(es)** dropdown.

A screenshot of a web form element. It consists of a blue rectangular border containing the text "EPC Process(es)" in bold. Below the text is a white rectangular dropdown menu with a small downward-pointing triangle on the right side.

- **EPC Process(es):** This is a multi-select dropdown field that retrieves the list of processes from EPC.
- If Service is selected, it will enable the **EPC Service(s)** dropdown.

A screenshot of a web form element. It consists of a blue rectangular border containing the text "EPC Service(s)" in bold. Below the text is a white rectangular dropdown menu with a small downward-pointing triangle on the right side.

- **EPC Service(s):** This is a multi-select dropdown field that retrieves the list of capabilities from EPC.
- If Product is selected, it will both enable the **Product(s)** dropdown and reveal the [Product Documentation](#) section.

A screenshot of a web form element. It consists of a blue rectangular border containing the text "Product(s)" in bold. Below the text is a white rectangular dropdown menu with a small downward-pointing triangle on the right side.

- **Product(s):** This is a multi-select dropdown field that displays the list of products.
- Quality event relations are created in the [Related To](#) section of **Quality Event Settings**.

# 9.1.1.1. Product Documentation

If the Product option is selected in the **Related To** dropdown, it will both enable the **Product(s)** dropdown and reveal the **Product Documentation** section. Users can utilize the tabs in this section to assign different types of documentation—EPC rules and/or controls—to the product.

— Quality Event Related To (Optional)

Related To

EPC Process(es)

EPC Service(s)

Product(s)

Product

Product Regulation Documentation

Product Control Documentation

Select Folder

Select...

Discard changes

Save changes

Selected	Parent	Identifier	Rule Name
(All)			

There is no data to display.

Select All

Deselect All

Assign Selected

Assigned Rules

#	Rule Name	Description	Versioning Type	Version	Link to Content

There is no data to display.

! To avoid repetition in the manual, similar functions across both tabs are collectively described below. Please note that this combination is solely for the purpose of the manual, and in the actual application, each tab operates independently with its specific functions.

1. **Select Folder:** This is a single-select field that displays the list of EPC object folders. Rather than in a dropdown menu, however, this list is displayed in a pop-up window.

- Once a parent EPC object folder is chosen, its child objects will populate the below grid.



Selected	Parent	Identifier	Rule Name
(All) ▼	Q	Q	Q
<input checked="" type="checkbox"/>	Quality Policy		Communication and Awareness
<input checked="" type="checkbox"/>	Quality Policy		Setting and Reviewing Quality Objectives

! In this grid, users can mark individual objects for assignment by checking the corresponding **Selected** checkbox. Selections can be saved by clicking the **Save Changes** button or simply by clicking outside the grid. To discard selections, click on the **Discard Changes** button.

- **Select All:** This button allows users to select all child objects in the grid for assignment.
- **Deselect All:** This button allows users to deselect all child objects in the grid.
- **Assign Selected:** This button allows users to assign the selected child objects in the

grid.

- Once assigned, these nodes will automatically populate the Assigned [Objects] grid.

Assigned Rules					
#	Rule Name	Description	Versioning Type	Version	Link to Content
	<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>
1	Communication and Awareness	The organization shall ensure that the quality 	Latest version	1.0000	<a href="#">Click here to open the rule</a>
2	Setting and Reviewing Quality	The organization shall define quality objectives, 	Latest version	1.0000	<a href="#">Click here to open the rule</a>

## 9.1.2. Quality Event Triggered from Audit Application

In the [final stage](#) of the Plan & Execute Audits workflow, the audit team leader can choose to trigger a quality event for selected observations linked to the audit plan.

— Trigger Quality Event(s) / CAPA(s)

Observations that are selected together in the corresponding dropdown below will create one quality event or CAPA instance. To create separate instances, select the observations one by one and click on either the Create Quality Event or Create CAPA button after each selection. An observation can only be selected and triggered once.

Observation(s) for Quality Event

Observation(s) for CAPA

Reviewer ?

Select...

Create Quality Event

Create CAPA

Before triggering the quality event, the team leader must designate a party (user, role, or group) to act as the reviewer. The selected party will be assigned the [Review the Issue](#) task. Details about the audit plan and the selected observations associated with the audit plan will be included in this task.

\* For more information on how to trigger a quality event directly from the **Audit** application, [click here](#). For further guidance on the **Audit** application in general, refer to the [User Manual for the Audit Application](#).

In the [Review the Issue](#) form, the following automatic configurations will be applied:

- The name of the quality event will be set to 'Event from Audit Plan – [Audit Plan ID – Audit Plan Name],' indicating its source.
- The ID of the quality event will be designated as 'QE-AF-[No.]'
- The event type will be set to **Audit Finding (Internal)**.
  - The **Event Type** field will be disabled to prevent further modifications.
- The **Audit Plan ID (Internal)** field will also be disabled

- It will retain the applicable value generated in the **Audit** application.

**Review The Issue [QE-AF-00027 - Event from audit plan AP-00021-Laboratory External Audit]**

<b>Quality Event Name</b>	<b>Created By</b>	<b>Creation Date</b>	<b>Quality Event ID</b>
Event from audit plan AP-00021-Laboratory External Audit	John.Doe	11/22/2023	QE-AF-00027
<b>Event Type</b>	<b>Severity</b>	<b>Quality Event Reviewer</b> ?	<b>Audit Plan (Internal)</b> ?
Audit Finding (Internal)	Select... ▼	Jane Doe	AP-00021

+ Additional Details

**Comment**

Need More Details

Correct Issue Immediately

No Issue (Close QE)

Send for modification

Save Form

\* When triggered directly from the **Audit** application, the event type Audit Finding is represented in the Quality Event ID by the abbreviation AF. When a quality event is created independently, however, Audit Finding is represented by the abbreviation AFI or AFE—depending on if it is internal or external.

## 9.2. Review the Issue

Once the [New Quality Event](#) form has been submitted, the assigned reviewer will receive a notification in their **Pending Tasks** prompting them to examine the issue.

Jane Doe

- Pending Tasks (1/1)**
- Drafts
- Completed Tasks

### Pending Tasks

Open in new window
 Change folder

Search...

:

	<input type="checkbox"/>	Flag	:	Prio...	:	Subject	:	Created at	:	Response ...	:	Done at	:	Sender
▶	<input type="checkbox"/>					Review The Issue [QE-NC-00053 - Una...		11/10/2023 19:...						John Doe

They will also receive an email notification informing them of the assigned task.

The screenshot displays an email client interface. At the top, a header bar contains the text "Review The Issue [QE-NC-00053 - Unauthorized Document Alterations]" and a search icon. Below this, the email header shows the sender as "noreply@interfacing.com" with a profile icon labeled "N", the recipient as "To: Jane Doe", and the timestamp "Fri 11/10/2023 10:12 AM". The email body contains a cautionary message: "CAUTION: This email originated from outside of Interfacing Organization. DO NOT CLICK LINK OR OPEN ATTACHMENTS unless you recognize the sender and know the content is safe." This is followed by a greeting "Hi," and a statement "You have a new quality event to review." The email then lists details for a quality event: "Quality Event ID: QE-NC-00053", "Quality Event Name: Unauthorized Document Alterations", and "Severity: Major". A blue hyperlink is provided: "https://dbp-dev-1.interfacing.com/dbp?redirect=/home/private%23%2Ftaskform%3Ftld%3Dc0c2d53e-7c29-408e-b75d-05eae50a0a8c#/" . The email concludes with "Regards," and at the bottom, there are two buttons: "Reply" and "Forward".

Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the [Review the Issue](#) form. In this form, users can review all previously entered information pertaining to the quality event and, where applicable, make necessary modifications. Users can also offer feedback or comments and determine the next course of action.

Review The Issue [QE-NC-00053 - Unauthorized Document Alterations]



Quality Event Name	Created By	Creation Date	Quality Event ID
Unauthorized Document Alterations	John.Doe	11/10/2023	QE-NC-00053

Event Type	Severity	Quality Event Reviewer ?
Non-Conformity	Major	[User] Jane Doe

Additional Details

Business Division ?	Business Line ?	Category	Source
Quality Management	Quality Assurance	QMS	Internal Document Review
<b>Reason</b>		<b>Site(s)</b>	
Uncontrolled Documents		North America - Canada - Montreal	

**Issue Statement**

Paragraph

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During a routine internal document review, it was discovered that several critical documents had been altered without proper authorization.

Attach any relevant document(s)

⬆

Max 100 files, 2000MB each

↺

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Authorization Re...

⋮

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Document Chang...

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+ Quality Event Related To (Optional)

**Review Notes**

Paragraph ▼
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**Comment**

Need More Details

Correct Issue Immediately

No Issue (Close QE)

Send for modification

✿ For guidance on common form functions, please refer to the [dedicated section in the manual](#).

1. **Review Notes:** This is a rich text field that allows users to provide notes and observations related to the quality event.
2. **Comment:** This field allows users to add comments related to the quality event.
3. **Need More Details:** This button allows users to submit the issue for further exploration.
  - If selected, the creator of the quality event will be tasked with [gathering additional details](#).
4. **Correct Issue Immediately:** This button allows users to promptly contain or correct the identified issue.
  - If selected, the creator of the quality event will be tasked with implementing the necessary [containment or correction measures](#).

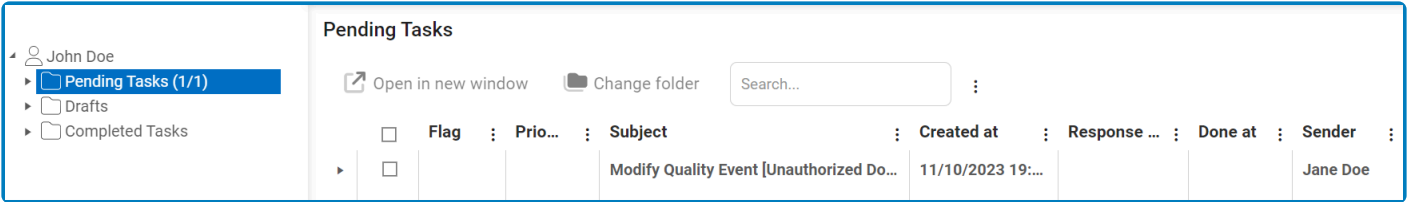
✿ Users can decide to contain the issue immediately if, upon initial review, the quality event is determined not to require action items or escalation to CAPA.

5. **No Issue:** This button allows users to close the quality event, if upon review they find there is no underlying issue.
  - This brings the [Quality Event](#) workflow to an end.
6. **Send for Modification:** This button allows users to send the quality event back for modification.

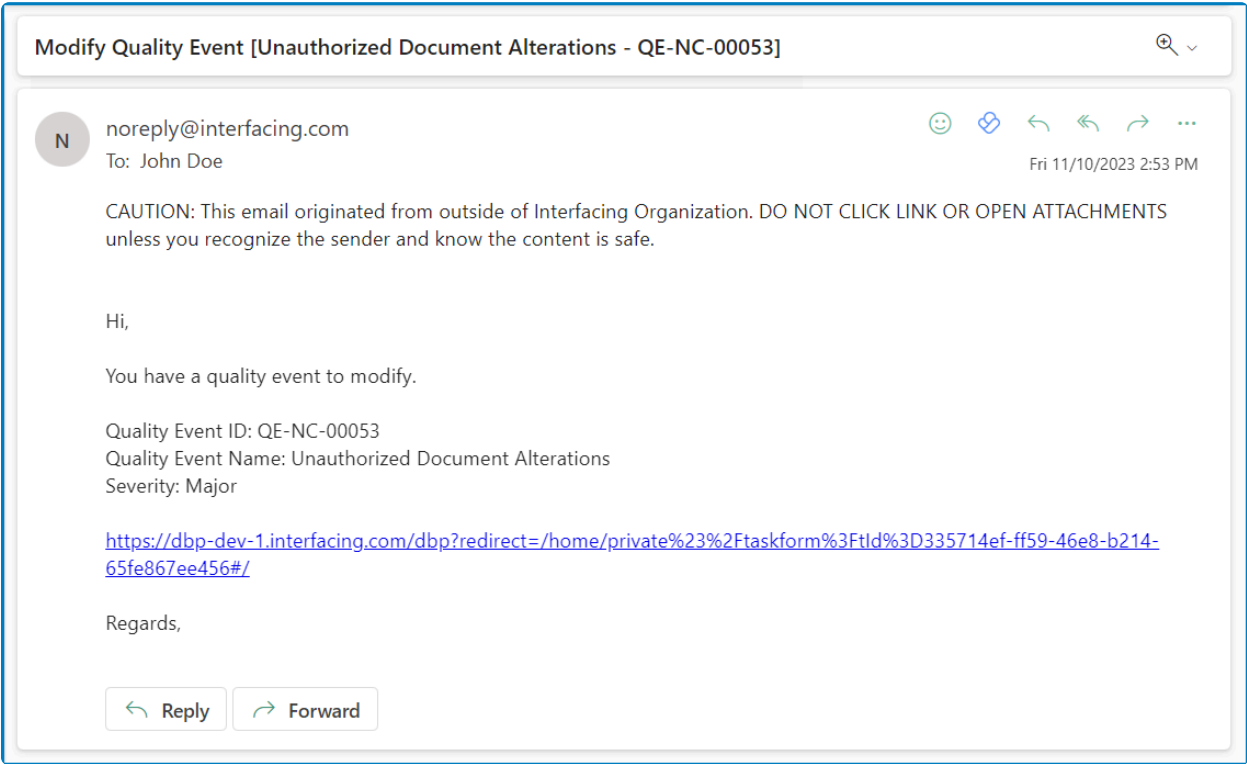
- If selected, the creator of the quality event will be tasked with [modifying it](#).

# 9.3. Modify Quality Event

If the reviewer rejects the quality event, the creator will receive a notification in their **Pending Tasks** prompting them to make modifications.



They will also receive an email notification informing them of the assigned task.



Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the Modify the Quality Event form. This form is largely a duplicate of the New Quality Event form, with the exception being that the fields are all populated with previously entered information. Users can modify all of these fields.

To avoid unnecessary repetition, only the notable aspects of the Modify form will be listed below.

## 1. Comments

Users can provide notes or comments on the modified quality event. They can also review or respond to comments left by the reviewer.

Review Notes

Paragraph

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Thank you for submitting the quality event related to Unauthorized Document Alterations. Your diligence in bringing this issue to our attention is crucial for maintaining the integrity of our documentation processes. Overall, the submission provides a good overview; however, I have added a detailed comment below regarding the attached files.

Comment

Add ➡ 

The attached files lack sufficient detail to fully understand the nature and extent of the unauthorized alterations. Please provide a more comprehensive breakdown of the changes made, specifying the sections affected and the reasons for the alterations. Additionally, include any relevant timestamps or version history to aid in the investigation and resolution process.

Written by Jane Doe on 11/10/2023 12:00 AM



The attached files lack sufficient detail to fully understand the nature and extent of the unauthorized alterations.

Thank you for your feedback. I will promptly address the concerns raised and provide a more detailed breakdown of the unauthorized alterations.




Written by John Doe on 11/10/2023 7:54 PM

↙

User Name / Date / Time

Reply

↓

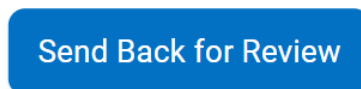
Delete ➡ 

↑

Edit

## 2. Send Back for Review


At the bottom of the Modify the Quality Event form, there is the following button:



- **Send Back for Review:** This button allows users to send the quality event back for review.
  - If upon review, the quality event is rejected again, this process will repeat.

# 9.4. Contain/Correct Issue

If the reviewer submits the quality event for immediate containment or correction, the creator will receive a notification in their **Pending Tasks** prompting them to address and rectify the issue.

 An issue is submitted for immediate containment if, upon initial review, the quality event is determined not to require action items or escalation to CAPA.

John Doe

- Pending Tasks (1/1)
- Drafts
- Completed Tasks

Pending Tasks

Open in new window Change folder Search...

	Flag	Prio...	Subject	Created at	Response ...	Done at	Sender
<input type="checkbox"/>			Contain/Correct Issue [QE-NC-00053 - ...	11/10/2023 20:...			Jane Doe

They will also receive an email notification informing them of the assigned task.

Contain/Correct Issue [QE-NC-00053 - Unauthorized Document Alterations]

N noreply@interfacing.com

To: John Doe

Fri 11/10/2023 3:51 PM

CAUTION: This email originated from outside of Interfacing Organization. DO NOT CLICK LINK OR OPEN ATTACHMENTS unless you recognize the sender and know the content is safe.

Hi,

You have a quality event to contain/correct.

Quality Event ID: QE-NC-00053  
Quality Event Name: Unauthorized Document Alterations  
Severity: Major

<https://dbp-dev-1.interfacing.com/dbp?redirect=/home/private%23%2Ftaskform%3Ftld%3Dc0c2d53e-7c29-408e-b75d-05eae50a0a8c#/>

Regards,

Reply

Forward

Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the Contain/Correct Issue form. In this form, users can review the details of the quality event, report immediate containment measures, and then decide whether to conclusively close the quality event or proceed with submitting it for further exploration.

## Contain/Correct Issue [QE-NC-00053 - Unauthorized Document Alterations]

Quality Event Name	Created By	Creation Date	Quality Event ID
Unauthorized Document Alterations	John.Doe	11/10/2023	QE-NC-00053

Event Type	Severity	Quality Event Reviewer ?
Non-Conformity	Major	Jane Doe

+ Additional Details

- Immediate Containment

Provide the details of the containment measures

Attach any relevant document(s)

Paragraph
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Max 100 files, 2000MB each

Need More Details

Close QE

Save Form

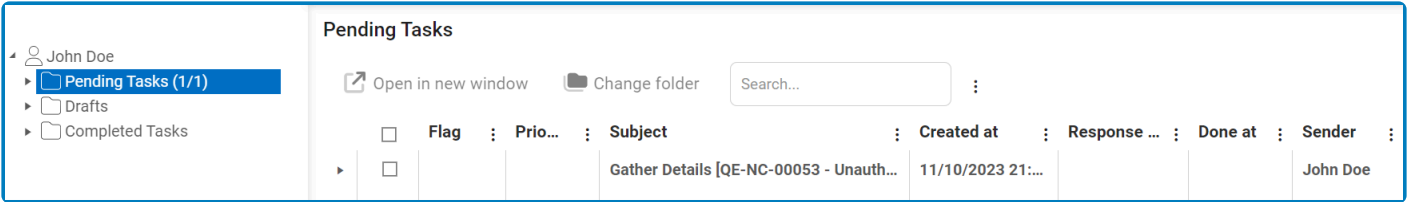


For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

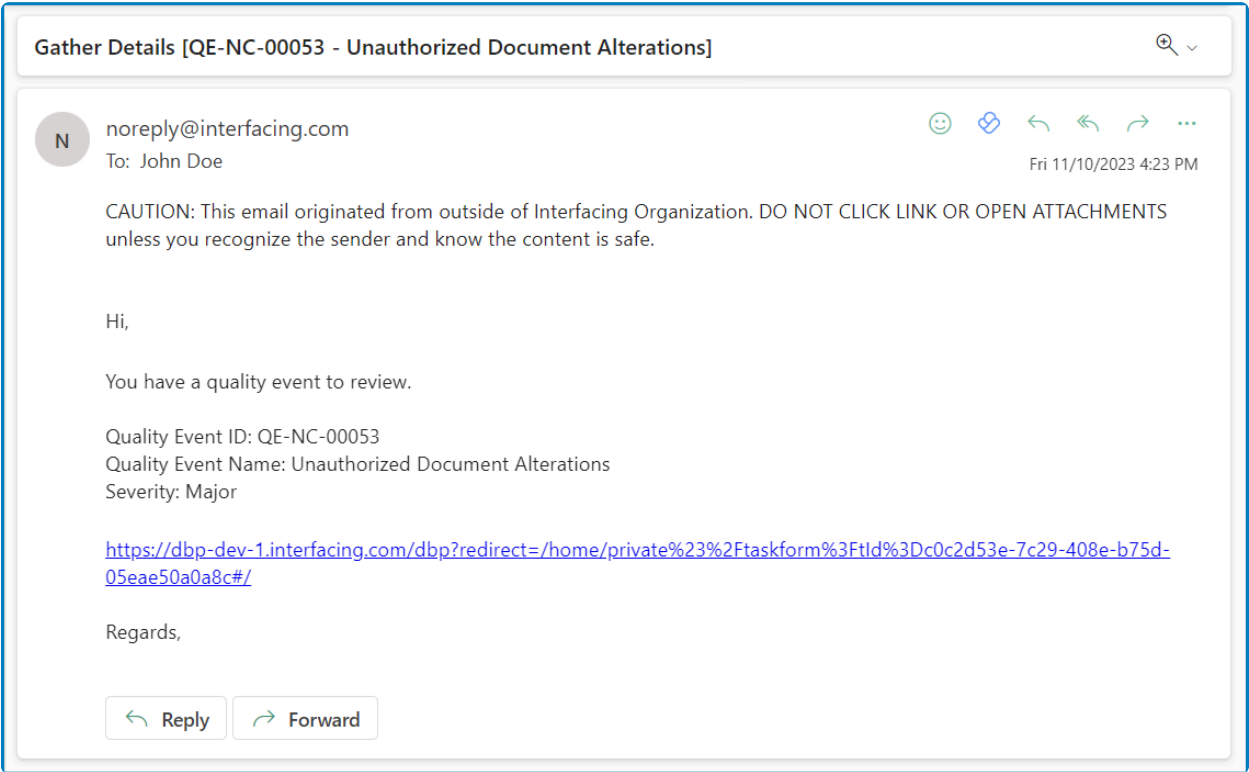
- Attach Any Relevant Documents:** This is an attachment field that allows users to upload any documents related to the issue containment.
- Provide the Details of the Containment Measures:** This is a rich text field that allows users to provide detailed information about the implemented containment measures.
- Need More Details:** This button allows users to submit the issue for further exploration.
  - If selected, the creator of the quality event will be tasked with [gathering additional details](#).
- Close QE:** This button allows users to close the quality event, bringing the [workflow](#) to an end.
- Save Form:** This button allows users to save the form. It will remain in the **Pending Tasks** folder.

# 9.5. Gather Details

If the quality event is submitted for further exploration, the creator will receive a notification in their **Pending Tasks** prompting them to gather the necessary details.



They will also receive an email notification informing them of the assigned task.



Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the Gather Details form. In this form, users can conduct a more in-depth investigation of the quality event, analyzing its root cause, identifying associated risks, and proposing specific action items to rectify the issue. Following this investigation, users can make the decision to either close the quality event or submit it for CAPA assessment.

## Gather Details [QE-NC-00053 - Unauthorized Document Alterations]

Quality Event Name	Created By	Creation Date	Quality Event ID
Unauthorized Document Alterations	John.Doe	11/10/2023	QE-NC-00053

Event Type	Severity	Quality Event Reviewer ?
Non-Conformity	Major	Jane Doe

+ Additional Details

+ Immediate Containment

+ Gather Details (Root Cause Analysis)

+ Associated Risk(s)

+ Associated Action Item(s)

Send for CAPA Assessment
Close
Save Form

1. **Accordions:** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.

- [Additional Details](#)
- [Immediate Containment](#)
- [Gather Details \(Root Cause Analysis\)](#)
- [Associated Risk\(s\)](#)
- [Associated Action Item\(s\)](#)

\* The **Immediate Containment** accordion is only included in this form if users had previously attempted to immediately contain the issue.

2. **Send for CAPA Assessment:** This button allows users to submit the quality event for CAPA assessment.
  - If selected, the assigned reviewer will be tasked with [assessing whether the quality event requires an escalation to CAPA](#).
3. **Close:** This button allows users to close the quality event, bringing the [workflow](#) to an end.
4. **Save Form:** This button allows users to save the form. It will remain in the **Pending Tasks** folder.



# 9.5.1. Additional Details

In this section of the Gather Details form, users can review additional details about the quality event.

— Additional Details

Business Division ?

Quality Management

Business Line ?

Quality Assurance

Category

QMS

Source

Internal Document Review

Reason

Uncontrolled Documents

Site(s)

North America - Canada - Montreal

Issue Statement

During a routine internal document review, it was discovered that several critical documents had been altered without proper authorization.

Attach any relevant document(s)

Additional Details on Doc...

...

Authorization Records.pdf

...

Document Changes.pdf

...

— Quality Event Related To (Optional)

Link this Quality Event to EPC Processes, Services or Products using the fields below.

Related To

Process

EPC Process(es)

Document Control

EPC Service(s)

Product(s)

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### 9.5.2. Immediate Containment

In this section of the Gather Details form, users can review the measures undertaken for the immediate containment of the issue.



This accordion is only shown in the form if the issue had been submitted for immediate containment in a previous stage of the workflow.

- Immediate Containment

**Provide the details of the containment measures**

**Document Freeze and Access Restriction:**

- Immediate action was taken to freeze access to the affected documents, preventing further unauthorized alterations. Access controls were reviewed and modified to restrict document access to authorized personnel only.

### Backup Restoration and Validation:

- The unaltered versions of the affected documents were promptly restored from the most recent backup. This measure not only recovered the original state of the documents but also established a secure foundation for the subsequent investigation into the unauthorized alterations.

**Attach any relevant documents**



Access Logs.pdf



# 9.5.3. Gather Details

In this section of the Gather Details form, users can provide additional details on the quality event.

Gather Details (Root Cause Analysis)

Provide additional details on the issue

Paragraph

A<sup>1</sup>

A<sup>2</sup>

A<sup>3</sup>

A<sup>4</sup>

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:

:


Attach any relevant document(s)

↑

Max 100 files, 2000MB each

↺

No data

 For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

- Attach Any Relevant Document(s):** This is an attachment field that allows users to upload any documents related to the quality event.
- Provide Additional Details on the Issue:** This is a rich text field that allows users to provide additional details on the issue.

## 9.5.4. Associated Risk(s)

In this section of the Gather Details form, users can add any risks associated with the quality event.

— Associated Risk(s)

Do you want to associate existing risks?

☐ Yes

☐ No

Risks

Add

Discard changes

Save changes

#	Risk Name	Description	EPC Iden...	EPC Iden...	Impact	Probability	Detectability	Score
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>				<input type="text"/>
There is no data to display.								

\* The type of single-select field used in this section of the form differs from the standard dropdown. For more details on this matter, [click here](#). For more details on the type of grid displayed and its features, [click here](#).

1. **Do You Want to Associate Existing Risks?:** This is a radio button that allows users to select only one option from a set of mutually exclusive options. Users can choose to whether to associate any existing risks with the quality event.
- If Yes is selected, the following fields become visible:

Do you want to associate existing risks?

☒ Yes ☐ No

Select Folder

Select...

Discard changes Save changes

#	Selected...	Parent	Identifier	Risk Name	Impact	Probability	Detectability	Score
	(All) ▼	🔍	🔍	🔍	🔍	🔍	🔍	🔍

There is no data to display.

Select All Deselect All Assign Selected

- **Select Folder:** This is a single-select field that displays the list of EPC risk folders. Rather than in a dropdown menu, however, this list is displayed in a pop-up window.

Select EPC Risk Folder

✕

- ▾ Root
  - ▾ Risks
    - Financial Risks
    - ▾ Security Risks
      - Information Security Risks

- Once a parent EPC risk folder is chosen, its child objects will populate the below grid.

Discard changes
Save changes










#	Selected	Parent	Identifier	Risk Name	Impact	Probability	Detectability	Score
1	<input checked="" type="checkbox"/>	Information Security Risks		Advanced Persistent Threats	Critical	Unknown in industry	Hard to Detect	16
2	<input checked="" type="checkbox"/>	Information Security Risks		Insider Threats	Significant	known in industry	Moderately Detectable	18
3	<input checked="" type="checkbox"/>	Information Security Risks		Malware Infections	Significant	Happened in company	Moderately Detectable	27
4	<input checked="" type="checkbox"/>	Information Security Risks		Password Policy Violations	Marginal	Happened in company	Easily Detectable	16
5	<input checked="" type="checkbox"/>	Information Security Risks		Phishing Attacks	Significant	known in industry	Moderately Detectable	18

Select All
Deselect All
Assign Selected

! In this grid, users can mark individual objects for assignment by checking the corresponding **Selected** checkbox. Selections can be saved by clicking the **Save Changes** button or simply by clicking outside the grid. To discard selections, click on the **Discard Changes** button


- **Select All:** This button allows users to select all child objects in the grid for assignment.
- **Deselect All:** This button allows users to deselect all child objects in the grid.
- **Assign Selected:** This button allows users to assign the selected child objects in the grid.
  - Once assigned, these nodes will automatically populate the Risks grid.

Add
Discard changes
Save changes
⋮

#		Risk Name	Description	EPC Ident...	EPC Ident...	Impact	Probability	Detectability	Score
1	 	Insider Threats	Insider threats involve individuals			Significant	known in industry	Moderately Detectable	18
2	 	Malware Infections	Malware, including viruses,			Significant	Happened in company	Moderately Detectable	27
3	 	Phishing Attacks	Phishing is a social engineering attack			Significant	known in industry	Moderately Detectable	18

! Risks from EPC cannot be modified. Users can, however, double-click on an EPC risk to access and review its details.

2. **Add:** This button allows users to add a risk to the quality event.
  - If selected, it will display the [Add Risk to Quality Event](#) form.

✿ As new risks are added, they populate the Risks grid. To perform additional customization and review, users can either click on the **Edit** (  ) icon beside

each risk or double-click on the risk itself.


Risks


Add



Discard changes



Save changes

#		Risk Name	Description	EPC Identi...	EPC Identi...	Impact	Probability	Detectability	Score
		<div>Q</div>	<div>Q</div>	<div>Q</div>	<div>Q</div>				<div>Q</div>
1	<div><div></div><div></div></div>	Data Integrity Compromise	Altering critical documents can lead <div></div>		RISK-11606	High	Medium	Moderately Detectable	36
2	<div><div></div><div></div></div>	Regulatory Non-Compliance	Unauthorized document alterations <div></div>		RISK-11607	Very High	Low	Very Easily Detectable	10
3	<div><div></div><div></div></div>	Reputational Damage	The discovery of unauthorized <div></div>		RISK-11608	Very High	Medium	Hard to Detect	60

To access the full risk description, click on the corresponding **Expand** (  ) button.

3. **Delete** (  ): This button allows users to delete a risk.

 To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.

 To access additional options or perform actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

# 9.5.4.1. Add Risk to Quality Event

In the Add Risk to Quality Event, users can create a new associated risk.

Add Risk to Quality Event

Name

Description

Paragraph

A<sup>Ⓐ</sup> A<sup>Ⓐ</sup> A<sup>Ⓐ</sup> A<sup>Ⓐ</sup> B I U

Impact

Select...

Probability

Select...

Detectability

Select...

Score

Add to EPC


Select...

Selected EPC Folder

EPC Identifier

Save and Return

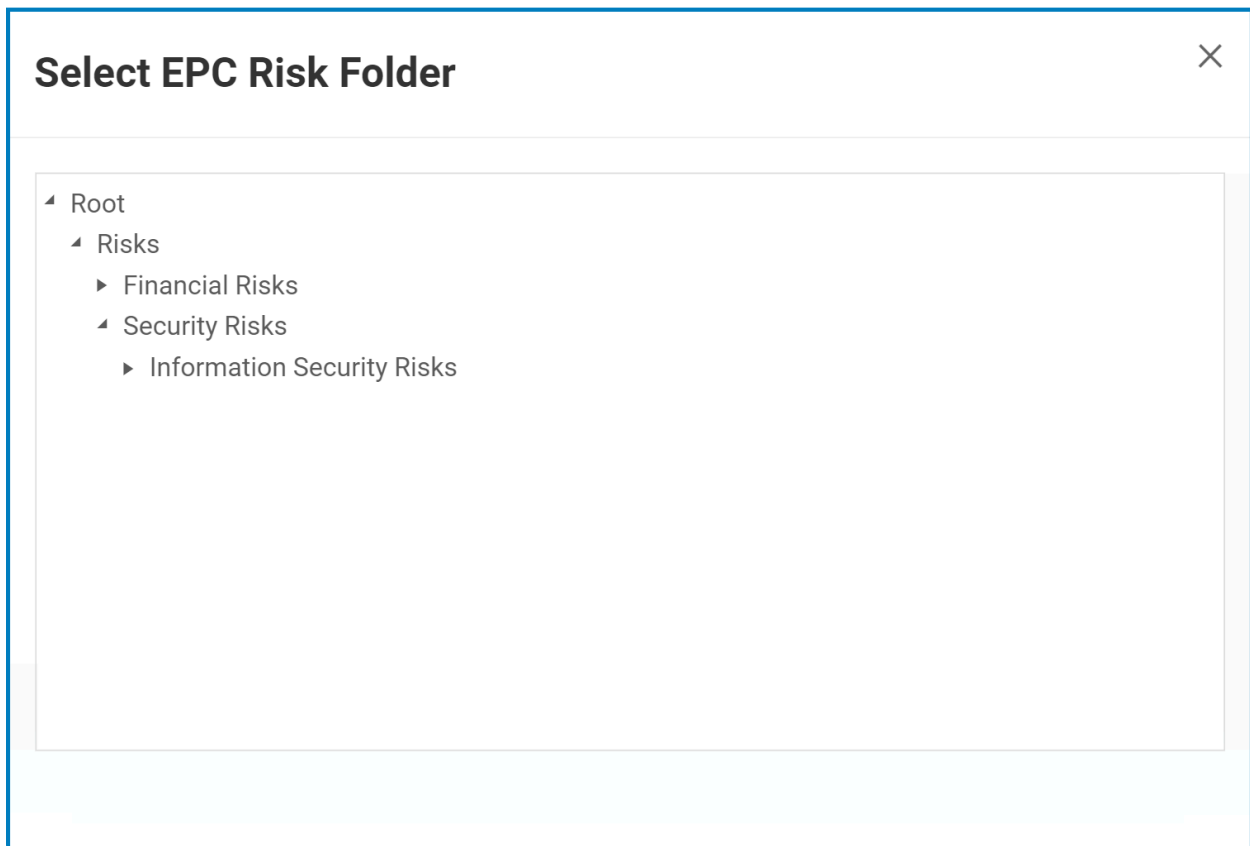
Save and New

 For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

- Name:** This is a text field that allows users to input a name for the risk. It is a mandatory field.
- Description:** This is a rich text field that allows users to provide a description of the risk.
- Impact:** This is a single-select dropdown field that retrieves the list of impact levels from EPC. It is a mandatory field. It allows users to specify the impact level of the identified risk.
  - Impact Levels: Very Low, Low, Medium, High, Very High.
- Probability:** This is a single-select dropdown field that retrieves the list of probability levels from EPC. It is a mandatory field. It allows users to specify the probability or likelihood of the identified risk occurring.



- Probability Levels: Very Low, Low, Medium, High, Very High.
- 5. **Detectability**: This is a single-select dropdown field that retrieves the list of detectability levels from EPC. It is a mandatory field. It allows users to specify the degree to which the identified risk can be detected.
  - Detectability Levels: Very Easily Detectable, Easily Detectable, Moderately Detectable, Hard to Detect, Very Hard to Detect.
- 6. **Score**: This field is automatically populated with the score once the impact, probability, and detectability levels have all been selected.
  - For more information on how the score is calculated, [click here](#).
- 7. **Add to EPC**: This is a single-select field that displays the list of EPC risk nodes. Rather than in a dropdown menu, however, this list is displayed in a pop-up window.



- Once an EPC risk node/folder has been selected, its name will populate the **Selected EPC Folder** field.

**Selected EPC Folder**

Information Security Risks



The purpose of the **Add to EPC** field is to allow users to add their newly created risk to EPC. The node/folder selected will act as the location of the new risk in

## EPC.

8. **EPC Identifier:** This is a text field that allows users to assign an identifier to the risk in EPC for tracking and reference purposes.
9. **Save and Return:** This button allows users to save the risk and return to the [Gather Details](#) form.
10. **Save and New:** This button allows users to save the risk and open a new form to create another risk.



In EPC, users can define the options displayed inside the **Impact**, **Probability**, and **Detectability** dropdowns. We run a scheduler that periodically checks if this data has been altered. If so, the dropdowns will automatically update to reflect the latest changes in EPC.

## 9.5.4.1.1. Risk Scoring System

---

In both the **Quality Event** application and EPC, risks are scored according to the following system:

### Impact

- If Very Low is selected, then the score = 1
- If Low, then the score = 2
- If Medium, then the score = 3
- If High, then the score = 4
- If Very High, then the score = 5

### Probability

- If Very Low is selected, then the score = 1
- If Low, then the score = 2
- If Medium, then the score = 3
- If High, then the score = 4
- If Very High, then the score = 5

### Detectability

- If Very Easily Detectable is selected, then the score = 1.
- If Easily Detectable, then the score = 2
- If Moderately Detectable, then the score = 3
- If Hard to Detect, then the score = 4
- If Very Hard to Detect, then the score = 5

**Total Score = (Impact Level Score) x (Probability Level Score) x (Detectability Level Score)**

# 9.5.5. Associated Action Item(s)

In this section of the Gather Details form, users can create actions to be implemented as part of the quality event.


Associated Action Item(s)

Add



Discard changes

Save changes

	Action ID	Action Name	Description	Action Type	Action Owner
	<input type="text"/>	<input type="text"/>	<input type="text"/>		
There is no data to display.					

 For more details on this type of grid and its features, [click here](#).













1. **Add:** This button allows users to add an action item to the quality event.
- If selected, it will display the [Add Action Item to Quality Event](#) form.


 As actions are added, they populate the grid. To perform additional customization and review, users can either click on the **Edit** (  ) icon beside each action or double-click on the action itself.


Add


Discard changes


Save changes

	Action ID	Action Name	Description	Action Type	Action Owner
	<input type="text"/>	<input type="text"/>	<input type="text"/>		
 	AI-2023-00062	Conduct Document Control Training	Implement a comprehensive training program for all employees who handle	 Internal	John Doe
 	AI-2023-00063	Update Document Control Processes	Review and update document control processes. This update should include	 Internal	John Doe
 	AI-2023-00064	Strengthen Access Controls	Conduct a thorough review of access controls for sensitive documents.	 Internal	John Doe
 	AI-2023-00065	Implement Supplier Corrective Action	Some unauthorized alterations have been traced back to a supplier. Initiate a	 External	John Doe

To access the full action description, click on the corresponding **Expand** (  ) button.

2. **Delete** (  ): This button allows users to delete an action.

\* To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.

\* To access additional options or perform actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

## 9.5.5.1. Add Action Item to Quality Event

In the Add Action Item to Quality Event form, users can create a new action item to address or rectify the quality event.

**Add Action Item to Quality Event**

**Action Item Name**  
Provide a short description of the action to be done

**Priority**  
Select...

**Due Date**  
[Date Picker]

**Action Completion Reviewer** ?  
Select...

**Action Item Owner**  
Select...

+ Details of the action

+ Additional Details

Save and Return Save and New

\* For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Action Name:** This is a text field that allows users to input the name of the action item. It is a **mandatory** field.
2. **Priority:** This is a single-select dropdown field that displays the list of priority levels.
  - Priority Levels: High, Medium, Low.
3. **Due Date:** This is a date picker field that allows users to input/select the due date for the action. It is a **mandatory** field.
4. **Action Completion Reviewer:** This is a single-select dropdown field that retrieves the list of users, roles, and groups in the system. It is a **mandatory** field. It allows for the selection of the user, role, or group responsible for reviewing the completion of the action.
5. **Action Item Owner:** This is a single-select dropdown field that retrieves the list of users. It is a **mandatory** field. It allows for the selection of the user responsible for executing the action.
6. **Accordions:** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.
  - [Details of the Action](#)
  - [Additional Details](#)

7. **Save and Return:** This button allows users to save the action item and return to the [Gather Details](#) form.
8. **Save and New:** This button allows users to save the action item and open a new form to create another action item.

#### 9.5.5.1.1. Details of the Action

In this section of the Add Action Item to Quality Event form, users can define the details that shape the action item. This includes choosing the type of action to be taken and specifying the corresponding action plan.

— Details of the action

Action Type

☒ Internal

☐ External

Action ?












☐ Is a Retraining or New Training Required?

☐ Does EPC Documentation Need Updating?

☒ Other

What is the action to be done?

Paragraph ▾

A<sup>Ⓐ</sup> ▾ AI ▾ A ▾ A ▾ B I U         ▾  ▾  

1. **Action Type:** This is a radio button that allows users to select only one option from a set of mutually exclusive options. It is a mandatory field. Users can choose either an internal or external action type.
  - If the Internal is selected, the following field becomes visible:

Action Type

☒ Internal ☐ External

Action ?

☐ Is a Retraining or New Training Required?  
☐ Does EPC Documentation Need Updating?  
☒ Other

- **Action:** This is a radio button that allows users to select only one option from a set of mutually exclusive options. It is a mandatory field. It allows users to choose the type of internal action to be taken.
  - Depending on the option selected, different fields will be revealed. **For more information on the internal action type options, [click here](#).**

- ✿ By default, the action type is set to Internal, making the **Action** radio



button visible. This radio button disappears if users switch the selection to [External](#).

- If [External](#) is selected, the following fields become visible:

**Action Type**

☐ Internal ☒ External

**Supplier**

Select... ▾

Supplier Representative Name	Supplier's Phone	Supplier's Email
------------------------------	------------------	------------------

- **Supplier:** This is a single-select dropdown field that retrieves the list of suppliers (from the [Supplier List](#) module of the **Supplier** application). It is a **mandatory** field. It allows users to select the supplier for which the **Supplier Corrective Action Report (SCAR)** will be issued.
- **Supplier Representative Name:** This field is automatically populated with the name of the representative associated with the selected supplier.
- **Supplier's Phone:** This field is automatically populated with the phone number associated with the selected supplier.
- **Supplier's Email:** This field is automatically populated with the email address associated with the selected supplier.

**Supplier**

XYZ Widget Company ▾

Supplier Representative Name	Supplier's Phone	Supplier's Email
Erika Mustermann	(800) 555-0100	erika.mustermann@xyz.com



All supplier-related information is obtained from the **Supplier** application. To learn more about how to use this application, please refer to the accompanying [User Manual](#).

## 9.5.5.1.1.1. Internal Action Type Options

---

Through the **Action** radio button, users are presented with the following options:

**Action Type**

☒ Internal ☐ External

**Action ?**

☐ Is a Retraining or New Training Required?  
☐ Does EPC Documentation Need Updating?  
☒ Other

1. [Is a Retraining or New Training Required?](#)
2. [Does EPC Documentation Need Updating?](#)
3. [Other](#)

# 9.5.5.1.1.1.1. Is a Retraining or New Training Required?

## Option 1: Is a Retraining or New Training Required?

If this option is selected, it will reveal the following grid:

Action Type

☒ Internal ☐ External

Action ?

☒ Is a Retraining or New Training Required?  
☐ Does EPC Documentation Need Updating?  
☐ Other


Training(s) Required

Add

Discard changes

Save changes

#	Training Name	Departments	Roles	Users	Groups
There is no data to display.					

 For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Add:** This button allows users to add a training request.
  - If selected, it will display the Select Training Request form.

Select Training Request

⋮ ×

Click on the **[+]** to create a new training

+

Existing Training

Select...

Each of the dropdowns below will display the current trainee(s) assigned to the selected training. If the training does not apply to a listed trainee, please remove them.

Departments

Roles

Users

Groups

Save and Return

Save and New

- +

: This button allows users to create a new training.
  - If selected, it will display the [New Training](#) form.

✿ For more information on defining and executing trainings, refer to the [User Manual for the Training Application](#).

- Existing Training:** This is a single-select field that retrieves the list of existing trainings (from the [Training List](#) module of the **Training** application). Rather than in a dropdown menu, however, this list is displayed in a pop-up window.

Select Training


⋮ ×



#	Training Name	Major Version	Assessment Method	Objectives	Departments	Roles
	🔍	🔍	🔍	🔍	🔍	🔍
1	Document Control Training	2	Attendance	This training serves to both ensure		
2	Employee Health & Safety Training	2	Attendance	The objective is to enhance employee		
3	Information Security Awareness Training	1	Attendance	The objective is to enhance employees'	Information Technology	
4	ISO 9001 Implementation Training	4	Certification	The purpose of this training is to provide	Quality Management, Quality Assurance	Quality Assurance Manager
5	Risk Management & Risk-Based Thinking Training	1	Score	The objective of this training is to enable	Quality Management	Chief Risk Officer

! To appear in this window, trainings must have an active status and be


approved. Users can select a training by double-clicking on it from the grid.

- **Departments:** This is a multi-select dropdown field that displays the list of departments. It allows users to assign the training to one or more departments.
  - Once a training is selected, this field is automatically populated with the departments assigned to the training. Users can add to/edit the items in this field.
- **Roles:** This is a multi-select dropdown field that displays the list of roles. It allows users to assign the training to one or more roles.
  - Once a training is selected, this field is automatically populated with the roles assigned to the training. Users can add to/edit the items in this field.
- **Users:** This is a multi-select dropdown field that displays the list of users. It allows users to assign the training to one or more users.
  - Once a training is selected, this field is automatically populated with the users assigned to the training. Users can add to/edit the items in this field.
- **Groups:** This is a multi-select dropdown field that displays the list of groups. It allows users to assign the training to one or more groups.
  - Once a training is selected, this field is automatically populated with the groups assigned to the training. Users can add to/edit the items in this field.
- **Save and Return:** This button allows users to save the training request and return to the [Add Action Item to Quality Event](#) form.
- **Save and New:** This button allows users to save the training request and open a new form to create another training request.

✿ As trainings are added, they populate the [Training\(s\) Required](#) grid. To perform additional customization and review, users can either click on the **Edit** (  ) icon beside each training or double-click on the training itself.

Training(s) Required						
<div> <span>Add</span> <span>Discard changes</span> <span>Save changes</span> </div>						
#		Training Name	Departments	Roles	Users	Groups
1	 	Document Control Training				Documentation Team

2. **Delete** (  ): This button allows users to delete a training.

✿ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.

## 9.5.5.1.1.1.2. Does EPC Documentation Need Updating?

### Option 2: Does EPC Documentation Need Updating?

If this option is selected, it will reveal the following fields:

**Action Type**  
☒ Internal ☐ External

**Action ?**  
☐ Is a Retraining or New Training Required?  
☒ Does EPC Documentation Need Updating?  
☐ Other

**Module**  

Select... ▼

**Improvement Requests**  

Discard changes

Save changes

⋮

#	Module	Path	Name	Identifier	Status	Improvement Requests
There is no data to display.						

\* The type of single-select field used here differs from the standard dropdown. For more details on this matter, [click here](#).

1. **Module:** This is a single-select dropdown field that retrieves the list of EPC modules (Process, Document, Rule, Control, and Capability). It allows users to select only one value at a time from the dropdown.
  - Once a module is selected, the **Folder** field becomes visible:

**Module**  

Process ▼

**Folder**  

▼

- **Folder:** This is a single-select field that displays a list of the selected module's EPC nodes. Rather than in a dropdown menu, however, this list is displayed in a pop-up window.

- Once a parent EPC object node is chosen, its child nodes will populate the EPC Objects grid.

Module
Folder

Process

EPC Objects

Discard changes
Save changes

#	Selected	Parent	Identifier	Name	Status
1	<input type="checkbox"/>	Document Control		Document Development & Management	PUBLISHED
2	<input type="checkbox"/>	Document Control		Document Retrieval and Distribution	PUBLISHED

Select All
Deselect All
Assign Selected



In this grid, users can mark individual object nodes for assignment by checking the corresponding **Selected** checkbox. Selections can be saved by clicking the **Save Changes** button or simply by clicking outside the grid. To discard selections, click on the **Discard Changes** button

- Select All:** This button allows users to select all child nodes in the grid for assignment.
- Deselect All:** This button allows users to deselect all child nodes in the grid.
- Assign Selected:** This button allows users to assign the selected child nodes in the grid.
  - Once assigned, these nodes will automatically populate the Improvement Requests grid.

Improvement Requests

Discard changes
Save changes

#		Module	Path	Name	Identifier	Status	Modification Request
1		Process	Processes > Document Control	Document Development & Management		PUBLISHED	
2		Process	Processes > Document Control	Document Retrieval and Distribution		PUBLISHED	




To make an improvement request for a specific object, simply edit inside the corresponding **Improvement Request** column.


- Delete** (): This button allows users to delete a training.



To confirm the deletion of items in the grid, click on the **Save Changes** button or

simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.



For additional options or actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.



If this option is selected, during the execution of the action item, an improvement request (IR) will automatically be triggered in EPC.



# 9.5.5.1.1.1.3. Other

## Option 3: Other

If this option is selected, it will reveal the following field:

Action Type

☒ Internal ☐ External

Action ?

☐ Is a Retraining or New Training Required?

☐ Does EPC Documentation Need Updating?

☒ Other

What is the action to be done?

Paragraph ▾

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1. **What is the action to be done?:** This is a rich text field that allows users to provide information about the action to be taken.
  - For more details on this field, [click here](#).

### 9.5.5.1.2. Additional Details

In this section of the Add Action Item to Quality Event form, users can define additional details about the action item.

— Additional Details

Type

▼

Reference No

Category

Select...

▼

Compliance Program

Select...

▼

Source

Quality Event

Business Division ?

Select...

▼

Business Line ?

Select...

▼

Site

▼

Additional Description

Paragraph ▼

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Attach any relevant documents (optional)

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Max 20 files, 2000MB each

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No data

— Budget

Budget

Add

Discard changes

Save changes

⋮

#	Budget Item	Description
There is no data to display.		

✿ For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Type:** This is a single-select dropdown field that displays the list of types or classifications. It allows users to classify the action based on its purpose or nature.
  - Types: Correction, Corrective, Effectiveness Check, Improvement, or Preventive.
    - If Effectiveness Check is selected, it will reveal the following field:

Type

Effectiveness check

Source

Effectiveness Check Frequency

- **Effectiveness Check Frequency:** This is a single-select dropdown field that retrieves the list of predefined frequencies. It allows users to specify the frequency at which the effectiveness check will be conducted.
  - Frequencies are created in the [Frequency](#) section of **General Settings**.

\* A [correction](#) is an action that is taken to rectify or eliminate a detected issue. A [corrective action](#) is one that is taken to prevent the reoccurrence of an issue. An [effectiveness check](#) is a measure of whether or not a corrective action has eliminated a detected issue. An [improvement](#) is an action implemented to enhance existing processes, systems, products, or services. A [preventive action](#) is one that is taken to prevent a potential issue that has not yet occurred.


2. **Reference No.:** This is a text field that allows users to input a reference number for the action item, if applicable.
3. **Category:** This is a single-select dropdown field that retrieves the list of predefined categories. It allows users to specify the category to which the action belongs.
  - Action item categories are created in the [Category](#) section of **General Settings**.
4. **Compliance Program:** This is a single-select dropdown field that retrieves the list of predefined compliance programs. It allows users to select the applicable compliance program for the action.
  - Compliance types are created in the [Compliance Types List](#) section of **General Settings**.
5. **Source:** This is a text field that allows users to specify the source of the action.
  - This field will be automatically populated with the application to which the action item is linked. Users can still modify the field.
6. **Business Division:** This is a single-select dropdown field that retrieves the list of business divisions or departments. It allows users to specify the relevant business division for the action.
  - Once a parent department is selected from this field, it will filter the items in the **Business Line** dropdown.
7. **Business Line:** This is a single-select dropdown field that retrieves the list of business lines

associated with the selected business division. It allows users to specify the relevant business line for the action.

- All child departments of the selected parent department will be displayed in this list.
8. **Site:** This is a multi-select dropdown field that retrieves the list of predefined location sites. It allows users to specify the site associated with the action.
- Site options in this dropdown adhere to the following template: [Region] – [Country] – [Site].

The screenshot shows a modal window titled "Site". At the top is a search bar with a magnifying glass icon. Below it is a list of items, each with a checkbox and text: "Select All", "North America - Canada - Alberta", "North America - Canada - Calgary", "North America - Canada - Montr...", and "North America - Canada - Toronto". At the bottom of the modal are two buttons: "OK" and "Cancel".

- Site options are created in the [Site](#) form. To properly set up a site, however, users will need to first set up the corresponding region in the [Region](#) form and the corresponding country in the [Country](#) form.
    - For example, to establish Montreal as the site for the action, users will first need to set up North America as a region and Canada as a country in the associated forms.
      - These forms are all found in the [Location](#) section of **General Settings**.
9. **Description:** This is a rich text field that allows users to provide a description of the action.
10. **Attach Any Relevant Document(s):** This is an attachment field that allows users to upload any documents relevant to the action.
11. **Add:** This button allows users to add a budget item for the action.
- If selected, it will display the [Add Budget Item](#) form.




✿ As new budget items are added, they populate the [Budget](#) grid. To perform additional customization and review, users can either click on the **Edit** (  ) icon beside each item or double-click on the item itself.


Budget


Add



Discard changes



Save changes

#		Budget Item	Description	Cost
1	 	Training Materials & Resources	Develop or acquire training materials, including presentations, handouts, and online resources, to support the document control training sessions. 	1,000.00

To access the full budget item description, click on the corresponding **Expand** (  ) button.

12. **Delete** (  ): This button allows users to delete a budget item.

 To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.

 To access additional options or actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

# 9.5.5.1.2.1. Add Budget Item

In the Add Budget Item form, users can create a new budget item for the action.

Add Budget Item

Budget Item Name

Cost

.0

Description

Paragraph

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Save and Return

Save and New

\* For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

- Budget Item Name:** This is a text field that allows users to input a name for the budget item.
- Cost:** This is a numeric updown field that allows users to input a cost for the budget item. Users can enter this number either manually or by clicking the increment/decrement arrows. The cost can be either a whole number or a decimal.
- Description:** This is a rich text field that allows users to provide a description for the budget item.
- Save and Return:** This button allows users to save the budget item and return to the [Add Action Item to Quality Event](#) form.
- Save and New:** This button allows users to save the budget item and open a new form to create another budget item.

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## 9.6. Review the Issue – Escalate to CAPA?

If the quality event is submitted for CAPA assessment, the assigned reviewer will receive a notification in their **Pending Tasks** prompting them to evaluate whether the issue requires an escalation to CAPA.

Jane Doe

- Pending Tasks (1/1)**
- Drafts
- Completed Tasks

### Pending Tasks

Open in new window
 Change folder

Search...

:

	<input type="checkbox"/>	Flag	:	Prio...	:	Subject	:	Created at	:	Response ...	:	Done at	:	Sender
▶	<input type="checkbox"/>					Review The Issue - Escalate to CAPA? ...		11/11/2023 06:...						John Doe

They will also receive an email notification informing them of the assigned task.

The screenshot displays an email client interface. At the top, a header bar contains the text "Review The Issue - Escalate to CAPA? [QE-NC-00053 - Unauthorized Document Alterations]" and a search icon. Below the header, the email header shows the sender as "noreply@interfacing.com" with a profile icon labeled "N", the recipient as "To: Jane Doe", and the date "Sat 11/11/2023 1:26 AM". The email body contains a cautionary message: "CAUTION: This email originated from outside of Interfacing Organization. DO NOT CLICK LINK OR OPEN ATTACHMENTS unless you recognize the sender and know the content is safe." This is followed by a greeting "Hi," and a statement "You have a new quality event to review." The email then lists details for a quality event: "Quality Event ID: QE-NC-00053", "Quality Event Name: Unauthorized Document Alterations", and "Severity: Major". A blue hyperlink is provided: "https://dbp-dev-1.interfacing.com/dbp?redirect=/home/private%23%2Ftaskform%3Ftld%3Dc0c2d53e-7c29-408e-b75d-05eae50a0a8c#/" . The email concludes with "Regards," and a footer area with "Reply" and "Forward" buttons.

Clicking on either the subject in **Pending Tasks** or the link in the email will direct users to the [Review the Issue – Escalate to CAPA?](#) form. This form, largely mirroring the [Gather Details](#) form, presents all fields in a read-only format. Users can review the investigation of the quality event, along with its associated risks and action items, before deciding whether to escalate.

Review The Issue - Escalate to CAPA? [QE-NC-00053 - Unauthorized Document Alterations]

Quality Event Name	Created By	Creation Date	Quality Event ID
Unauthorized Document Alterations	John.Doe	11/10/2023	QE-NC-00053

Event Type	Severity	Quality Event Reviewer ?
Non-Conformity	Major	[User] Jane Doe

+ Additional Details

+ Immediate Containment

+ Gather Details (Root Cause Analysis)

+ Associated Risk(s)

+ Associated Action Item(s)

Send the issue to CAPA?

Select...

Correct Issue Immediately

1. **Send the Issue to CAPA?:** This is a single-select dropdown field that displays a list of responses (Yes or No) to the question. It is a **mandatory** field.

- If Yes is selected, it will alter the page in the following way:

Send the issue to CAPA?

CAPA Reviewer

Yes

Select...

Send to CAPA

- **CAPA Reviewer:** This is a single-select dropdown field that retrieves the list of users, roles, and groups in the system. It is a **mandatory** field. It allows for the selection of the user, role, or group responsible for reviewing the CAPA.
- **Send to CAPA:** This button allows users to send the quality event to the **CAPA** application.
  - Selecting this button will conclude the [Quality Event](#) workflow and initiate the CAPA workflow.
  - The assigned reviewer will automatically receive the [Review CAPA](#) task,



which includes details about the quality event.

✿ For more information on the CAPA workflow, please refer to the [User Manual for the CAPA Application](#).

! Please note that if any of the action items added in the [Gather Details](#) form are external and the quality event is sent to CAPA, the [Create SCAR](#) task will be issued concurrently with the [Execute Action Items](#) task—both tasks assigned to the relevant owners.

- If [No](#) is selected, the page will remain unchanged, displaying only the **Correct Issue Immediately** button.

2. **Correct Issue Immediately:** This button allows users to submit the issue for immediate correction.

- If no action items were added in the [Gather Details](#) form and the **Correct Issue Immediately** button is selected, the quality event will be closed.
  - This brings the [Quality Event](#) workflow to an end.
- If action items were added in the [Gather Details](#) form and the **Correct Issue Immediately** button is selected, the assigned owners will be tasked with [correcting the issue with actions](#).
  - If any of the action types are external, it will trigger the SCAR workflow. The assigned owners will be tasked with [creating SCAR](#).

✿ If there is only one action item and it is external, users will only be tasked with creating SCAR—meaning that they will not receive the [Correct the Issue with Actions](#) task.

## 9.7. Correct the Issue with Actions

If the quality event is submitted for immediate correction, the assigned action item owner(s) will receive a notification in their **Pending Tasks** prompting them to correct the issue with actions.

✿ At this stage, if applicable, trainees will be notified of any trainings that have been assigned to them. For more information on the Training workflow, refer to the [User Manual for the Training Application](#).

✿ Similarly, if applicable, the assigned action item owner(s) will be tasked with creating SCAR. For more information on the SCAR workflow, [click here](#).


Clicking on the subject in **Pending Tasks** will direct the user to the [Correct the Issue with Actions](#) form.

#	Action ID	Action Name	Action Type	Status	Action Completed
1	AI-2023-00066	Conduct Document Control Training	Re-Training	Not Started	<input type="checkbox"/>
2	AI-2023-00067	Update Document Control Processes	EPC change request	Not Started	<input type="checkbox"/>
3	AI-2023-00068	Strengthen Access Controls	Other	Not Started	<input type="checkbox"/>

☐ Select to Mark All Actions as Completed

Complete

- Edit** ( ): This button allows users to access and execute an action item.
  - If selected, it will display the [Execute Action Item](#) form.
- Complete**: This button allows users to submit the completed form.
- Select to Mark All Actions as Completed**: This is a checkbox that, when selected, allows users to mark all actions in the grid as completed.
  - If selected, the **Action Completed** checkbox for each action will be selected.

✿ To access additional options or perform actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

# 9.7.1. Execute Action Item

In the Execute Action Item form, users can manage the execution of a specific action associated with the quality event.

Execute Action Item

Created By	Creation Date	Action ID
John Doe	11/11/2023	AI-2023-00066

Keep the status of the action updated as you make progress.

Action Item Name	Priority	Due Date
Conduct Document Control Training	High	11/19/2023

Action Completion Reviewer ?	Action Item Owner	Status
[User] Jane Doe	John Doe	Has Started

+ Details of the action

+ Additional Details

+ Enter Observation and/or Attach Evidence

Do you accept this action?

☒ Yes ☐ No

Request an Extension

☐ Action Completed

< Save and Previous

Save and Return

Save and Next >

1. **Status:** This is single-select dropdown field that displays the list of statuses. It allows users to select the current status of the action item.
- Statuses: Not Started, Has Started, In Progress, Completed, or Rejected.

✿ Users are encouraged to consistently update the status of their action item to reflect their progress.

2. **Accordions:** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.
- [Details of the Action](#)
  - [Additional Details](#)
  - [Observations and/or Evidence](#)

✿ The **Observations and/or Evidence** accordion is only included in this form if users confirm their acceptance of the action using the below radio button.

3. **Do You Accept This Action:** This is a radio button that allows users to select only one option from a set of mutually exclusive options. It is a **mandatory** field. Users can choose to either accept or reject the assigned action.
- If Yes is selected, signifying acceptance, a new accordion called **Observations and/or Evidence** will appear in the form.
  - If No is selected, signifying rejection, the status of the action item will automatically change to **Reject**.

✿ Users can similarly reject other actions listed in the [Correct the Issue with Actions](#) form.

! By making a choice regarding the acceptance of the action item, users define the path they will follow and the sections of the form that they will engage with.


4. **Request an Extension:** This button allows users to request an extension for the action deadline.
- If selected, it will reveal the extension request section, where users can input their requested new due date and provide a reason for the extension.

### Extension Request

Current Due Date

11/19/2023

New Due Date Requested



Reason for the extension

Cancel

Send Request

- **Send Request:** This button allows users to send the extension request to the assigned manager of the action, as determined by the **Action Completion Reviewer** dropdown in the [Add Action Item to CAPA](#) form.
  - The assigned manager(s) will receive the [Approve or Reject Extension Request](#) form.
- **Cancel:** This button allows users to cancel the extension request and hide the section.
- **Extension Request Status Tracking**

Action item owners can monitor the status of their extension requests. There are three possible states:

- **Extension Status: Pending** indicates that the extension request is awaiting approval.

#### Extension Status

Pending: Request Sent on 12/5/2023; New Request Date : 12/12/2023

- **Extension Status: Approved** indicates that the extension request has been approved.

#### Extension Status

The extension is approved to this new due date 12/12/2023.

Only 1 extension is permitted per action.

- **Extension Status: Rejected** indicates that the extension request has been rejected.

**Extension Status****Rejected****Only 1 extension is permitted per action.****Only one extension request is permitted per action item.**

5. **Save and Previous:** This button allows users to save their changes and navigate to the previous action in the grid.
6. **Save and Return:** This button allows users to save their changes and return to the [Correct the Issue with Actions](#) form.
7. **Save and Next:** This button allows users to save their changes and navigate to the next action in the grid.

**Note:** If the action has been classified as an effectiveness check (in the [Add Action Item to Quality Event](#) form), the following field will be accessible in the form:

**Effectiveness Check Duration**

- **Effectiveness Check Duration:** This is a single-select dropdown field that retrieves the list of predefined durations. It allows users to specify the duration of the effectiveness check.
  - Durations are created in the [Duration](#) section of **Action Item Setting**.

## 9.7.1.1. Details of the Action

In this section of the [Execute Action Item](#) form, users can review the details shaping the action. This includes the selected action type and the outlined action plan. The content in this section varies depending on the internal action type chosen in the [Add Action Item to Quality Event](#) form.

— Details of the action

**Action Type**  
☒ Internal ☐ External

**Action ?**  
☒ Is a Retraining or New Training Required?  
☐ Does EPC Documentation Need Updating?  
☐ Other

1. [Is a Retraining or New Training Required?](#)
2. [Does EPC Documentation Need Updating?](#)
3. [Other](#)



# 9.7.1.1.1. Is a Retraining or New Training Required?

## Option 1: Is a Retraining or New Training Required?

If this option was chosen, the form will feature the following grid:

Action Type

☒ Internal

☐ External

Action ?

☒ Is a Retraining or New Training Required?

☐ Does EPC Documentation Need Updating?

☐ Other

Training(s) Required

#	Training Name	Completed	N/A	Total	Is Completed
1	<div><div></div>Document Control Training</div>	0	0	0	<input checked="" type="checkbox"/>


1. **View** (): This button allows users to view the progress of a training.
- If selected, it will display the View Training Progress form.

View Training Progress

Document Control Training

#	User	Due Date	Is Not Applicable	Is Completed
1	Richard Roe	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
2	Joe Bloggs	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
3	Erika Mustermann	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
4	John Doe	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
5	Jan Janssen	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
6	Maria Ivanova	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
7	Jane Doe	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
8	Fred Bloggs	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
9	Max Mustermann	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>

- \* Users can utilize this form to track the overall training progress. When an assigned trainee completes the training, the corresponding **Completed** checkbox will be selected.

- \* To access additional options or actions related to the above grids, please utilize the kebab menu (  ) located in the upper rightmost corner.

# 9.7.1.1.2. Does EPC Documentation Need Updating?

## Option 2: Does EPC Documentation Need Updating?

If this option was chosen, the form will feature the following grid:

Action Type

☒ Internal ☐ External

Action ?

☐ Is a Retraining or New Training Required?  
☒ Does EPC Documentation Need Updating?  
☐ Other

Improvement Request(s) - Double-click on the row to access the respective IR status and path leading to the object

#		Modification Request	Module	Path	Name	Identifier	IR Number	IR Created
1		Revise and update process as needed.	Process	Processes > Document Control	Document Development &		<a href="#">IR-2023-63</a>	
2		Revise and update process as needed.	Process	Processes > Document Control	Document Retrieval and Distribution		<a href="#">IR-2023-64</a>	

\* During the execution of this type of action item, an improvement request (IR) is automatically triggered in EPC.

1. **Edit** (): This button allows users to access the modification request.
- If selected, it will display the Edit EPC Modification Request form.

## Edit EPC Modification Request

×

Processes > Document Control

[Click here to access the IR in EPC](#)

Module	Status	Identifier
Process	PUBLISHED	


### Modification Request

Review and update as needed.

IR Number	IR Status
IR-2023-59	OPEN

- To access the IR in EPC, click on the provided link.
  - In EPC, users can fulfill the terms of the IR.
    - They can, for example, revise and update the process, as instructed.
  - Users can also close the IR.
    - To close the IR, the user needs to meet at least one of the following requirements:
      - They must be assigned as accountable to the EPC object.
      - They must be an environmental administrator.
      - They must be the creator of the IR.
    - For instructions on how to close an IR in EPC, [click here](#).

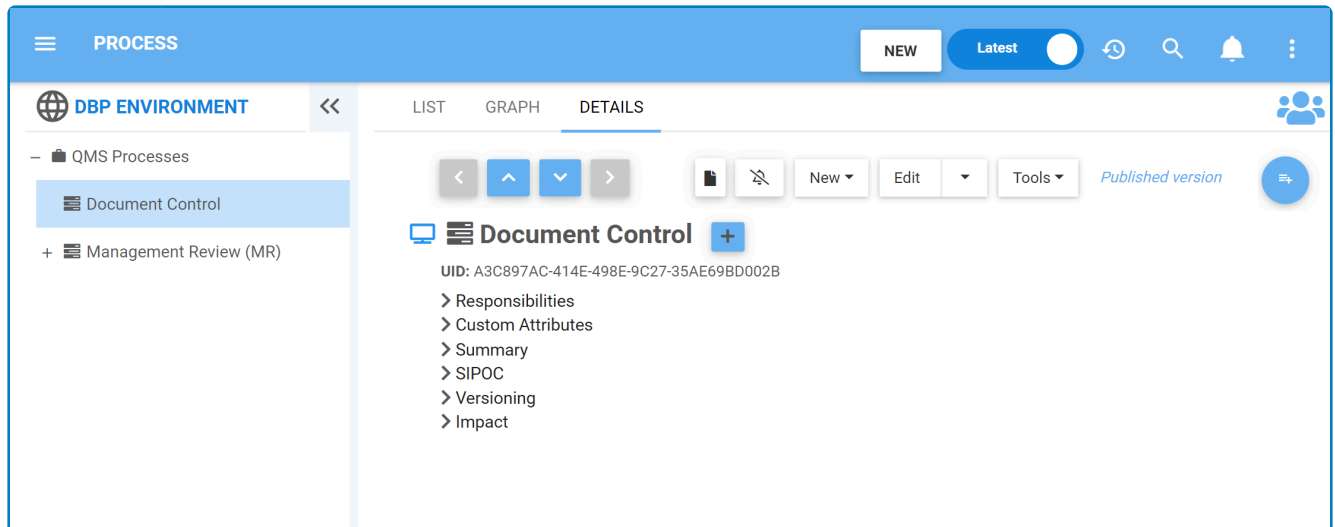


For [additional options or actions](#) related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

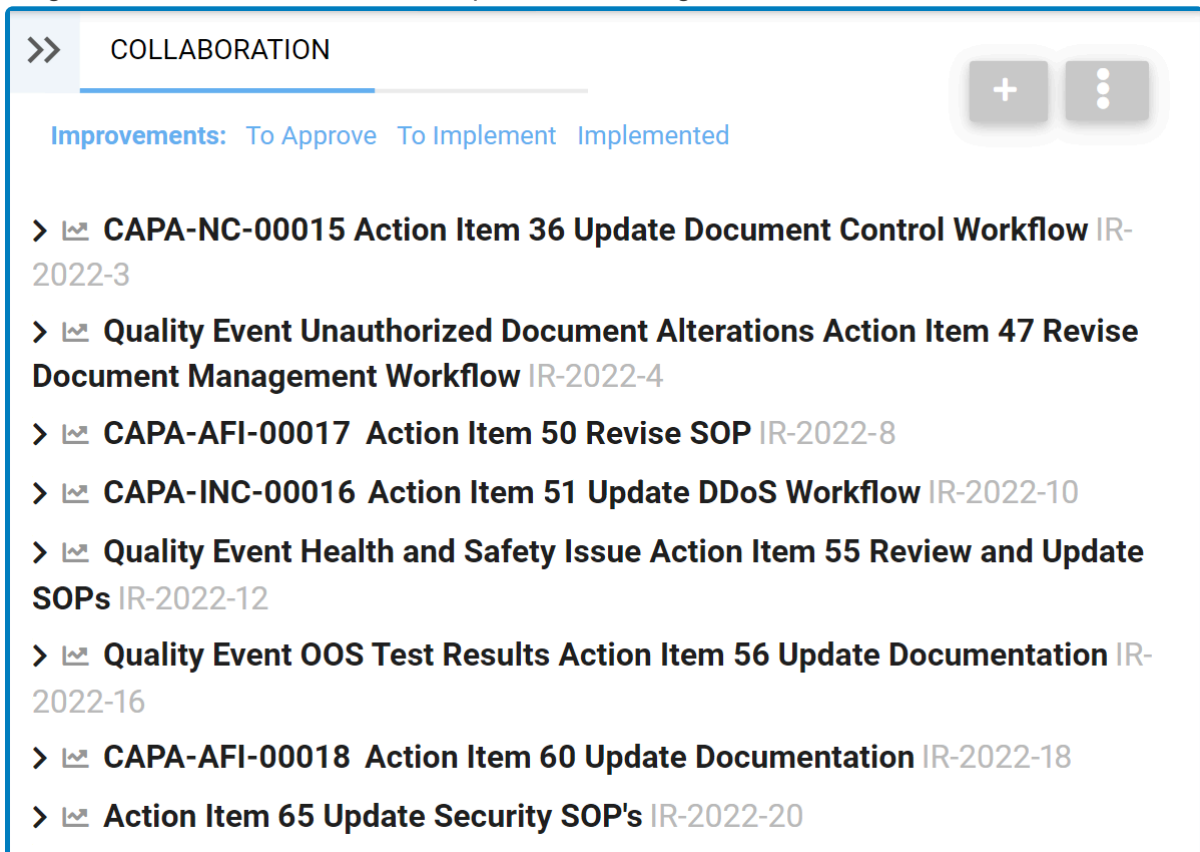
## 9.7.1.1.2.1. Close IR in EPC

To close an IR in EPC, the steps are as follows:

1. Once you have either found or been directed to the object in EPC, click on the **Collaboration** button (indicated by the arrow):





2. Selecting the **Collaboration** button will open the following tab:



3. Click on the relevant action item. It will display the following fields:
  - If the action belongs to the Quality Event workflow, it will be written as **Quality Event [Quality**

**Event Title] Action ID [Action Item Name].**



**Quality Event Unauthorized Document Alterations Action Item 47 Revise Document Management Workflow IR-2022-4**

Object Name: Document Control

Object Type: Process


Topic Type: Improvement Request    Topic Category: N/A

Topic Status: Opened

Priority: **N/A**    Impact: **N/A**    Value: **N/A**    Due Date: n/a


Close Topic


Approve / Reject




John Doe

7 hours ago

 Share

0 

0 

Revise and update as advised

Reply to this thread...

- If the action belongs to the CAPA workflow, it will be written as **CAPA ID Action ID [Action Item Name]**.

**>>** COLLABORATION

**Improvements:** To Approve To Implement Implemented

**✓** **CAPA-NC-00015 Action Item 36 Update Document Control Workflow IR-2022-3**

Object Name: Document Control  
Object Type: Process  
Topic Type: Improvement Request Topic Category: N/A  
Topic Status: Opened  
Priority: **N/A** Impact: **N/A** Value: **N/A** Due Date: n/a

Close Topic Approve / Reject

John Doe  
7 hours ago  
 Share

0 0

Revise and update as advised

Reply to this thread...

4. Click on the **Close Topic** button (indicated by the arrow).

**✓** **Quality Event Unauthorized Document Alterations Action Item 47 Revise Document Management Workflow IR-2022-4**

Object Name: Document Control  
Object Type: Process  
Topic Type: Improvement Request Topic Category: N/A  
Topic Status: Opened  
Priority: **N/A** Impact: **N/A** Value: **N/A** Due Date: n/a

Close Topic Approve / Reject

John Doe  
7 hours ago  
 Share

0 0

Revise and update as advised

Reply to this thread...

5. Selecting the **Close Topic** button will display the following page:

>>
COLLABORATION

+
⋮

Improvements: To Approve To Implement Implemented

## You are closing this topic

**Topic Type\***

Improvement Request

**Subject\***


Quality Event Unauthorized Document Alterations Action Item 47 Revise Document Manag

**Priority**

**Impact**

**Value**

**Due Date**

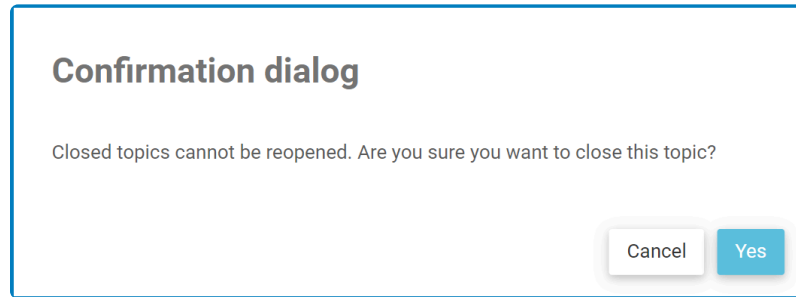
 Add Files

**Description\***

Cancel Close Topic

- **Topic Type/Subject:** These fields are disabled in this tab, preventing any modifications.
- **Priority:** This is a single-select dropdown field that displays the list of priority levels. It allows users to select only one value at a time from the dropdown.
- **Impact:** This is a single-select dropdown field that displays the list of impact levels. It allows users to select only one value at a time from the dropdown.
- **Value:** This is a single-select dropdown field that displays the list of value levels. It allows users to select only one value at a time from the dropdown.
- **Due Date:** This is a date picker that allows users to select the due date for the action item.
- **Add Files:** This is an attachment field that allows users to add/upload any relevant files.
- **Description:** This is a text field that allows users to input a description for the action item. It is a mandatory field. Users can expand this field to encompass multiple lines.
- **Cancel:** This button allows users to cancel the process.
- **Close Topic:** This button allows users to close the topic/IR.
  - Once selected, a pop-up window will appear with the following confirmation message:





- Click on either the **Cancel** button to cancel the process or the **Yes** button to confirm the closure.

# 9.7.1.1.3. Other

## Option 3: Other

If this option was chosen, the form will feature the following field:

Action Type

☒ Internal

☐ External

Action ?

☐ Is a Retraining or New Training Required?

☐ Does EPC Documentation Need Updating?

☒ Other

What is the action to be done?

Conduct a thorough review of access controls for sensitive documents. Implement stricter access permissions, ensuring that only authorized personnel have the necessary permissions to edit or modify specific documents.

# 9.7.1.2. Additional Details

In this section of the Execute Action Item form, users can review additional details about the action.

— Additional Details

Type	Reference No	Category	Compliance Program
Corrective		QMS	ISO 9001

Source	Business Division	Business Line	Site
Quality Event	Quality Management	Quality Assurance	North America - Canada - Montreal

Description

Implement a comprehensive training program for all employees who handle sensitive documents. This training should cover topics such as document version control, proper editing procedures, the importance of document integrity, and security measures to prevent unauthorized alterations. The goal is to ensure that employees understand the significance of proper document handling and are equipped with the knowledge and skills to adhere to document control policies effectively.

Attach any relevant documents (optional)

Max 20 files, 2000MB each

PDF

Training Program...

...

— Budget

Budget

Add

Discard changes


Save changes


⋮


#		Budget Item	Description	Cost
1	<div><div>🗑️</div><div>✎️</div></div>	Training Materials & Resources	Develop or acquire training materials, including presentations, handouts, and online resources, to support the document control training sessions. <div>🔗</div>	1,000.00

1. **Add:** This button allows users to add a budget item for the action.

- If selected, it will display the [Add Budget Item](#) form.

2. **Edit** (  ): This button allows users to edit an existing budget item.


3. **Delete** (  ): This button allows users to delete a budget item.

✳ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.

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To access additional options or actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

### 9.7.1.3. Enter Observations and/or Attach Evidence

In this section of the Execute Action Item form, users can provide observations and/or evidence relevant to the action.

Enter Observations and/or Attach Evidence

Evidence of completion of actions ?

Max 100 files, 2000MB each

No data

Enter your observations

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✿ For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Evidence of Completion of Actions:** This is an attachment field that allows users to upload documented proof of their completion of the action.
2. **Enter Your Observations:** This is a rich text field that allows users to enter any observations or notes relevant to the action execution. It is a **mandatory** field.

# 9.7.2. Approve or Reject Extension Request

Once the extension request has been sent, the assigned manager will receive a notification in their **Pending Tasks** prompting them to either approve or reject the request.

Jane Doe

Pending Tasks (1/1)

Drafts

Completed Tasks

Pending Tasks

Open in new window

Change folder

Search...

	Flag	Prio...	Subject	Created at	Response ...	Done at	Sender
<input type="checkbox"/>			Approve or reject extension request	11/12/2023 05:...			John Doe

They will also receive an email with the details.

New Extension Request for John Doe for Action Item AI-2023-00066 Conduct Document Control Training

N

noreply@interfacing.com

To: Jane Doe

Sun 11/12/2023 1:19 AM

CAUTION: This email originated from outside of Interfacing Organization. DO NOT CLICK LINK OR OPEN ATTACHMENTS unless you recognize the sender and know the content is safe.

Hi,

User John Doe is asking for an extension for the action item AI-2023-00066 - Conduct Document Control Training.

Completion of this action item is currently due 11/19/2023 12:00:00 AM.

The requested due date is 11/28/2023 12:00:00 AM.

<https://dbp-dev-1.interfacing.com/dbp?redirect=/home/private%23%2Ftaskform%3FtId%3D23f6834c-baf9-44fb-bc53-6fafcd61ef05#/>

Regards,

Reply

Forward

Clicking on either the subject in **Pending Tasks** or the link in the email should direct the manager to the Approve or Reject Extension Request form.

## Approve or reject extension request

Action Item Owner

John.Doe

Action Item Name

Conduct Document Control Training

Action ID

AI-2023-00066

Original Due Date

11/19/2023

New Due Date

11/28/2023

Action Item ID	Action Name	Internal Action Type	Due Date
AI-2023-00066	Conduct Document Control Training	Re-Training	11/19/2023

Reason for the extension

I am requesting an extension for the Nov. 19 deadline as I will be on vacation from Nov. 8 to 22.

Approve

Reject

1. **Approve:** This button allows the manager to approve the request.
  - If selected, the user will receive an email informing them of the approval and the new due date will be displayed on the [Execute Action Item](#) form.
2. **Reject:** This button allows the manager to reject the request.
  - If selected, the user will receive an email informing them of the rejection and the due date will stay the same on the [Execute Action Item](#) form.

# 9.8. Create SCAR

If any of the action items are external, the assigned action item owner(s) would also receive a notification in their **Pending Tasks** prompting them to create SCAR. This task and the [Correct the Issue with Actions](#) task are issued simultaneously.

✿ If there is only one action item and it is external, users will only be tasked with creating SCAR—meaning that they will not receive the [Execute Action Items](#) form

John Doe

- Pending Tasks (1/1)
- Drafts
- Completed Tasks

Pending Tasks

Open in new windowChange folderSearch...

	Flag	Prio...	Subject	Created at	Response ...	Done at	Sender
			Create SCAR	11/09/2023 16:...			Jane Doe

The assigned action item owner(s) will also receive an email notification informing them of the assigned task.

Create SCAR [S-0083]

N

noreply@interfacing.com  
To: John Doe

Thu 11/9/2023 11:32 AM

CAUTION: This email originated from outside of Interfacing Organization. DO NOT CLICK LINK OR OPEN ATTACHMENTS unless you recognize the sender and know the content is safe.

Hi,

You have been tasked with creating SCAR.

SCAR ID: S-0083

<https://dbp-dev-1.interfacing.com/dbp?redirect=/home/private%23%2Ftaskform%3FtId%3D50808465-51cf-4781-b4d3-78a07f471d38#/>

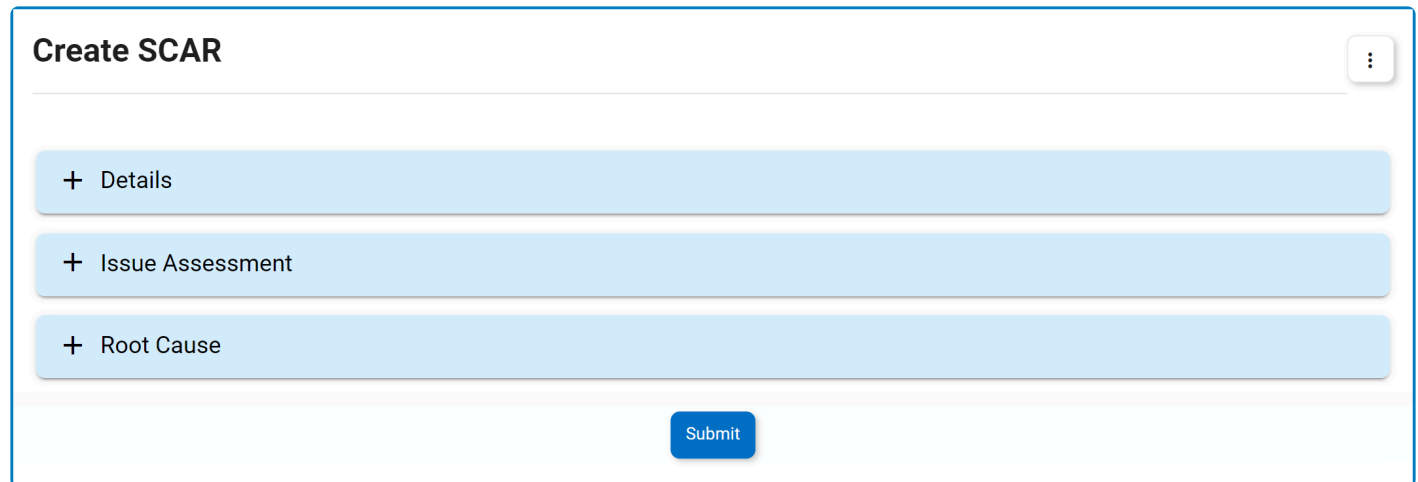
Regards,

Reply

Forward

Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the [Create SCAR](#) form. Upon its submission, this form will trigger the [SCAR](#) workflow. Users will be guided on how to navigate the first stage of this workflow throughout the **Create SCAR** portion of this manual. For later stages of the workflow, users will be redirected to the [Action Items User Manual](#), where this workflow is described in greater detail.





**Create SCAR**

+ Details

+ Issue Assessment

+ Root Cause

Submit

1. **Accordions:** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.
  - [Details](#)
  - [Issue Assessment](#)
  - [Root Cause](#)
2. **Submit Form:** This button allows users to submit the completed form.
  - Upon its submission, this form will trigger the SCAR workflow. The supplier will be [issued the SCAR via email](#).

### 9.8.1. Details

In this section of the Create SCAR form, users can define the details that shape the supplier corrective action report.

— Details

<b>SCAR ID</b>	<b>Initiation Date</b>	<b>Response Due Date</b>		
S-0089	<input type="text" value="12/07/2023"/> <span>✕</span> <span>📅</span>	<input type="text"/> <span>📅</span>		
<b>Initiator</b>	<b>Initiator Email</b>			
John Doe	john.doe@interfacing.com			
<b>Supplier</b>	<b>Supplier ID</b>	<b>Supplier Representative Name</b>	<b>Supplier's Email</b>	<b>Supplier's Phone</b>
<input type="text" value="Select..."/> <span>▼</span>				
<b>Issue Description</b>				
<div style="border: 1px solid #ccc; padding: 5px;"> <span>Paragraph ▼</span> <span>A<sup>B</sup> ▼</span> <span>A<sub>1</sub> ▼</span> <span><u>A</u> ▼</span> <span><b>A</b> ▼</span> <span><b>B</b></span> <span><i>I</i></span> <span><u>U</u></span> <span><del>S</del></span> <span>☰ ▼</span> <span>≡</span> <span>≡</span> <span>≡</span> <span>↻</span> <span>🔗</span> <span>“ ”</span> <span>🖼️</span> <span>📊 ▼</span> <span>▶ ▼</span> <span>↶</span> <span>↷</span> </div> <div style="border: 1px solid #ccc; height: 100px; margin-top: 5px;"></div>				

✿ For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **SCAR ID:** This field is automatically populated with a unique identifier when a new SCAR is created. Users cannot modify the field.
2. **Initiation Date:** This is a date picker that allows users to input/select the initiation date for the SCAR.
  - This field is automatically populated with today's date; however, users can still modify the entry.
3. **Response Due Date:** This is a date picker that allows users to input/select the due date for the supplier's response.
4. **Initiator:** This field is automatically populated with the name—full name and login name—of the user initiating the SCAR.
  - Users can modify this information in the [Organization Management \(Admin\)](#) module of the **Admin** application.
5. **Initiator Email:** This field is automatically populated with the initiator's email address.

- Users can modify this information in the [Organization Management \(Admin\)](#) module of the **Admin** application.
6. **Supplier:** This is a single-select dropdown field that retrieves the list of suppliers (from the [Supplier List](#) module of the **Supplier** application). It is a **mandatory** field. It allows users to select the supplier for which the **Supplier Corrective Action Report (SCAR)** will be issued.
  7. **Supplier ID:** This field is automatically populated with the ID associated with the selected supplier.
  8. **Supplier Representative Name:** This field is automatically populated with the name of the representative associated with the selected supplier.
  9. **Supplier's Email:** This field is automatically populated with the email address associated with the selected supplier.
  10. **Supplier's Phone:** This field is automatically populated with the phone number associated with the selected supplier.
  11. **Issue Description:** This is a rich text field that allows users to input the issue description.



All supplier-related information is obtained from the **Supplier** application. To learn more about how to use this application, please refer to the accompanying [User Manual](#).

## 9.8.2. Issue Assessment

In this section of the Create SCAR form, users can perform an assessment of the identified issue.

— Issue Assessment

☐ Unconfirmed/Test OK (Fault Not Found)

☐ Customer-Caused

☐ Validated Supplier Responsibility

✿ For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Unconfirmed/Test OK (Fault Not Found):** This is a checkbox that, when selected, allows users to assess the issue as unconfirmed or unsubstantiated (meaning that no evidence of fault was found during the evaluation).
  - If selected, it will reveal the following field:

☒ Unconfirmed/Test OK (Fault Not Found) ☐ Customer-Caused ☐ Validated Supplier Responsibility

Fault Not Found – Provide explanation and attach pictures/test report

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- **Fault Not Found:** This is a rich text field that allows users to provide an explanation for their assessment.
  - Users can also attach relevant pictures or test reports to support their explanation.
- 2. **Customer Caused:** This is a checkbox that, when selected, allows users to attribute responsibility for the issue to the customer.
  - If selected, it will reveal the following field:

☐ Unconfirmed/Test OK (Fault Not Found) ☒ Customer-Caused ☐ Validated Supplier Responsibility

Customer-Caused – Provide explanation and attach pictures/test report

Paragraph

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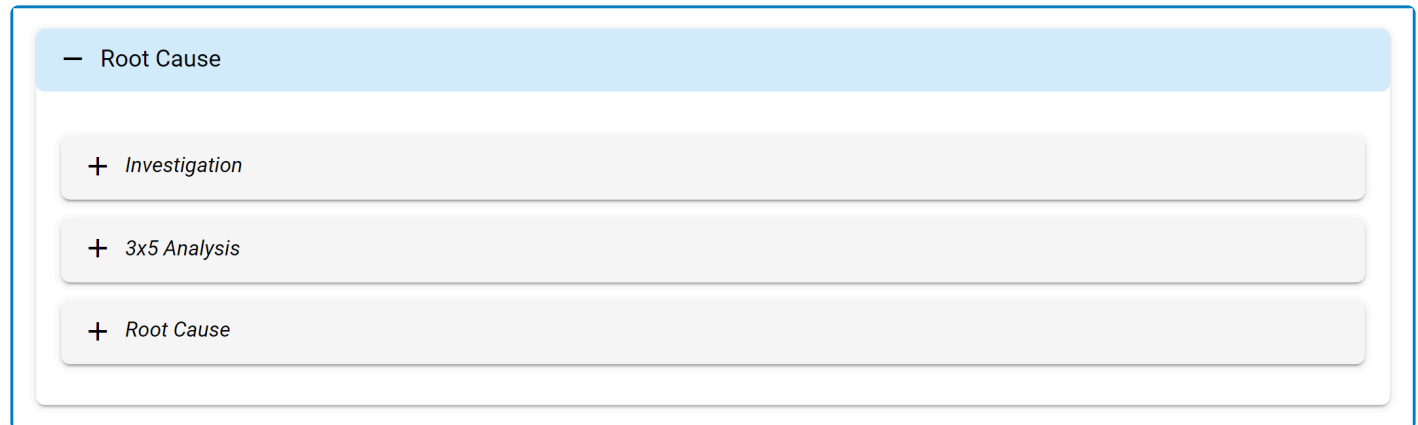
↷

- **Customer Caused:** This is a rich text field that allows users to provide an explanation for their assessment.
  - Users can also attach relevant pictures or test reports to support their explanation.
- 3. **Validated Supplier Responsibility:** This is a checkbox that, when selected, allows users to attribute responsibility for the issue to a validated supplier.

## 9.8.3. Root Cause

In this section of the [SCAR](#) form, users can investigate the root cause of the issue.

Inside the **Root Cause** accordion, there are three sub-accordions to consider:



The screenshot shows a blue header bar with a minus sign and the text "Root Cause". Below this header is a white container with three grey accordion items, each with a plus sign and text: "+ Investigation", "+ 3x5 Analysis", and "+ Root Cause".

1. [Investigation](#)
2. [3×5 Why Analysis](#)
3. [Root Cause](#)

✿ The [3×5 Why Analysis](#) accordion is a conditional (or dynamic) section. It will only be included in the form if the **Detailed Investigation** checkbox is selected in the [Investigation](#) accordion.

### 9.8.3.1. Investigation

In the **Investigation** accordion, users can examine and document the root cause of the identified issue.

— Investigation

When identifying the root cause, please make sure to consider the following questions. These questions will be reviewed by the SCAR initiator.

• Have you identified a fundamental breakdown or failure of a process?

• Is the identified root cause or solution applicable to that of other parts or processes?

• Have you corrected the element of the process that caused the issue?

• Have you ensured the escape will not reoccur?

• Have you addressed the issue to the high standard UTC and customer will agree?

Problem Statement

Paragraph

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☐ Detailed Investigation ?

Root Cause Description

Paragraph

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Root Cause Documents

📁 Upload Files

Max 10 files, 2000MB each

🔄

No data

☐ Unable to Determine Root Cause

✿ For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Problem Statement:** This is a rich text field that allows users to provide the problem statement.
2. **Detailed Investigation:** This is a checkbox that, when selected, allows users to include a detailed

investigation.

- If selected, it will reveal the [3×5 Why Analysis](#) accordion.

3. **Root Cause Description:** This is a rich text field that allows users to provide a description of the root cause.
4. **Root Cause Documents:** This is an attachment field that allows users to upload any documents related to the root cause investigation.
5. **Unable to Determine Root Cause:** This is a checkbox that, when selected, allows users to indicate their inability to determine a root cause.



## 9.8.3.2. 3×5 Why Analysis

In the **3×5 Why Analysis** accordion, users can examine the root cause of the issue by applying the 5Ws to three types of causes or failures.

✿ **5W = What, Where, When, Who, and Why. 3 Causes = Direct, Detection, and Systemic.**

### 1. Direct Cause

In this tab, users can examine and identify the immediate or specific cause of the problem. This is often the initial factor that directly led to the issue.

3x5 Why Analysis

Direct Cause

Detection Cause

Systemic Cause

What was the DIRECT or specific cause of the problem?  
What is the specific cause of the problem? Explain why the problem occurred (e.g. design/drawing error, manufacturing process, assembly/installation instructions):

What

Where

When

Who

Why

### 2. Detection Cause

In this tab, users can examine the factors that allowed the issue to pass through without detection. This involves understanding how the problem reached the customer or end-user without being intercepted.

— 3x5 Why Analysis

Direct Cause

**Detection Cause**

Systemic Cause

Why was the problem not DETECTED? How did it pass through to the customer?  
Explain why the problem was not detected by the quality/inspection system (How did we have an escape?):

**What**

**Where**

**When**

**Who**

**Why**

### 3. Systemic Cause

In this tab, users can explore how the broader system, including business processes, contributed to the problem. This involves identifying any systemic failures or weaknesses that may have played a role in the emergence of the issue.

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**— 3x5 Why Analysis**

Direct Cause    Detection Cause    **Systemic Cause**

How did the SYSTEM contribute to the problem? Did any business processes fail?

How was the problem introduced? Was there a failure or weakness in a process, procedure, work instruction or standard?

**What**

**Where**

**When**

**Who**

**Why**

### 9.8.3.3. Root Cause

In the **Root Cause** accordion, users can identify and analyze the underlying factors contributing to non-conformance.

Root Cause

Root causes for direct, detection, and systemic causes are required

CAUTION: OPERATOR ERROR WILL NOT BE ACCEPTED AS CAUSE

DIRECT CAUSE: What is the root cause for the technical problem that caused the non-conformance? (Examples: Inadequate tooling, fixturing, gaging, handling, work instructions.)

Paragraph ▾ A<sup>Ⓐ</sup> ▾ A<sup>I</sup> ▾ A ▾ A ▾ B I U S ≡ ▾ ⑆ ⑇ ≡ ≡ 🔗 “ 🖼️ 📊 ▾ ▶ ▾ ↶ ↷

DETECTION CAUSE: How did the non-conformance escape the process? Why did the quality system fail to detect the non-conformance? (Examples: inadequate in-process/final inspection, testing, process control)

Paragraph ▾ A<sup>Ⓐ</sup> ▾ A<sup>I</sup> ▾ A ▾ A ▾ B I U S ≡ ▾ ⑆ ⑇ ≡ ≡ 🔗 “ 🖼️ 📊 ▾ ▶ ▾ ↶ ↷

SYSTEMATIC CAUSE: How did the product development/production/support processes contribute to the problem? (Examples: inadequate requirement flow down, manufacturing process planning, configuration management.)

Paragraph ▾ A<sup>Ⓐ</sup> ▾ A<sup>I</sup> ▾ A ▾ A ▾ B I U S ≡ ▾ ⑆ ⑇ ≡ ≡ 🔗 “ 🖼️ 📊 ▾ ▶ ▾ ↶ ↷

✿ For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Direct Cause:** This is a rich text field that allows users to identify the root cause for the technical problem leading to the non-conformance.
2. **Detection Cause:** This is a rich text field that allows users to examine how the non-conformance escaped detection.
3. **Systematic Cause:** This is a rich text field that allows users to assess how product development,

production, and support processes contributed to the problem.

## 9.9. Check Issue Correction

Once all action items have been completed, the assigned reviewer will receive a notification in their **Pending Tasks** prompting them to verify the issue correction.

✿ If any of the action items are external, this step will take place after the completion of the SCAR workflow.

Jane Doe

▶ Pending Tasks (1/1)

▶ Drafts

▶ Completed Tasks

Pending Tasks

Open in new window

Change folder

Search...

<input type="checkbox"/>	Flag	Prio...	Subject	Created at	Response ...	Done at	Sender
▶ <input type="checkbox"/>			Check Issue Correction [QE-NC-00053...	11/12/2023 06:...			John Doe

They will also receive an email notification informing them of the assigned task.

Check Issue Correction [QE-NC-00053 - Unauthorized Document Alterations]

N

noreply@interfacing.com

To: Jane Doe

Sun 11/12/2023 1:19 AM

CAUTION: This email originated from outside of Interfacing Organization. DO NOT CLICK LINK OR OPEN ATTACHMENTS unless you recognize the sender and know the content is safe.

Hi,

You have a quality event to validate.

Quality Event ID: QE-NC-00053  
Quality Event Name: Unauthorized Document Alterations  
Severity: Major

<https://dbp-dev-1.interfacing.com/dbp?redirect=/home/private%23%2Ftaskform%3Ftld%3Dc0c2d53e-7c29-408e-b75d-05eae50a0a8c#/>

Regards,

Reply

Forward

Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the Check Issue Correction form. In this form, users can review the investigation of the quality event, along with its associated risks. They can also review the execution history of the associated actions.

Check Issue Correction [QE-NC-00053 - Unauthorized Document Alterations]

Quality Event Name

Unauthorized Document Alterations

Created By

John.Doe

Creation Date

11/10/2023

Quality Event ID

QE-NC-00053

Event Type

Non-Conformity

Severity

Major

Quality Event Reviewer

Jane Doe

+ Additional Details

+ Immediate Containment

+ Gather Details (Root Cause Analysis)

+ Associated Risk(s)

- Associated Action Items(s)

	Action ID	Action Name	Description	Action Type	Action Owner
	<input type="text"/>	<input type="text"/>	<input type="text"/>		
	AI-2023-00062	Conduct Document Control Training	Implement a comprehensive training program for all employees who handle	Internal	John Doe
	AI-2023-00063	Update Document Control Processes	Review and update document control processes. This update should include	Internal	John Doe
	AI-2023-00064	Strengthen Access Controls	Conduct a thorough review of access controls for sensitive documents.	Internal	John Doe
	AI-2023-00065	Implement Supplier Corrective Action	Some unauthorized alterations have been traced back to a supplier. Initiate a	External	John Doe

Close QE

1. **View** ( ): This button allows users to view an action.
- In viewing mode, users cannot make any modifications. They can, however, download attached files and access/download any available [templates](#).
2. **Expand** ( ): This button allows users to view the full action description.
3. **Close QE**: This button allows users to to close the quality event, bringing the [workflow](#) to an end.

To access [additional options or perform actions](#) related to the grid, please utilize the kebab menu ( ) located in the upper rightmost corner.

# 10. Quality Event List

In this module, users can access a list of all quality events created using the application.

## Search Panel

All fields inside the search panel act as search boxes. Any value inputted inside them will be used as search criteria to filter and retrieve data from the grid, if possible.

Search Panel

Event Type

Severity

Source

Business Division

Business Line

Select... ▾

Select... ▾


Select... ▾

Select... ▾

Select... ▾

Filter

Clear Filter

 For more guidance on how to utilize single-select dropdown fields, [click here](#)


1. **Event Type:** This is a single-select dropdown field that allows users to filter by event type.
2. **Severity:** This is a single-select dropdown field that allows users to filter by severity level.
3. **Source:** This is a single-select dropdown field that allows users to filter by source.
4. **Business Division:** This is a single-select dropdown field that allows users to filter by business division.
5. **Business Line:** This is a single-select dropdown field that allows users to filter by business line.
6. **Filter:** This button filters the results according to the entered search criteria.
7. **Clear Filter:** This button clears the filters that were used in the previous search and allows users to again view the full data set.



## Grid

Inside the grid, events are primarily organized by values derived from the [Quality Event](#) workflow.



	Status	Quality Event ID	Quality Event Name	Event Type	Created By	Creation Date	Business Division
	<input type="text" value="Q"/>	<input type="text" value="Q"/>	<input type="text" value="Q"/>			<input type="text" value="Q"/>	
	Review the issue	QE-INC-00001	Chemical Spill Incident	Incident	John.Doe	04/10/2023 22:30	Health & Safety
	Contain / Correct Issue	QE-AFI-00003	Cleaning & Sanitization Procedure Gap	Audit Finding (Internal)	Jane.Doe	04/10/2023 21:16	Health & Safety
	Send to CAPA	QE-AFI-00002	Unauthorized Access to Customer Data	Audit Finding (Internal)	Richard.Roe	04/10/2023 21:14	Information Technology
	Gather Details / Risks & Actions	QE-COM-00002	Damaged Product Complaint	Complaint	Joe.Bloggs	29/09/2023 13:49	Customer Service
	Issue is contained	QE-NC-00001	Unauthorized Document Alterations	Non-Conformity	John.Doe	29/09/2023 04:15	Quality Management
<div> <div>5</div> <div>Page 1 of 2 (6 items) &lt; 1 of 2 &gt;</div> </div>							

1. **View** (templates.

 To access [additional options or perform actions](#) related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.