TRIAL INTERACTIVE

# TRIAL INTERACTIVE QMS V10.7 - USER GUIDE V1.0

TRANSPERFECT LIFE SCIENCES

# APPROVALS

## Product Owner

| | |
|---|---|
| Name: Jay Smith | Title: Senior Director, Product Management |
| Signature:<br>Reason for signature:<br>Date: | |

## Quality Assurance

| | |
|---|---|
| Name: Scott Jordan | Title: Director, QA & Systems Validation |
| Signature:<br>Reason for signature:<br>Date: | |

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# VERSION HISTORY

| Author | Revision | Date | Change History |
|---|---|---|---|
| Salil Joshi<br>Samuel Pawar<br>Mansi Kandhare | 1.0 | 28-Apr-2025 | Initial Document Creation. |

# WHAT'S NEW IN TRIAL INTERACTIVE QMS V10.7?

This section explains the overview of new features in Trial Interactive v10.7.

## Quality Records Module in Collaborate Rooms

This feature introduces the Quality Records module, a powerful addition to the Collaborative Workspace (CWS) Room Type that enhances the way organizations track and manage their Quality Management System (QMS) records. This module provides a Dashboard and supports key record types such as Incidents, Evidence, CAPA (Corrective and Preventive Actions), Action Items, and Effectiveness Checks, with future expansions to include Change Management, Audits, and Findings.

To maintain structured governance, rooms with the Quality Records module enabled offer access control. Specific editor-level users can be restricted from creating documents and viewing in-process documentation within the Documents module, ensuring proper security.

Super Admins can enable the module through room settings, after which admins and room managers in the room gain instant access, while other users require explicit permissions. With tailored actions and permissions, organizations can fine-tune access to creating Incidents, CAPAs, and restricting document creation, ensuring only the right people have the right level of control. With this addition, teams can elevate their quality management practices, maintain compliance with ease, and drive operational excellence within the collaborative workspace.

The Quality Module is accessible from the 'Waffle' menu, with user access controlled through the 'Quality Module' action, ensuring that only authorized users i.e., readers, editors, and room managers etc. can manage and oversee quality processes.

## Record Type Management

The Record Type Settings feature introduces a structured and efficient approach to managing record-related workflows, forms, and configurations within the system. Designed to streamline record type management, this functionality provides administrators with the ability to create, edit, and configure record types, authority types, workflows, and teams in a centralized interface.

By categorizing record types in a hierarchical tree structure based on predefined main topic classifications, users can easily navigate and manage record-related processes. This feature mirrors the existing Document Types settings but is specifically tailored to enhance record workflow configurations. In this way, for the main type 'CAPA', there can be defined sub-types such as 'CAPA Plan', 'SCAR', 'Continuous Improvement Plan', 'Risk Mitigation Plan', etc. Each of these subtypes can have its workflow, forms, fields, teams, and general configurations, allowing great flexibility.

Users can define key record details, including naming conventions, workflow rules, due dates, and field settings, through a dedicated Fields Tab. The system also supports import/export capabilities and maintains a change log for version tracking and compliance. Automated notifications and structured workflows ensure seamless record processing, enhancing transparency and operational efficiency.

By offering a systematic approach to record management, this feature improves compliance, streamlines workflow execution, and enhances collaboration across teams, ultimately driving efficiency in record handling and decision-making.

## Team Management

Team Management allows users to create and manage teams responsible for reviewing and performing necessary actions on the records. Teams can be assigned authority types for workflow stages, record approvals, and other system-configured action items. Users can add or remove team members, link teams to specific record or document types, and manage authority levels, ensuring structured collaboration and compliance.

Teams can be associated with specific document types (for responsible departments) and record types (for QMS workflows). By streamlining team assignments and authority configurations, this feature enhances efficiency, accountability, and workflow automation within the system.

## Record Type Settings

The new Record Type Settings has a centralized and structured interface for creating, managing, and configuring record types and their associated workflows, forms, and fields. Designed to mirror the familiar Document Types settings, this functionality focuses specifically on creating records for Incident, CAPA, and Action Items.

Users can navigate a hierarchical tree structure that organizes record types by predefined categories based on forms designated as 'main topic' in the Form Settings. This structure provides clarity and consistency across the system, supporting robust configuration at both top-level and subtype levels.

Through this interface, users can manage multiple aspects of record types, including:

- Creating, editing, and deleting types and subtypes under each form category.
- Importing and exporting record type configurations.
- Managing naming rules and field behaviors per record type.
- Viewing changes via the change log.

The Record Type Settings ensure seamless configuration of record types, supporting compliance, traceability, and process efficiency.

## Workflow Management

The QMS Workflow Management introduces a structured and configurable approach to defining and managing quality workflows within the Quality Management System. With a dedicated Workflow Settings Page, users gain a centralized interface to configure and manage workflows, ensuring seamless control over processes.

The introduction of Workflow Management enables workflow creation, allowing users to define workflow names, descriptions, record types, and stages while leveraging a wizard-based setup that guides them step by step through the configuration process. Users can customize workflow stages and statuses, assign role-based permissions, and designate responsible teams or individuals for each stage to ensure the record is reviewed and transitioned to the next stage. Additionally, users can link forms to specific workflow stages. To further enhance efficiency, the notification options support group-based alerts and escalation levels, ensuring timely communication. Workflow management enhances traceability, governance, and compliance, providing organizations with a seamless way to structure and optimize quality processes.

## Incident Management

The Incident Management feature introduces a structured approach to capturing, investigating, and resolving quality issues within the Quality Module. Serving as the centralized entry point for quality concerns, the Incident Form ensures that reported issues are accurately documented, assessed, and swiftly escalated as needed. By seamlessly integrating with Investigations, Action Items, and CAPA (Corrective and Preventive Actions), this feature empowers organizations to proactively manage risks, drive compliance, and enhance overall product and service quality.

Incidents are categorized as Main Types, with the option to include Sub Types for better organization and tracking. The workflow-driven approach ensures that incidents progress through assessment, investigation, assessment, root cause analysis, and corrective action implementation, helping to prevent recurring issues. Key fields such as Record Type and Team allow organizations to configure workflows and assign responsibilities effectively.

Additionally, automated notifications, real-time dashboards, reports, and analytics provide visibility into issue trends, ensuring proactive resolution and continuous improvement. Integrated audit trails and compliance tracking help maintain detailed records, supporting regulatory adherence and quality assurance.

By offering a systematic and structured process for incident resolution, this feature enhances quality control, risk management, and overall operational efficiency, allowing organizations to maintain high standards in product and service delivery.

The Incident Workflow Processing feature streamlines incident management by automating submission, validation, and assignment. It enhances compliance, improves transparency, and reduces manual intervention.

When an originator submits an incident, the system verifies its type and record type to check for a predefined workflow. If a match is found, the record enters the workflow; otherwise, the originator is notified.

Role-based access controls ensure data integrity. The originator's access is downgraded to read-only, while team members gain controlled visibility. Assigned authorities can manage incidents via the Assignments View, ensuring accountability.

This workflow-driven approach enables efficient incident tracking, structured collaboration, and proactive issue resolution through automated transitions and notifications.

## Incident Record Security Design

The Incident Record Security Design Specification introduces a robust and flexible access control model to support the upcoming Records module within the Quality Management System (QMS). This design ensures that sensitive quality records, such as Incidents, Investigations, and CAPAs, are securely managed throughout their lifecycle, with permissions dynamically adjusted based on user roles, team assignments, and workflow progression.

At its core, this feature enforces record-level security, ensuring each incident record has individualized access rules. Users gain visibility and edit rights based on their roles (e.g., Admins, Process Owners), direct assignments (e.g., Investigators, Workflow Participants), or actions taken within the system. Room-level settings allow Super Admins to activate the Records module and configure access at a granular level, while supporting the separation of privileges between the Records and Documents modules.

Upon creation, incident records automatically grant access to key stakeholders, including the Originator, Process Owner, and Room Admins. As the incident progresses through the workflow, permissions are adapted in real-time, ensuring originators transition to a read-only role, while team members and stage-specific contributors gain access aligned with their responsibilities. Special provisions allow external Investigators to participate without compromising broader system visibility.

Additionally, clear rules govern record deletion and obsolescence, balancing administrative control with data integrity. Draft records can be deleted by Originators and Admins, while workflow-submitted records can only be marked obsolete by authorized users.

This security design supports scalable, audit-ready governance of quality records, enabling organizations to maintain strict data confidentiality, ensure proper accountability, and streamline compliance. By embedding permission logic into the incident lifecycle, this feature fosters a secure, transparent, and collaborative environment for managing quality events.

## CAPA Workflow Processing

The CAPA Workflow Processing feature optimizes Corrective and Preventive Action (CAPA) management by issue identification, root cause analysis, and action tracking. It enhances compliance, accountability, and efficiency, ensuring a structured resolution process for quality incidents.

When a CAPA is initiated, the system validates the issue, assigns responsible parties, and tracks corrective and preventive actions through a predefined workflow. Each stage supports role-based access, ensuring secure collaboration and controlled visibility. The system automatically notifies assigned users, guiding them through investigation, corrective measures, and verification steps.

With CAPA Workflows, notifications, and documented traceability, this feature improves regulatory compliance, prevents recurring issues, and strengthens overall quality management.

## Action Item Workflow Processing

The Action Item Workflow Processing feature optimizes Corrective and Preventive Action (CAPA) management by supporting the creation of Action Items. This enhances compliance, accountability, and efficiency, ensuring a structured action plan and management process for quality incidents and CAPAs.

When an Action Item is initiated, the system validates the issue, assigns responsible parties, and tracks task execution through a predefined workflow. Each stage supports role-based access, ensuring secure collaboration and controlled visibility. The system automatically notifies assigned users, guiding them through the execution of the action item.

## QMS Workflow Engine Enhancements

This release introduces a powerful enhancement to the QMS Workflow Engine that dynamically configures and assigns QMS Roles based on the type and category of each record. Designed to ensure the right people are involved at each stage of a CAPA or investigation, the new functionality integrates Record Types, Workflows, Teams, and Forms to drive intelligent, metadata-based user assignments.

Now, when initiating a workflow (e.g., CAPA, Investigation), the system uses the record's metadata, such as Type and Category, to automatically determine the correct Teams and associated Authority Types (Process Owner, Contributor, Approver).

For instance, a CAPA categorized under 'Technology' would automatically involve the Head of IT and Technical Support as lead investigators, as per the configurations, ensuring a faster, more accurate response aligned with the organization's quality protocols.

This enhancement empowers Administrators to configure dynamic review groups that are automatically assigned to workflow steps based on record metadata such as category, type, and subtype. The system supports hierarchical mapping of Record Types and uses these to determine the appropriate Teams and Authority Types for each workflow.

Within each Team, users can be assigned one or more Authority Types, such as Process Owner, Contributor, or Approver, etc., representing the specific role or 'hat' they wear in the context of a given record.

These Authority Types are further defined by their level of involvement (Assigned, Escalation, Informed), ensuring accurate participation across the workflow. Workflow Configuration Profiles provide control over workflow behavior, including step order, visibility of fields, authority-to-action mappings, and targeted notifications.

When a workflow is initiated, the system notifies the authority types in each stage (depending on the notification configurations). The authority then has to perform the relevant actions and transition the record to the next stage.

# INTRODUCTION TO QMS

A Quality Management System (QMS) is a structured framework designed to ensure that an organization consistently meets customer requirements and regulatory standards while improving overall efficiency and performance. It encompasses policies, processes, and procedures that guide employees in maintaining quality across all operations, from product development to service delivery.

A well-implemented QMS fosters a culture of continuous improvement, risk management, and compliance with industry best practices such as ISO 9001. By systematically monitoring and controlling quality-related activities, organizations can enhance customer satisfaction, reduce errors, and achieve sustainable growth. Ultimately, a QMS serves as a foundation for operational excellence, helping businesses streamline processes, increase transparency, and maintain a competitive edge in their respective industries.

## What is a QMS?

A quality management system (QMS) is defined as a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis.

ISO 9001:2015, the international standard specifying requirements for quality management systems, is the most prominent approach to quality management systems.

A QMS handles the following essential records:

- Complaints
- Investigations
- CAPA
- Action Items
- Change Control
- Root Cause Analysis
- Effectiveness Checks
- Risk Analysis
- Audits
- Findings and Observations
- Training Management
- Controlled Documents

## QDMS: Quality Document Management System

### Content Management for Quality and Beyond

Configurable Indexes, Workflows, Document Types, Required Documents, and Dashboards, TI provides a single place for Content Management. Create rooms to share and collaborate on clinical documentation for trials, Quality Management, Regulatory, Departmental Workspaces, and much more. TI is designed to align document work streams with regulatory compliance practices for document authoring, approval, control, and training.

## Author to Archive

Complete the end-to-end process, collaborative document review and authoring, version control, automated approval, and periodic review processes with built-in 21 CFR 11 compliant electronic signatures.

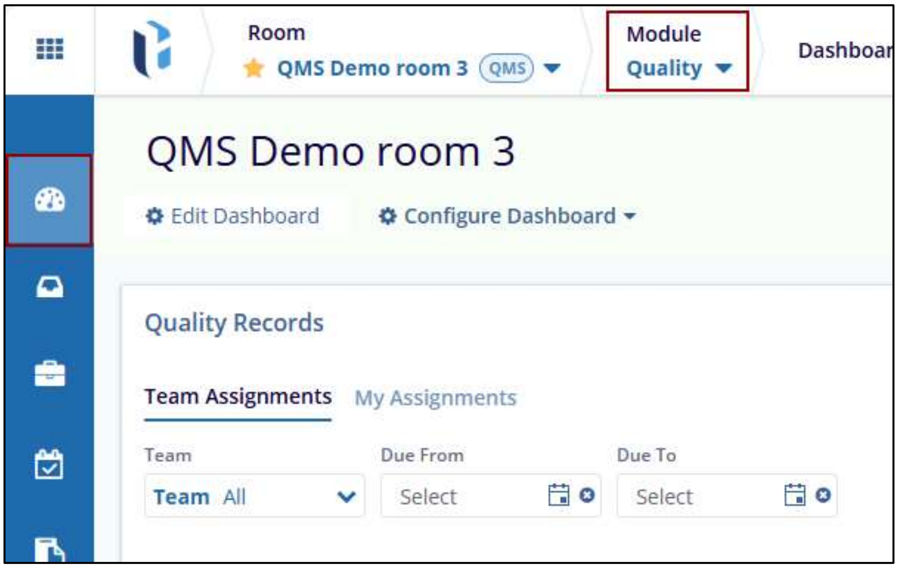
## Integrated Process for SOPS and Policies

Review and approval cycles, TI Content Management is completely integrated with Global Learn for procedural document training. Content Management rooms can also be linked to eTMF rooms for seamless sharing of study documentation.

# DASHBOARD

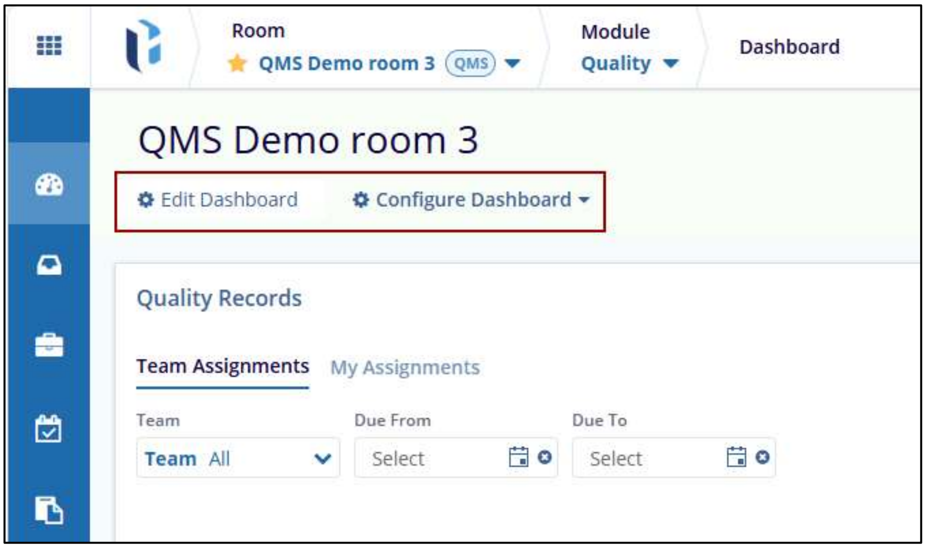
Quality Dashboards displaying records assigned to them or their teams through the My Assignments and Team Assignments Dashlets. Users can interact with these records using filters, charts, and grid views.

Within the Quality module, the Dashboard page is displayed.




The dashboard includes the following edit options:

- Edit Dashboard
- Configure Dashboard

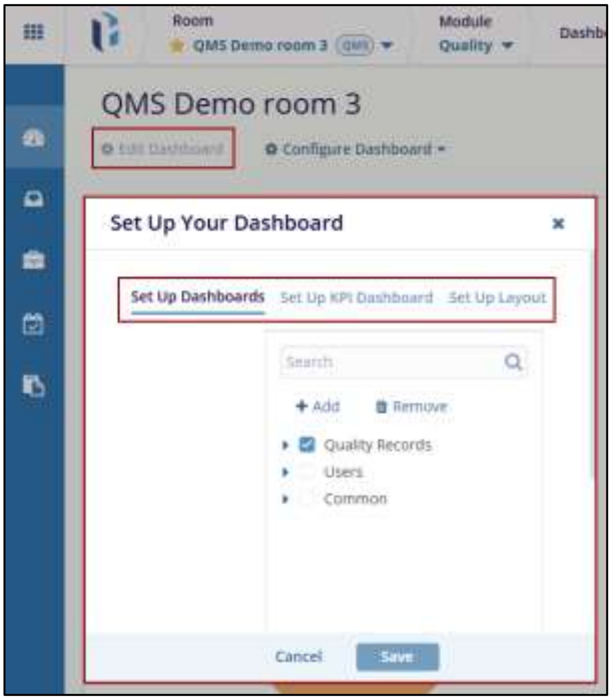



## Edit Dashboard

The Edit Dashboard allows users to customize the dashboard by adding or removing tabs, reorganizing layout options, and customizing the dashboard to show the information that is most important to the user. It ensures a personalized view for better accessibility of required data.

Steps to Edit the Dashboard:

1. Navigate to the Dashboard section in the Quality module.
2. Click on the Edit Dashboard button located at the top left of the Toolbar.
3. Once clicked on Edit Dashboard, the Set Up Your Dashboard window will appear.
4. It includes the relevant options, such as:
    - Set Up Dashboards: For selecting or adding widgets.
    - Set Up KPI Dashboard: For managing key performance indicators.
    - Set Up Layout: For customizing the layout.

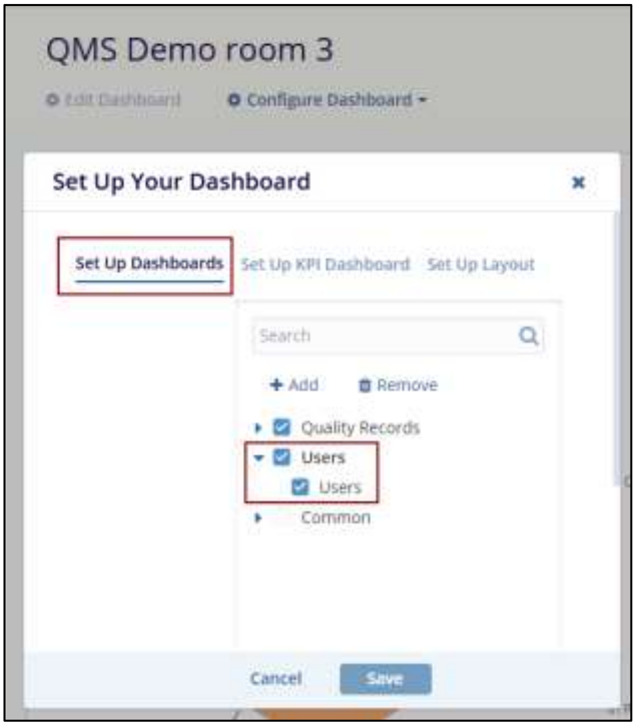



## Set Up Dashboards

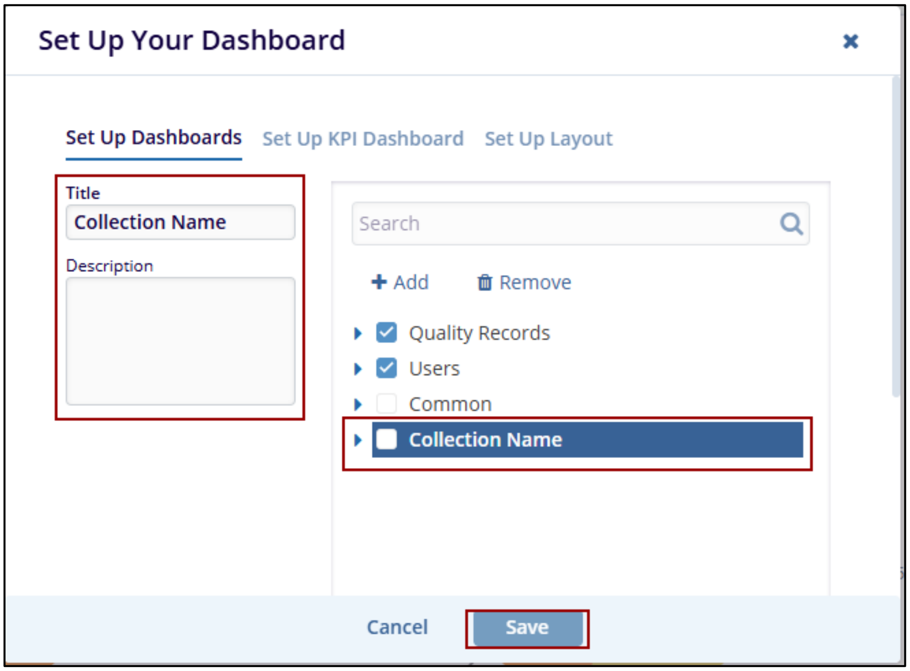
The Set-Up Dashboards allow users to customize their dashboards by adding, removing, or managing dashlets. Dashlets are individual components that display specific types of data or functionality on the dashboard, helping users personalize their view to highlight the most relevant information.

Steps to set up the dashboard.

1. The Set Up Your Dashboard window appears. By default, the Set-Up Dashboard option is displayed. Expand the fields using the arrow and select the required checkbox.




2. Click the Save button on the Set Up Your Dashboard window. The selected options are displayed on the Dashboard.
3. Click on the Add button, and a new entry will appear under the list of available dashlet as (collection Name). While adding a new dashlet, the user has to mention the Title and Description in the left-side fields.
4. Once all necessary changes are completed. Click the Save button at the bottom of the popup window to apply the changes.

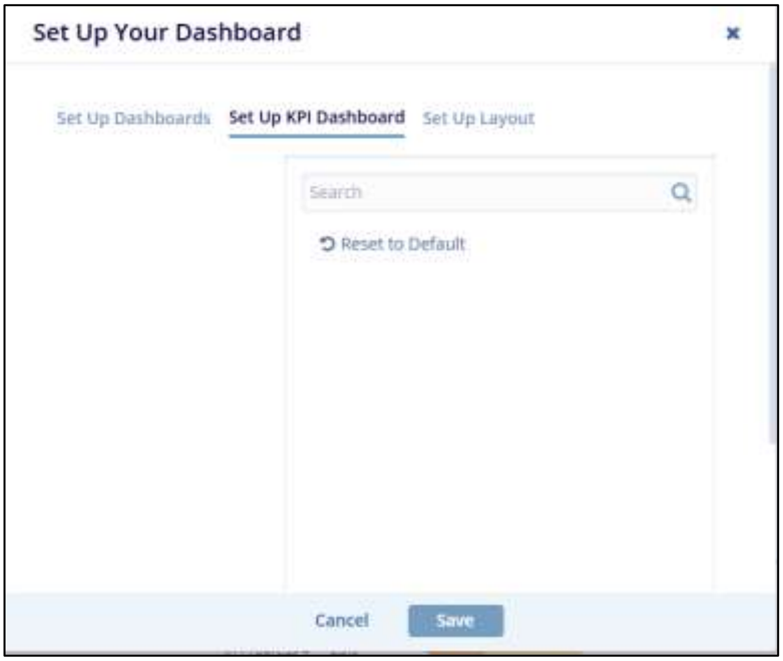


## Set Up KPI Dashboard

The Set Up KPI Dashboard allows users to configure key performance indicator (KPI) metrics on the user's dashboard. The selected dashlets are displayed on the top right corner of the screen.

Steps to set up the KPI dashboard.

1. From the Set Up Your Dashboard window. Click on the Set Up KPI Dashboard option.



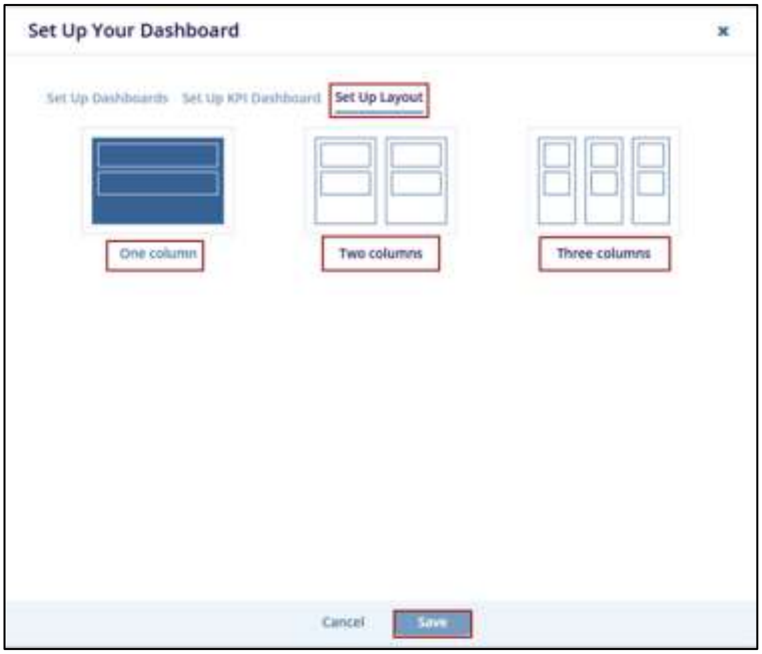

2. Click on Reset to Default to revert all KPI configurations if available to the original system-defined settings
3. Once all necessary changes are completed. Click the Save button at the bottom of the popup window to apply the changes or click the Cancel button to discard changes.

## Set Up Layout

The Set-Up Layout allows users to customize the visual structure of the dashboard by choosing a column-based layout. This ensures that the dashboard is organized according to user preferences. The user has the option to select from one, two, or three Columns.

Steps to set up the Layout:

1. From the Set Up Your Dashboard window. Click on the Set-Up Layout.
2. Select one of the available options of Layout:
    - One Column: Arrange all dashlets in a single vertical column.
    - Two Columns: Splits dashlets into two evenly spaced columns.
    - Three Columns: Divides dashlets across three narrower columns.
3. Click the Save button to confirm and apply the selected layout or use the Cancel button to discard the changes.




## Configure Dashboard

The Configure Dashboard helps the user to arrange the dashboard as required. This includes Configure Dashlets dashboards.

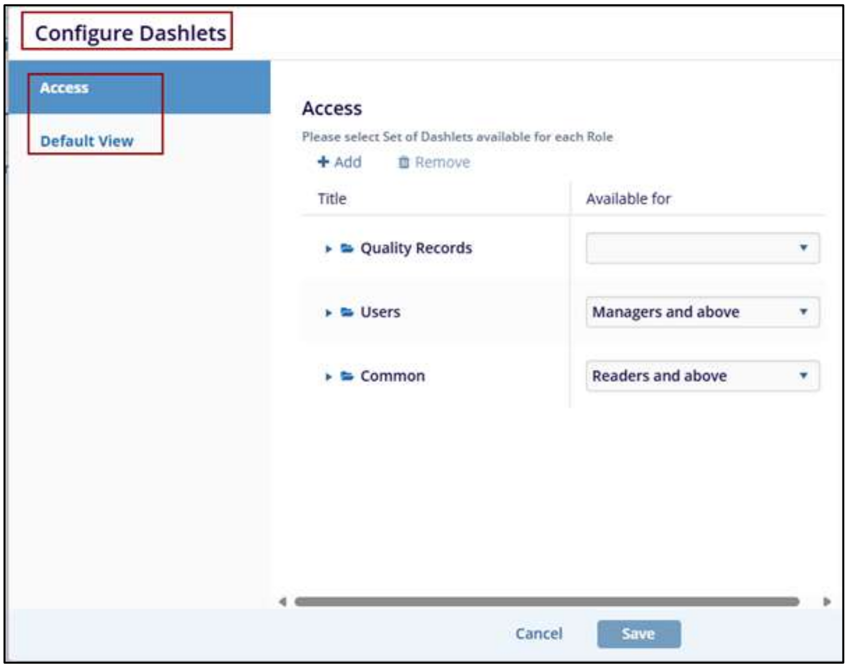

### *Configure Dashlets*

The Configure Dashlets allows administrators to manage the availability and visibility of dashlets on the dashboard for different user roles. Dashlets are individual components that display specific data or functionality, such as documents, users, or key metrics, making the dashboard customizable and role-specific.

Steps to Configure the Dashlets.

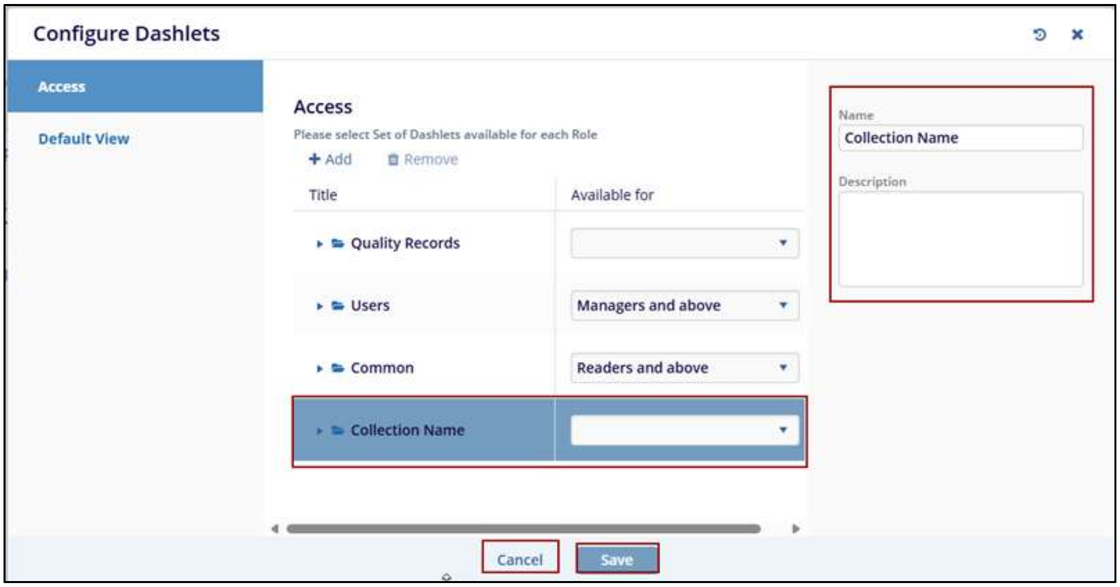
1. Click the Configure Dashboard button next to the Edit Dashboard button. The user can see the dropdown menu Configure Dashlets.
2. Click on the Configure Dashlets, and the Configure Dashlets window will pop up.
3. The Configure Dashlets window will display two tabs on the left:

- Access: To select a Set of Dashlets available for each Role
- Default View: To select the Default list of Dashlets for each Role.

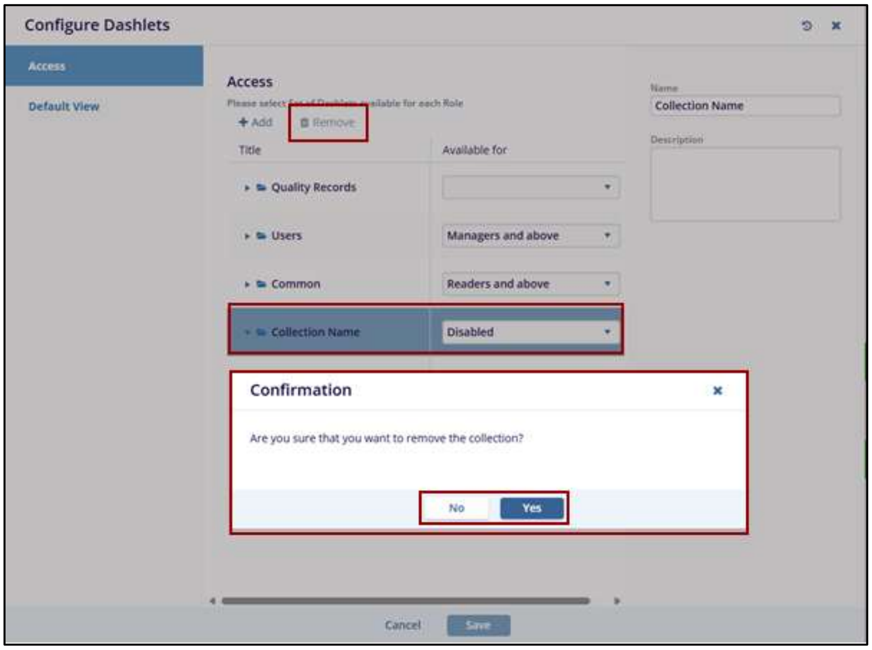



4. In the Access tab, the user can select the roles from the dropdown menu under the Available or column to assign dashlets to specific roles and click the Save button to save the changes and the Cancel to discard the changes.

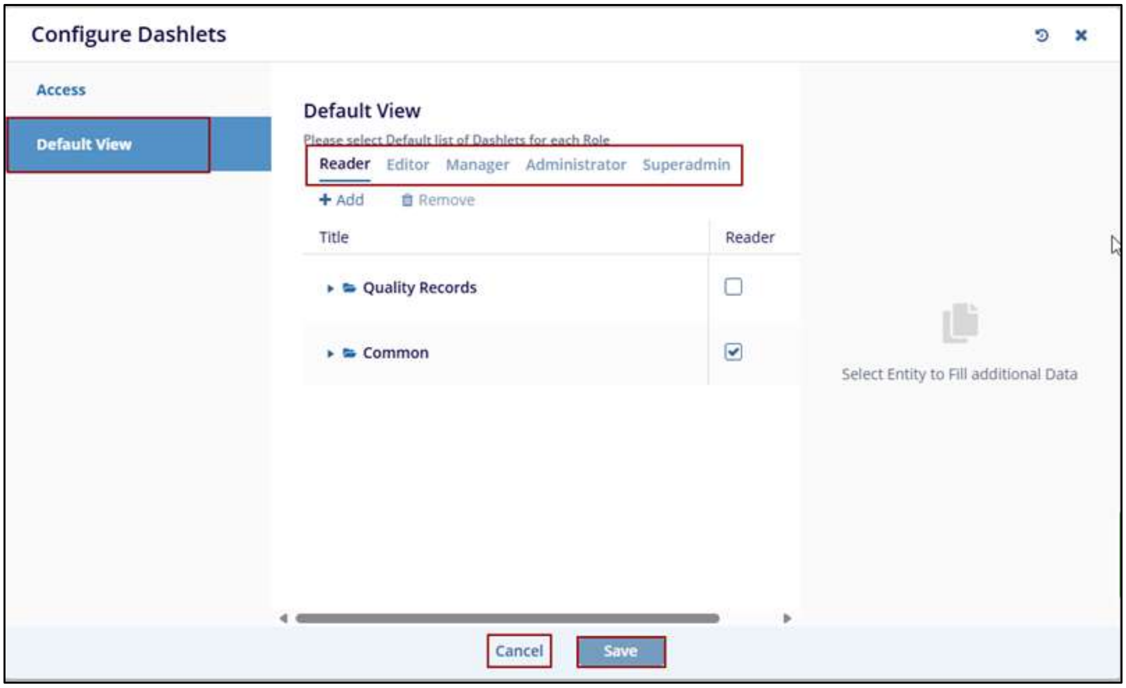

5. Click on the Add button, and a new entry will appear under the list of available dashlet as (collection Name). While adding a new dashlet, the user has to mention the Name and Description in the right-side fields.




6. Click the Remove button to initiate the removal process. A confirmation window will appear with the message: 'Are you sure that you want to remove the collection?' Also, the user can only remove the newly added fields and not the pre-defined fields.



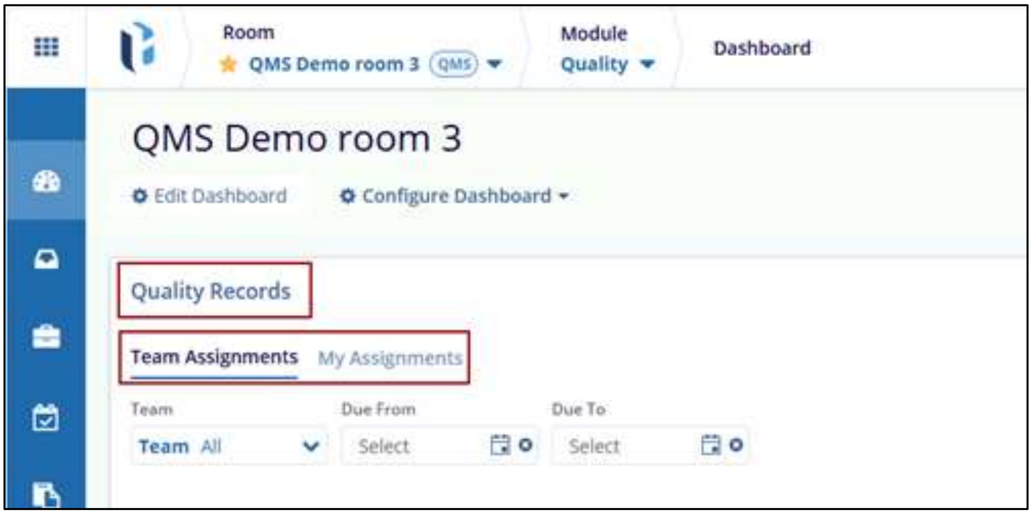

7. Click Yes to remove the selected name and No to discard the change.
8. Switch to the Default View tab, and select the required and appropriate checkboxes for the roles mentioned – Reader, Editor, Manager, and Administrator.
9. Click on the Save button at the bottom of the pop-up window to save the changes or click Cancel to discard the changes.




## Quality Records

The Quality Records dashlet consists of two sections:

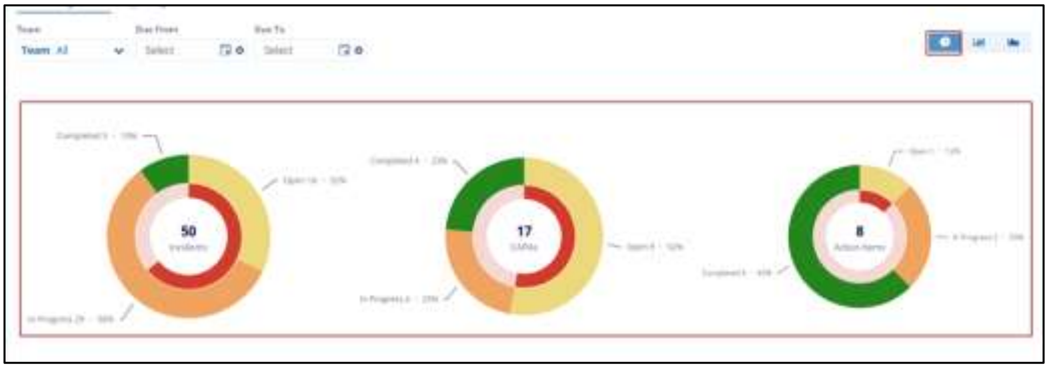
- Team Assignments
- My Assignments



The Quality Records section also presents the records in chart format, for example:

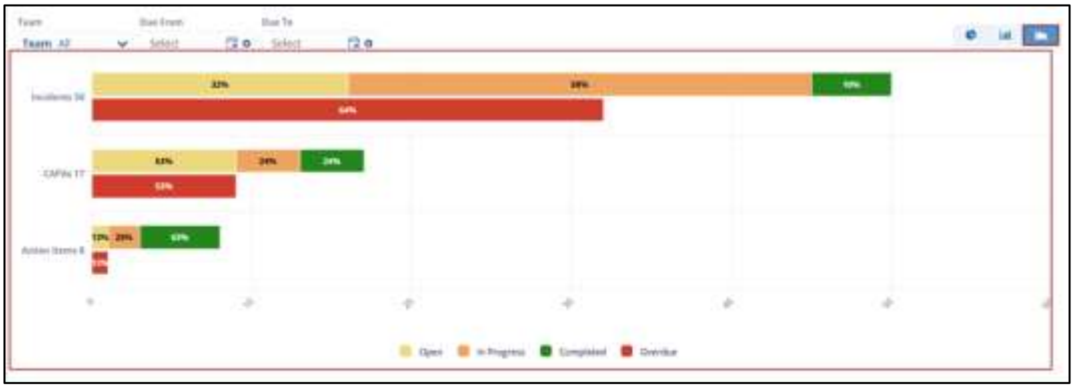
- Donut Chart
- Stacked Column Chart
- Stacked Bar Chart

Donut Chart: A Donut Chart displays data in a circular format, similar to a pie chart, with a hollow center, making it easier to compare proportions across categories.



Stacked Column Chart: A Stacked Column Chart displays data in vertical columns where values are stacked on top of each other, showing the total and the contribution of each category.

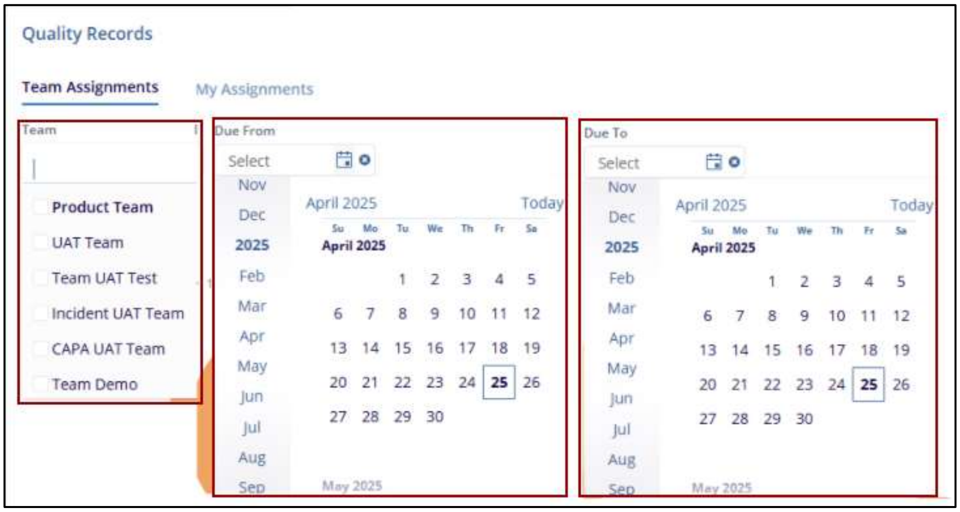
Stacked Bar Chart: A Stacked Bar Chart displays data in horizontal bars where segments are stacked to show both the total and the breakdown across categories.



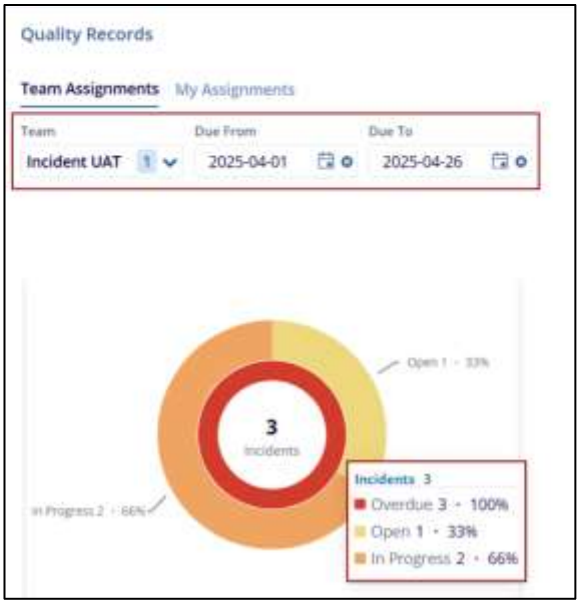
*Team Assignments*

Users with Manager and above access levels can view the Team Assignments tab in the Quality Record Dashlet.

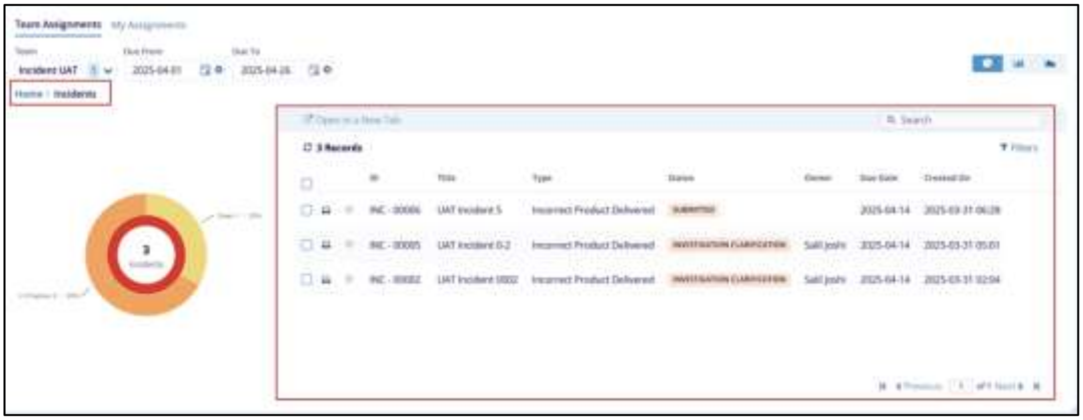
1. Expand the Team drop-down and the user can view the records created by Teams. Additionally, the user can apply filters for "Due From" and "Due To" and selects dates for each Team Assignments.




2. Based on the selected Team and Dates, the corresponding information is displayed in the chosen chart format.
3. Hovering the mouse over the chart displays the count and percentage of overdue records of assignments based on their status and corresponding color:
   - Overdue
   - Open
   - Pending
   - In Progress
   - Completed




4. Clicking on the chart displays the Team Assignment Records next to it, showing information related to the selected Team.

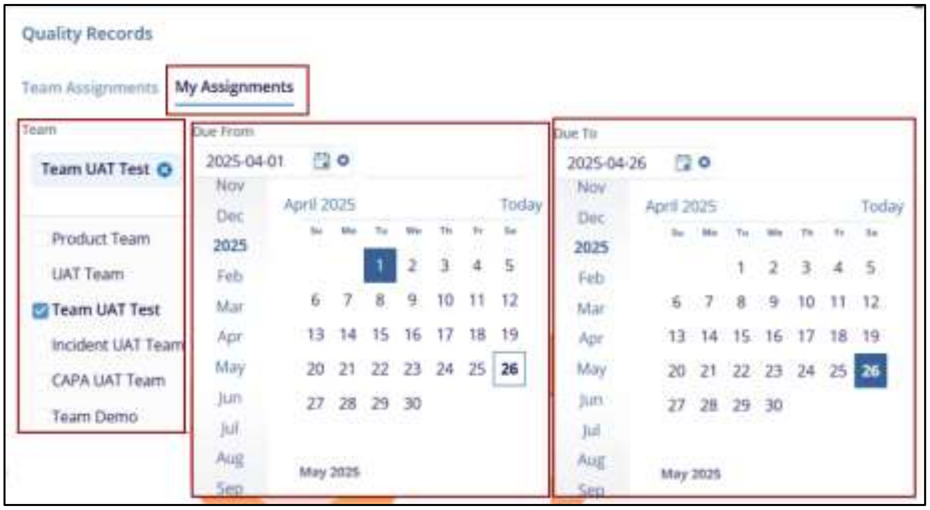



5. Click on the Home on the left side of the screen below the selected Team. The user navigates back to the chart view.

### *My Assignments*

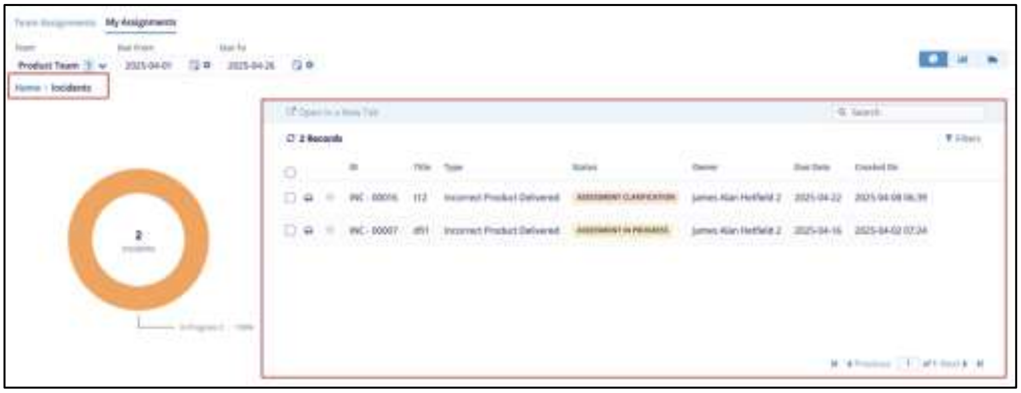
Users with Editor access levels the My Assignments tab displays only those records that are assigned to a particular user.

1. Expand the Team drop-down the user can view the Assignments created by Teams. Additionally, the user can apply filters for "Due From" and "Due To" and selects dates for each Team Assignments.




2. Based on the selected Team and Dates, the corresponding information is displayed in the chosen chart format.
3. Hovering the mouse over the chart displays the count and percentage of overdue records of assignments based on their status and corresponding color:
   - Overdue
   - Open
   - Pending
   - In Progress
   - Completed


4. Clicking on the chart displays the Team Assignment Records next to it, showing information related to the selected Team.



5. Click on the Home on the left side of the screen below the selected Team. The user navigates back to the chart view.
6. The Refresh icon updates the displayed data, ensuring the latest information is shown based on the current selections.

# SEARCH IN QMS

To perform search activities within the Quality Module, users must have the appropriate access permissions. This section specifically covers how to search for Incidents, CAPAs, and Action Items. General search actions applicable across the system have already been covered in the Searching in TI section.

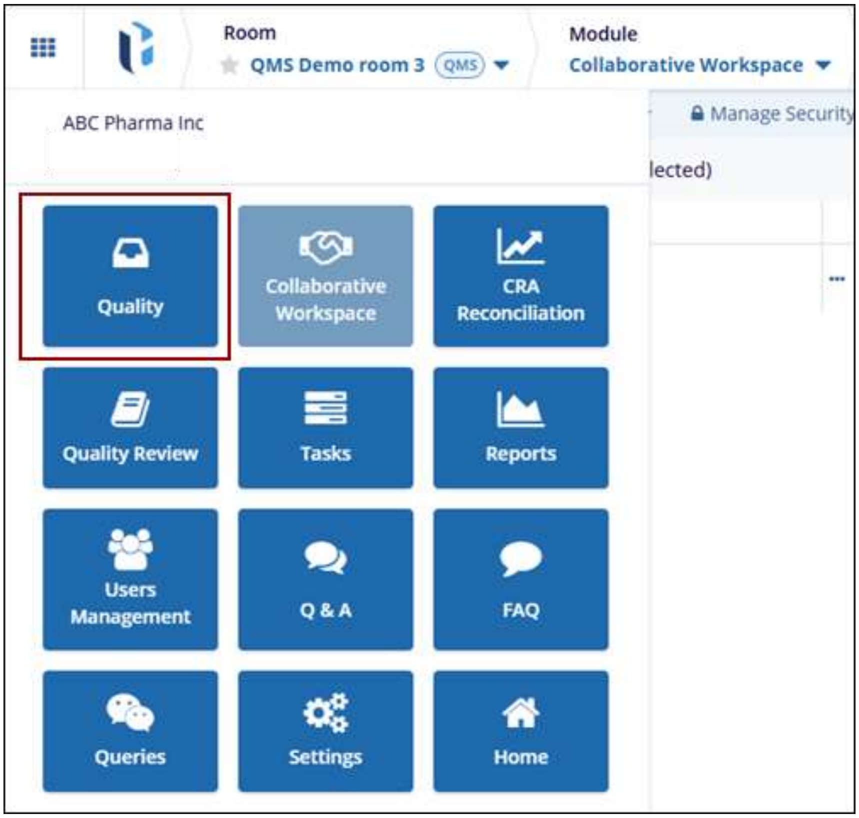
Note: The Search and Filter Fields settings can be configured from the Form Settings screen, provided the user has the necessary access permissions.

Steps to Perform a Search in the Quality Module:

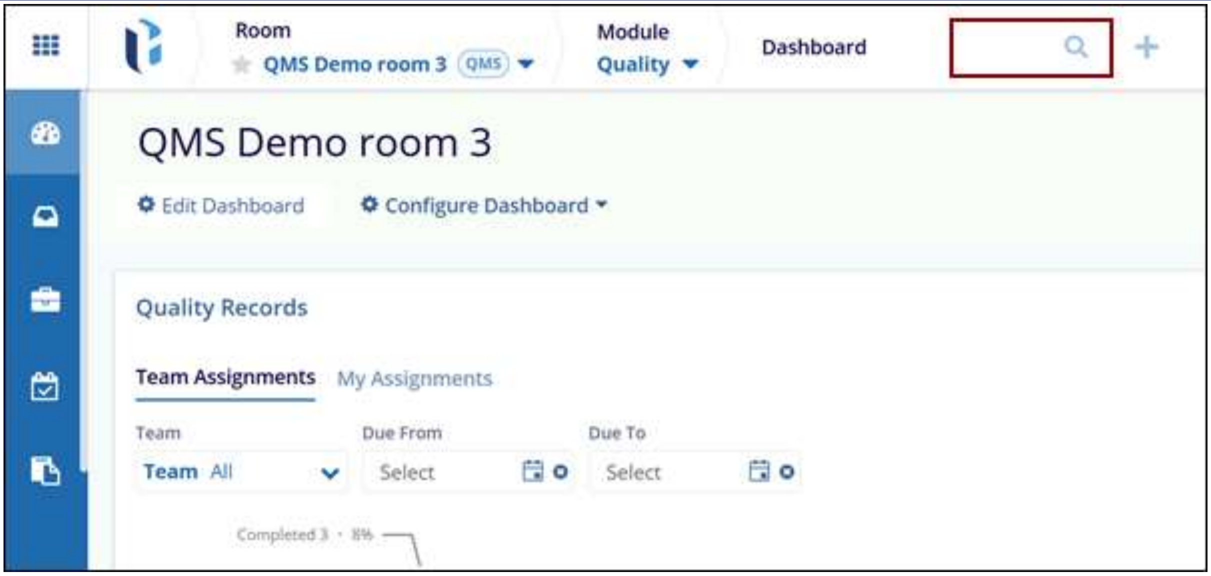
1. From the Home Page, navigate to the room to perform the search activity.

   Note: Once inside a room, search functions are available globally across the application, as the top search bar is always accessible. The steps below outline a structured approach to performing a search.

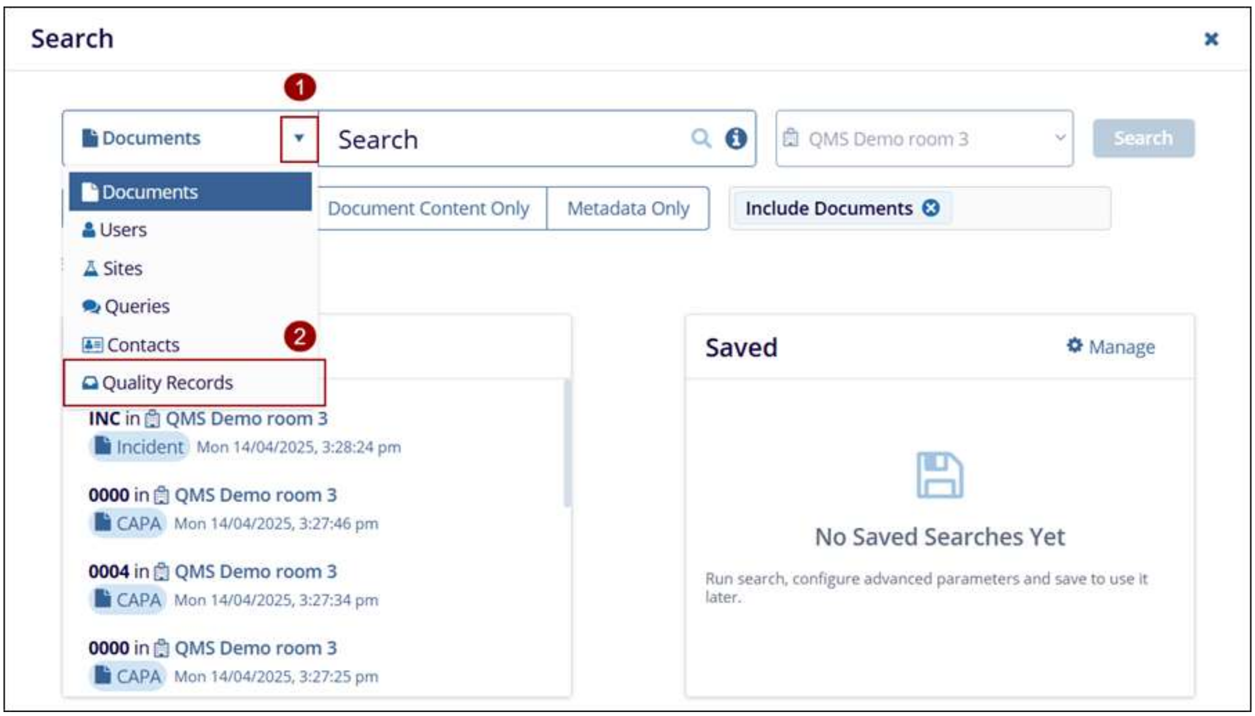
2. Click the Waffle Menu located at the top-left corner of the screen, then select Quality Module. Users will be redirected to the Quality Module's Dashboard screen.




3. Click the Search button at the top-right corner of the screen to open the Search window.



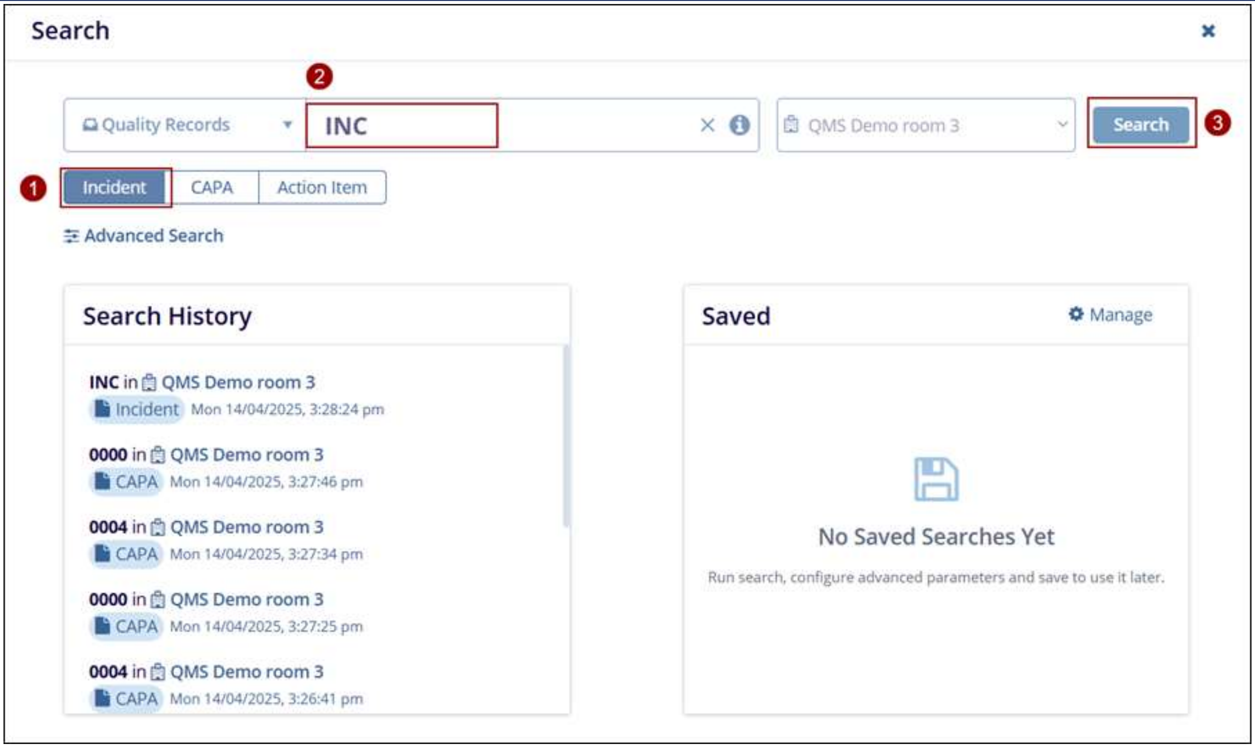

4. In the search screen, click the dropdown menu at the top-left to display the available search categories.



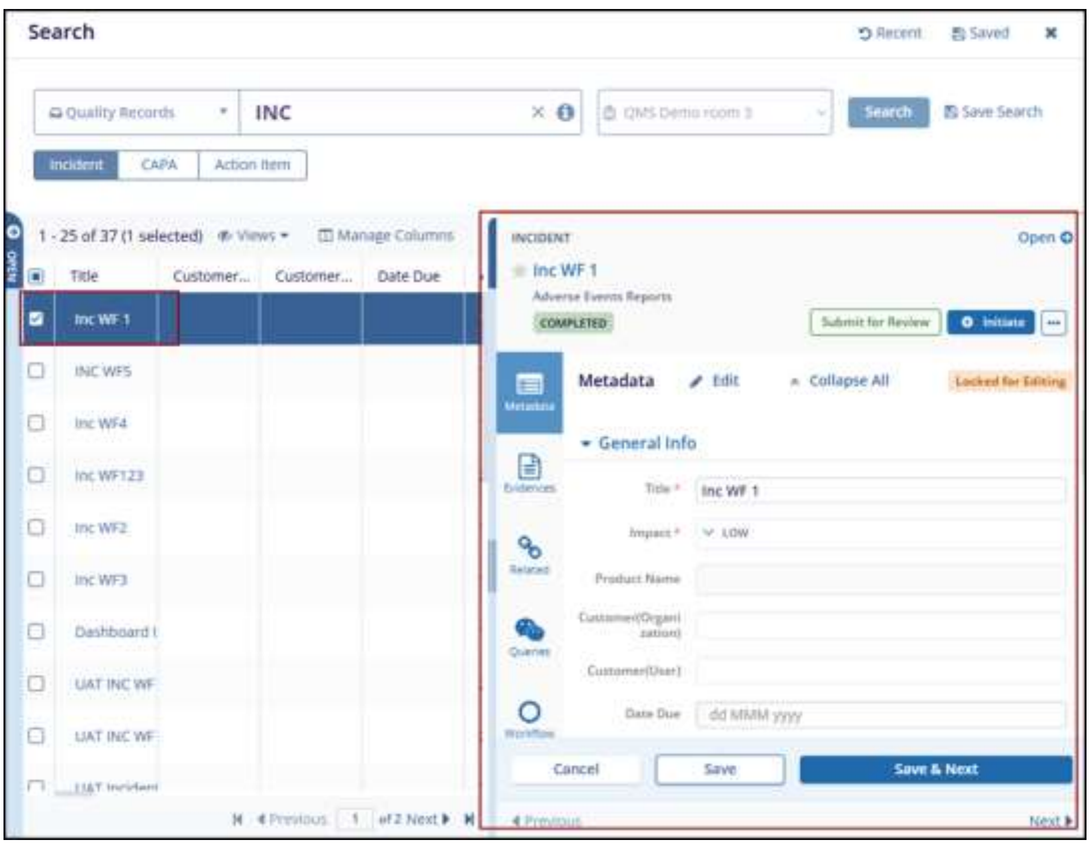

5. From the dropdown, select Quality Records. Here, three tabs will display Incident, CAPA, and Action Item.

   Note: The steps for searching each of these record types are the same. Simply select the appropriate tab to begin. By default, the Incident tab is selected.

6. Click Incident and Enter at least three characters, Digits of the title or ID of the incident. Once entered, click the Search button.

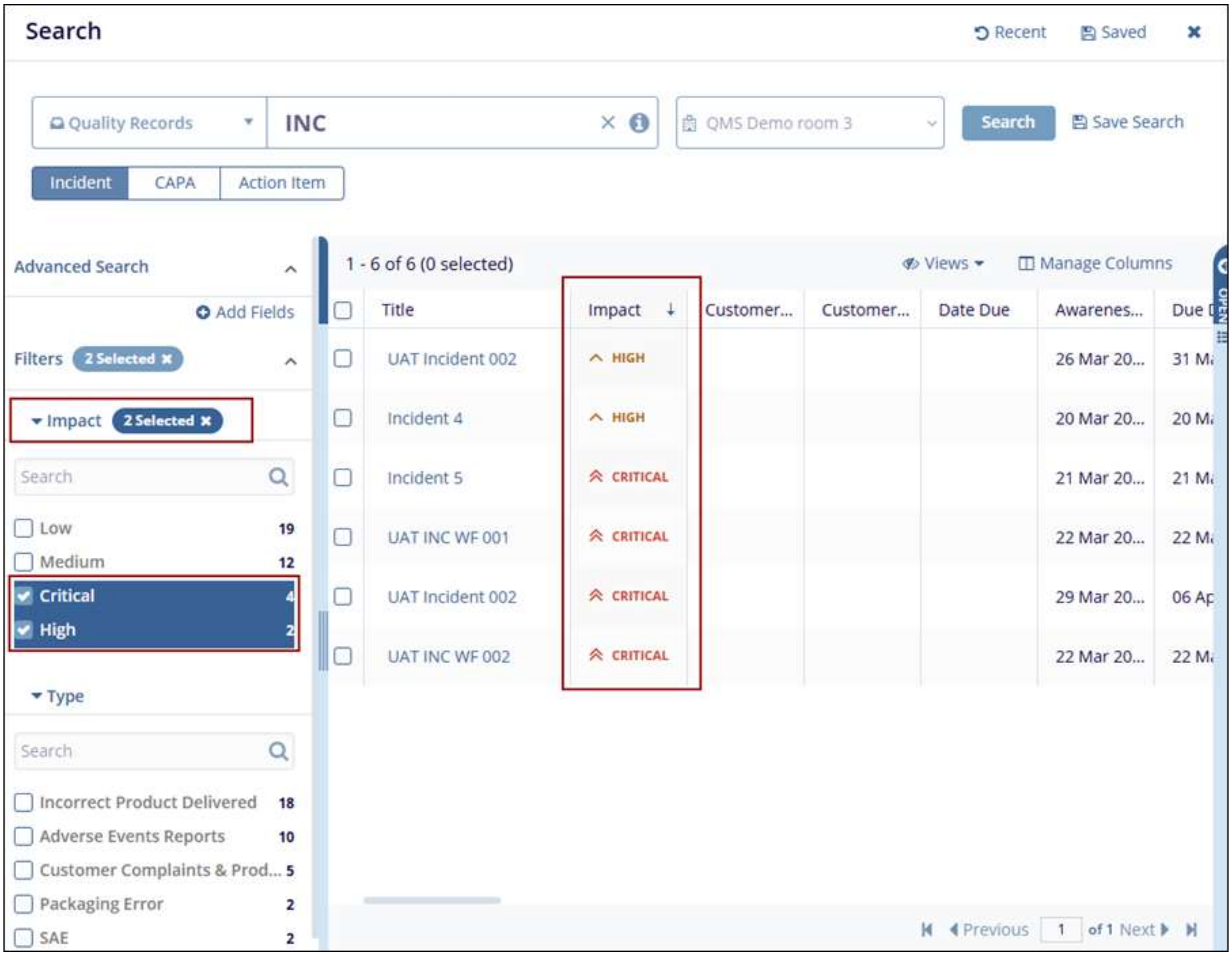



7. The results will be displayed in a grid view. Click the checkbox next to the desired record to view its metadata, which will appear on the right side of the screen.



Steps to Perform a Filter in the Quality Module:

1. After results are displayed, the filter panel is visible on the left side of the screen.
2. Apply a Filter
   For example, to filter by Impact:
   - Click the dropdown arrow next to the Impact filter.
   - Select the desired filter options (e.g., *Critical*, *High*).
3. Once filters are applied, the grid will auto-refresh to show only the matching records. Refer to the screenshot below.



# TEAMS

The Teams that allow users to create and manage teams that are responsible for handling assignments related to Records and Documents. These teams can be designated for specific workflow stages, record approvals, or other configured actions within the system. Users will be able to add or remove team members, associate teams with specific record or document types, and manage associated Authority Types.

1. Team Listing and Management

   Team Listing:

   The Team Listing screen allows users to view all existing teams in a module and manage them:
   Displays all created teams with information about:
   - Team name
   - Members count
   - Description
   - Purpose (Responsible Parties, QMS)
   - Document types count (For the Responsible Department purpose)
   - Record types count (For QMS purposes)

   Team Management Actions:

   - Add - Users can create a new team with QMS purpose - required to provide the assigned level for each Authority Type.
   - Edit - modify existing teams in the QV panel.
   - Delete - Deleting a team will prompt a confirmation dialog.

2. Team Page – Details

   The General Details section of a team provides an overview of the team's main information:

   - Team Name: Editable name of the team.
   - Description: A detailed description of the team's role, which is editable.
   - Purpose: for now, agreed to have this list of purposes, which will affect team functionality and configuration
     - QMS - enables ability to link record types and team be responsible for conducting WF stage
     - Responsible Parties - enables ability to link Document Types

   Actions available:
   - Edit - enables edit mode for the team
   - Change Log - Displays a history of team modifications

   Authority section gives ability to manage authorities:

   List of authority Type members columns:

   - authority type
   - Assigned

- Escalated
- Informed
- Actions

3. Team Page - Document Types

Teams can be associated with specific Document Types, allowing them to manage documents and actions related:

Actions available:

- Add Document Types: Users can add document types to the team by selecting from a categorized list (e.g., Investigative Site, Recruitment Plan, etc.).
- Remove: Users can remove a document type from the team, which triggers a confirmation modal.

Columns:

- Category: Document Types category
- UDID: Universal Document Type ID number - configured in settings
- Type: Document Type name
- Paths: The full path of each document type is displayed for clarity.

4. Team Page – Members

Team members can be added or removed to manage responsibilities for records or workflow stages:

- Add Members: Existing Users or groups can be added to the team using the 'Add Members' option. A search and filter option helps in finding relevant members or groups.
- Remove: Members can be removed from the team using the 'Remove' option, which triggers a confirmation modal. Only if the user has no Authority Type assignment.
- Check Member details: the user can open the QV panel of a group or user and check additional details.
- Edit authority type on the user QV panel: section authority type, BUT if a user is the last one with Level Assigned for Authority Type, then this type can be edited only on the Team Details page. And the system on hover shows a message about it.

Default Columns:

- Roles: Each team member has a designated role (e.g., Admin, Editor, Reader)
- Status: an active/inactive status.
- Name
- Email
- Phone
- Expiration: user end date
- Authority Type: combined with level

5. Team Page - Record Types

Teams can be linked to specific Record Types, allowing them to handle relevant tasks and workflow stages:

Actions available:

- Add Record Types: Users can add record types to the team by selecting from a categorized list (e.g., Product Incident, CAPA, Action Item)
- Remove Record Types: Record types can be removed from the team, which triggers a confirmation modal
- Columns
- Category: Record types category
- UDID: Universal Record Type ID - configured in settings
- Type: actual Record Type name

To access the Teams modal, follow the steps below.

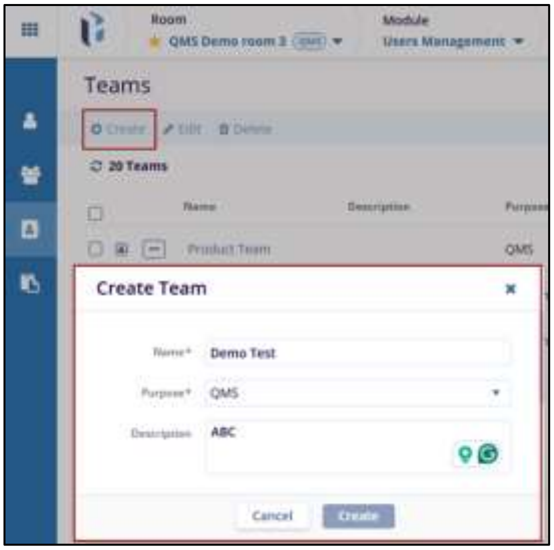
1. Navigate to the Users Management module within the QMS room, or click the Module dropdown and select the Users Management module option.
2. Navigate to the left-hand menu and select the Teams modal.


3. The Teams screen displays options to Create, Edit and Delete the teams' related actions.

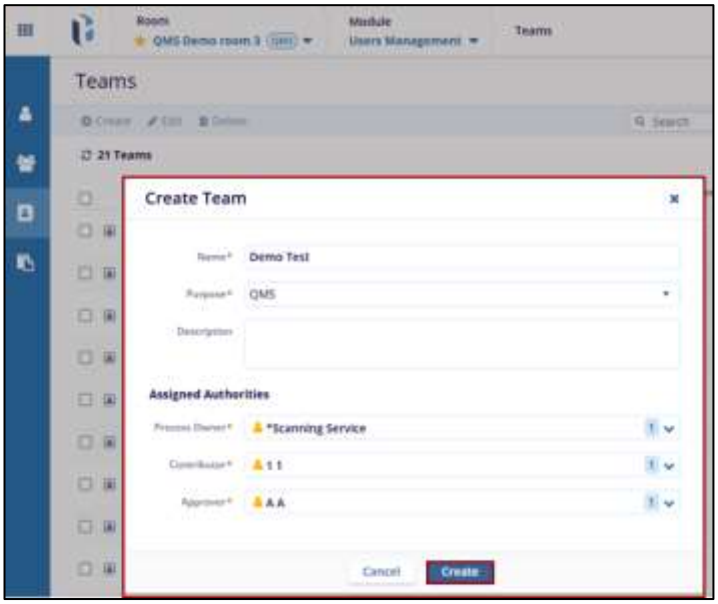
## Create Teams

To create the Teams, follow the steps below.

1. Click the Create option on the top menu bar. The Create Team pop-up window is displayed.
2. Fill in the below required fields:
   - Name
   - Purpose: the purpose should be QMS only
   - Description (optional)




3. The Assigned Authorities section appears once the user selects the 'Purpose as QMS'.
4. Fill in the below required fields:
    - Process Owner
    - Contributor
    - Approver
5. Click on the Create button.




## Key Terms

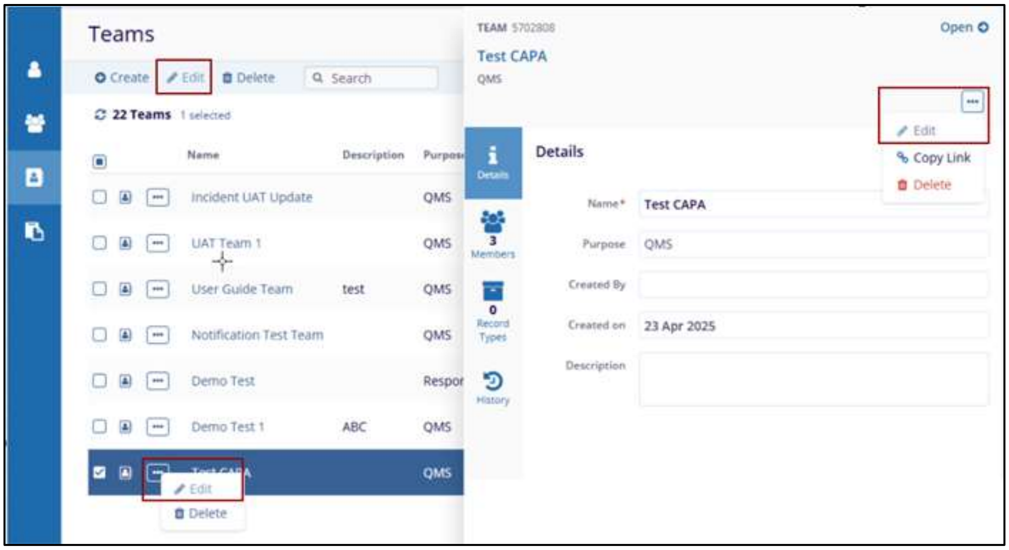
- Team: A Team is a group of users assigned to a record and its associated workflow to ensure appropriate participation throughout all workflow stages. Teams are organized by Authority Types (such as Process Owner, Contributor, Approver), with each authority further defined by levels, i.e., Assigned, Escalated, and Informed etc., that specify responsibility and notification roles.

- Authority Type: Authority Type defines the roles within a team that are responsible for specific workflow stages, e.g., Process Owner, Contributor, Approver. Each Authority Type can be configured with different levels of involvement, allowing flexible stage assignment and escalation logic.
- Process Owner: The primary person responsible for the record's workflow. This role leads and manages key stages such as assessment, implementation, or execution (e.g., Supervisor, CAPA Lead).
- Contributor: A contributor is a supporting participant involved in completing the investigation or other custom stages (e.g., Investigators or SMEs). A contributor can edit only the forms assigned to them during their active stage, e.g., Investigation. However, workflow configuration can extend their access to other forms as needed for that stage.
- Approver: An approver responsible for reviewing and approving the outcomes of the process (e.g., Quality Assurance reviewers). This authority can edit only the forms assigned to them during their active stage (e.g., Quality Feedback). However, workflow configuration can extend their access to other forms as needed for that stage.
- Authority Levels: The Authority Level defines the degree of involvement a team member has in a specific workflow stage, based on their Authority Type (e.g., Process Owner, Contributor, Approver). Each Authority Type is configured with three levels, which control how and when users are involved:
    - Assigned: These are the primary users responsible for performing actions at a workflow stage.
    - Escalated: These are the backup users who are engaged if the assigned users do not act within the defined escalation period.
    - Informed: These are the users who receive notifications about the workflow but are not responsible for taking action.

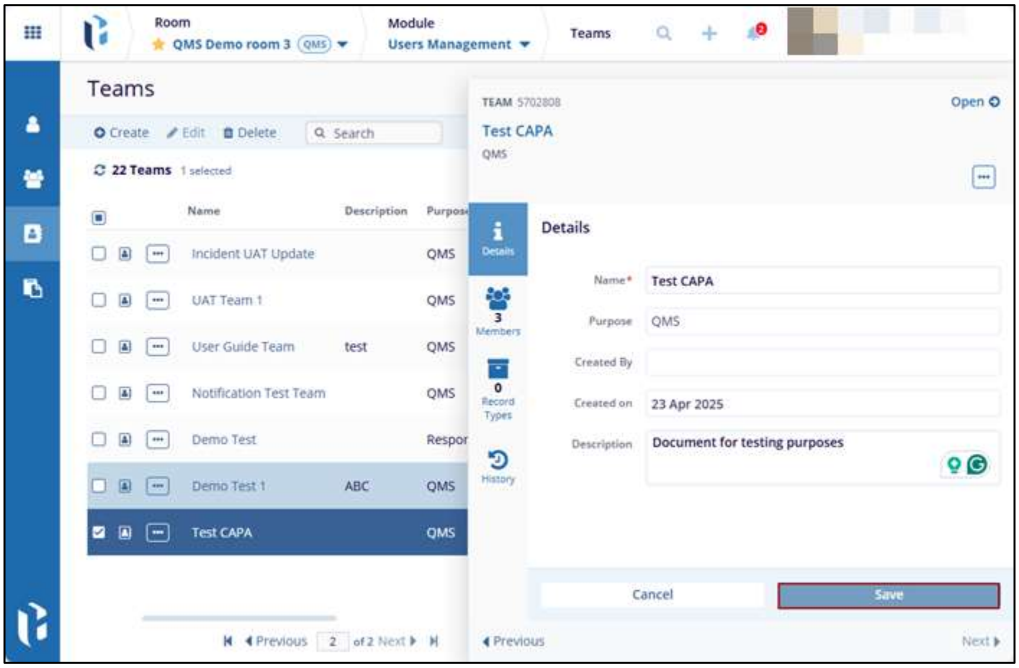
## Edit Team

To edit the Teams, follow the steps below.

1. Click on the name of the Team and click the Edit option on the top menu bar.
   Note: The user can access the Edit option either through the three-dot menu next to the created Team in the grid or from the three-dot menu in the metadata panel.



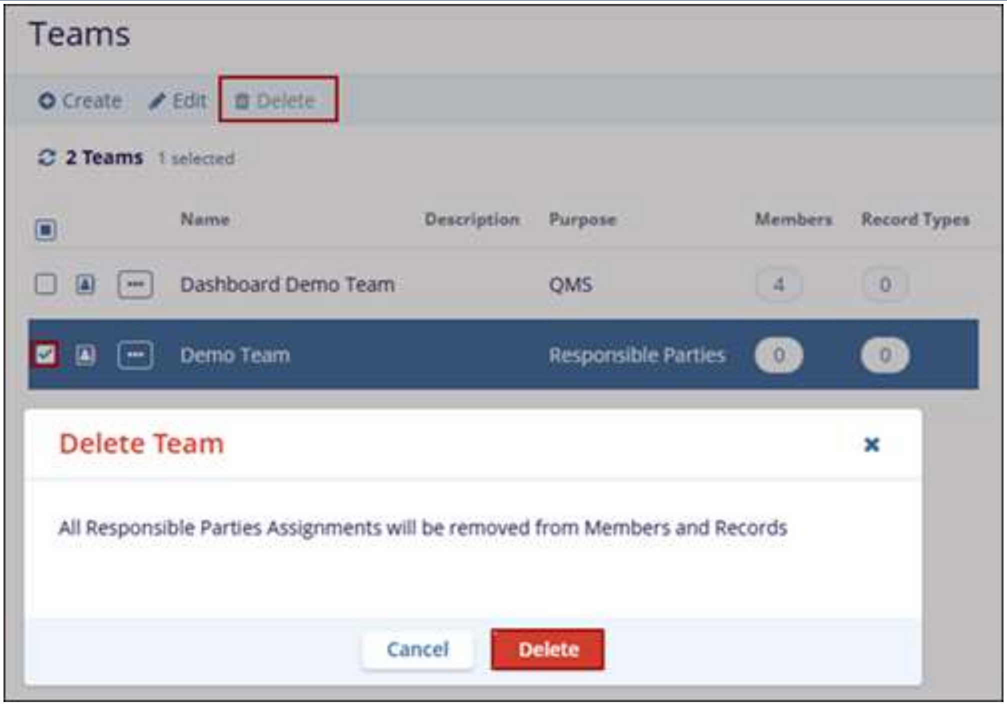

2. Make some changes in the Teams and click the Save button in the metadata panel on the right side of the screen.



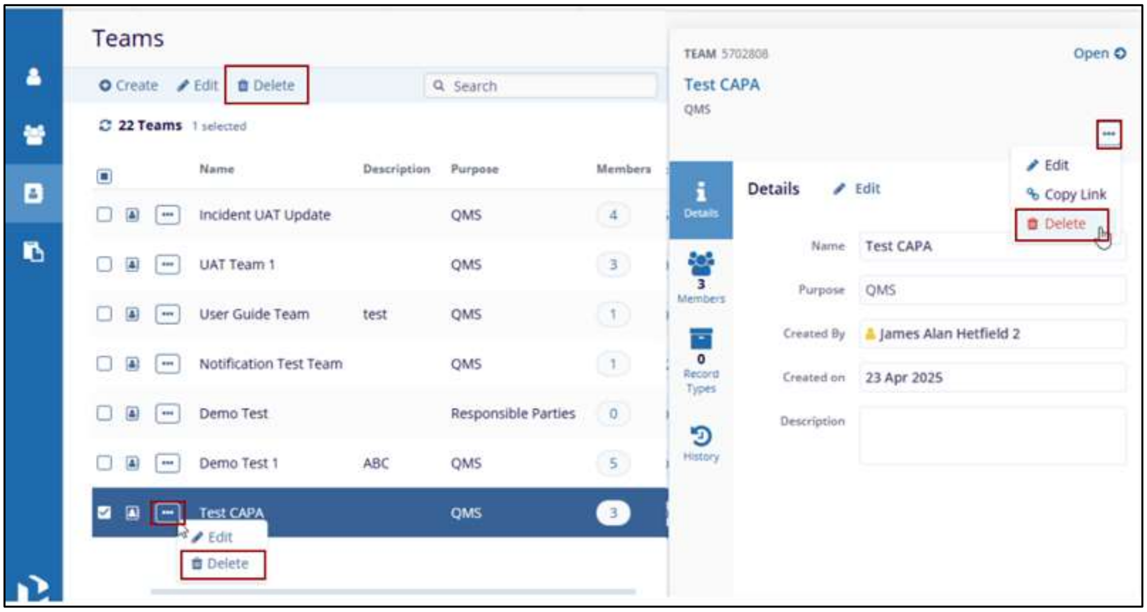

## Delete Team

To delete the Teams, follow the steps below.

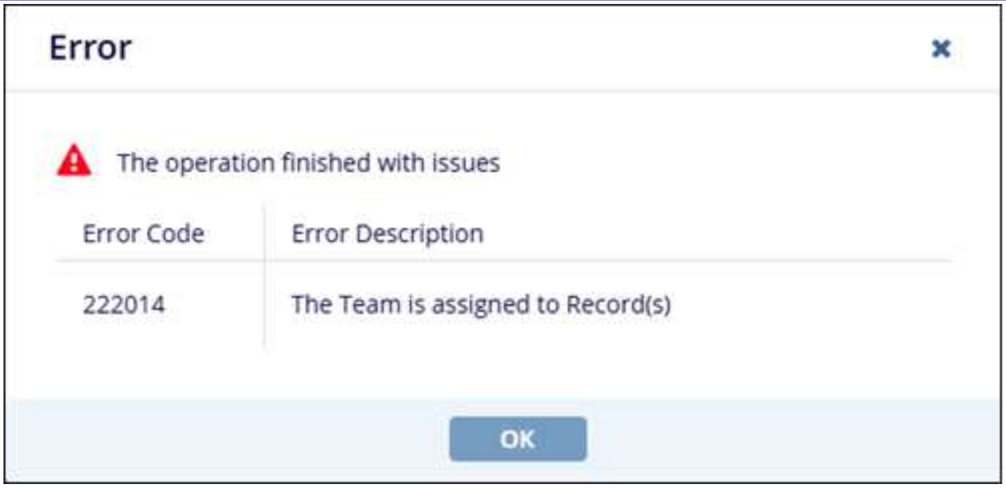
1. Click on the name of the Team and click the Delete option on the top menu bar.
2. On the confirmation popup, click on the Delete button to confirm the deletion.



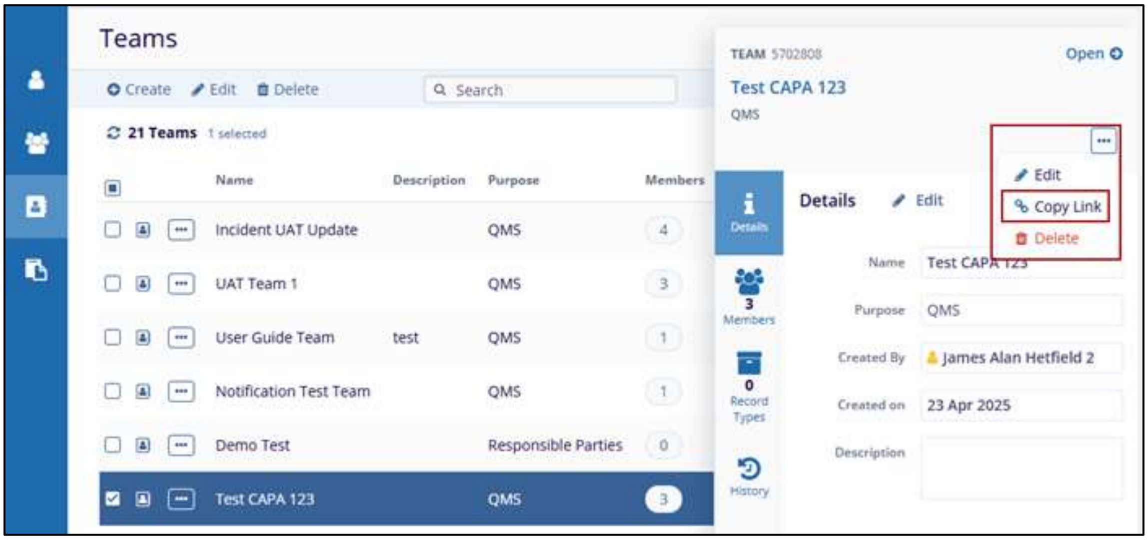

3. The user can access the Delete option either through the three-dot menu next to the created Team in the grid or from the three-dot menu in the metadata panel.




Important: When a team is associated with specific record types that are also associated with QMS Approval Workflow, users cannot delete the team, and upon a deletion attempt, the following popup is displayed.

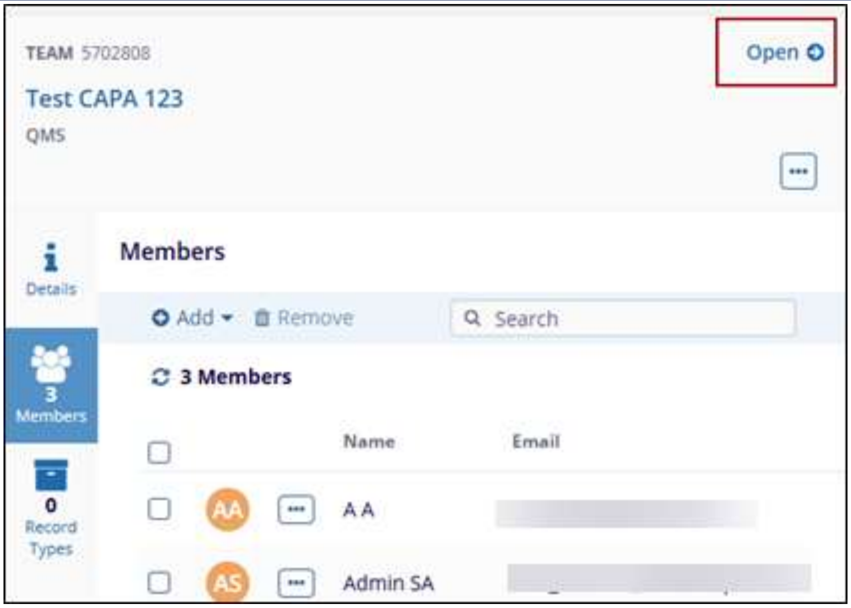



4. Expand the three-dot menu and click the Copy Link option on the right side of the metadata panel. However, the user can send the link of the selected Teams if required.




5. The Metadata Panel displays the detailed information of the selected Teams, such as:
   - Open Arrow: opens the Teams details page
   - Eclipse dots: displays the options - Edit, Copy Link, and Delete
   - Details tab: about the Team
   - **Member's tab:** associated with the Team
   - Record Types tab: displays the record types associated with the Teams
   - History tab: displays the record of the actions made for the selected Team

6. Click the Open Arrow, and the user navigates to the Teams Details page.

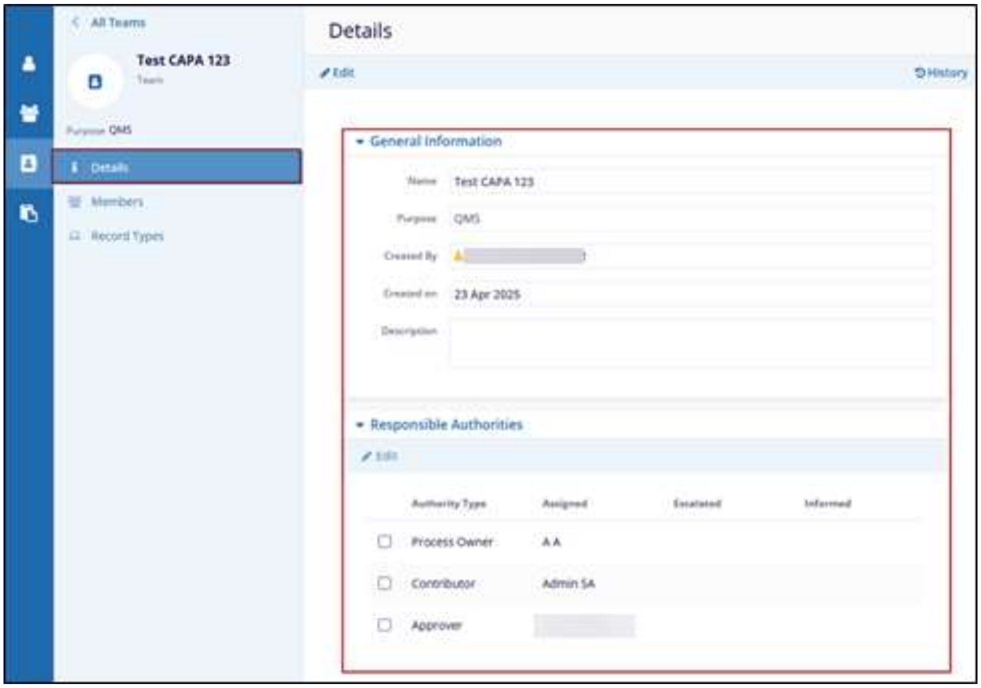


TEAM 5702808
Open
Test CAPA 123
QMS
Details
Members
Add
Remove
Search
3 Members
3
Members
0
Record Types
Name
Email
AA
A A
AS
Admin SA

## Teams Details Page

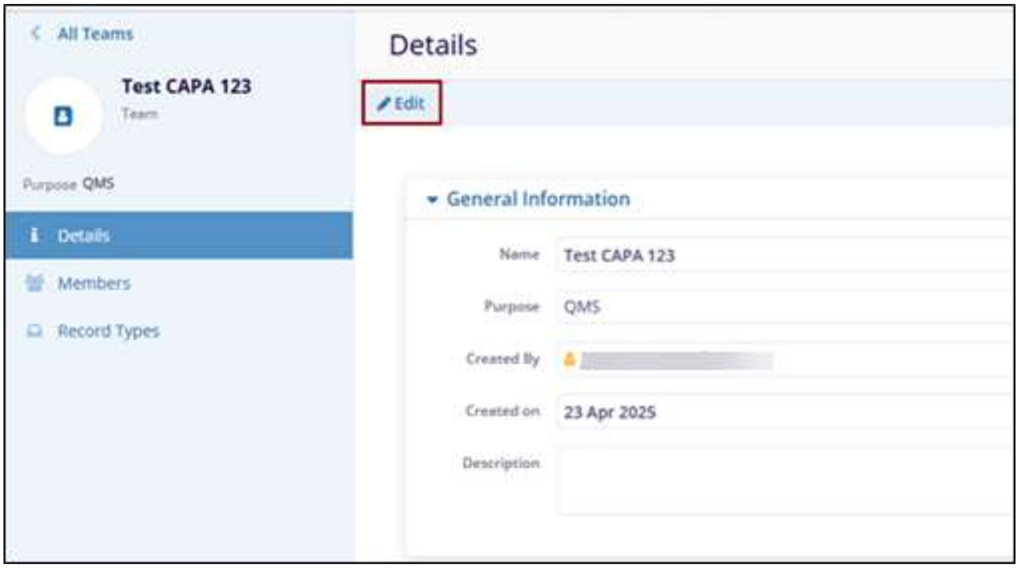
To access and edit details on the Teams Details page, follow the steps below.

1. The Teams Details page displays the General Information and, Responsible Authorities section within the Details tab.

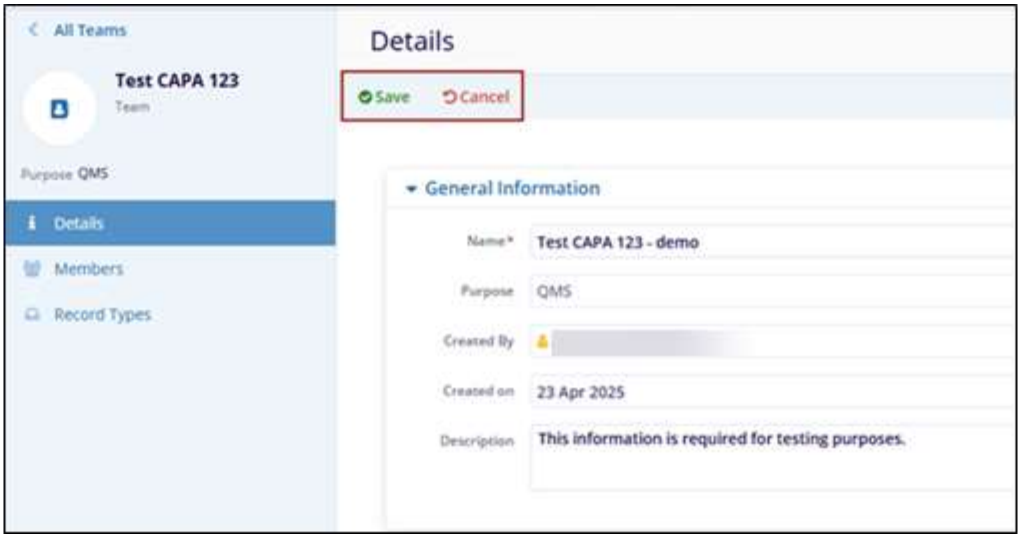



2. To edit the General Information section, follow the steps below.

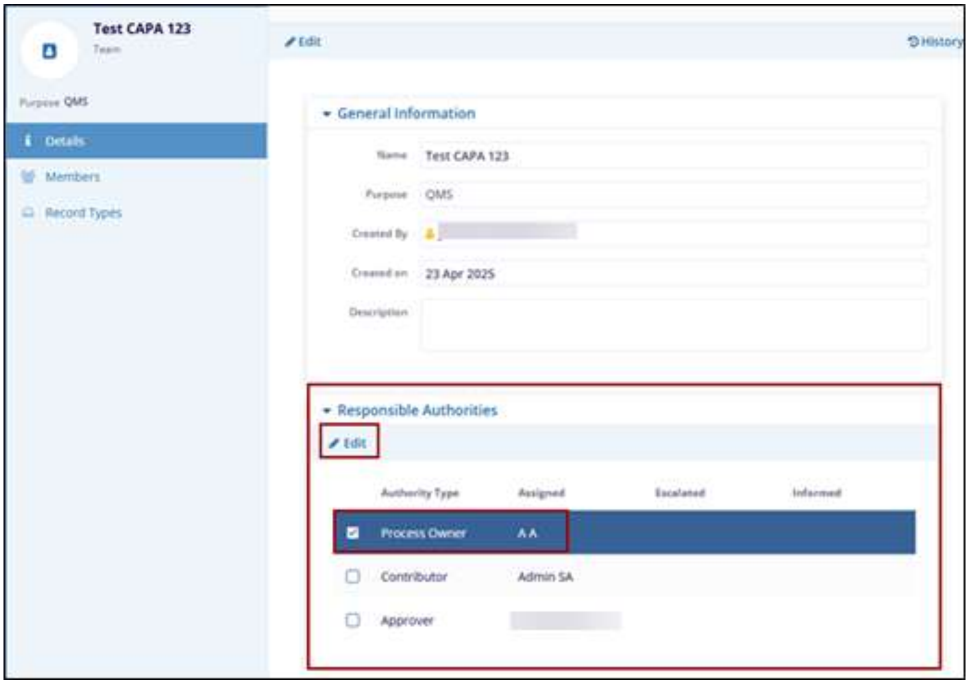
   - Click the Edit button on the top menu bar, and the user can see that only the Name and Description fields are editable.



- Make the required changes and click the Save button to save the changes. Similarly, click on the Cancel button to discard the changes on the top menu bar.

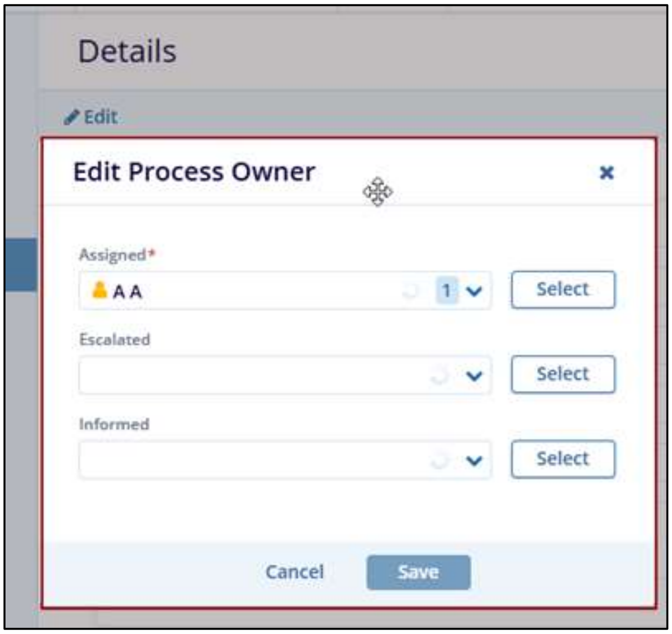



3. To edit the Responsible Authorities section e.g., Process Owner
    - Check the check box of the associated Responsible Authority while creating the Teams. The Edit button gets enabled.
    - Click the Edit button on the top menu bar of the Responsible Authorities section.

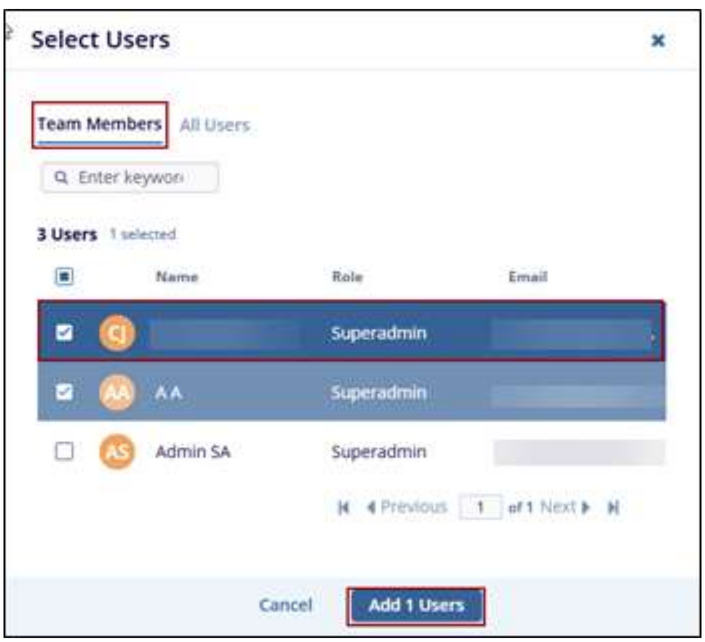



- The Edit Process Owner pop-up window appears with the following options:

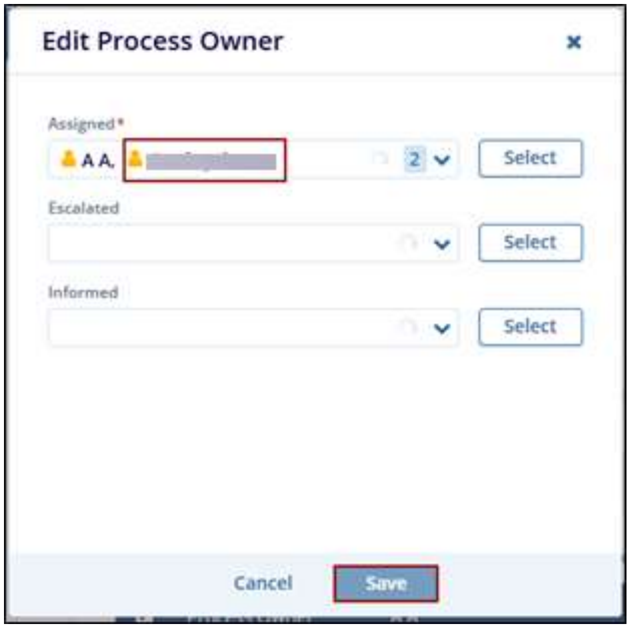
- Assigned: This field is pre-filled with the name of the user added during the Team creation process.
- Escalated
- Informed



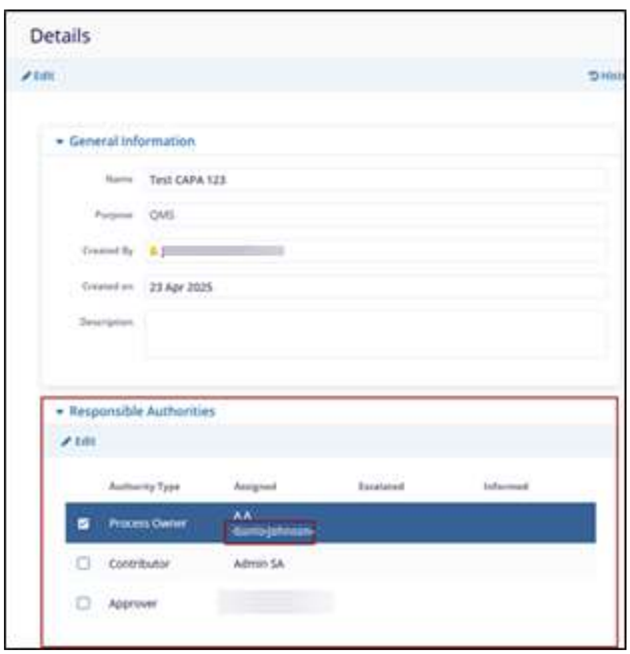

- Each option—Assigned, Escalated, and Informed—has a Select button next to it. Click the corresponding Select button to add users to that specific role.
- The Select Users pop-up window displays two tabs: Team Members and All Users. By default, the Team Members tab is selected, showing a list of users associated with the team.



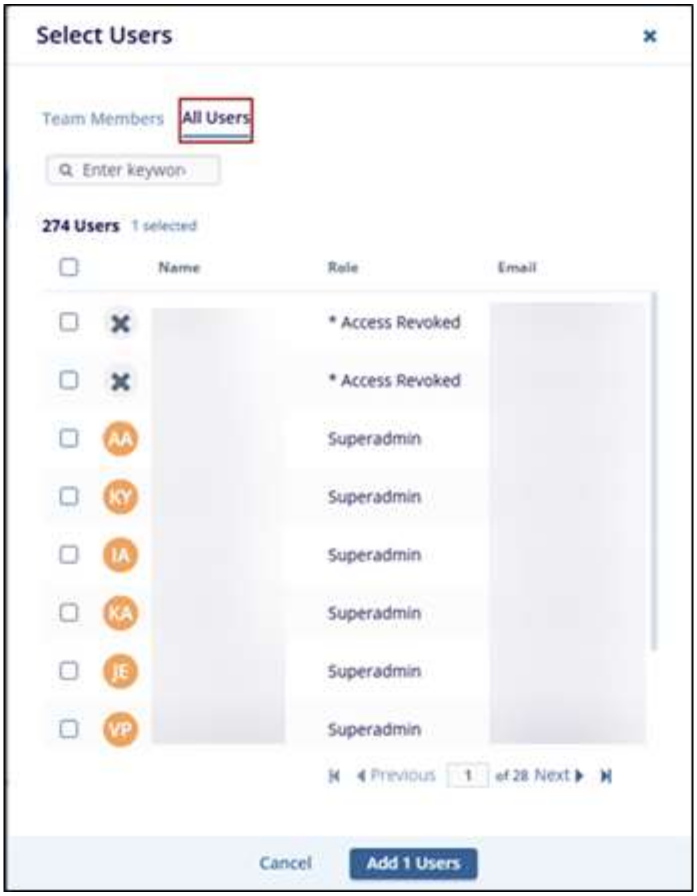
- Click the Add 1 Users on the bottom of the Select Users pop-up window.
- The user navigates back to the Edit Process Owner pop-up window; hence the selected user is added in the Assigned field.
- Click the Save button on the Edit Process Owner pop-up window.




- The user navigates back to the Teams Details page; however, the added user is displayed in the Assigned column in the 'Responsible Authorities' section.




- On the 'Select Users' pop-up window the All-Users tab displays the list of all users from where the users can be added as per the requirement.

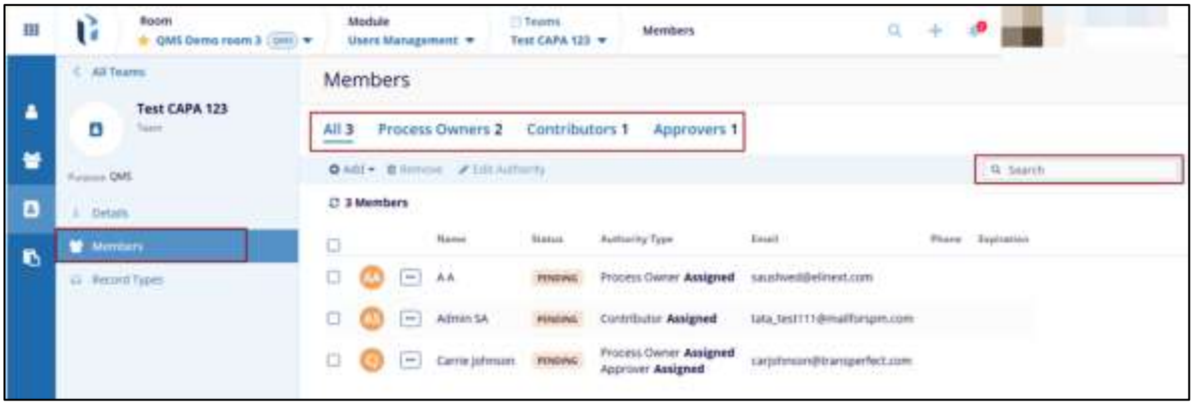



Note: Follow the same steps for the Escalated and Informed options within the Edit Process Owner pop-up window.

4. To edit the Contributor and Approver sections within the Responsible Authorities – please click the link: Teams Details Page, Responsible Authorities section.

## Members

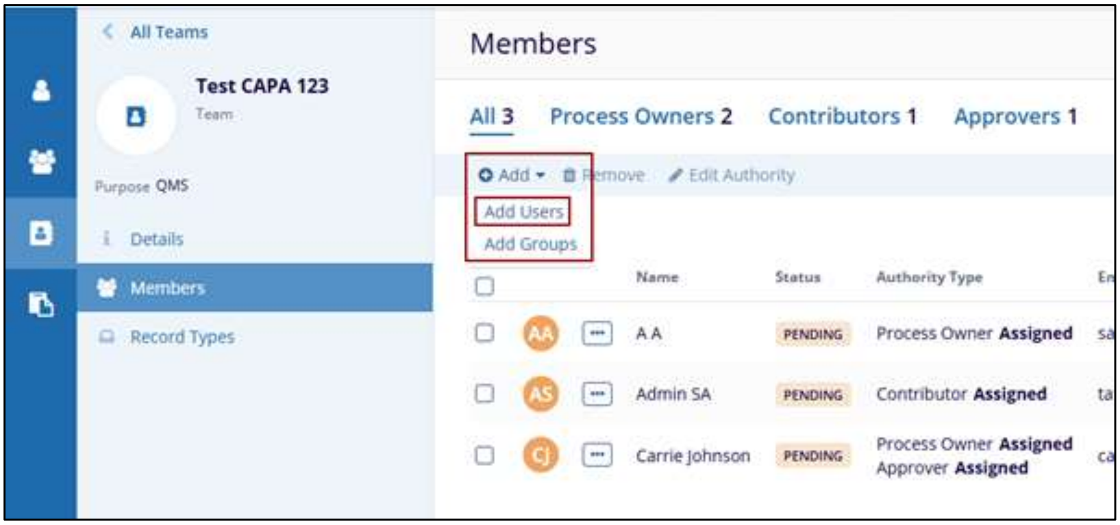
The Members page displays a list of users linked to the team, along with options to Add, Remove, or Edit their authority roles. It also includes tabs showing the count of users in each team and provides a Search function for easy user lookup.



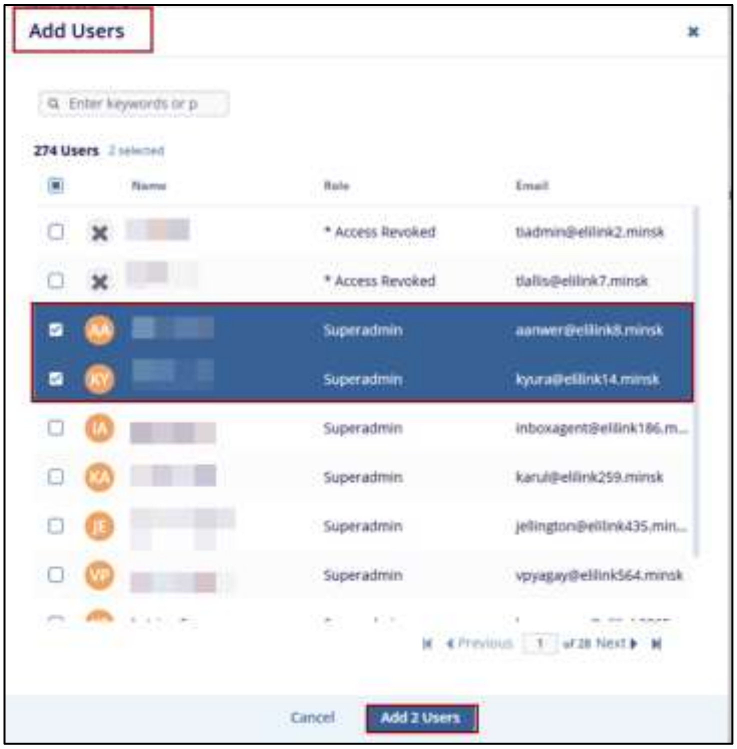

To add the members, follow the steps below.

<u>Add Users</u>

1. Expand the Add button on the top menu bar the two options are displayed:
   - Add Users
   - Add Groups



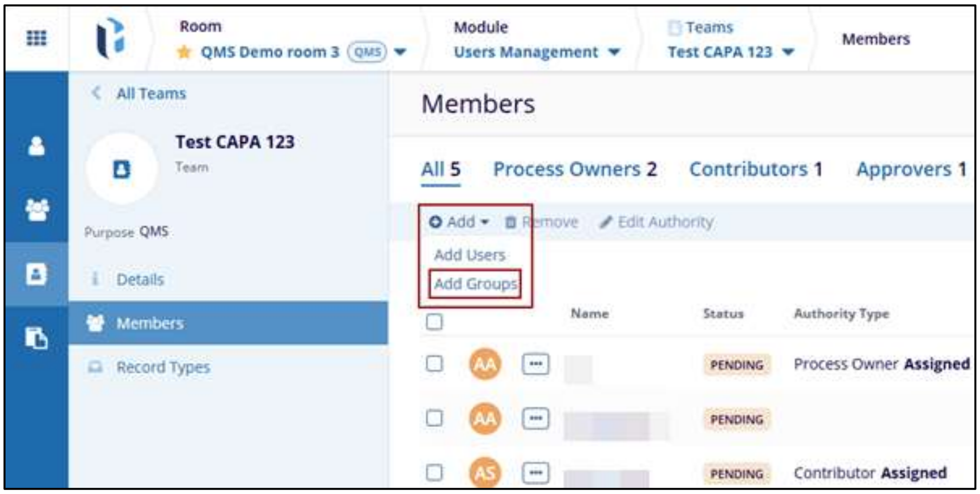

2. Click the Add Users option, and the Add Users pop-up window is displayed with the list of users.
3. Check the check box of the required users and click the Add Users button at the bottom of the Add Users pop-up window.



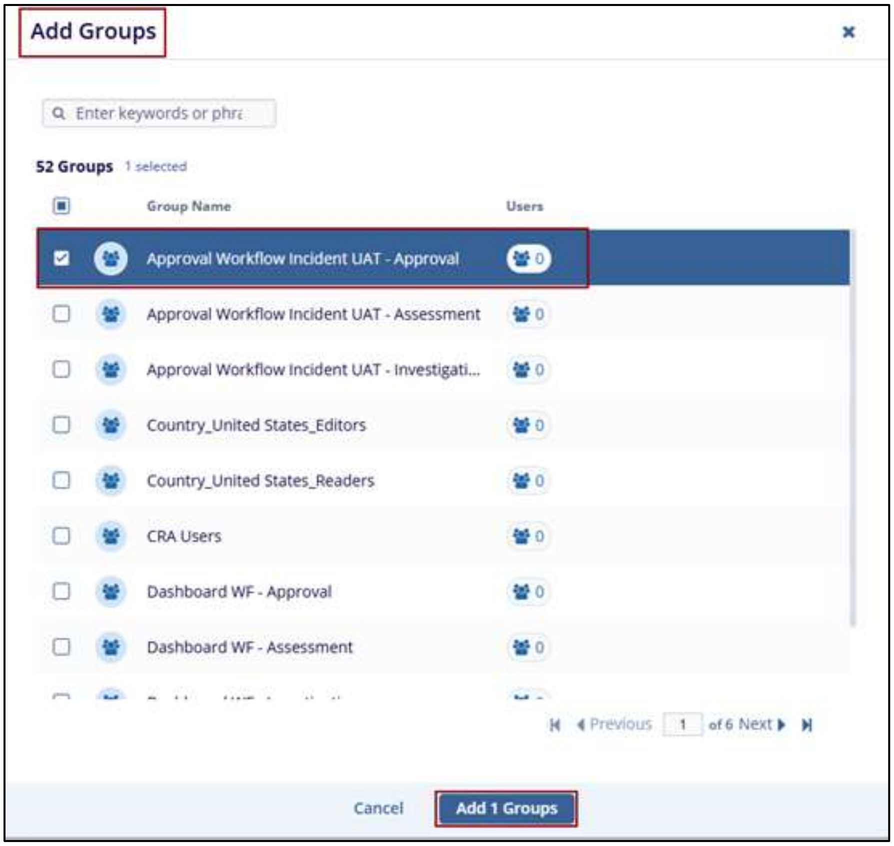

4. The added users are displayed on the main page.

## Add Groups

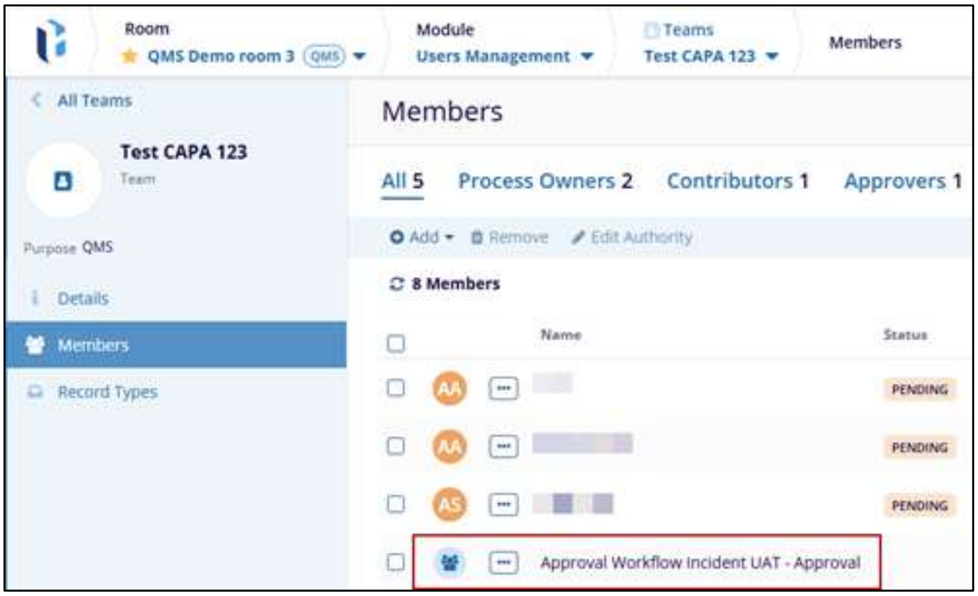
1. Expand the Add button and click the Add Groups option, the Add Groups pop-up window is displayed with the list of groups.




2. Check the check box of the required users and click the Add Groups button on the bottom of the Add Groups pop-up window.




3. The added group is displayed on the main page.



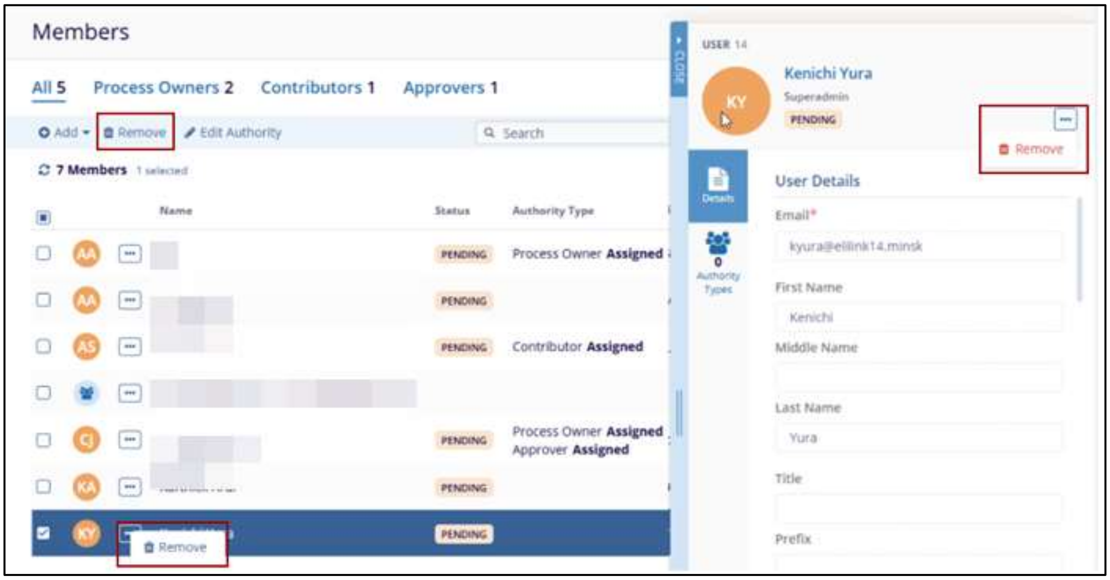

## Remove Users/Groups

Follow the steps below to remove the users/groups from the teams:

1. Select the checkboxes next to the Users/Groups that need to be removed from the Members page grid view.

Note: Ensure that the selected Users/Groups are not assigned by any of the Regulatory Authorities types.

2. Click the Remove button on the top menu bar.
   Note: The user can access the Remove option either through the three-dot menu next to the created Team in the grid or from the three-dot menu in the metadata panel.

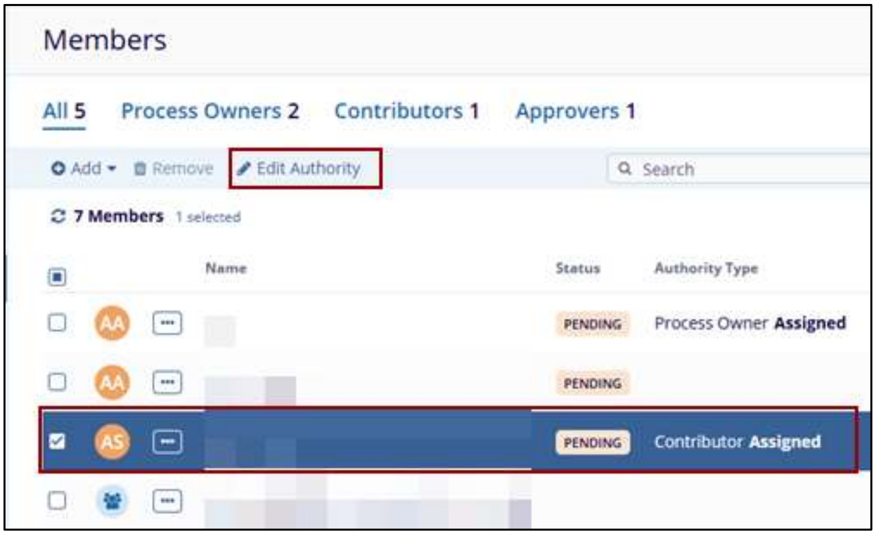



3. The Remove Member? Pop-up window is displayed with the Cancel and Remove buttons.
4. Click the Remove button to remove the users/groups and Cancel button to discard the changes.


## Edit Authority

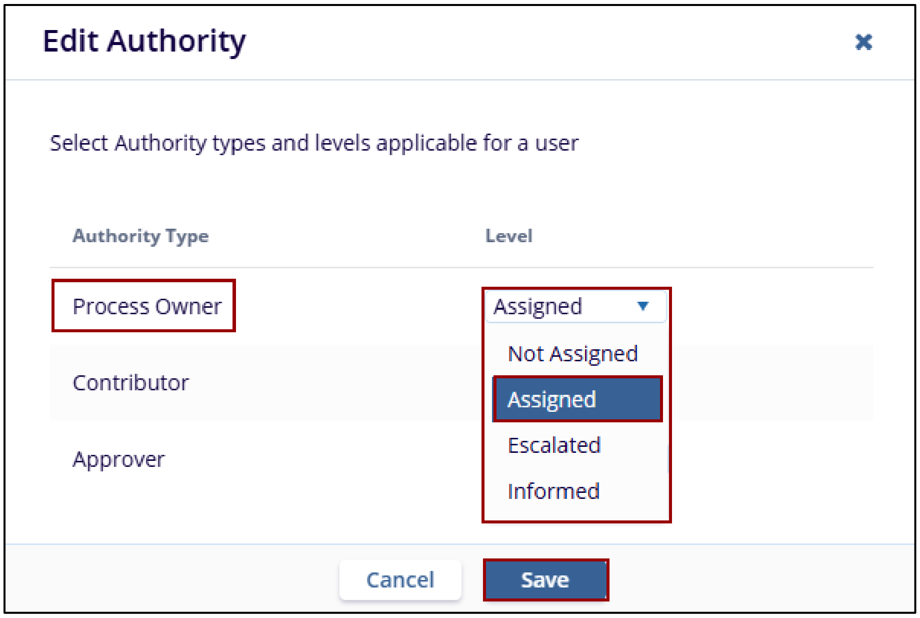
Follow the steps below to edit the authority from the teams:

1. Select the checkboxes next to the Users/Groups for which the authorities need to be edit from the Members page grid view.
2. Click the Edit Authority button either from the top menu bar or from the ‘Metadata Panel’ click Edit within the Authority Types tab.
   Note: Ensure that the selected Users/Groups should have the assigned Regulatory Authorities types.

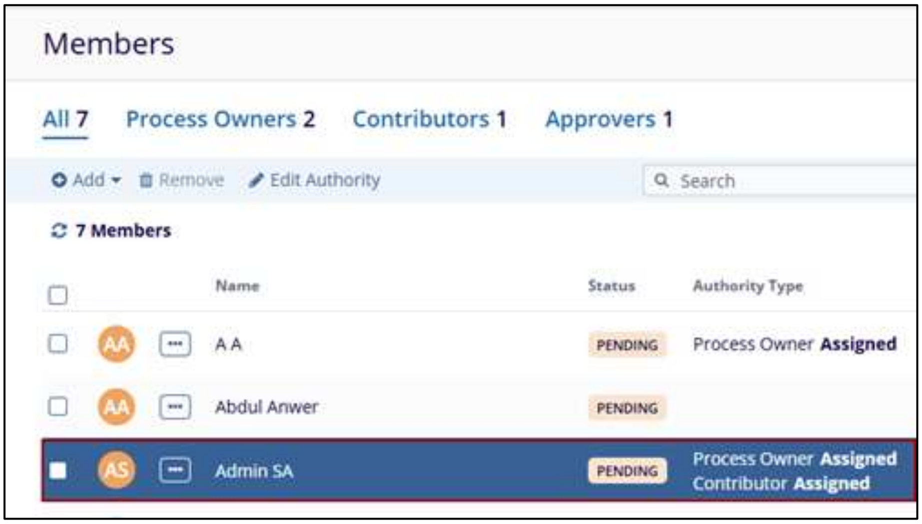



3. The Edit Authority pop-up window is displayed with the Authority Types and Level columns.


4. Click the drop-down arrow and select the appropriate Authority Level for the Authority Types that are not yet linked to the Team.
5. Click the Save button.




6. The user can see the Assigned Authority in the Authority Type column on the main Members page.




## Search

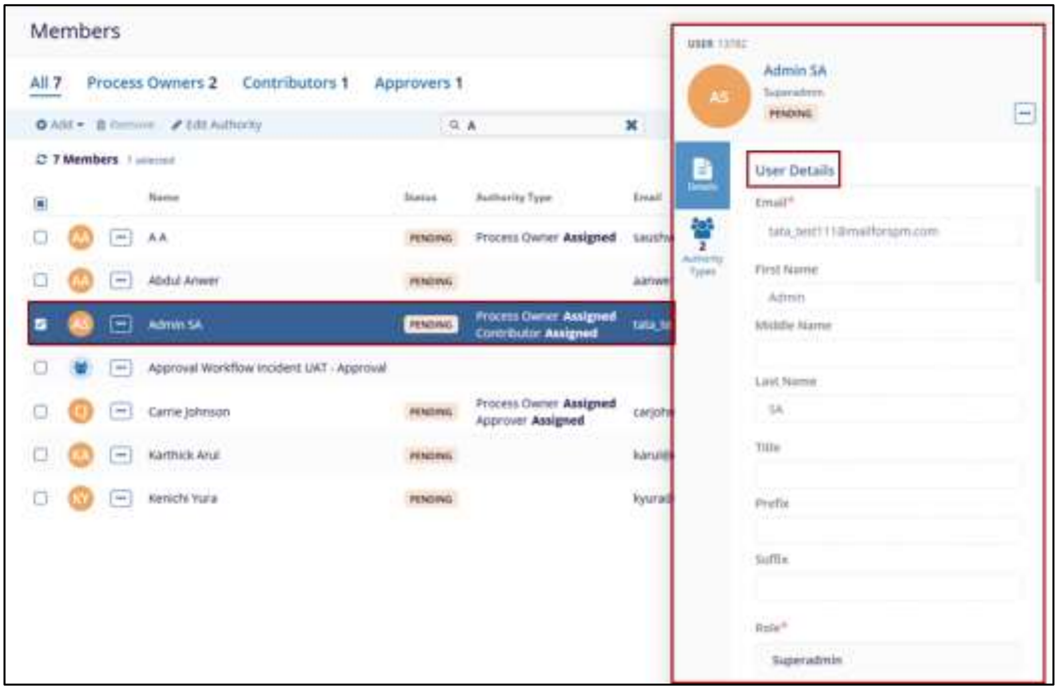
The Search functionality allows users to quickly locate specific users or groups within the Members page by entering keywords or filters. As the user types in the search bar, the grid dynamically updates to display matching results, making it easier to manage large lists of members.

1. Click the Search field and type the keyword or initial Teams name and click enter.
2. The search results should be displayed on the main Members page.


<u>Metadata Panel</u>

The Metadata Panel displays the detailed information of the selected Teams.

1. Select the Teams on the left side of the screen and the Metadata Panel is displayed on the right side of the same page.
2. The user can see the User Details such as:
    - First Name
    - Last Name
    - Country
    - Role
    - Email
    - Actions and so on...



3. The Authority Types tab in the metadata panel displays the types of Authorities associated with the selected Teams.

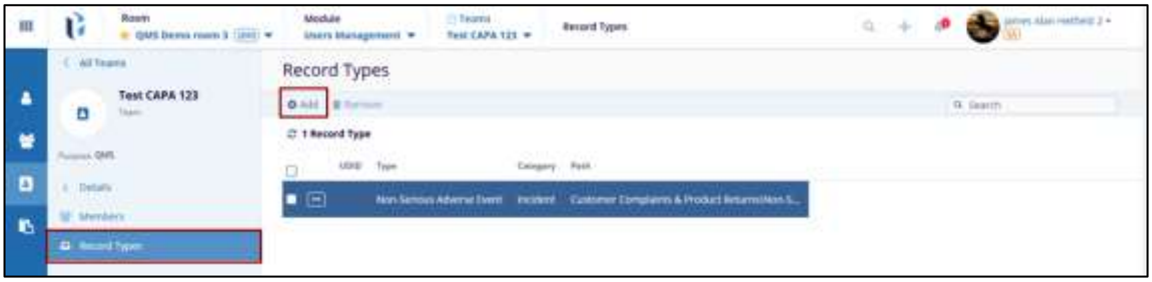
## Record Types

The Record Types page displays the records based on the Categories, such as:

- Incident
- CAPA
- Action Items

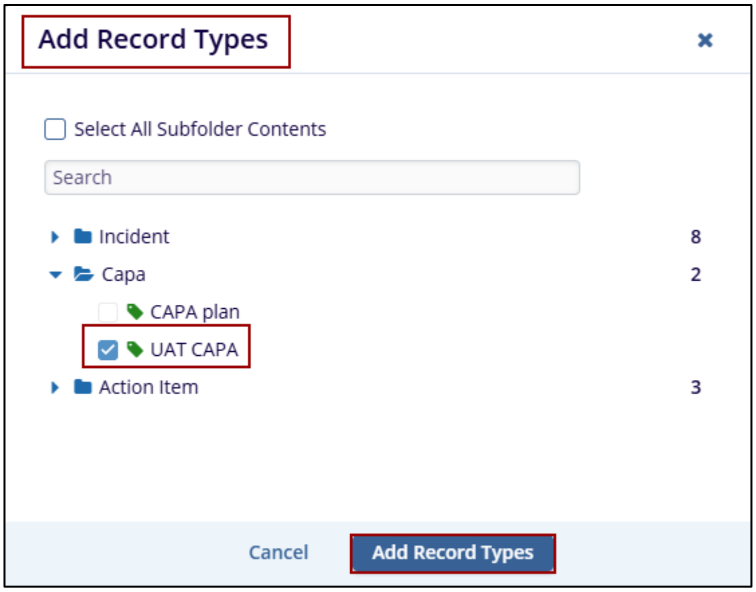
To add the Record Types, follow the steps below:

1. Click the Add button on the top menu bar within the Record Types page.



2. The Add Record Types pop-up window is displayed with the list of Categories.
3. Expand the Category and select the Subfolder Content from the list on the 'Add Record Types' pop-up window.
4. Click the Add Record Types button at the bottom of the Add Record Types pop-up window.

Note: To select all subfolder contents at once from the chosen category, the user must check the Select All Subfolder Contents checkbox in the Add Record Types pop-up window.




5. The selected record type from the chosen category is displayed on the Record Types page.


Search

The Search functionality allows users to quickly locate specific users or groups within the Members page by entering keywords or filters. As the user types in the search bar, the grid dynamically updates to display matching results, making it easier to manage large lists of members.

1. Click the Search field and type the keyword or initial Teams name and click enter.
2. The search results should be displayed on the main Members page.


Record Types
Add
Remove
UAT
1 Record Type
UDID
Type
Category
Path
UAT CAPA
Capa
UAT CAPA

# QMS WORKFLOW SETTINGS

The 'Settings' section allows Admin users to configure QMS workflows, Stage Statuses, Record Statuses, Form Settings, and Field Values.

## Workflow Management

The Workflow Management section within the QMS Settings has a comprehensive Workflow Settings Page that simplifies and enhances the configuration of Quality Management System (QMS) workflows. It offers an intuitive, wizard-driven interface that guides Admin Users through the creation and customization of workflows, enabling precise control over stages, statuses, permissions, notifications, and actions associated with each record type.

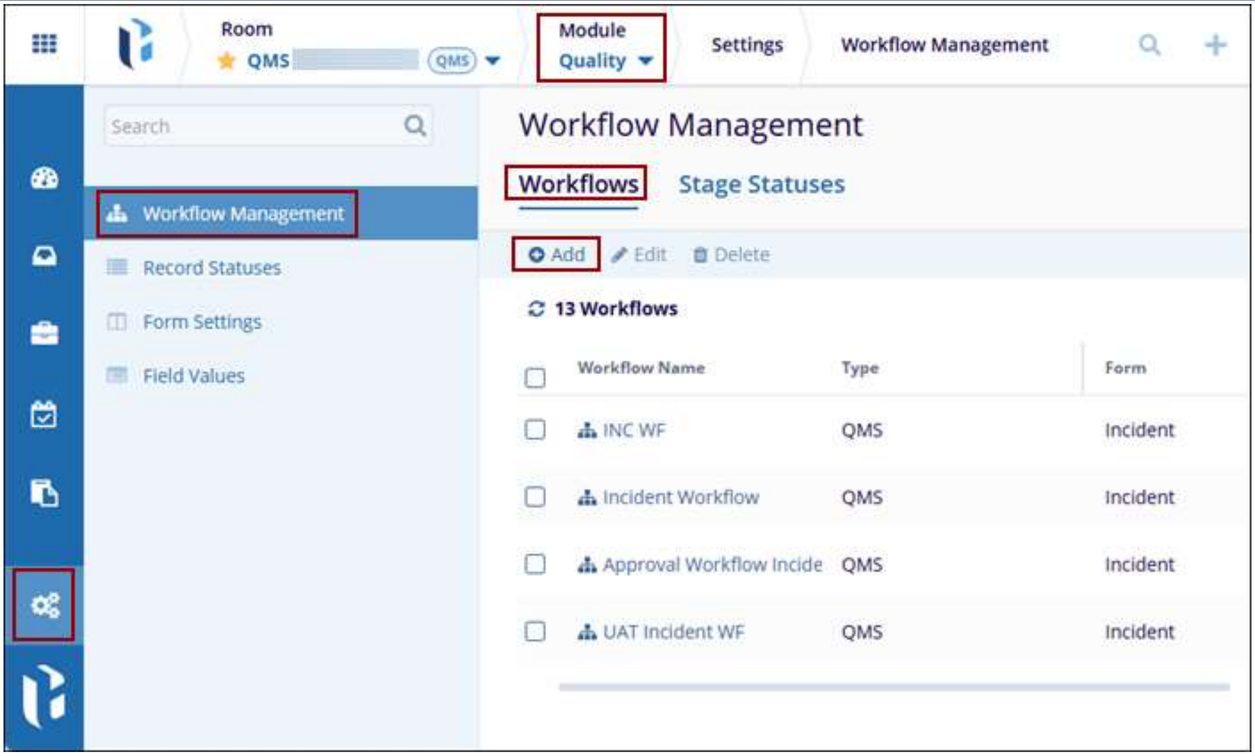
Key Benefits

- Creating QMS workflows from the 'Workflows' page.
- Defining workflows with essential details such as name, profile type, description, record type, and workflow stages.
- Managing record and stage statuses via the newly introduced Record Status and Stage Status sections.
- Configuring stage-level settings, including permissions, authority assignments, form linking, field visibility, requirements, and validation rules.
- Assigning responsible teams or users to workflow stages through preconfigured roles or manual selection.
- Linking forms to workflow stages to control access and editing based on assigned authorities.
- Setting up advanced notification options, including group alerts and escalation levels, to support efficient communication throughout the workflow lifecycle.

### Create a Workflow

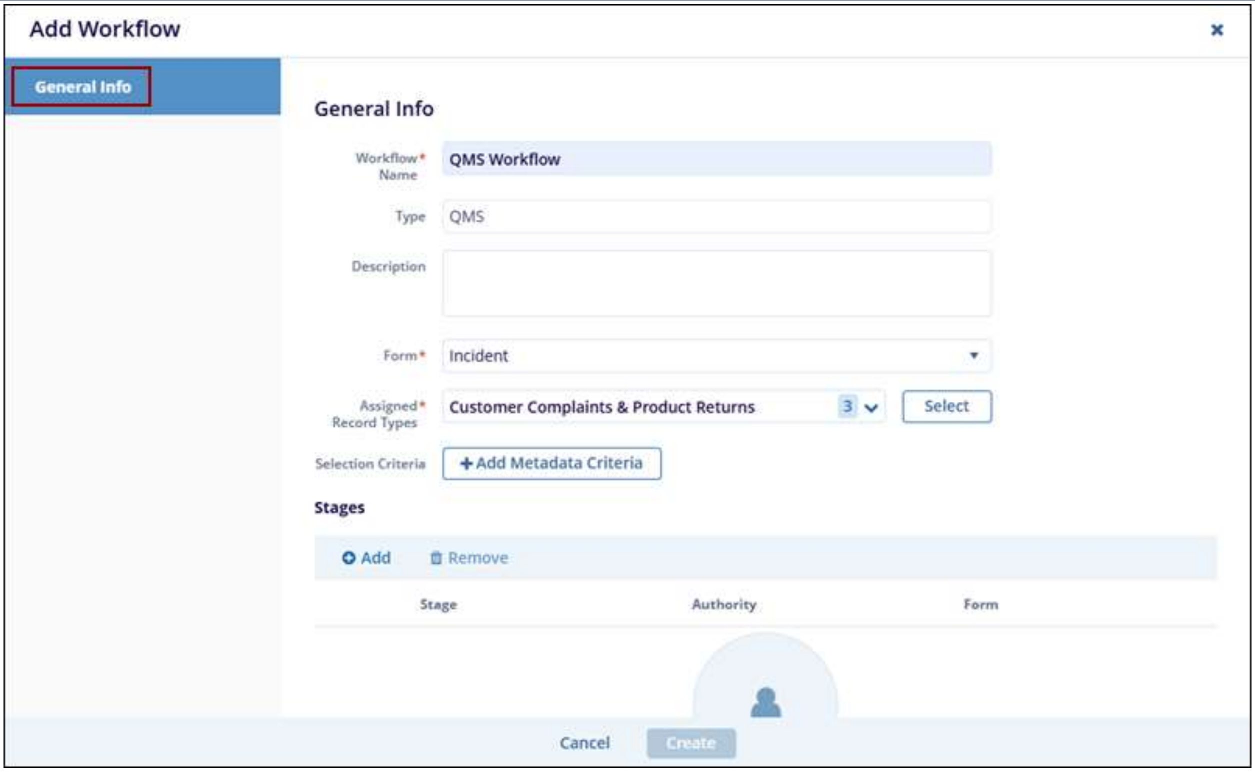
To create a workflow, follow the steps below.

1. From the Quality module, click on the Settings menu > Workflow Management > Workflows tab.
2. Click on the +Add button.

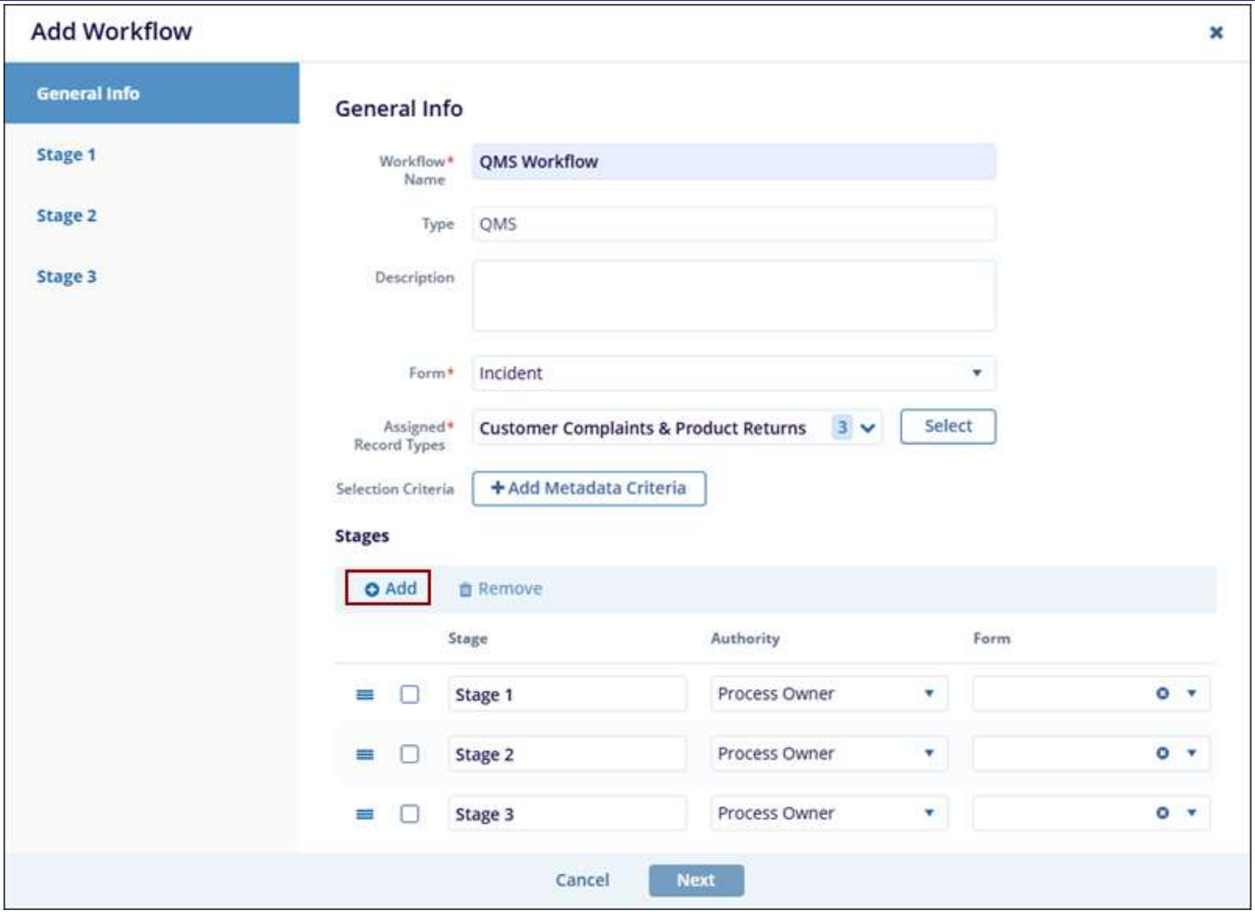



3. On the 'Add Workflow' form, fill in the following details in the 'General Info' section.

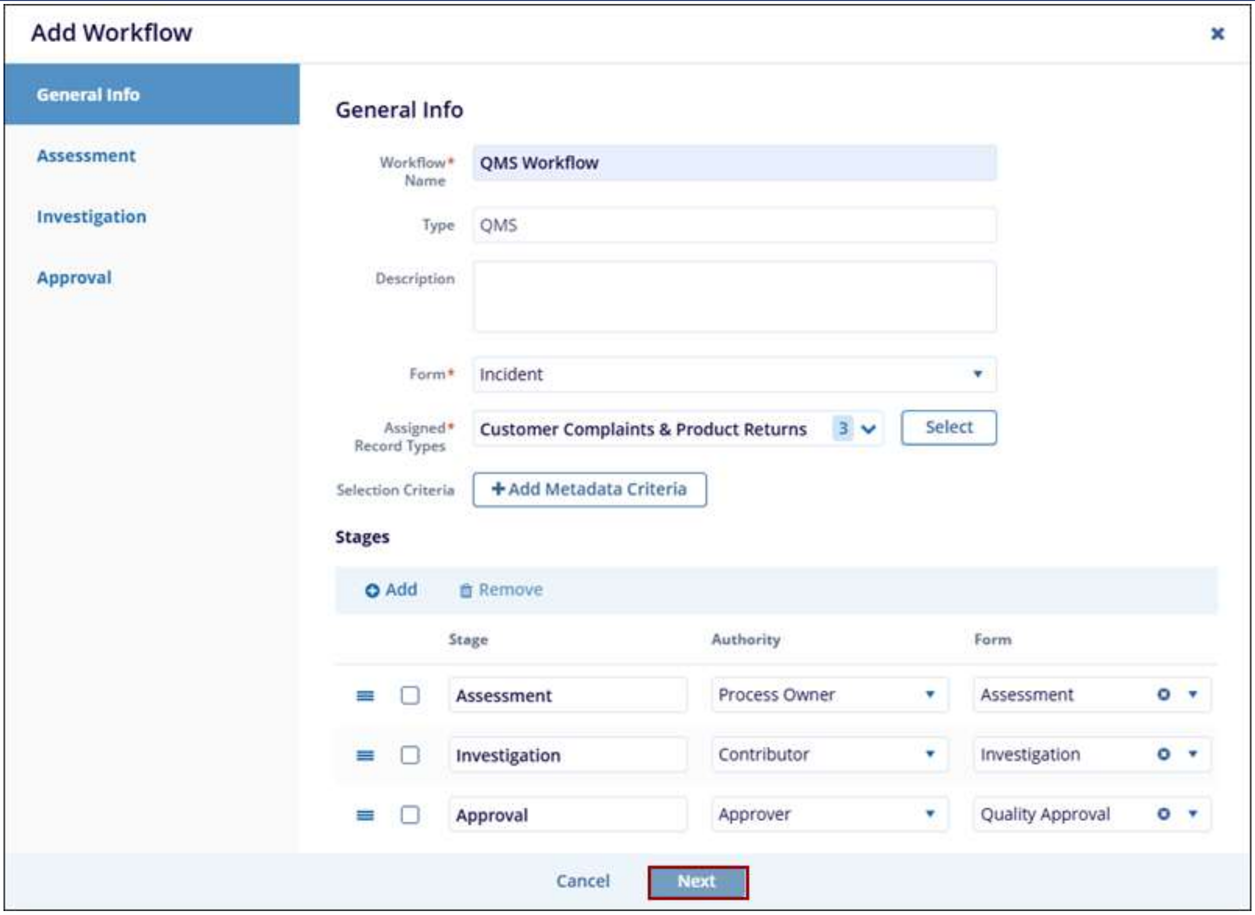
   a. Workflow Name*: Provide a name for the workflow.
   b. Type: The workflow type 'QMS' is auto-populated and non-editable.
   c. Description: Optionally add a suitable description for the workflow.
   d. Form*: Select any one of the forms, i.e., Incident, CAPA, Action Item, etc.
   e. Assigned Record Types*: Select one or multiple record types as per requirements. The 'Assigned Record Types' dropdown displays options based on the form selected.




4. In the ‘Stages’ section, click on the +Add button and add the required number of stages to the workflow.




5. Rename each stage, associate an authority with the stage, select the form type, and click on the Next button.




6. Within each stage of the workflow, access the following tabs and configure the necessary details.

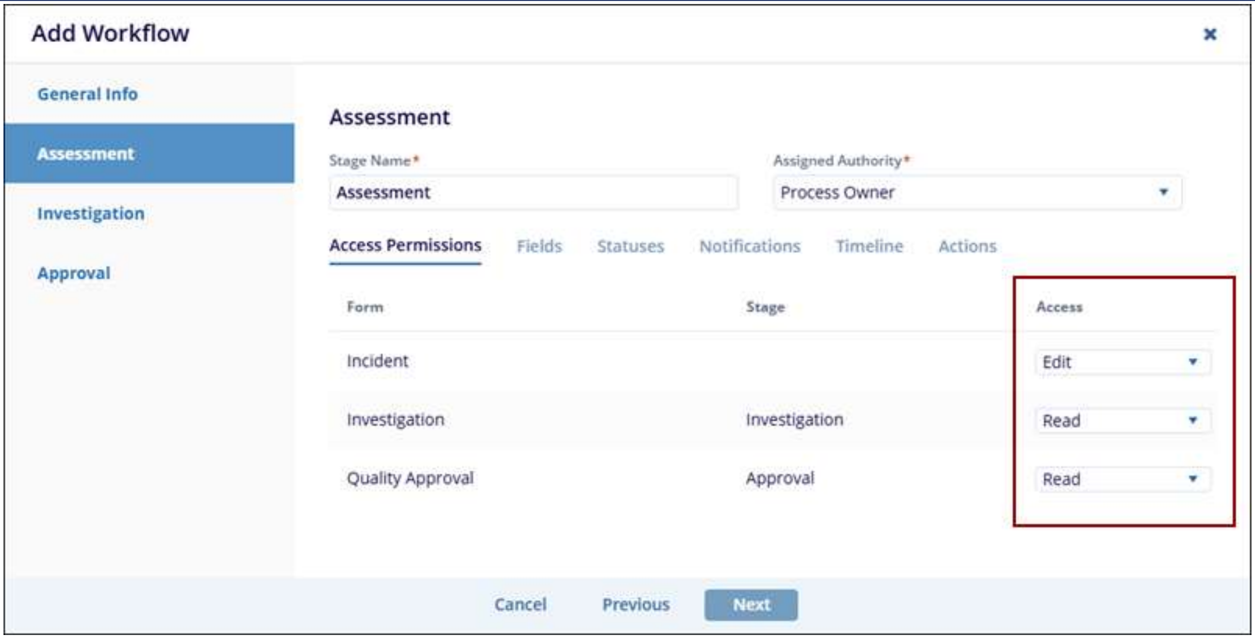
    a. Access Permissions
    b. Fields
    c. Statuses
    d. Notifications
    e. Timeline
    f. Actions

<u>Access Permissions</u>

This tab allows Admins to define read/edit access for the assigned authority to the main form (e.g., Incident) and related forms (e.g., Investigation, QA) during the stage. These permissions define whether the assigned authority at a specific stage can view or modify the record, either within the current stage or across other stages, depending on the configuration.

To configure access permissions, follow the steps below.

- Use the 'Access' dropdown in this tab to select either **'Read'** or **'Edit'**.

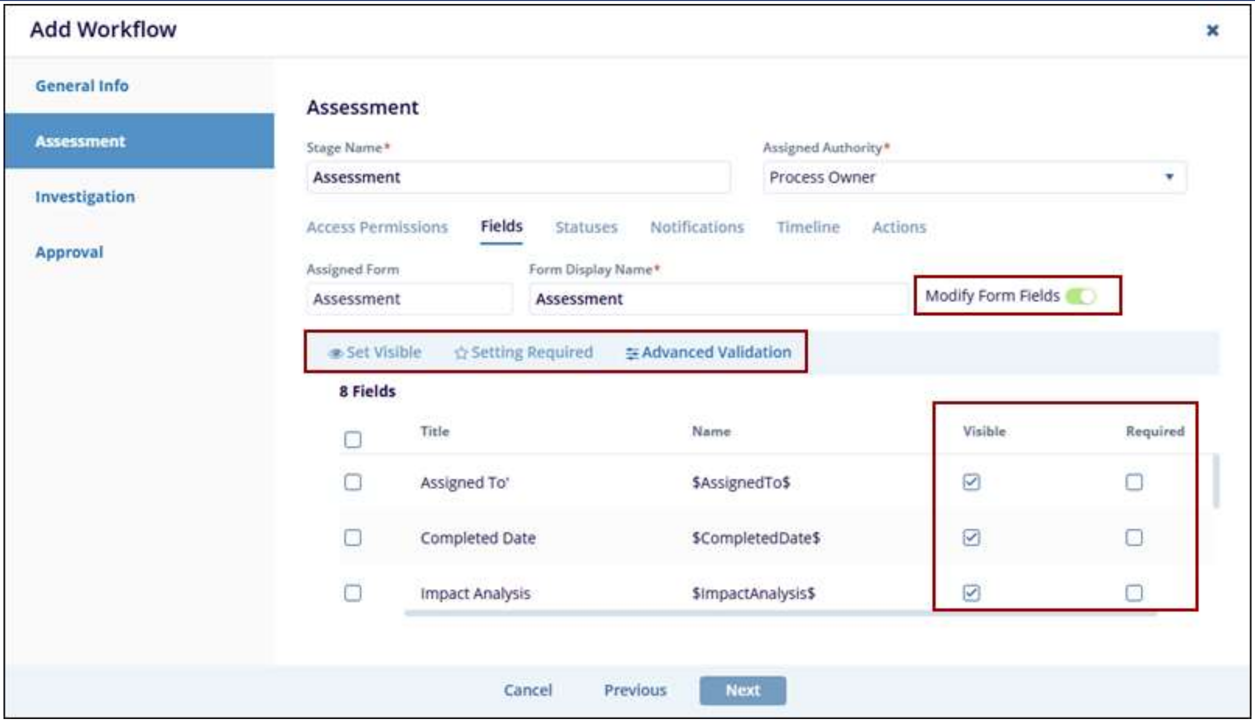



## Fields

The Fields tab allows Admins to configure the display name of the form assigned to the stage and manage field visibility, requiredness, and advanced validation.

To edit the form fields, follow the steps below

- Enable the **'Modify Form Fields'** toggle switch.
- Once enabled, check or uncheck the 'Visible' or 'Required' checkbox to configure each field to be visible, required, or both.
- Select individual fields to update their visibility, mark them as setting required, or apply advanced validation rules.




## Statuses

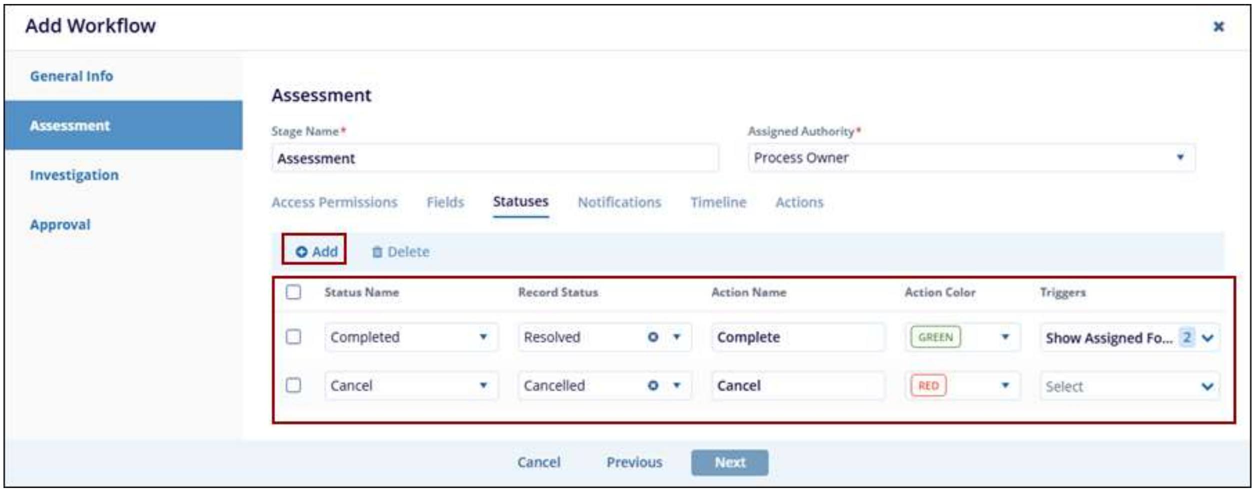
The Statuses tab allows Admins to define the statuses that can be applied during a particular stage.

To configure the statuses, follow the steps below.

- Click the **'+Add'** button to create the required number of status records.
- Choose a Status Name from the dropdown list, which displays options configured under the **'Stage Statuses'** section.
- Select the appropriate Record Status from the dropdown, populated based on configurations in the **'Record Statuses'** section.
- Enter an Action Name corresponding to the selected status. This name will appear as a clickable button in the record's quick view panel.
- Choose an Action Color from the dropdown. The action button will display in the selected color.
- Select one or more Triggers from the dropdown. When the action button is clicked, the associated trigger will prompt the user to complete a specified action before the record status is updated.

    - Show Assigned Form: Displays the form assigned to this stage so the user can complete it.
    - Show Additional Participants: Allows the user to assign additional contributors (from the team or outside) to help fulfill the responsibilities of the current stage.
    - Provide Comment: Prompts the user to add a comment or explanation when setting the status.

- Send Clarification: Opens a modal to send a query/clarification request to another authority before proceeding.
- Pending Contributors: Shows the list of pending contributors.



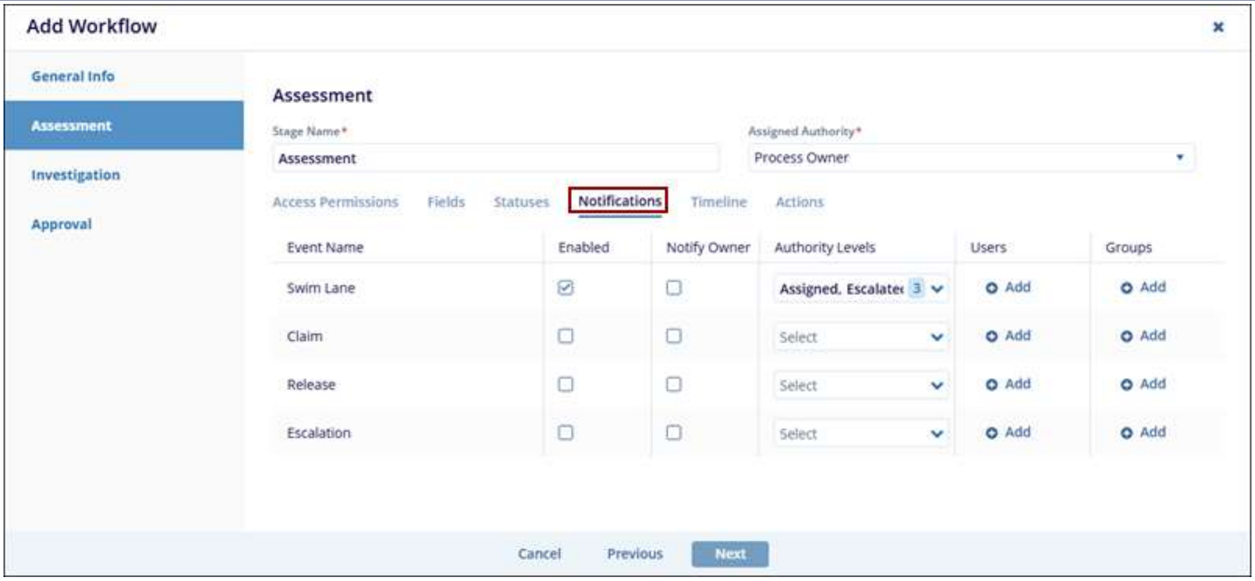

## Notifications

The Notifications tab allows workflow creators to select users, groups, and authority levels who will receive the notifications and under what circumstances at a specific workflow stage for the following notification types.

- Swim Lane: Triggered when the record enters a stage, either by progressing to it or returning from a later stage. This notifies the relevant parties that their stage is now active.
- Claim: Sent when a user claims the stage to inform others that someone has taken ownership of the tasks for that stage.
- Release: Triggered when the record is released from the particular stage.
- Escalation: Triggered when the stage remains unclaimed or incomplete beyond the defined escalation period, alerting escalation-level users to intervene.

To configure the notifications, follow the steps below.

- Click on the 'Enabled' checkbox for the following events to enable sending the notification emails to the assigned users, authority types, and groups.
- Click on the 'Notify Owner' checkbox for each event to enable sending the notification emails to the record owners.
- Select the Authority Levels, i.e., Assigned, Escalated, and Informed, from the dropdown that should receive the notification.
- Add the additional users and groups who will review the record by clicking on the +Add button under the 'Users' or 'Groups' headers for each event name.



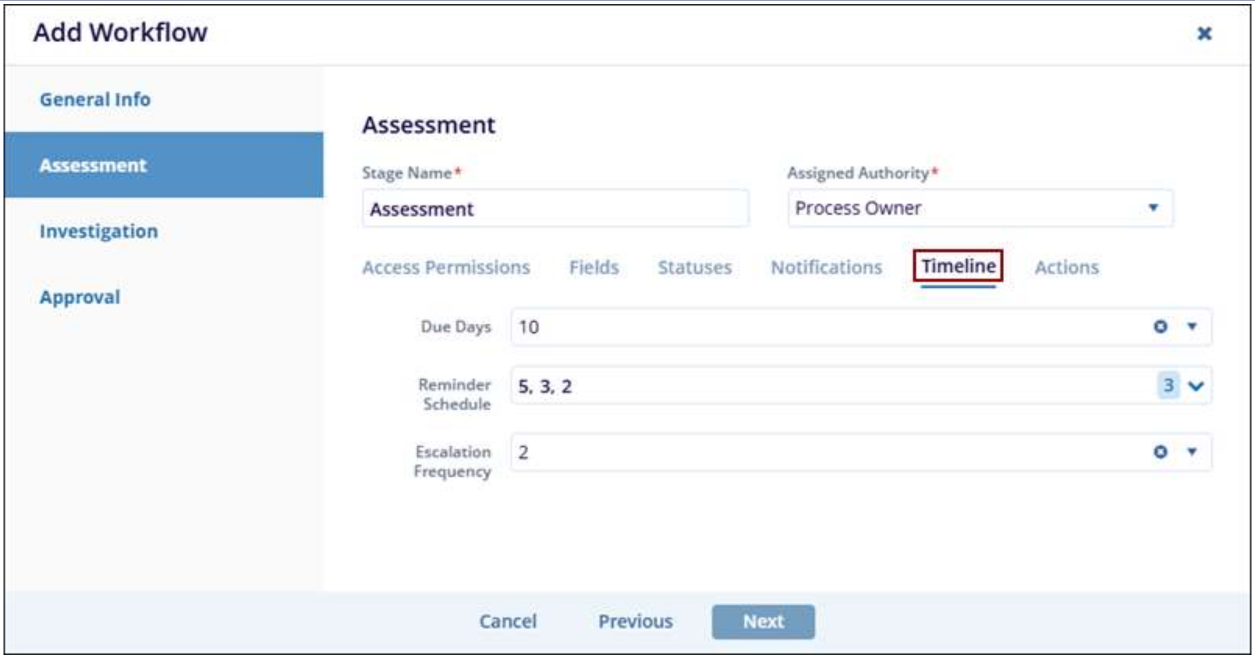

## Timeline

The 'Timeline' tab allows users to define the due days, reminder schedule, and escalation frequency to ensure timely task execution and support automated follow-ups and escalations to maintain workflow efficiency and accountability.

- Due Days: Defines how many days the assignee has to complete the stage once it is initiated.
- Reminder Schedule: Defines the number of days after which, if no action is taken, the stage will escalate to the users assigned at the escalation level.

To configure the timelines, follow the steps below.

- Click on the 'Due Days' dropdown and select the number of days from the dropdown options.
- Click on the 'Reminder Schedule' dropdown and select one or multiple options.
- Click on the 'Escalation Frequency' and select an option from the available dropdown options.



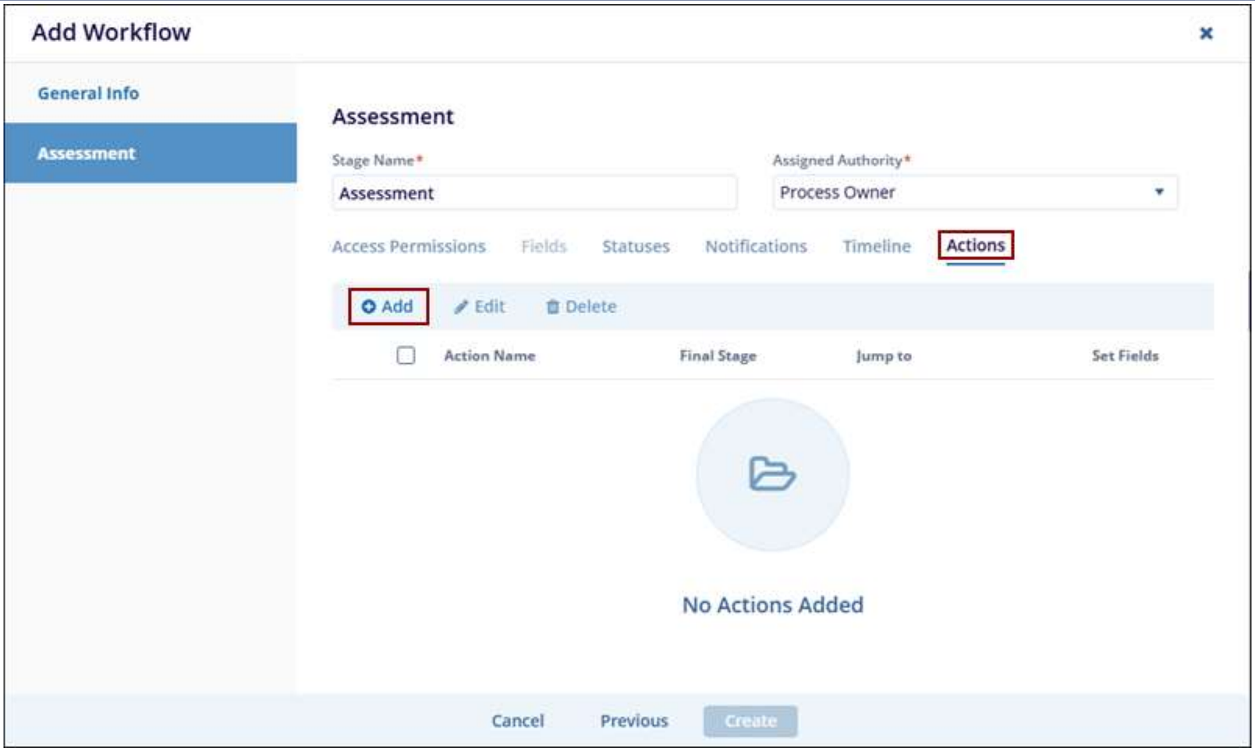

Actions:

The Actions tab enables the configuration of automated custom actions based on specific field values in the assigned form. These actions are triggered dynamically during stage processing to guide workflow logic or transitions.

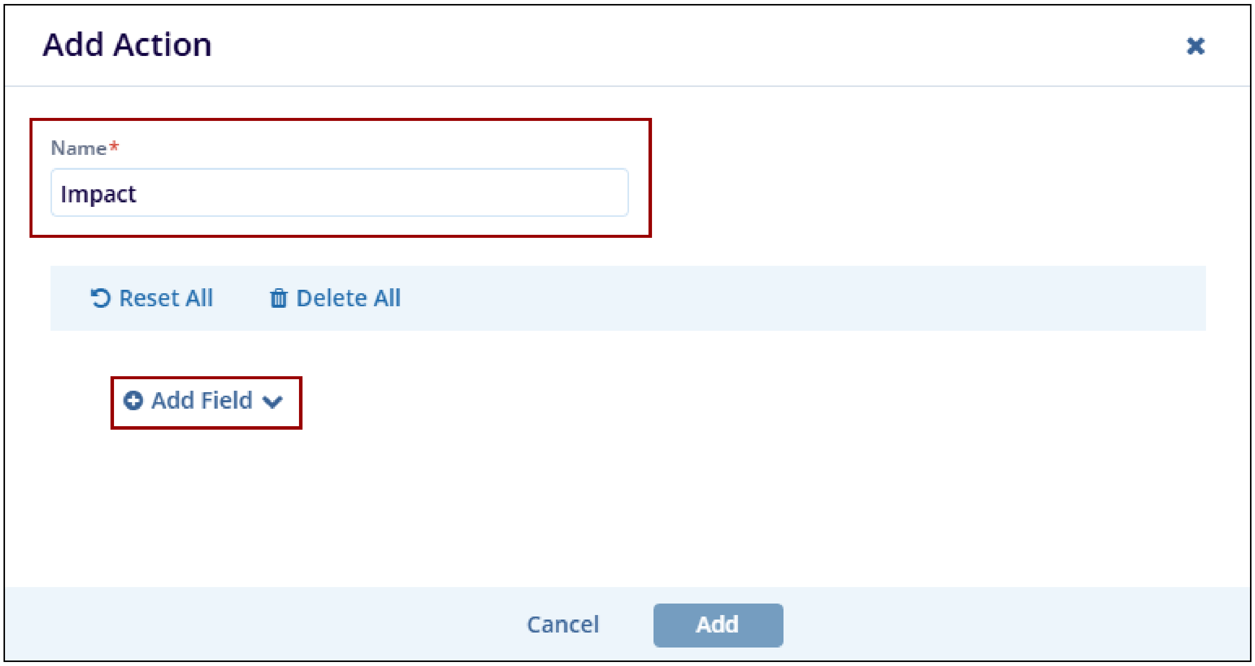
Add Actions:

To add an action, follow the steps below.

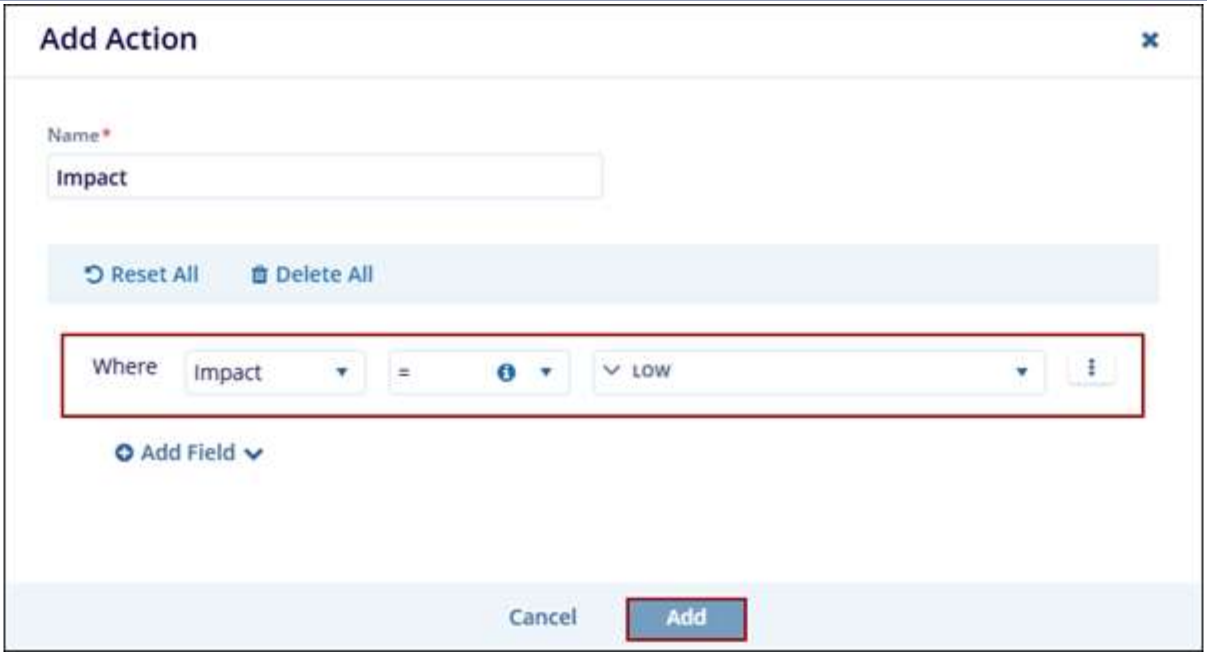
- Click on the +Add button within the Actions tab.




- On the Add Action modal window, provide a name to the action and click on the +Add Field button.



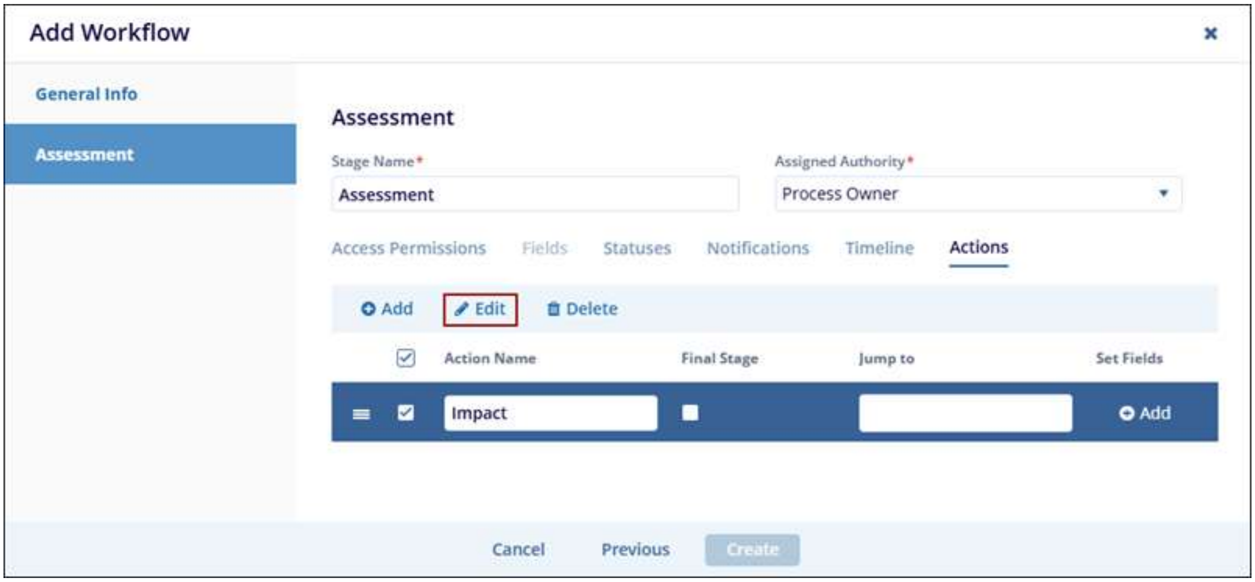

- Configure the condition by specifying the values and the logical operators, and click on the 'Add' button.



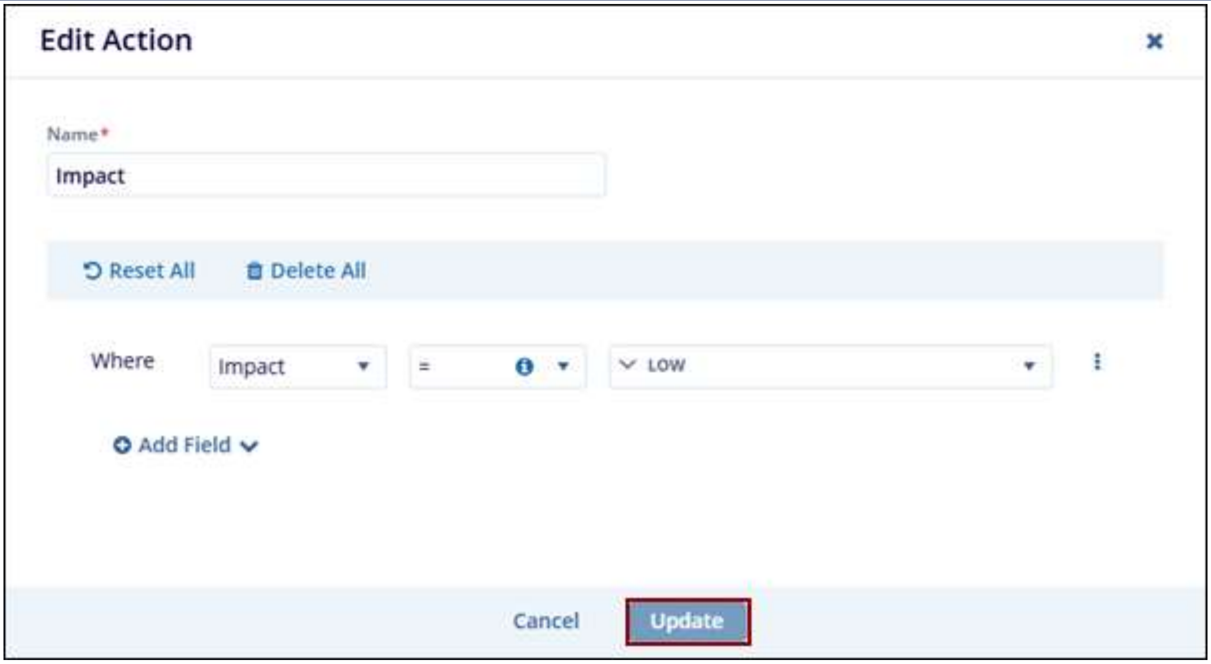

## Edit Action

To edit an action, follow the steps below.

- Select an action and click on the ‘Edit’ button.



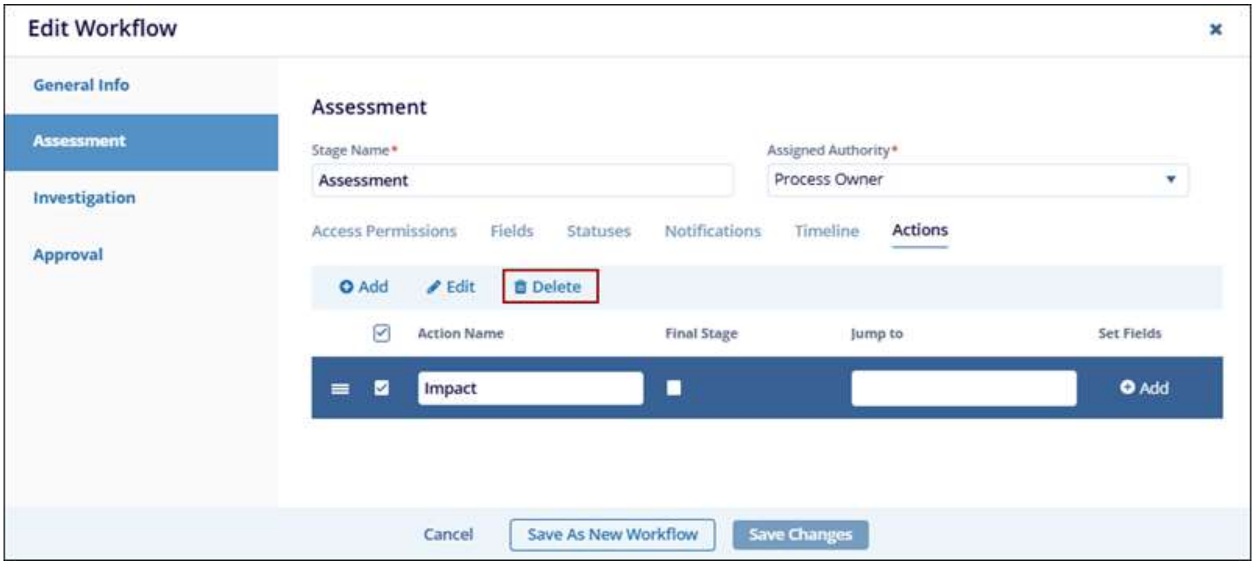

- On the ‘Edit Action’ window, make the required changes and click on the ‘Update’ button.



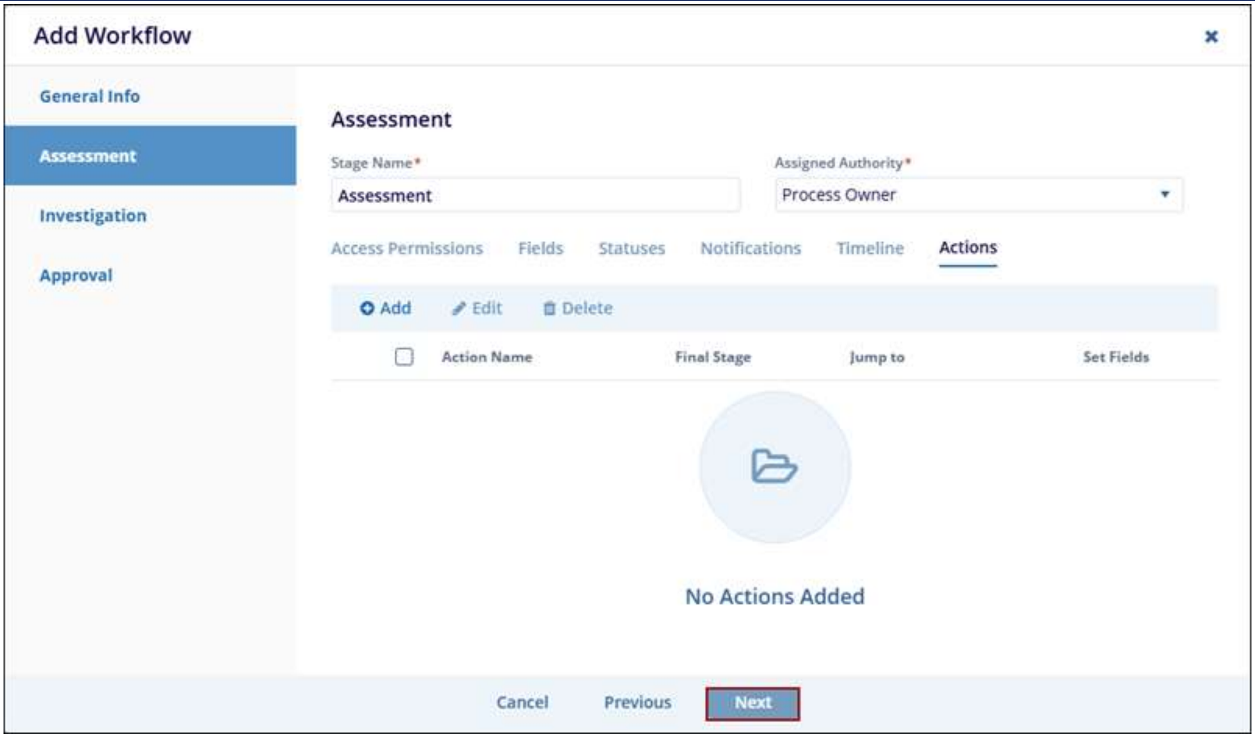

## Delete Action

To delete an action, follow the steps below.

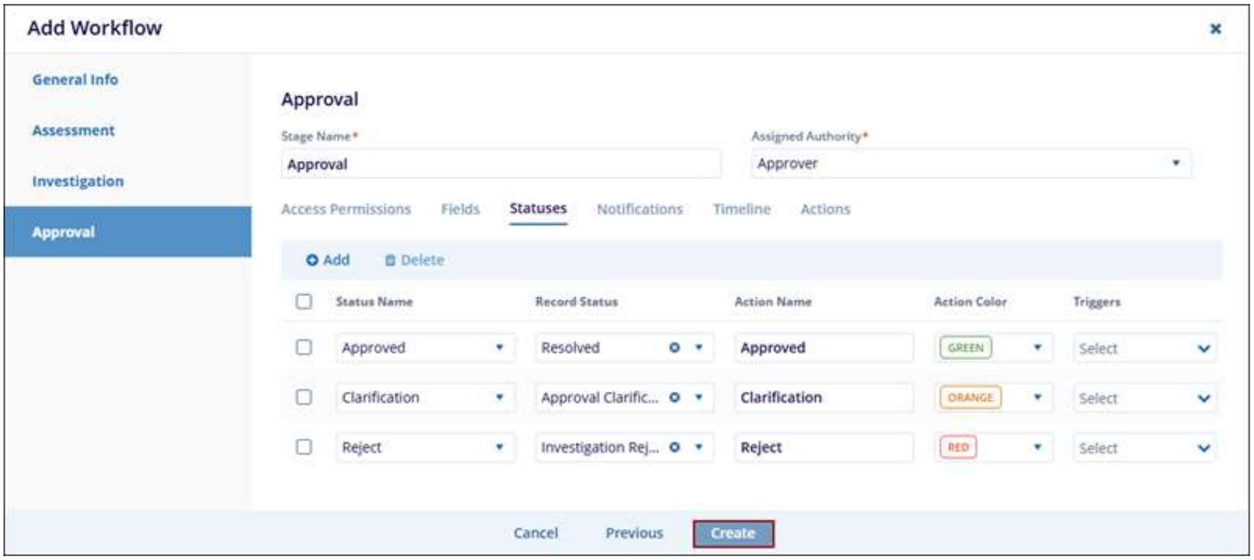
- Select an action and click on the 'Delete' button.




7. Once the required details are added and configured in the first stage, click on the 'Next' button to proceed to the next stage and perform similar configurations until the last stage.



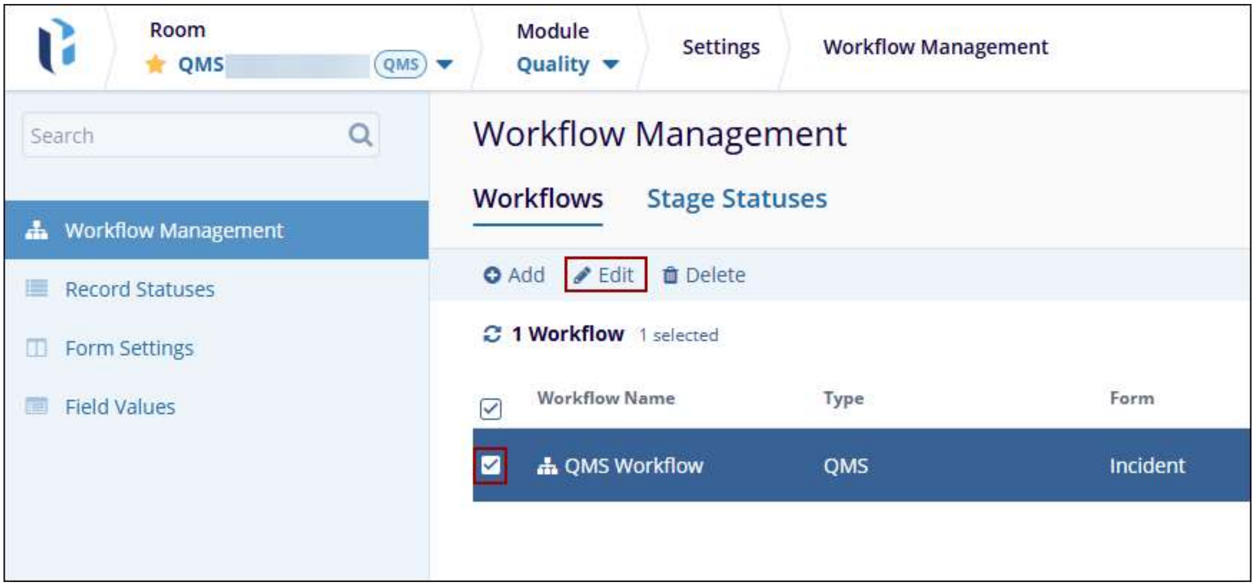

8. Click on the ‘Create’ button once the details are configured in the last stage.



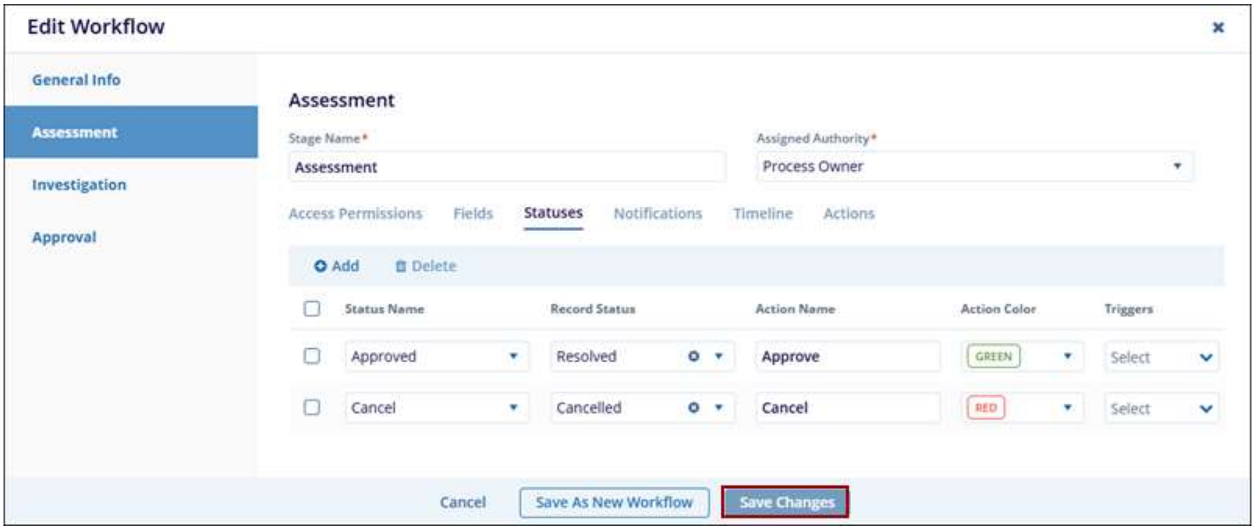
## Edit Workflow

To edit a workflow, follow the steps below.

1. On the ‘Workflows’ screen, select a workflow and click on the ‘Edit’ button from the top menu bar.




2. On the ‘Edit Workflow’ screen, make the required changes in each stage and click on the ‘Save Changes’ button.

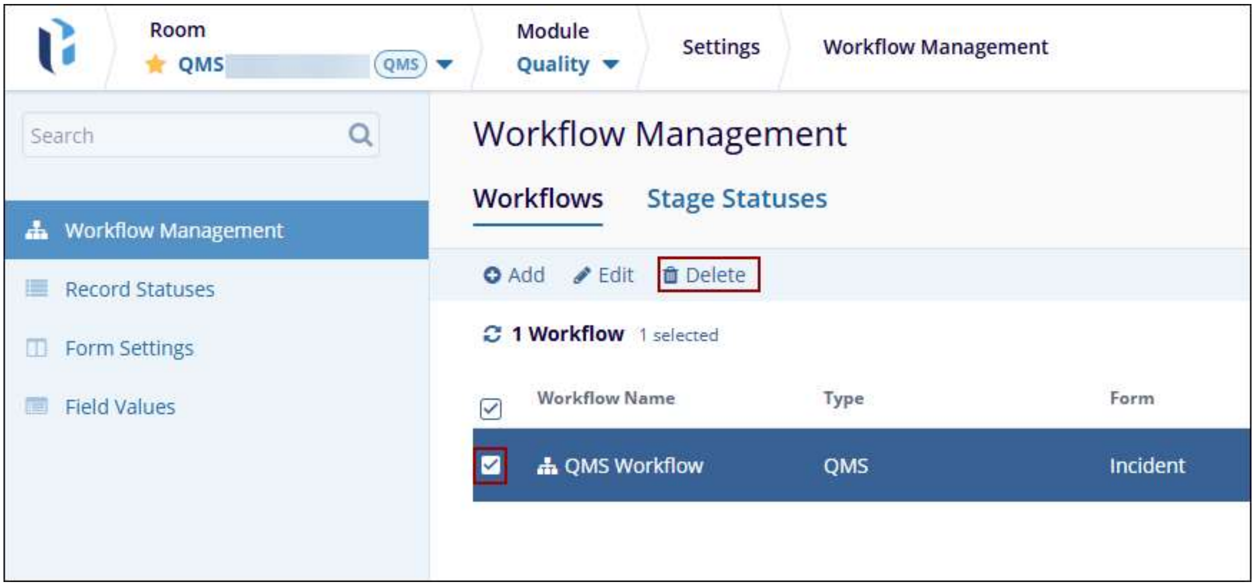



Note: Only records created after the workflow update will follow the updated workflow. Records that were already part of the workflow before the update will continue following the original workflow.

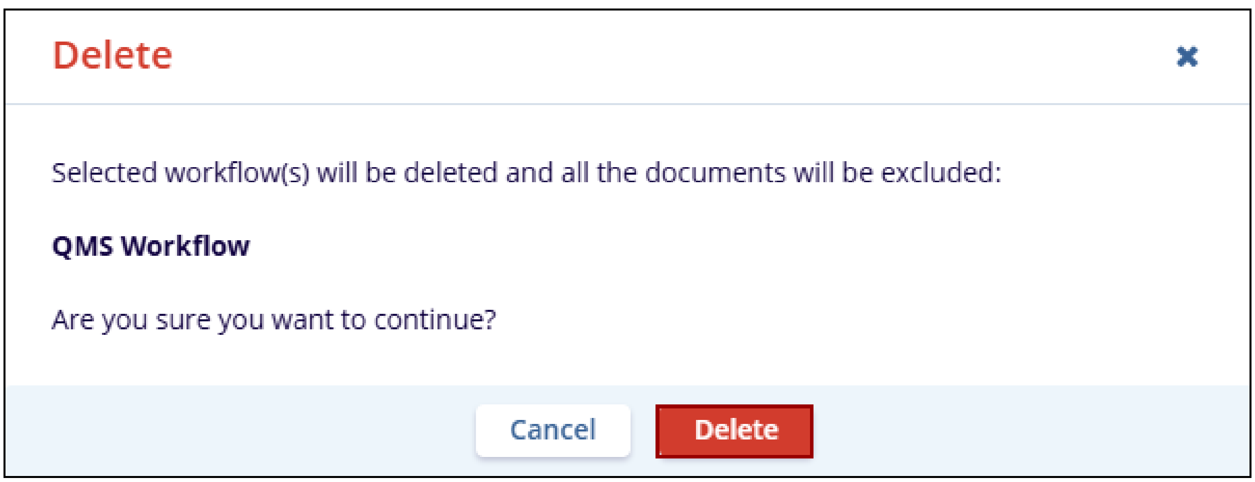
## Delete Workflow

To delete a workflow, follow the steps below.

1. On the ‘Workflows’ screen, select a workflow and click on the ‘Delete’ button from the top menu bar.




2. Click on the ‘Delete’ button on the confirmation pop-up to confirm the workflow deletion.



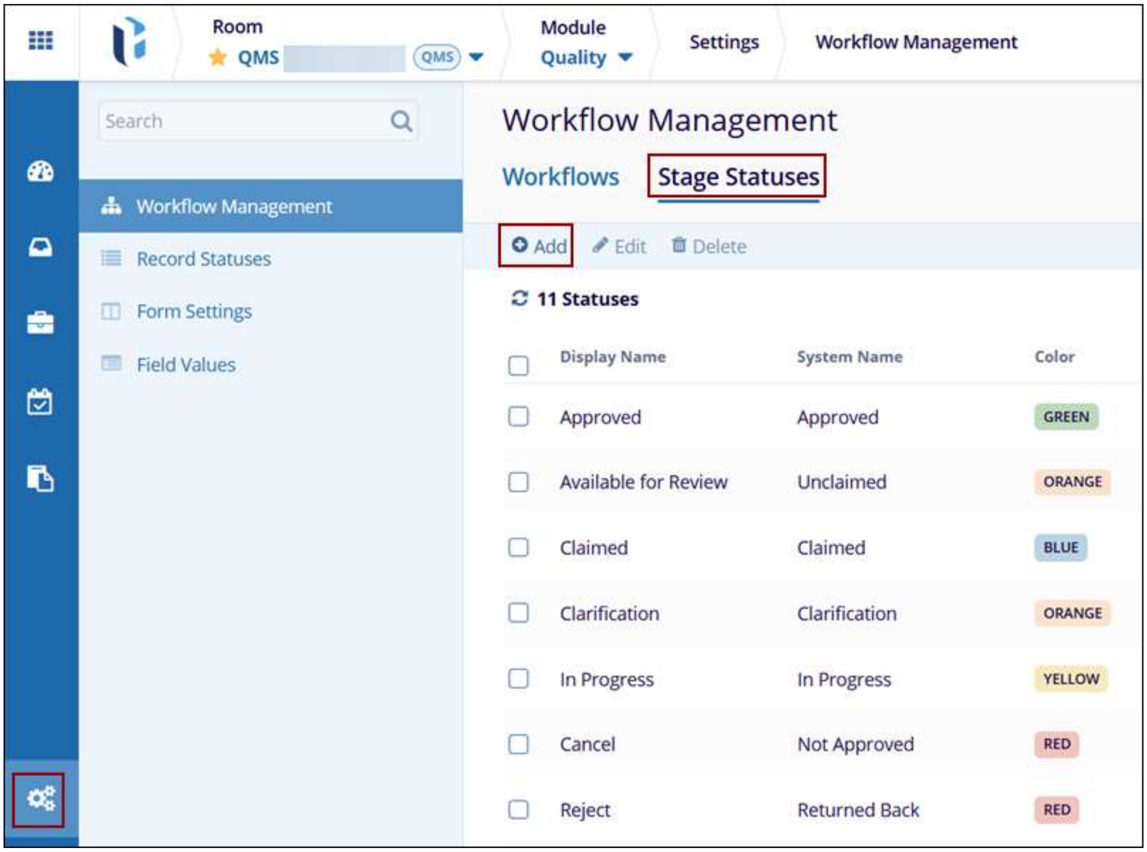
## Stage Statuses

The Stage Statuses tab allows Admin users to manage a list of stage statuses used in QMS workflows by adding, editing, or deleting them as needed. These statuses define the possible actions and transitions within each stage.

### Add Stage Status

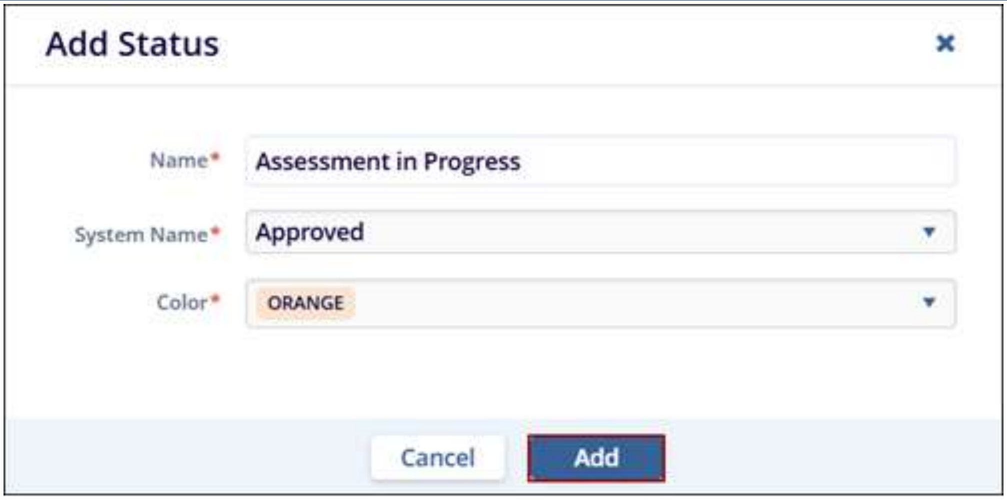
To add a stage status, follow the steps below.

1. From the Quality module, click on the Settings menu > Workflow Management > Stage Statuses tab.
2. Click on the +Add button within the Stage Statuses tab.




3. On the 'Add Status' dialog box, mandatorily add the following details and click on the 'Add' button.

    a. Name*: Add a name for the status.
    b. System Name*: Select a system name from the available dropdown options.
    c. Color*: Select a color from the available dropdown options.

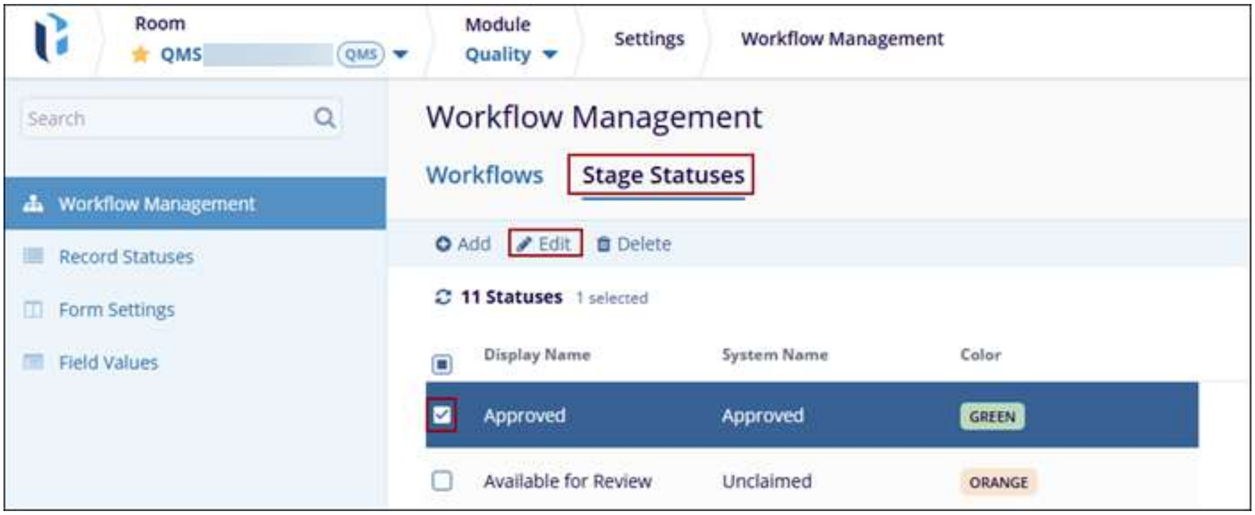



Note: The stage status will be displayed alongside a record when it reaches the corresponding workflow stage as defined in the workflow configuration.

## Edit Stage Status

To edit the stage status, follow the steps below.

1. Select a stage status within the 'Stage Statuses' tab and click on the 'Edit' button.

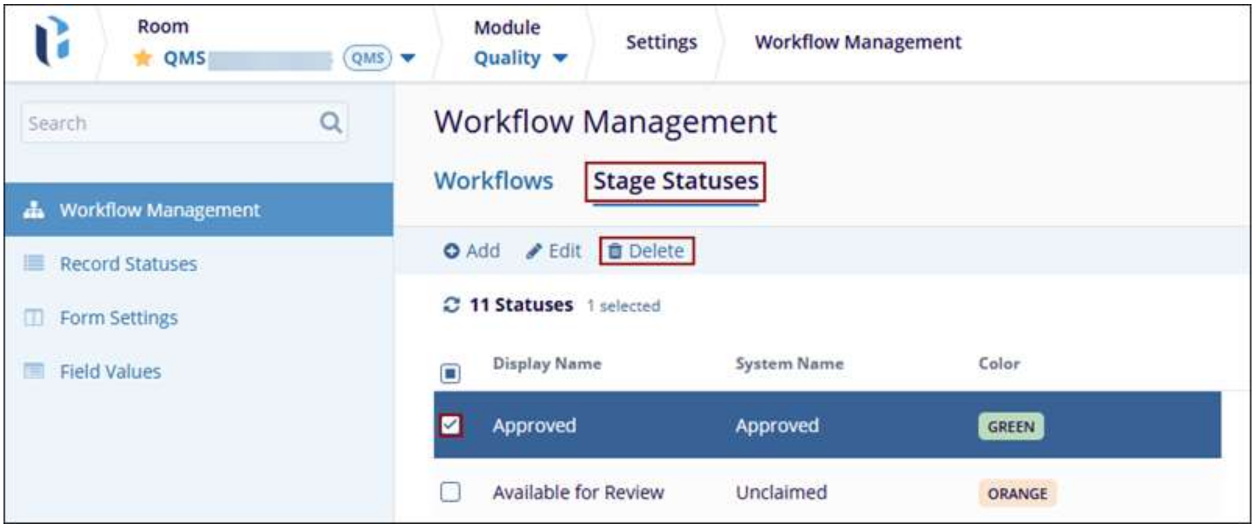



2. Make the necessary changes to the Name*, System Name*, and Color* fields and click on the Save button.

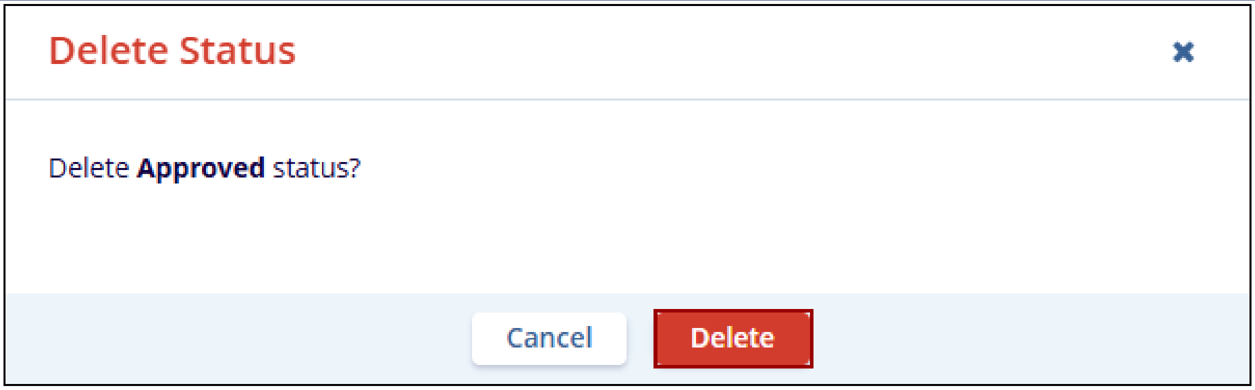

## Delete Stage Status

To delete a stage status, follow the steps below.

1. Select a stage status within the ‘Stage Statuses’ tab and click on the ‘Delete’ button.




2. Click on the ‘Delete’ button on the confirmation popup.


Delete Status
Delete Approved status?
Cancel
Delete

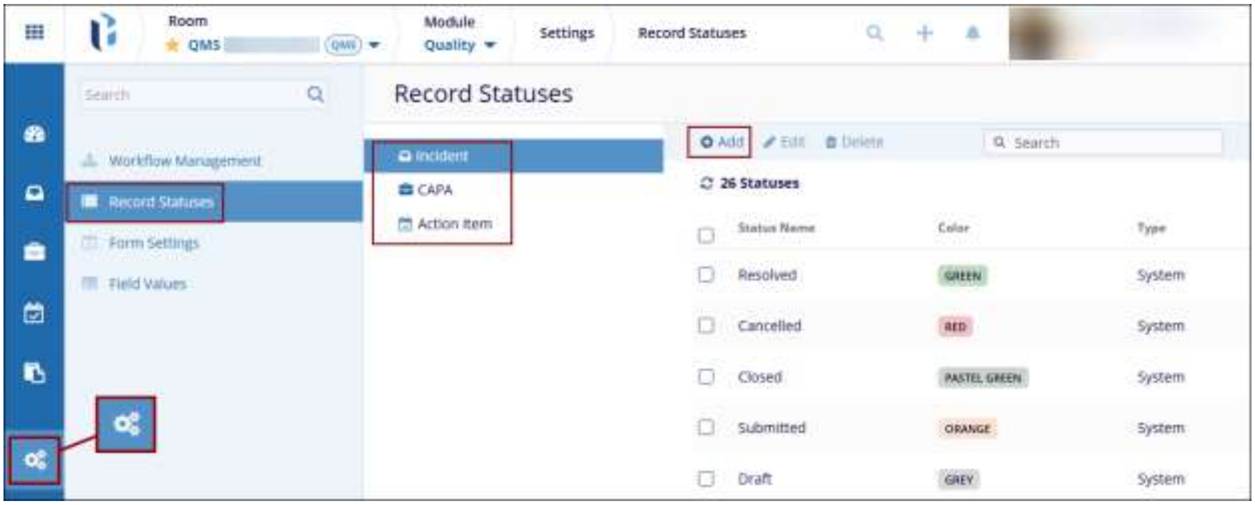
## Record Statuses

The Record Statuses tab allows Admin users to manage a list of statuses used in QMS workflows by adding, editing, or deleting the record statuses as needed. After configuring the record statuses in this section, the Record Status dropdown in the Workflow Creation wizard will display the available options.

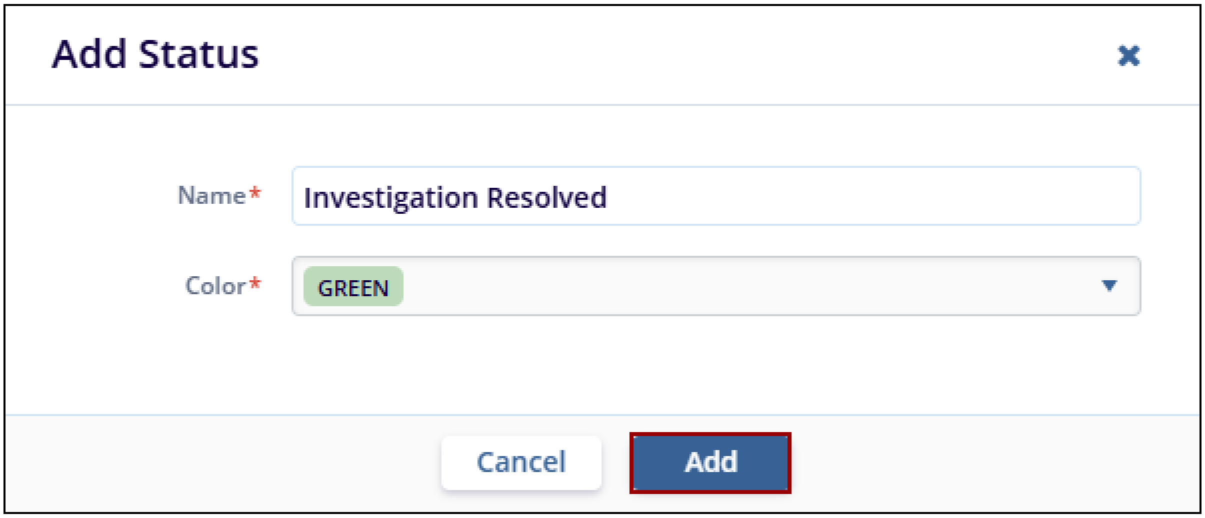
### Add Record Statuses

To add record statuses, follow the steps below.

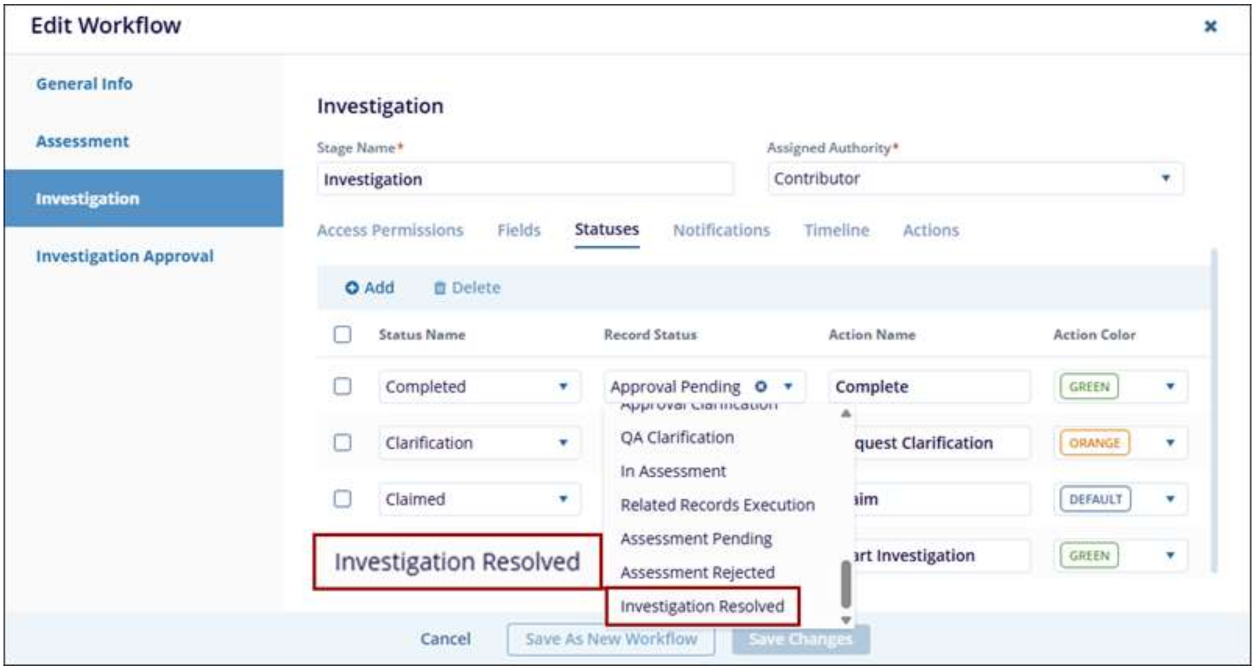
1. From the Quality module, click on the Settings menu > Record Statuses.
2. Select either Incident, CAPA, or Action Item to add record statuses to the respective forms.
3. On the selected form, click on the '+Add' button.




4. On the Add Status dialog box, fill in the following fields and click on the 'Add' button.



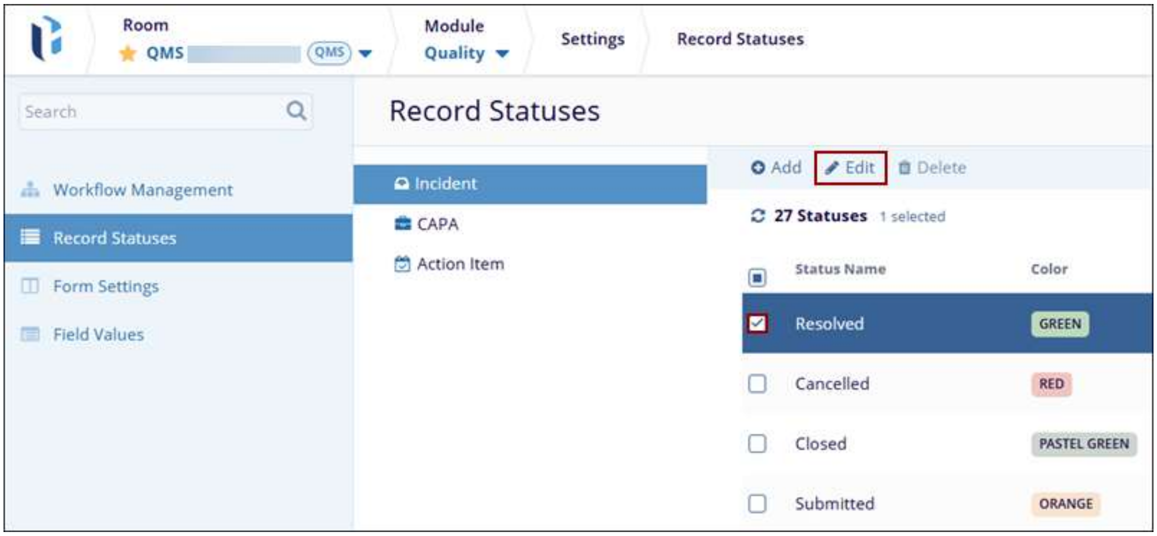
5. After adding the required record statuses, users can assign a status within the workflow stage using the 'Record Status' dropdown.




## Edit Record Status

To edit a record status, follow the steps below.

1. Select a status from the Record Statuses screen and click on the 'Edit' button.

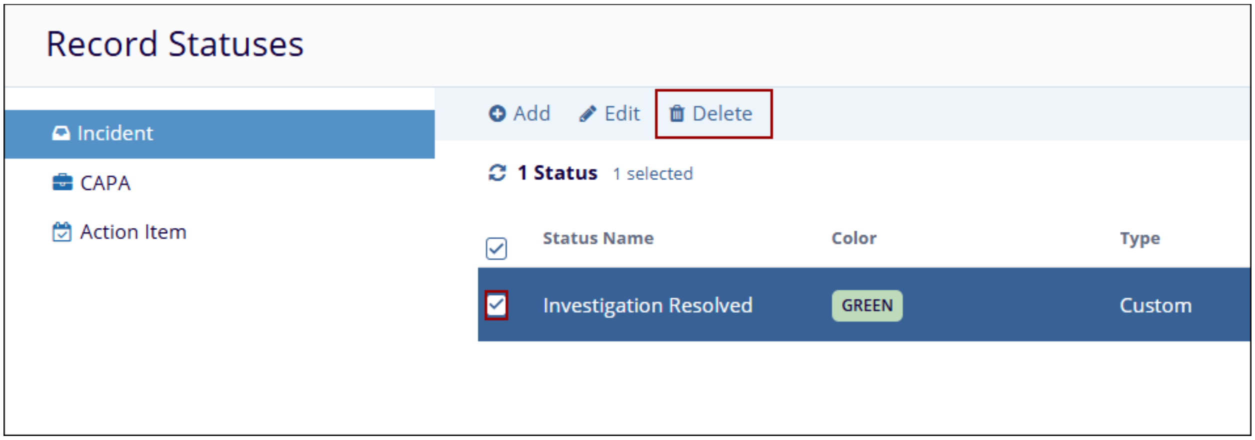



2. On the Edit Status dialog box, make the required changes to the Name* and Color* fields and click on the 'Save' button.

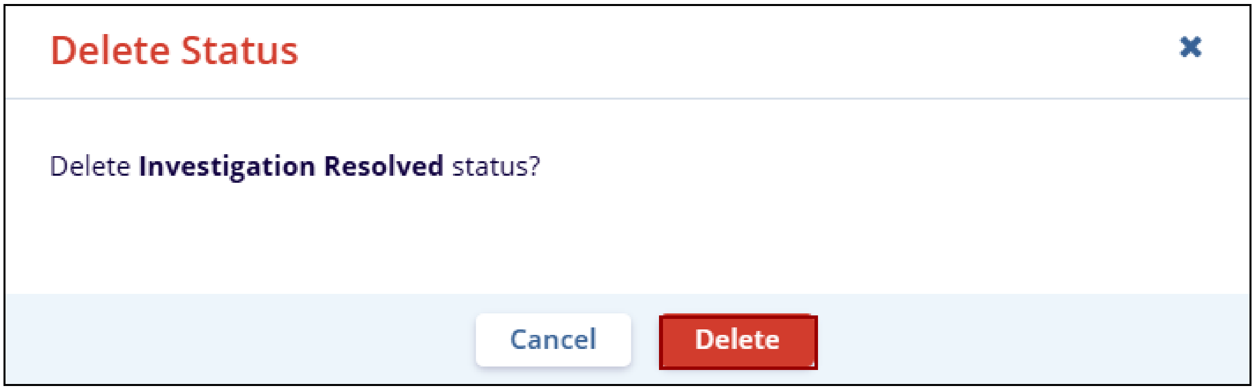

## Delete Record Status

To delete record statuses, follow the steps below.

1. Select a custom record status from the Record Statuses screen and click on the 'Delete' button.




2. Click on the 'Delete' button on the confirmation popup.



Note: Users are not allowed to edit 'System Statuses'. When a system record status is selected, the Delete button is disabled.

## Form Settings

The Form Settings page displays all forms relevant to the Quality module. Users can view and configure these forms, define their relationships as Main Topics or Sub Topics, and manage field-level settings to align forms with organizational requirements.

Each record type is linked to a specific set of forms, each corresponding to various stages within the associated workflow. Forms are composed of configurable fields tied to that record type. These fields can be arranged on the form, reordered, and displayed across multiple columns, with support for larger rich text fields that can span multiple columns.

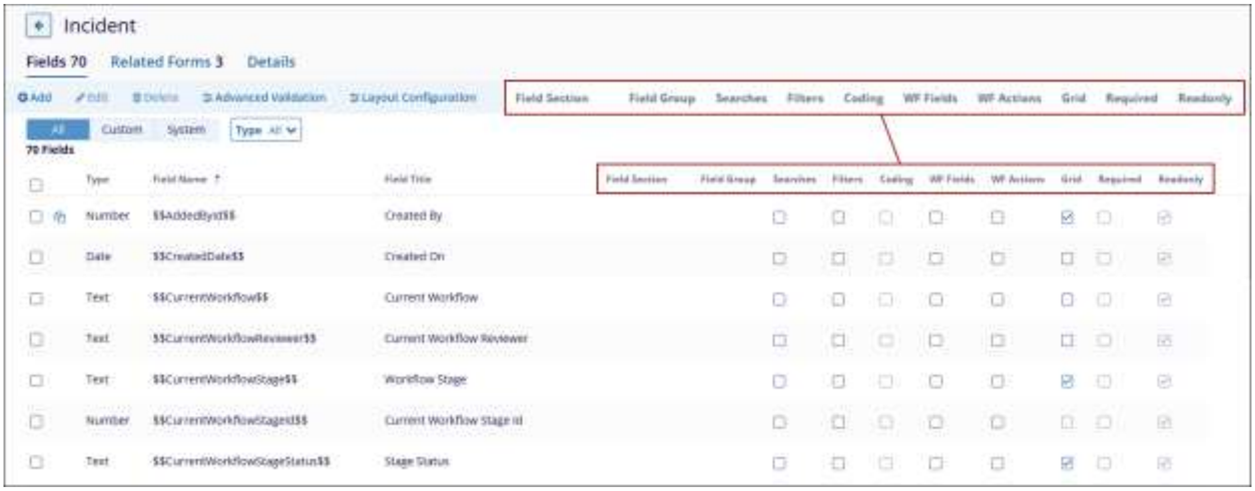
Additionally, for each form, fields can be set as visible or hidden, and marked as required or optional.

To access the Form Settings page, follow the steps below.

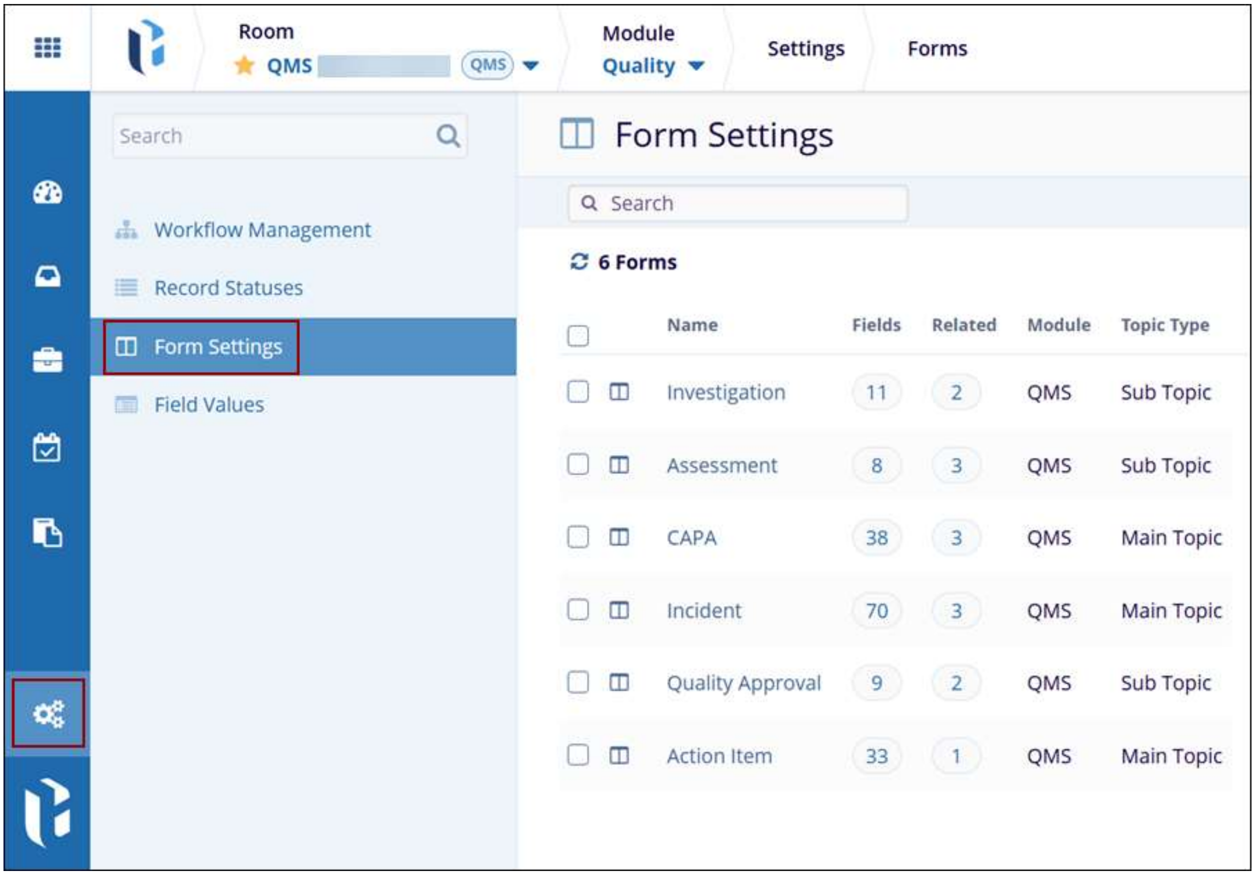
1. From the Quality module, click on the Settings menu > Form Settings.
2. The Form Settings page displays the forms associated with the Quality module, with the following columns

    a. Name: The name of the form is visible to users.
    b. Fields: Displays the number of fields in the form.
    c. Related: Indicates the number of related static forms.
    d. Module: Displays the module where the form is used
    e. Topic Type: Indicates whether the form is a
    f. Main Topic or Sub Topic.

3. Check or uncheck the following checkboxes for each field to enable or disable the corresponding action, respectively.



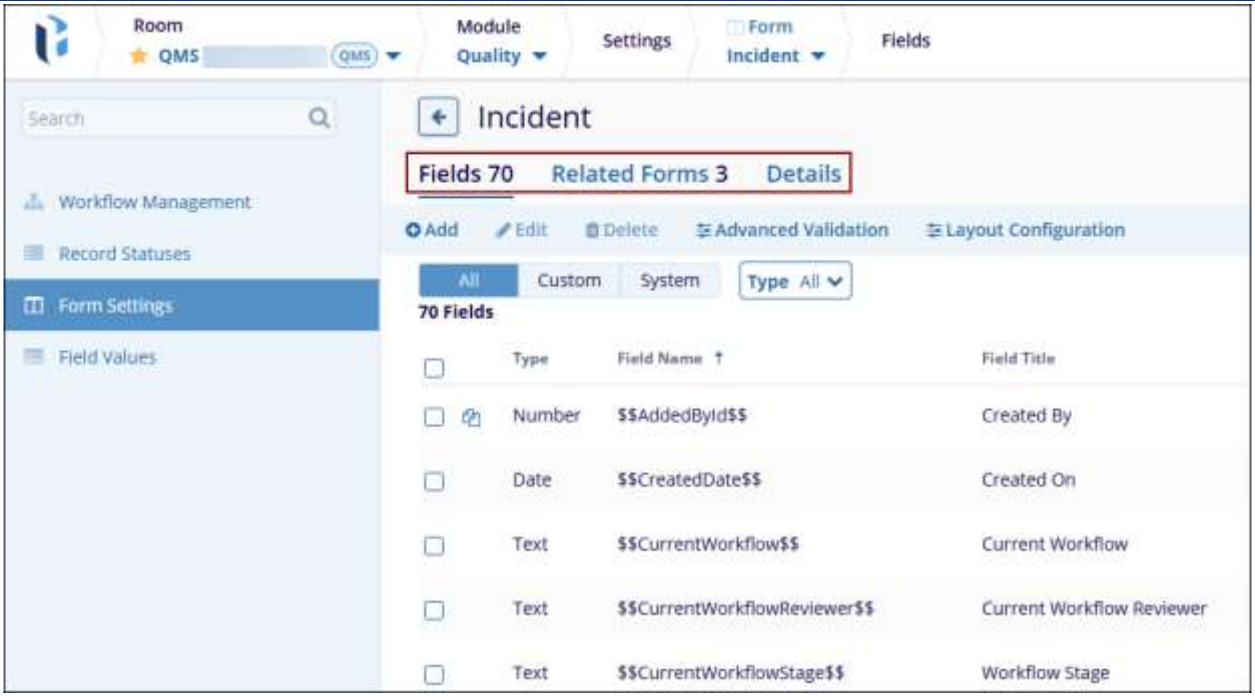
4. Click on the hyperlinked form name to configure the form settings.




5. The Forms screen displays the following tabs

   a. Fields: Displays fields configured within the form
   b. Related Forms: Displays the associated forms
   c. Details: Displays additional information about the form.

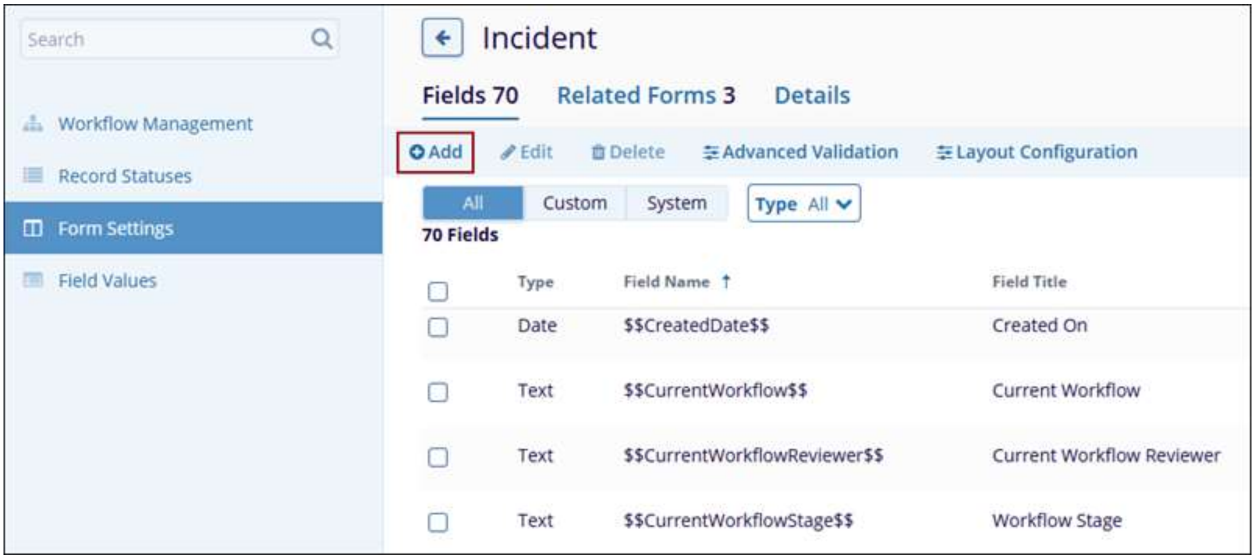
6. Additionally, users can add, edit, and delete form fields along with applying advanced validation and layout configuration.




## Add Form Fields

To add form fields, follow the steps below.

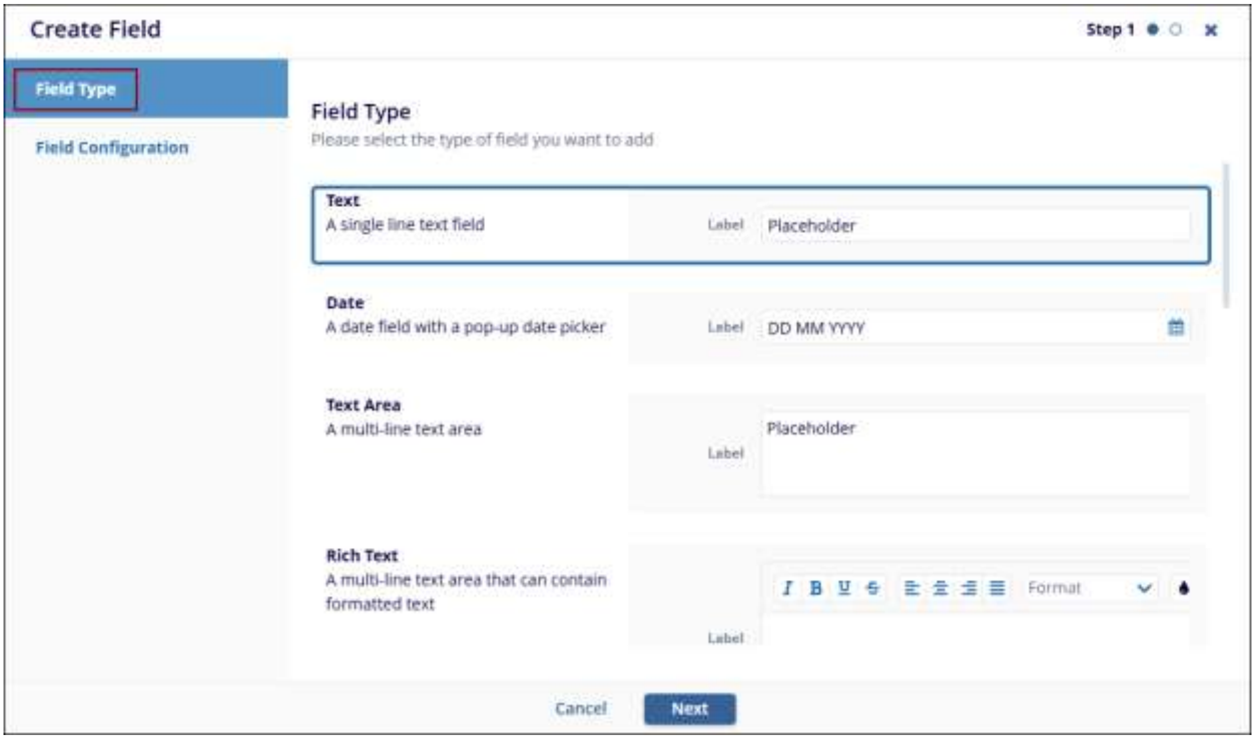
1. Navigate to the 'Fields' tab of a form, e.g., Incident, and click on the +Add button.



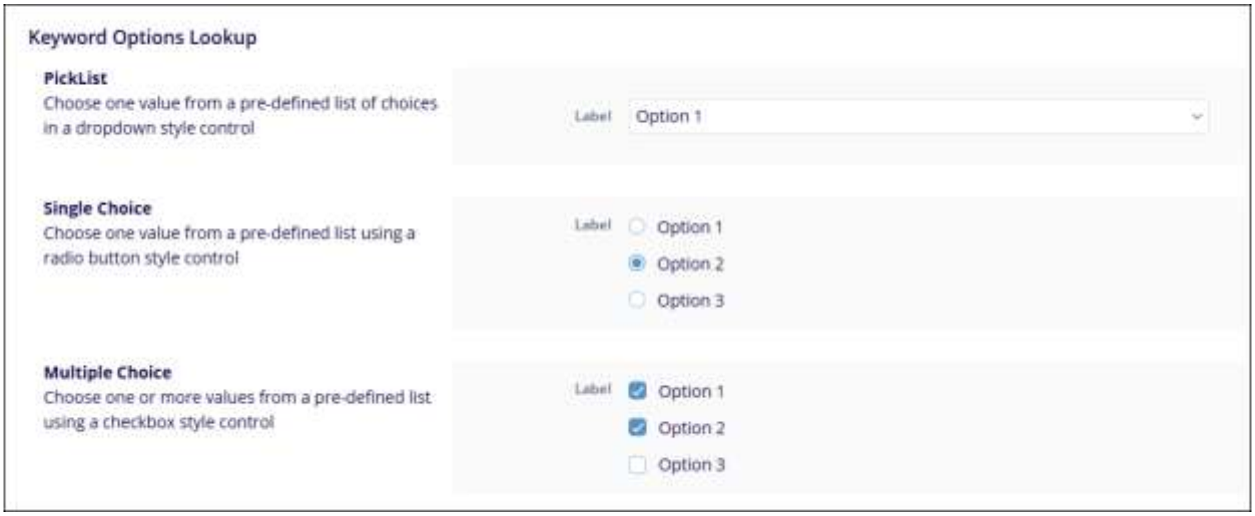

2. On the 'Create Field' form, select a 'Field Type' from the available options and click on the Next button.

    a. Text: A single-line text field.

b. Date: A date field with a pop-up date picker.
c. Text Area: A multi-line text area.
d. Rich Text: A multi-line text area that can contain formatted text.
e. Number: A field that contains only a number.



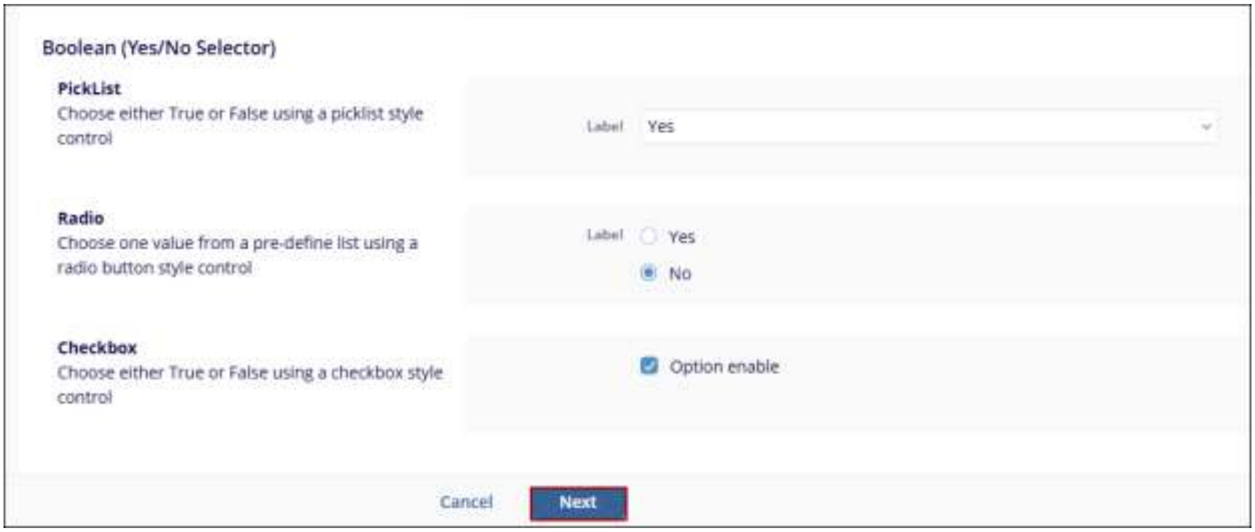

f. Keyword Options Lookup
   i. Picklist
   ii. Single Choice
   iii. Multiple Choice




g. Boolean (Yes/No Selector)
   i. Picklist

ii. Radio

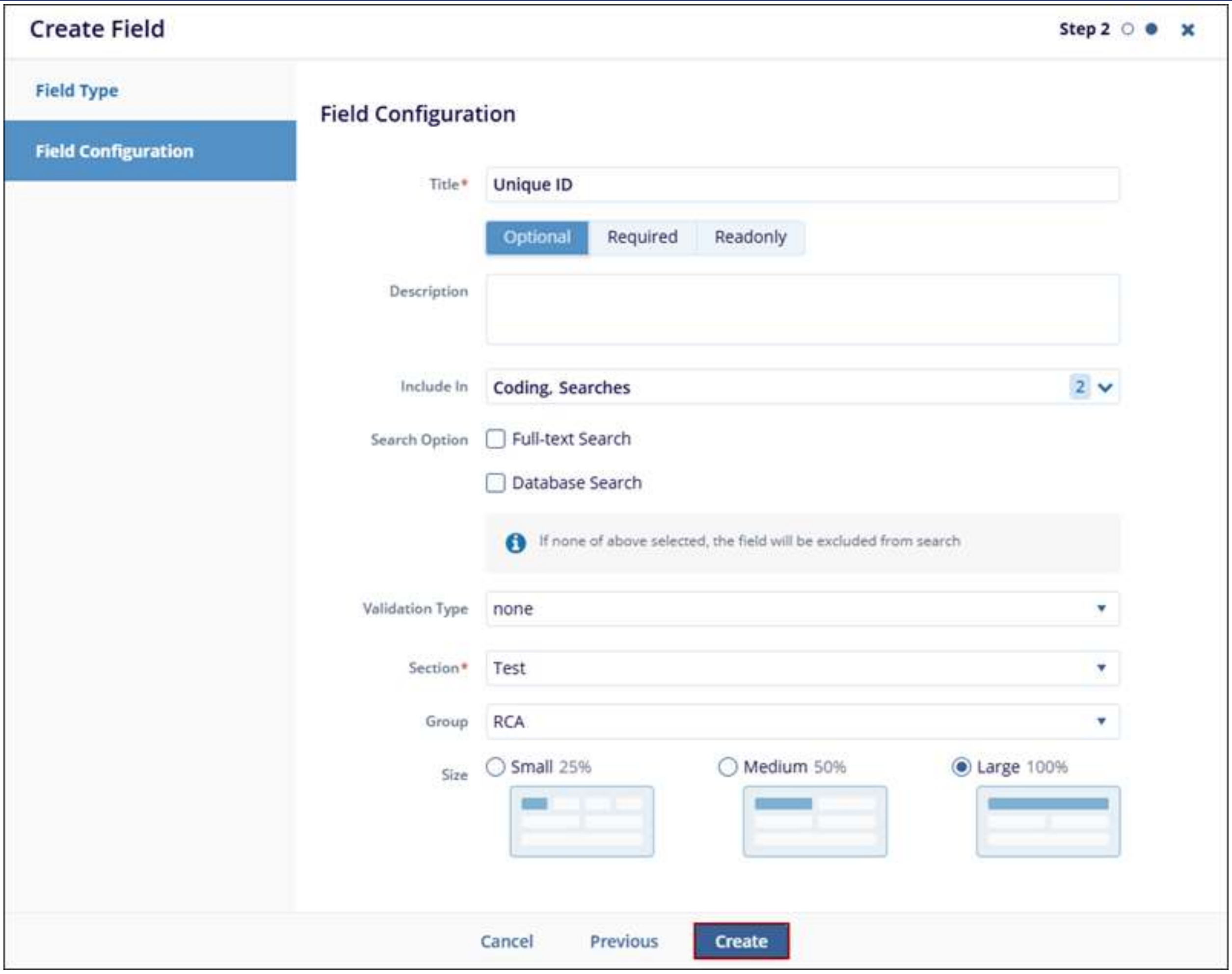
iii. Checkbox



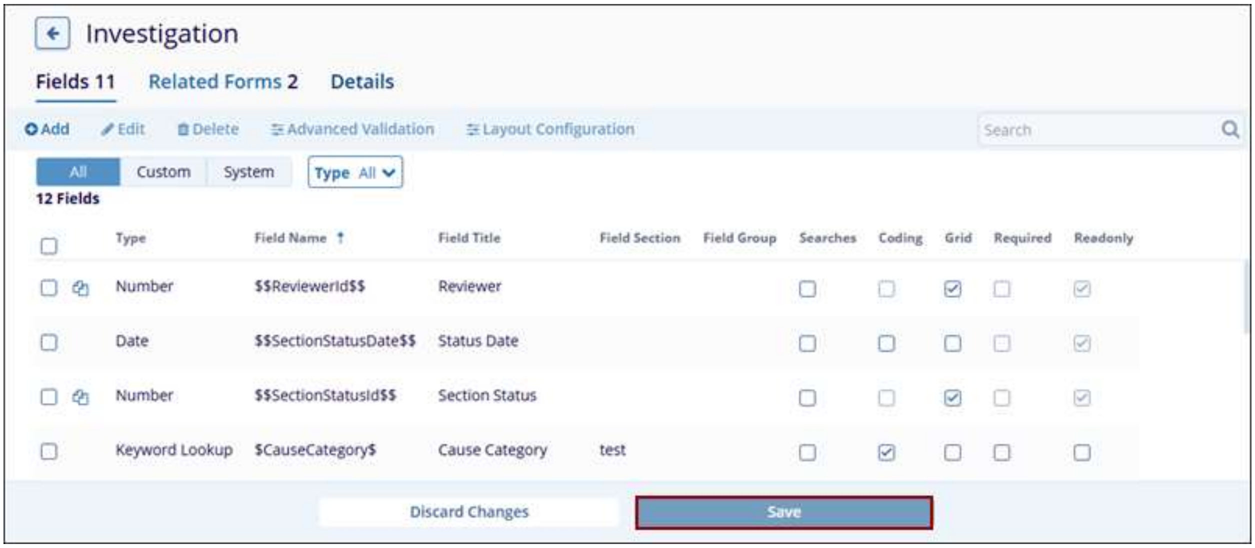

3. On the Field Configuration step, configure the following fields.

    a. Title*: Provide a title to the field.
    b. Field behavior: Select whether the field should be 'Optional', 'Required', or 'Read-Only'.
    c. Description: Add a relevant description to the field.
    d. Include In: Select Coding, Grid, and Searches from the dropdown.
    e. Search Option (if 'Searches' is selected in 'Include In' field): Select either Full-Text Search or Database Search or both by clicking on the checkboxes.
    Note: If no option is selected, this field is excluded from the search.
    f. Validation Type: Select the validation type from the available dropdown options, i.e., Alpha, Alpha-numeric, Alpha Configurable, or Range.
    g. Section* (if 'Coding' is selected in the 'Include In' field): Select an option from the dropdown list.
    h. Group (if 'Coding' is selected in the 'Include In' field):
    i. Size: Select either Small, Medium, or Large.

4. Once the necessary details are configured, click on the 'Create' button.



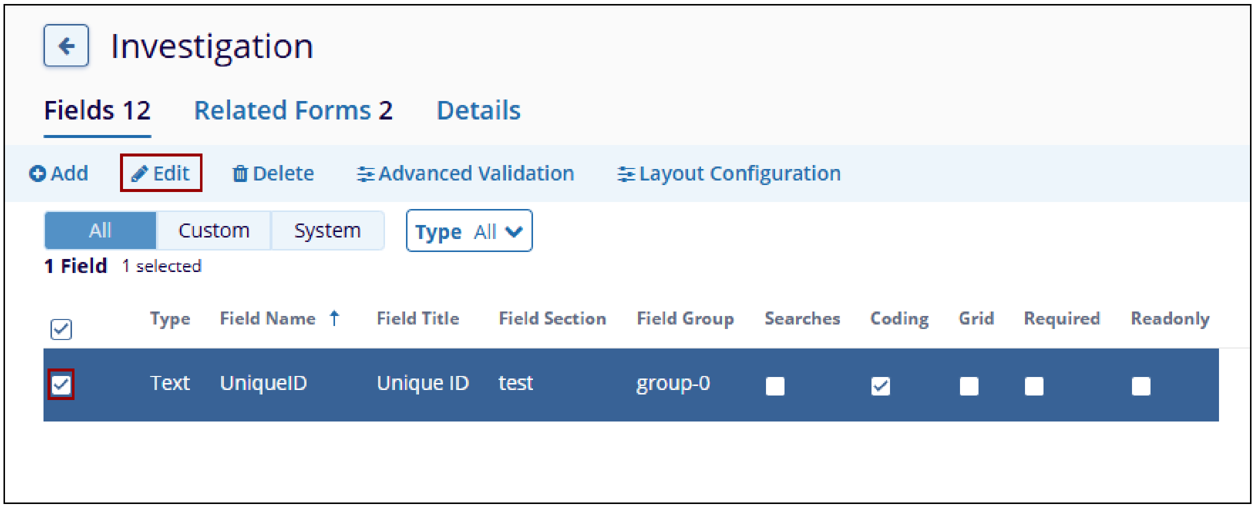

5. Click on the Save button on the 'Fields' tab.



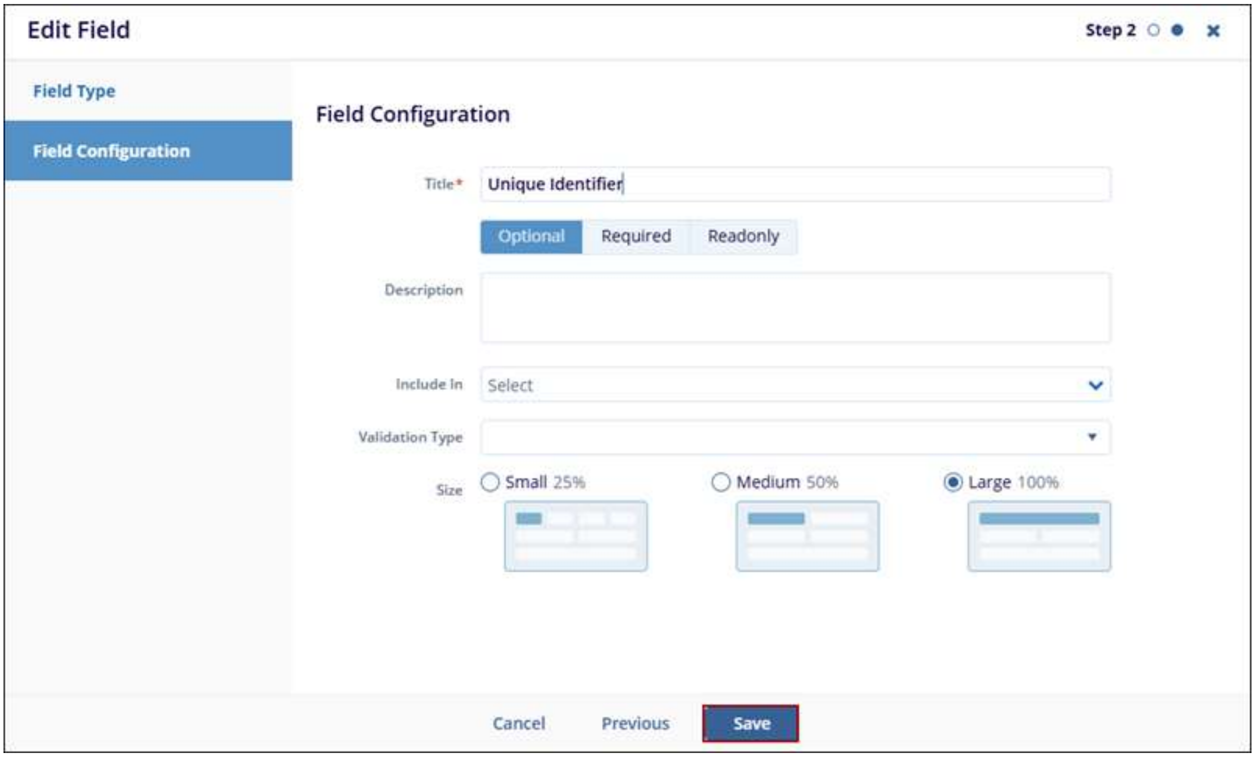
## Edit Form Fields

To edit form fields, follow the steps below.

1. Select a field to edit from the 'Fields' tab and click on the 'Edit' button.



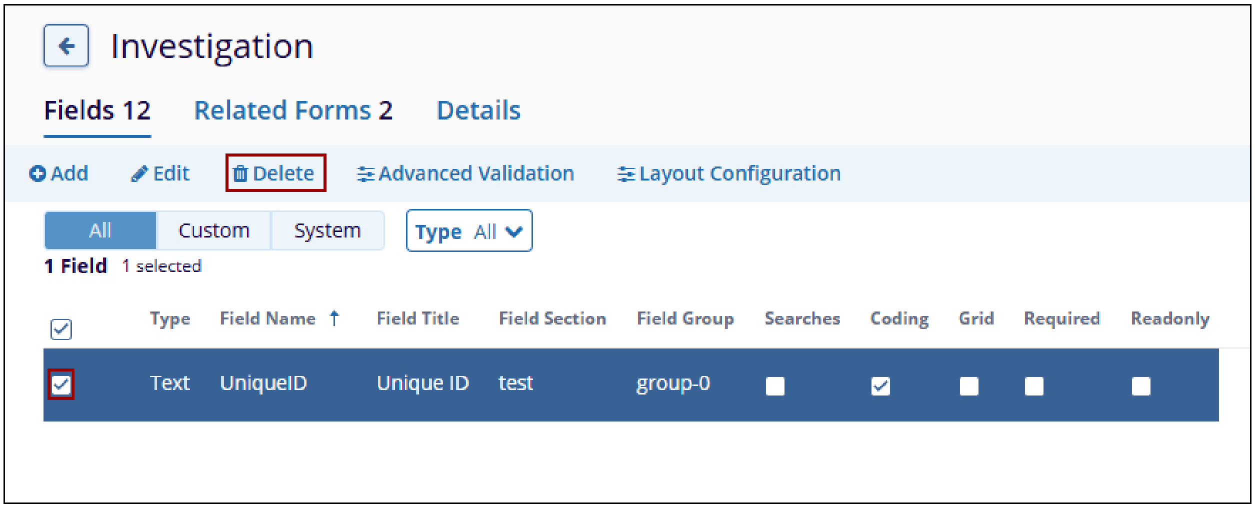

2. On the 'Edit Field' form, make the required edits in the 'Field Type' and 'Field Configuration' steps and click on the Save button.



### Delete Form Field

To delete a form field, follow the steps below.

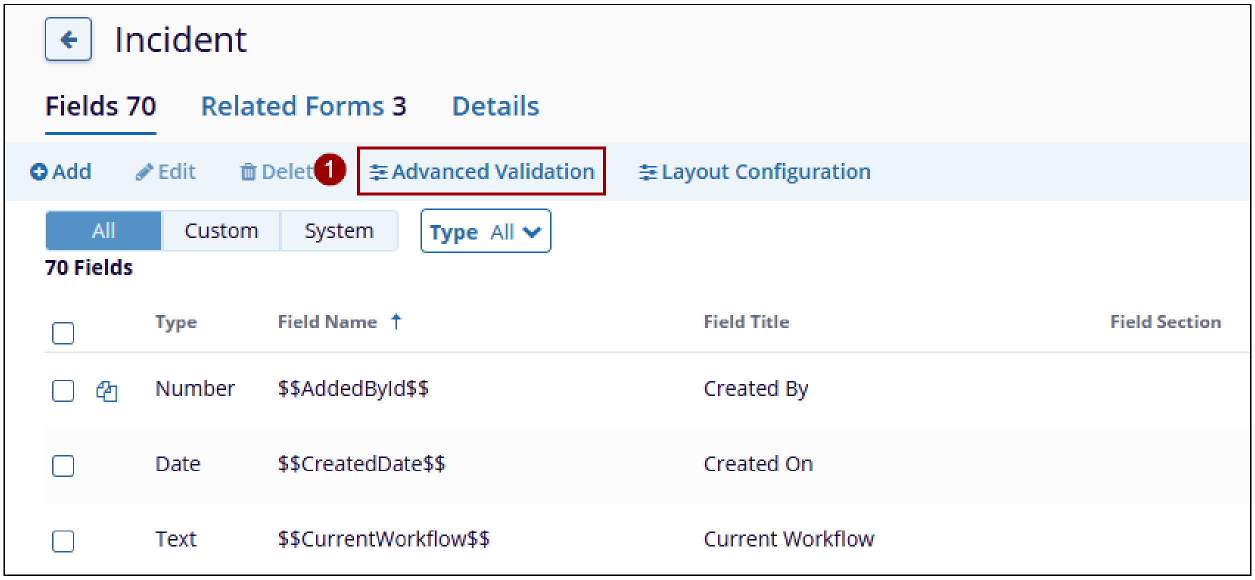
1. Select a field to delete from the 'Fields' tab and click on the 'Delete' button.



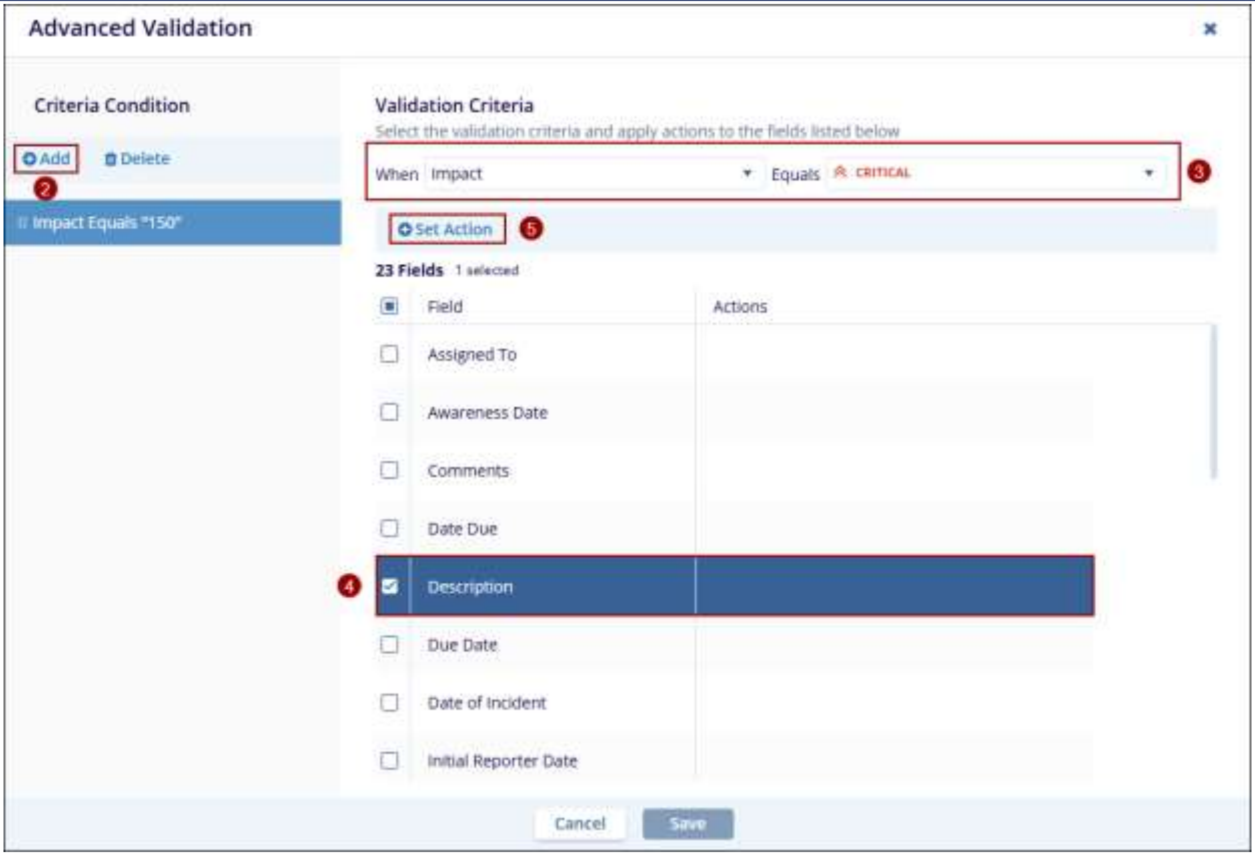

### Advanced Validation

To configure the Advanced Validation criteria, follow the steps below.

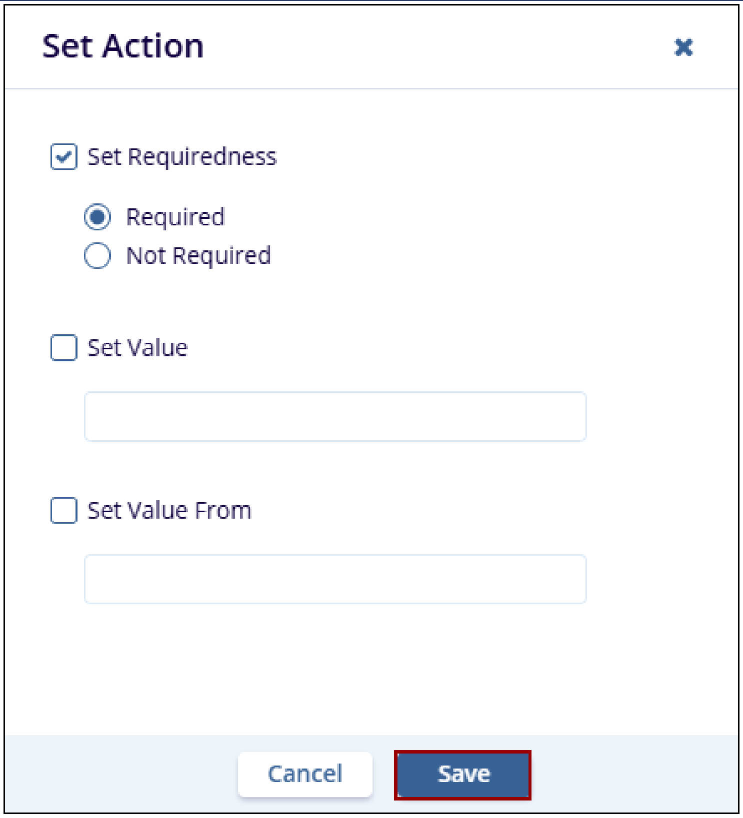
1. On the Fields tab, select 'Advanced Validation' from the top menu bar.



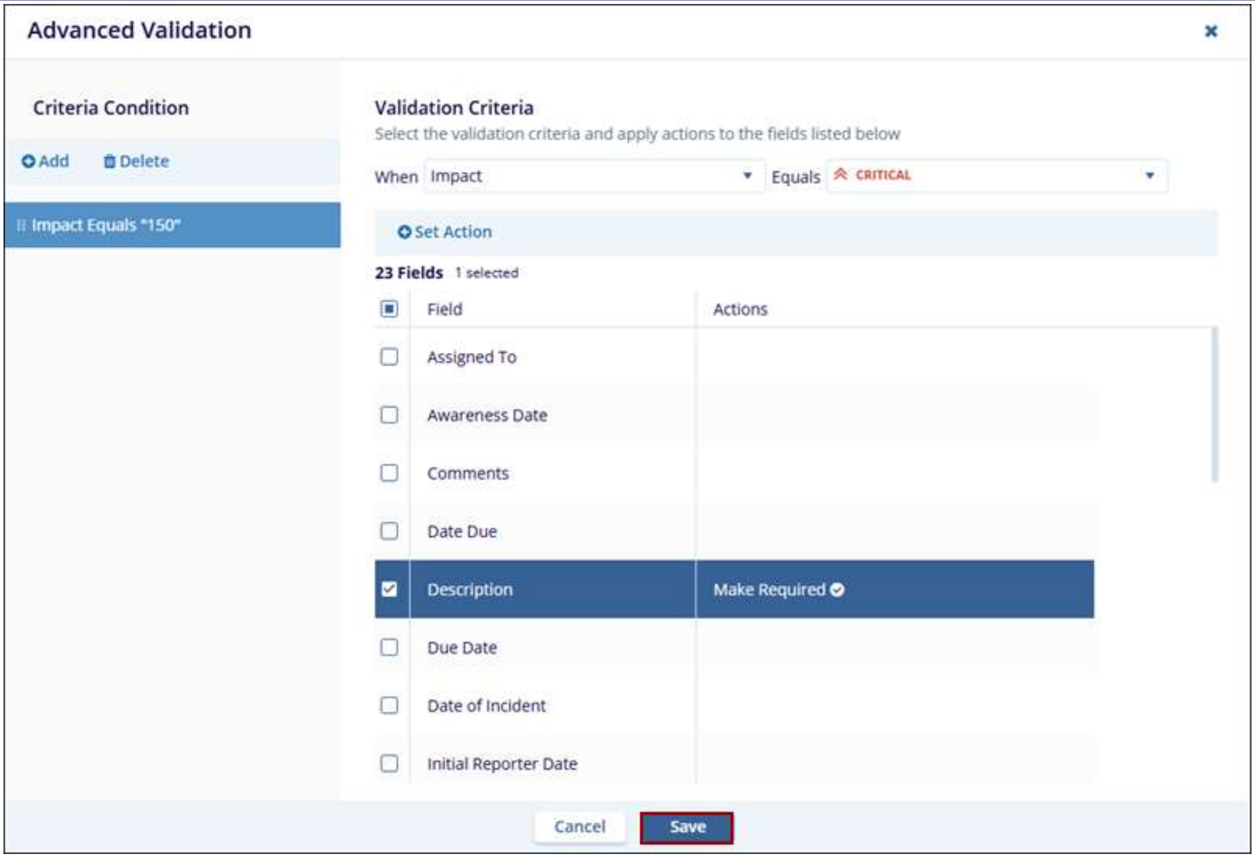

2. On the 'Advanced Validation' screen, click on the '+Add' button under the 'Criteria Condition' section.
3. Under the Validation Criteria section, add values for 'When' and 'Equals' criteria fields.
4. Select a field from the list.
5. Click on the +Set Action button.




6. On the Set Action pop-up, define the field behavior within the form by selecting any one of the following and click on the Save button.
    a. Set Requiredness
        i. Required
        ii. Not Required
    b. Set Value
    c. Set Value From




7. On the Advanced Validation screen, the action appears against the field. Click on the Save button.



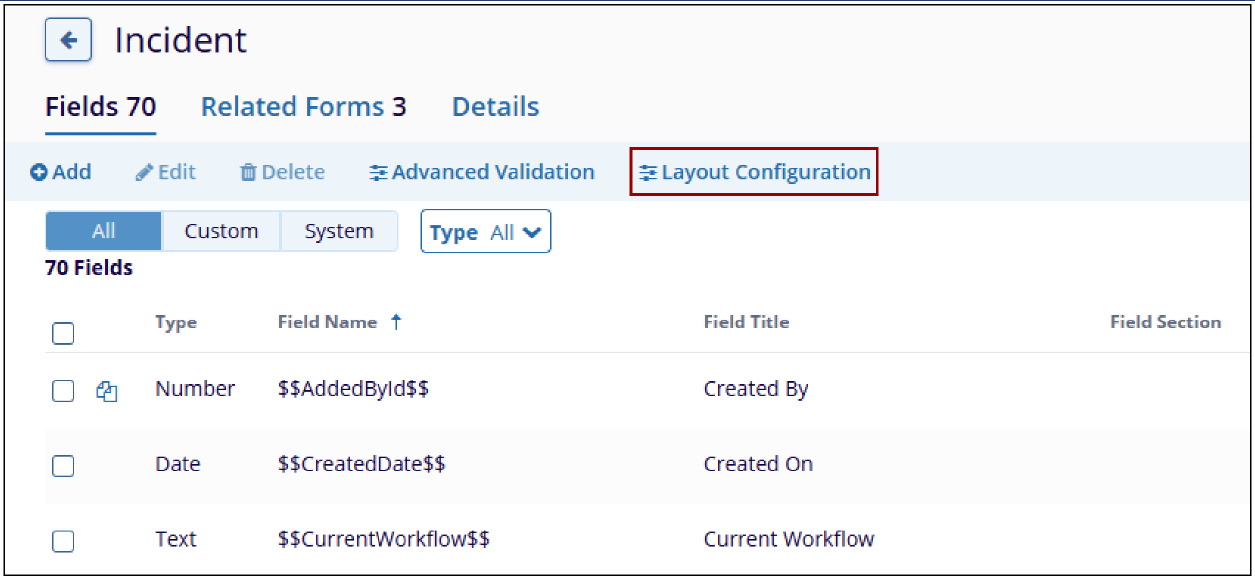

Important

- In the above example, the validation rule is defined as: 'When Impact is set to Critical, the Description field becomes required.'
- This means that when a user creates a record, i.e., Incident, CAPA, or Action Item, etc., where this validation is applied and selects 'Critical' as the Impact, they must provide a value in the Description field before proceeding, i.e., the Description field becomes mandatory.

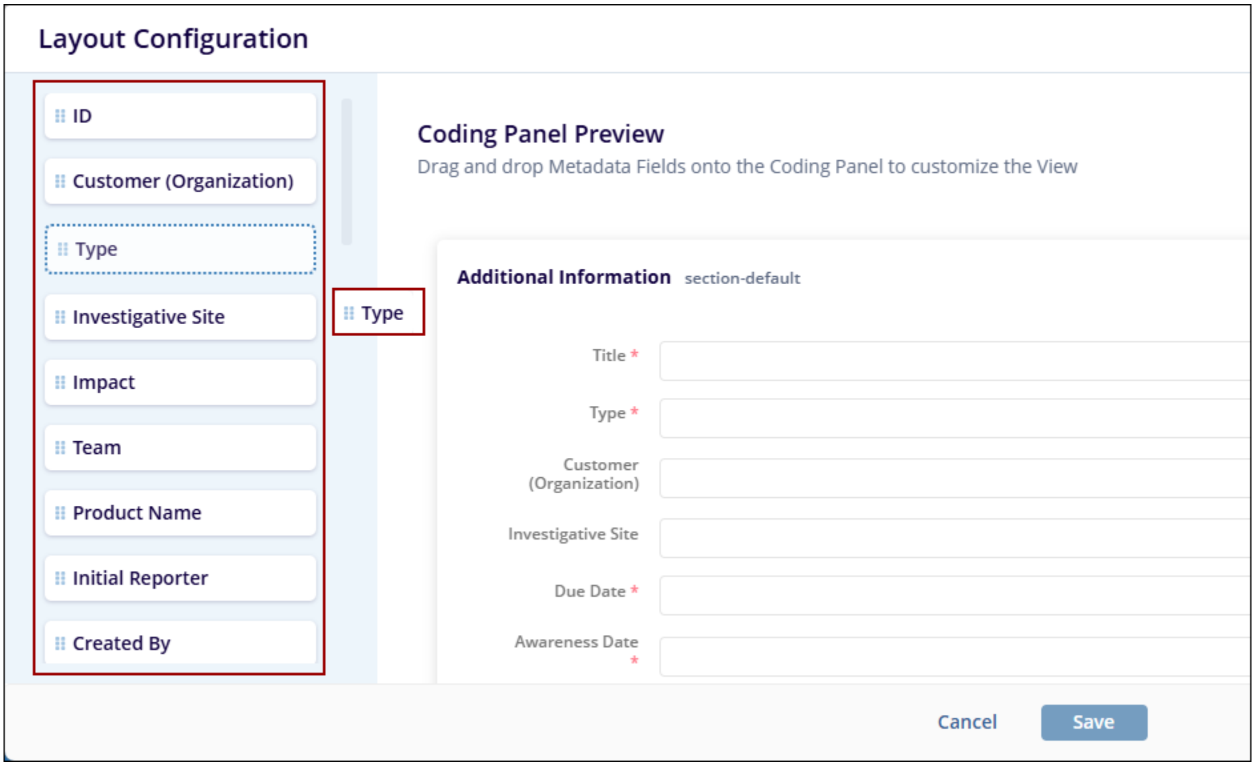
## Layout Configuration

To configure the layout of a form, follow the steps below.

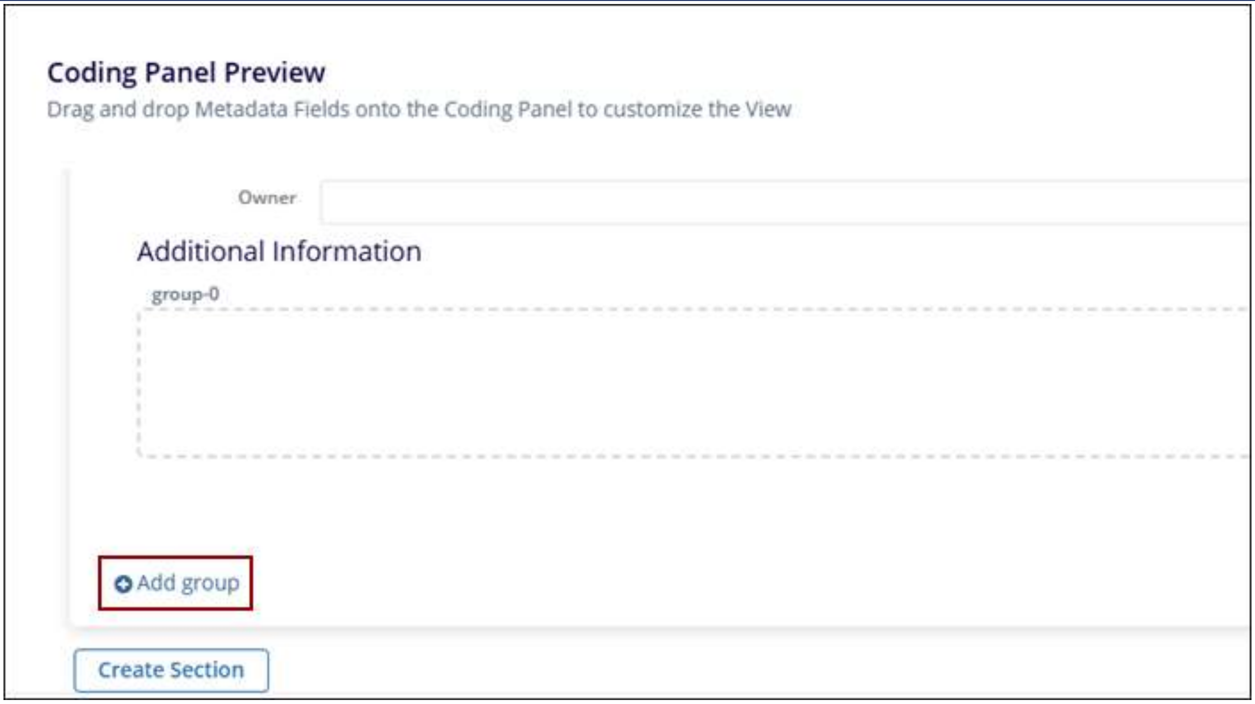
1. Select 'Layout Configuration' from the top menu bar on the Fields tab.




2. On the Layout Configuration screen, drag and drop a metadata field from the left sidebar to arrange it in the desired order, allowing the configuration of how the metadata fields are displayed on the form.

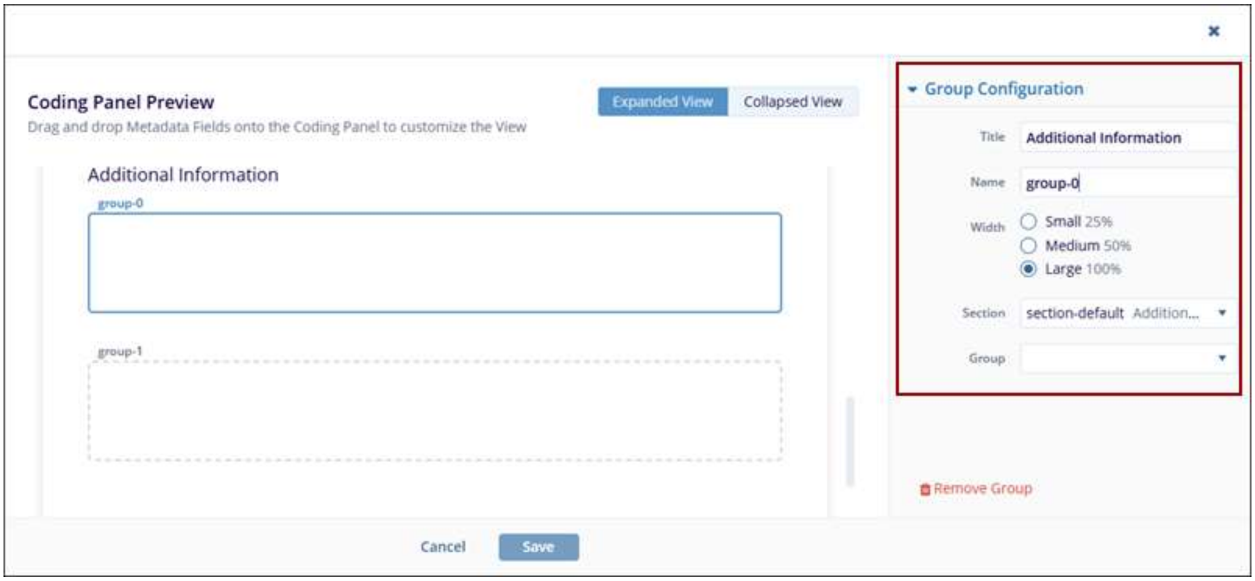



3. Within the Coding Panel Preview section, click on the +Add Group button.



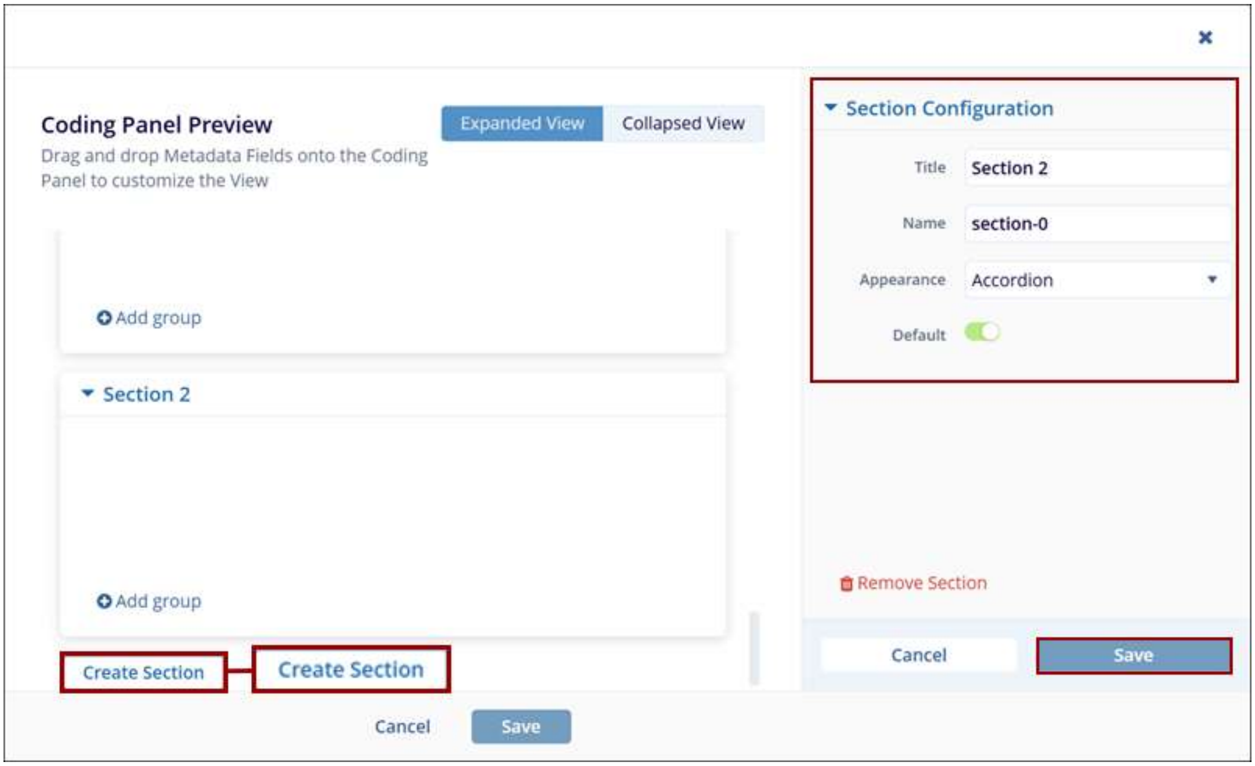

4. Click on the blank area of the added group and configure the following details under the 'Group Configuration' section and click on the 'Save' button.

    a. Title
    b. Name
    c. Width
    d. Section
    e. Group

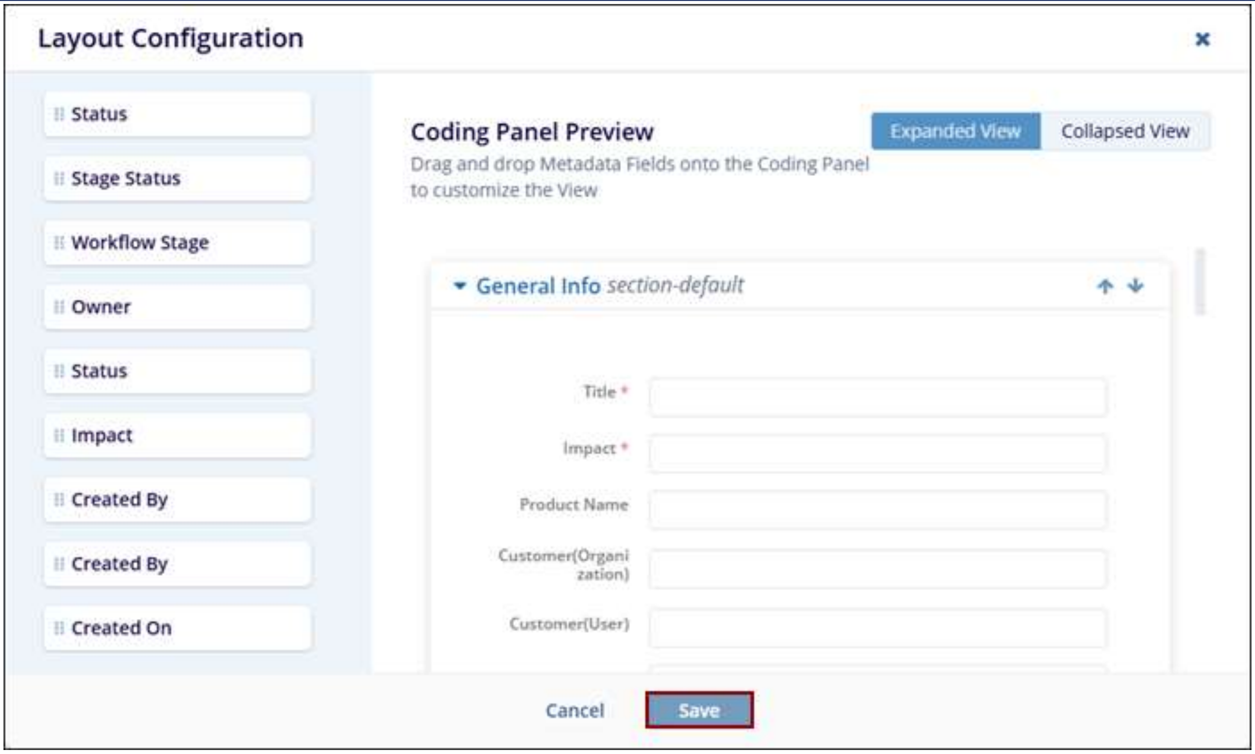


5. To create an additional section in the form, click on the '**Create Section**' button within the Coding Panel Preview.
6. Within the 'Section Configuration' add the following details and click on the 'Save' button.

    a. Title
    b. Name
    c. Appearance
    d. Default




7. Once all the configurations are made, click on the 'Save' button at the bottom of the 'Layout Configuration' screen.

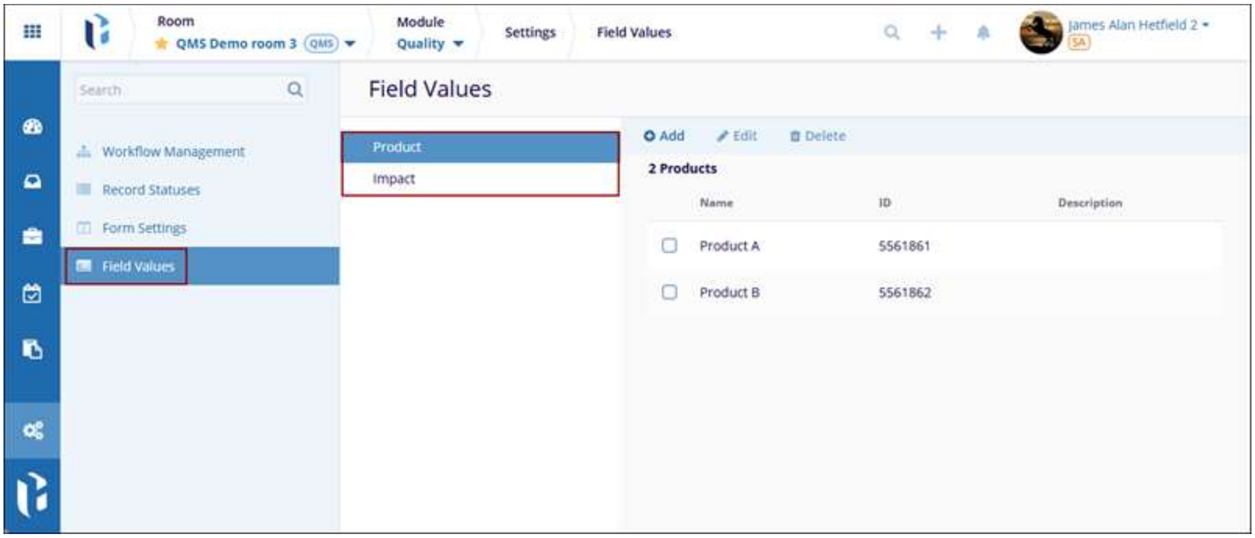



## Field Values

The ‘Field Values’ section allows users to define the products and edit the Impact field values on the form.

To access the ‘Field Values’ page, follow the steps below.

1. From the Quality module, click on the Settings menu > Field Values.
2. Select either ‘Product’ or ‘Impact’ and make the necessary configurations.



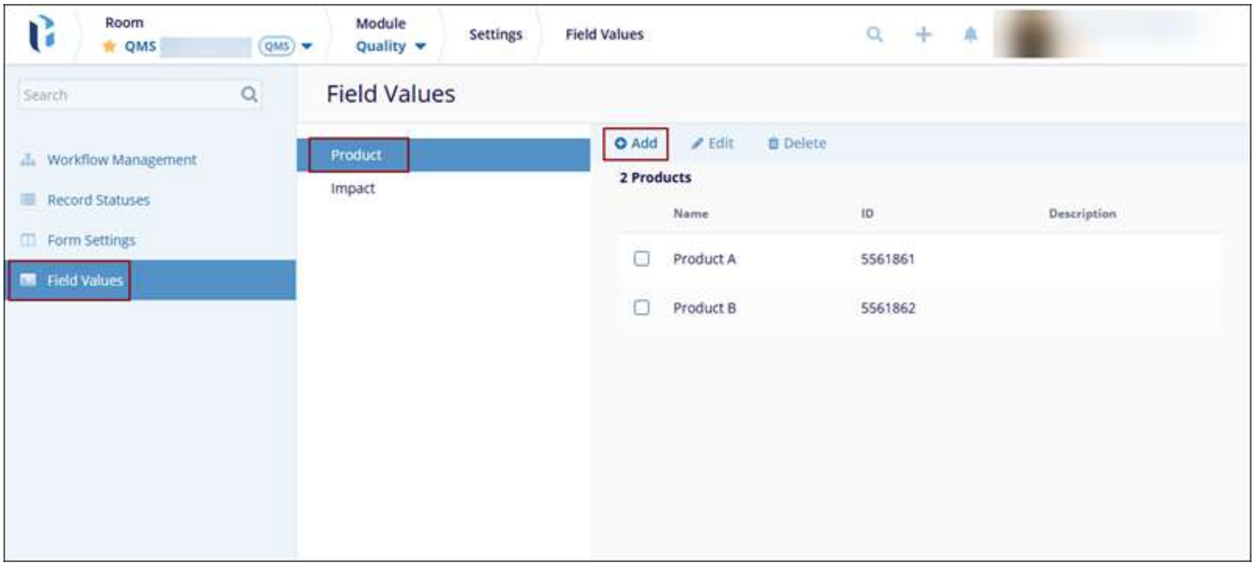
## Products

The ‘Products’ tab allows Admin users to configure a list of products that the Originator or Record Creator users define in the Incident, Action Item, and CAPA forms.

### Add Product

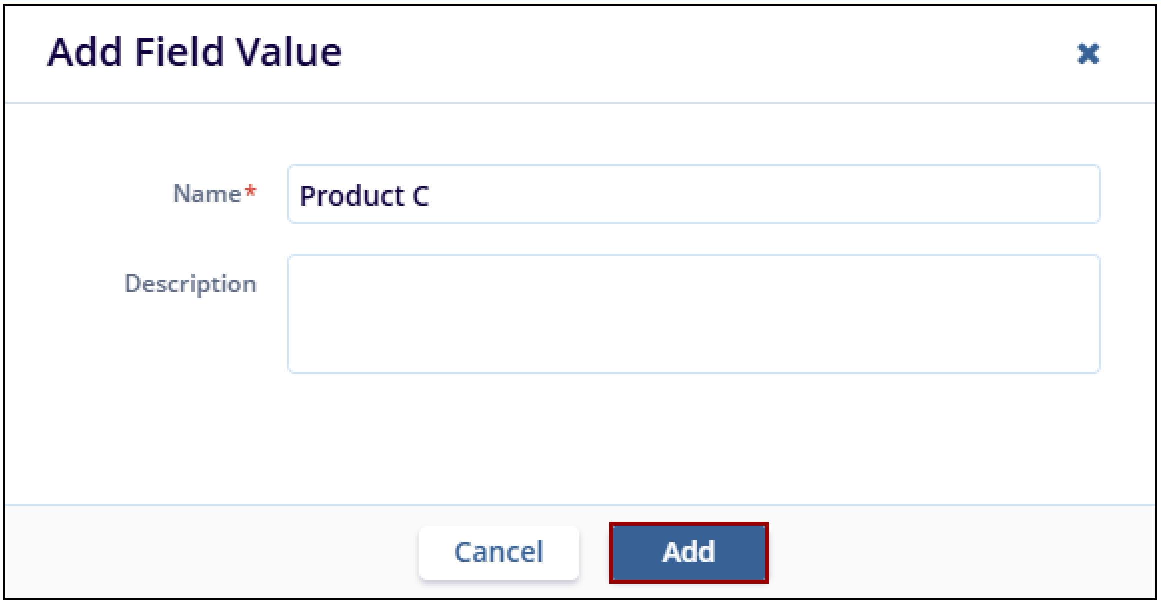
To add a product, follow the steps below.

1. Navigate to the Settings > Field Values > Products section and click on the ‘+Add’ button.




2. On the ‘Add Field Value’ dialog box, add the following details and click on the ‘Add’ button.

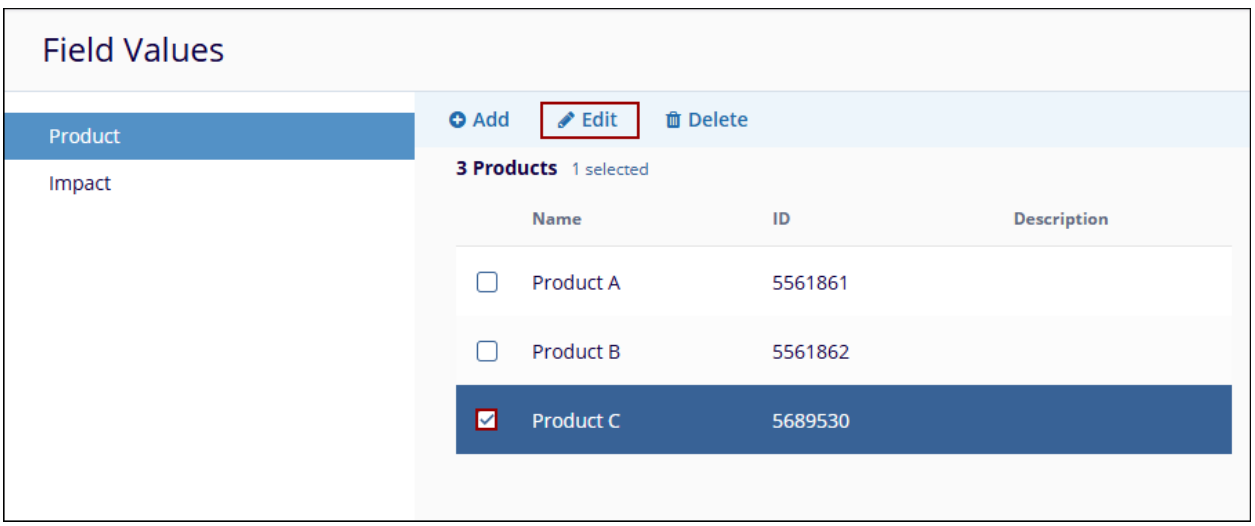
    a. Name*: Provide a name for the product.
    b. Description: Optionally add the product description.




Edit Product

To edit a product, follow the steps below.

1. Select a product to edit and click on the ‘Edit’ button from the top menu bar.

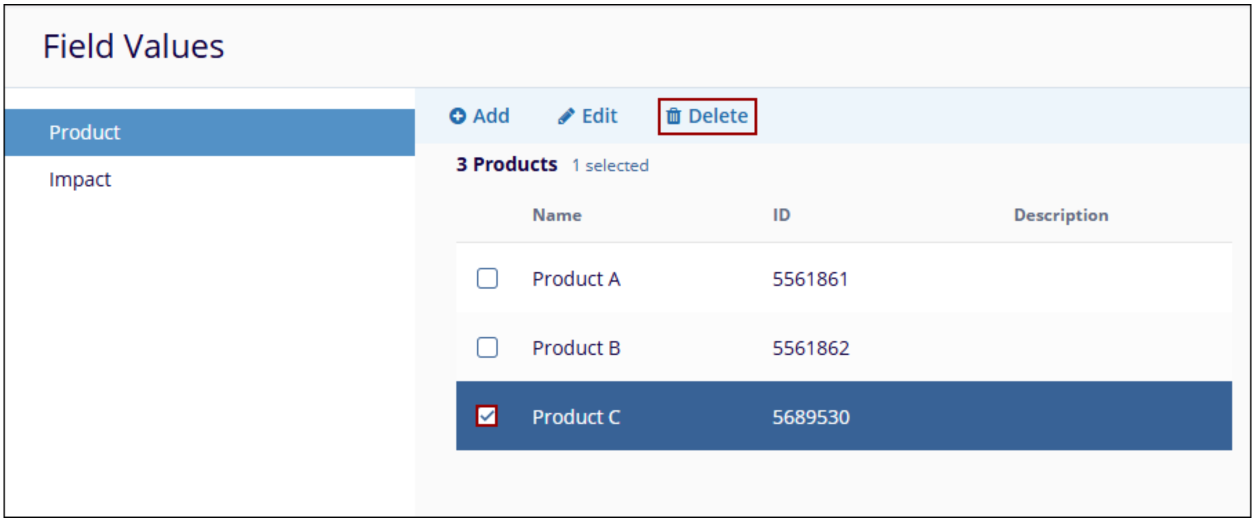



2. Make the required changes on the ‘Edit Field Value’ dialog box and click on the ‘Save’ button.

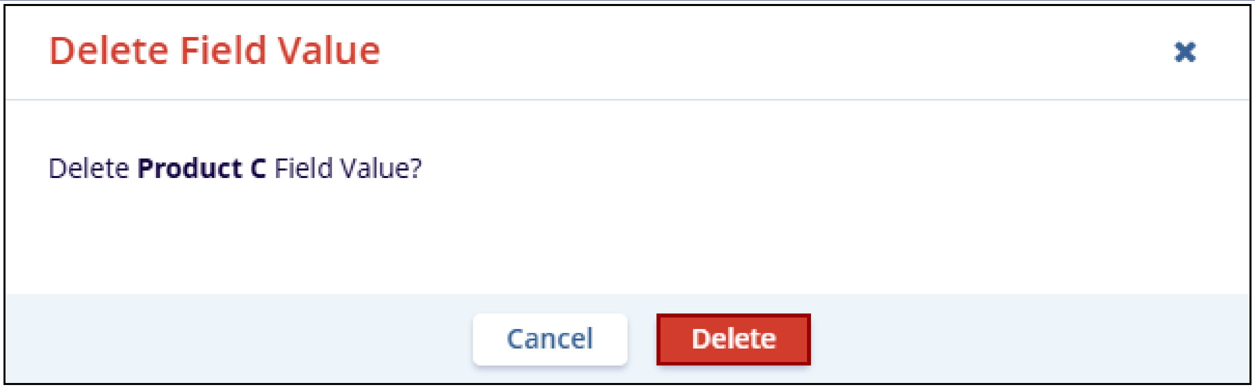

Delete Product

To delete a product, follow the steps below.

1. Select a product to delete and click on the 'Delete' button from the top menu bar.




2. Click on the 'Delete' button on the confirmation popup.

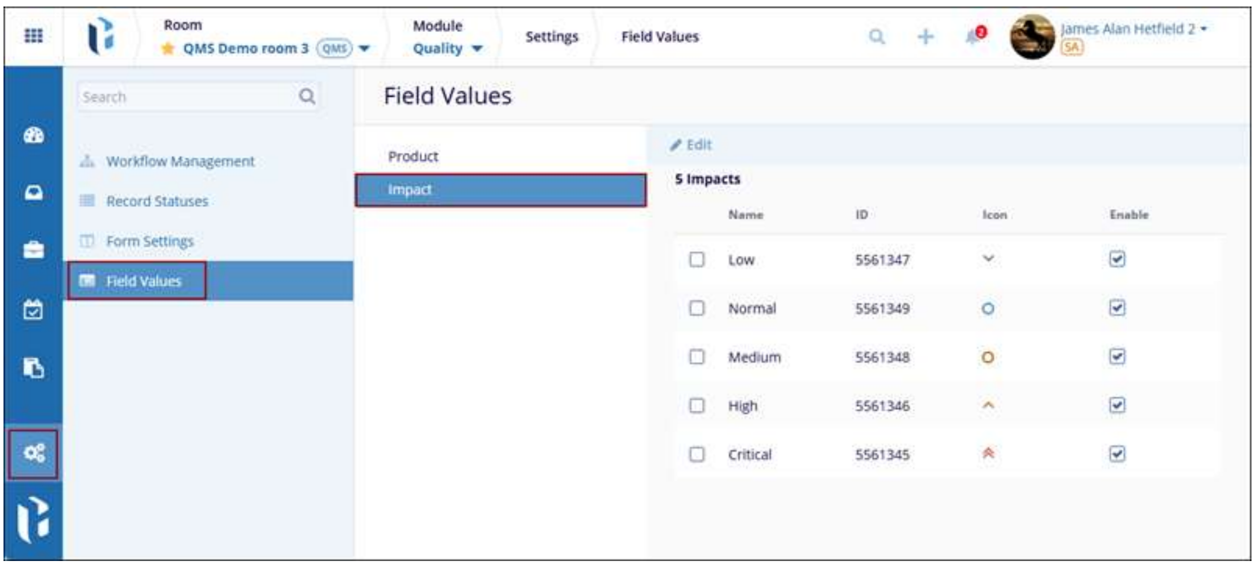



## Impact

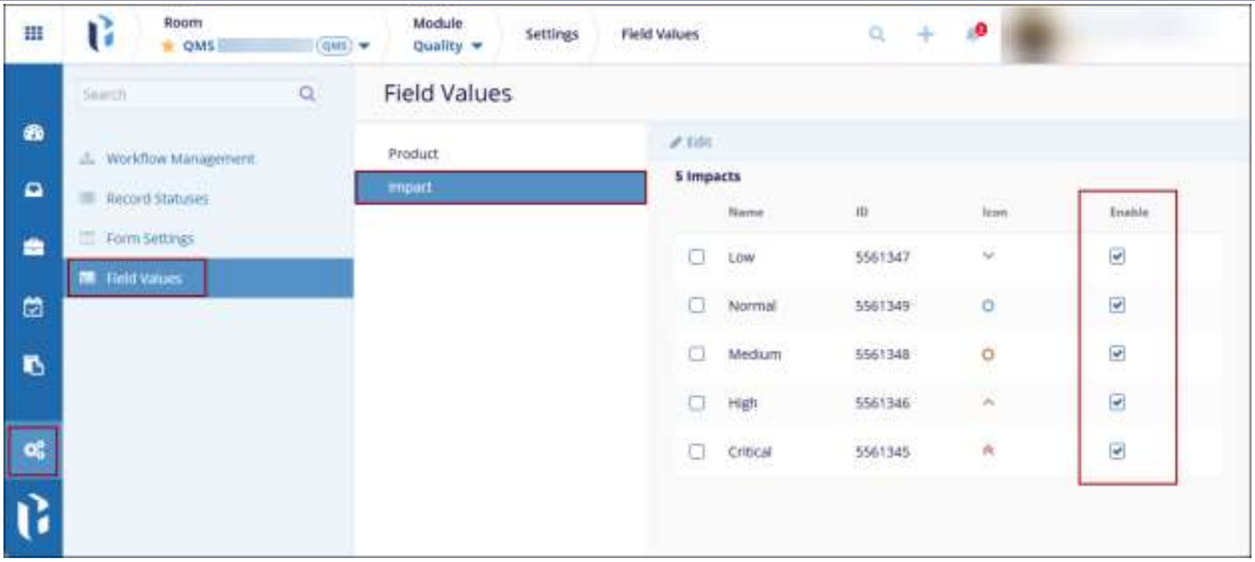
The ‘Impact’ section displays the default out-of-the-box values that can be added in the ‘Impact’ field of the Incident, CAPA, and Action Item forms. Admin users can control the fields visibility and edit the display name.

To edit the impact fields, follow the steps below.

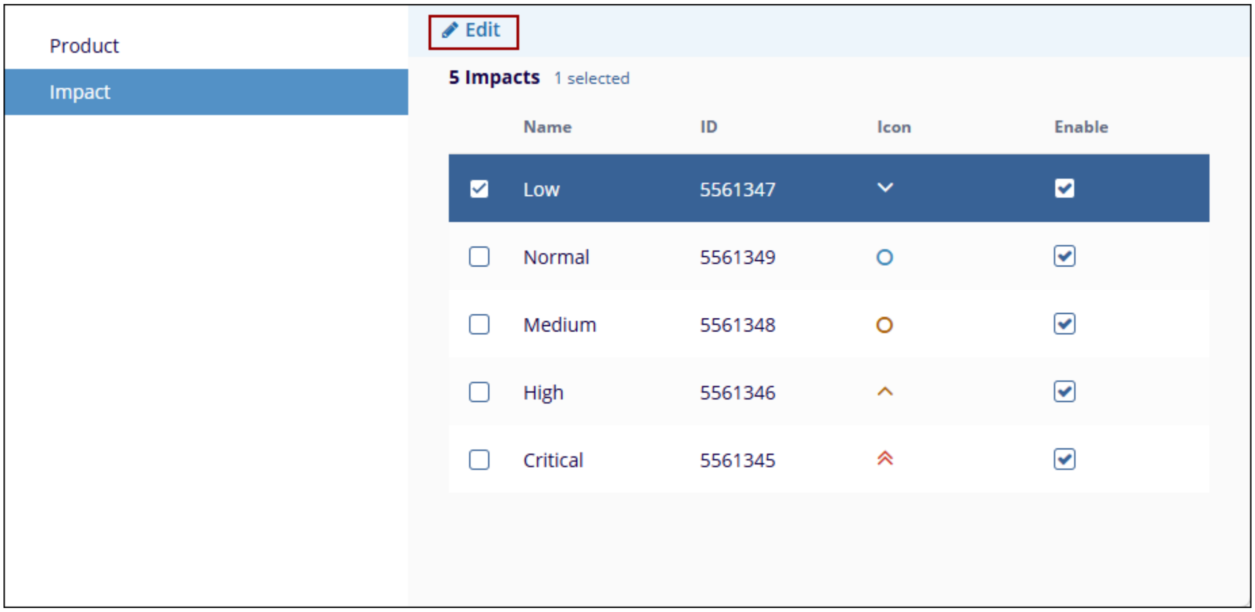
1. Navigate to the Quality Module > Settings > Field Values > Impact section.



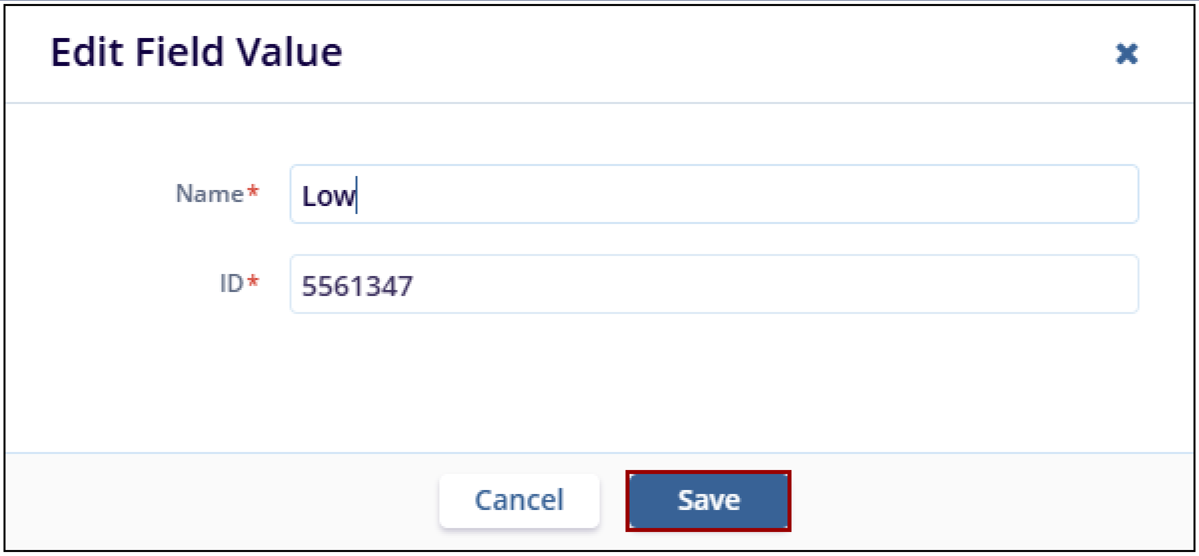

2. Check or uncheck the checkbox under the ‘Enable’ header to display the impact value in the Incident, CAPA, or Action Item form.




3. Select a value and click on the 'Edit' button from the top menu bar.




4. On the 'Edit Field Value' popup, edit the name and click on the 'Save' button at the bottom.

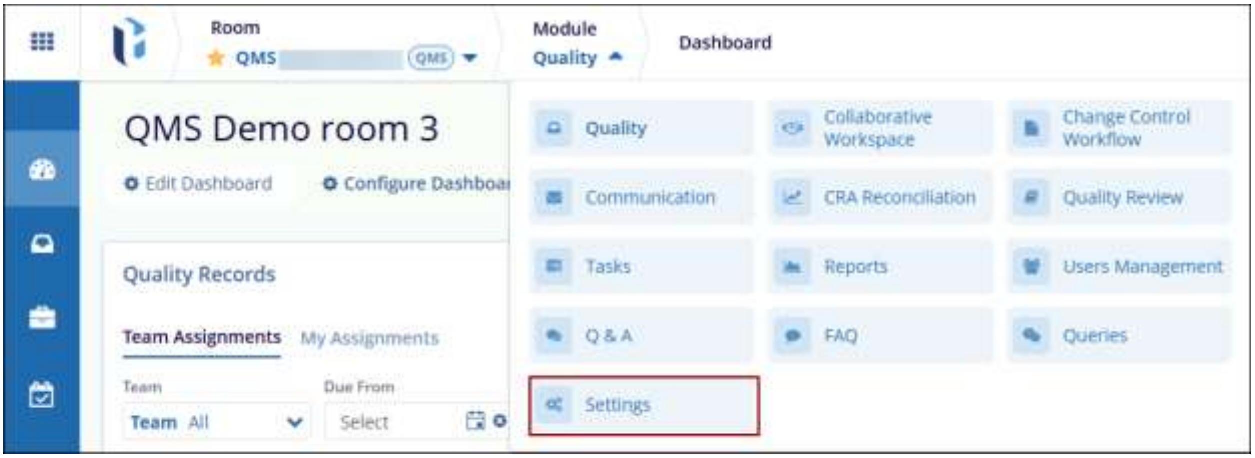

Edit Field Value
Name*
Low
ID*
5561347
Cancel
Save

# QMS ROOM SETTINGS

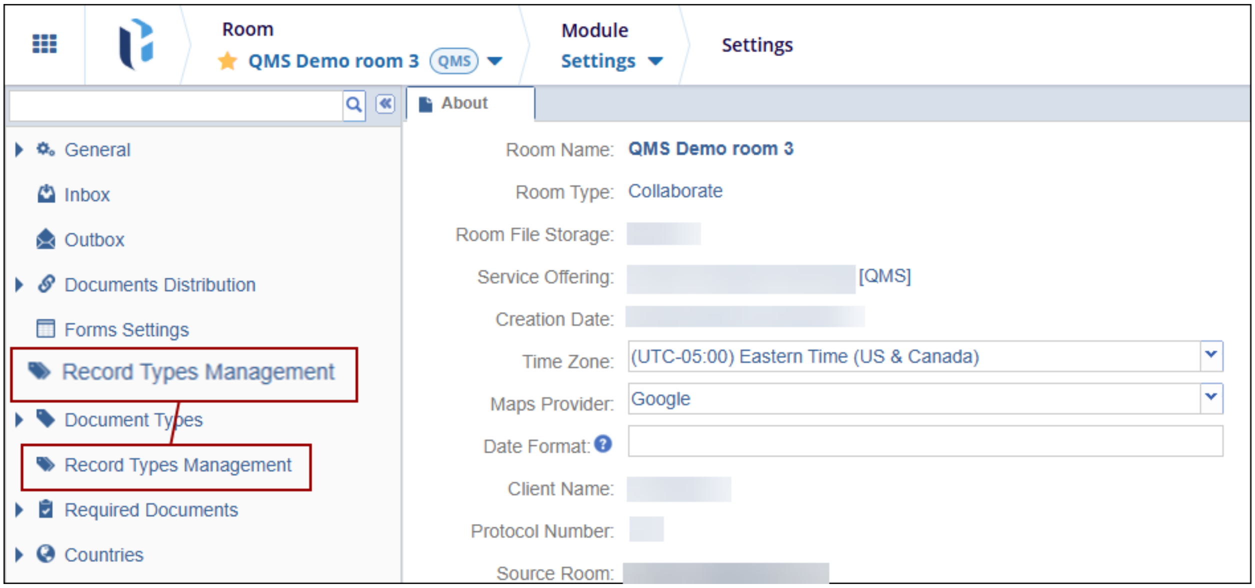
The Record Type Management in the Room Settings allows Admin users to enable the creation, management, and configuration of record types. The Record Types Management settings page displays a structured interface to manage record types and their associated forms, workflows, and field settings. Record types are displayed in a tree structure, categorized by pre-defined categories based on forms with the 'main topic' type.

To access the Record Types Management settings page, follow the steps below.

1. Click on the 'Modules' dropdown and select the 'Settings' module.




2. From the Settings, select the 'Record Types Management' from the left-hand navigation pane.



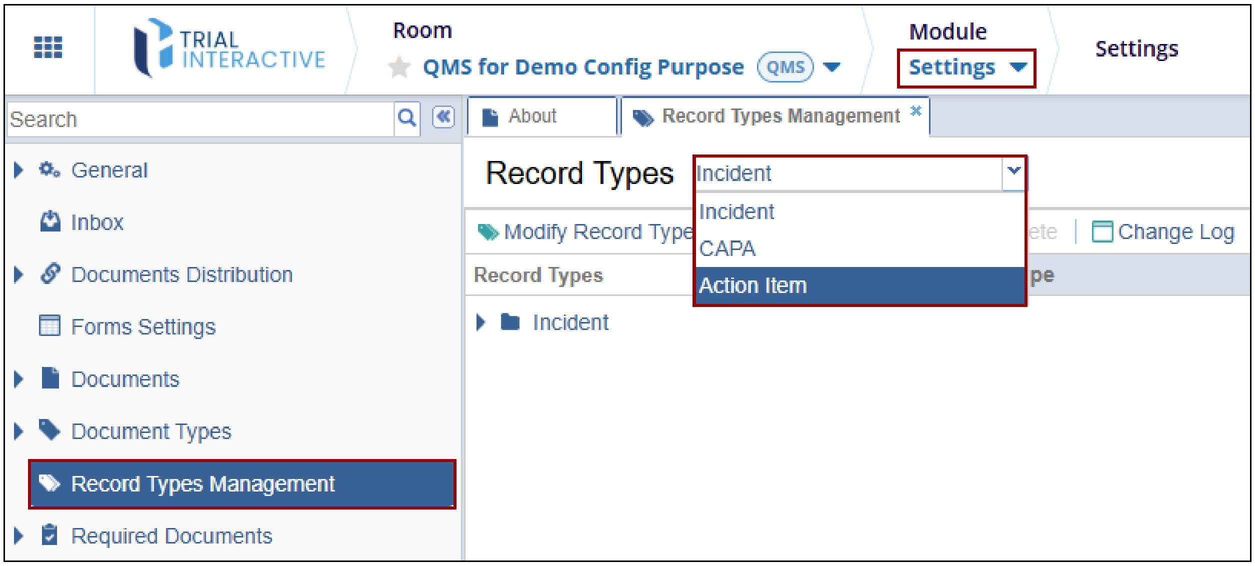
## Record Types

The Record Types page displays the Record types organized in a hierarchical tree structure, where the top level represents form types such as 'Incident' or 'CAPA'. These top-level form types are based on forms designated as 'main topic' within the Form Settings. Categories beneath each form type are automatically mapped to their corresponding form. The system includes Form (Entity) Type Management, where the available form types are hardcoded and cannot be added or removed through the user interface. However, users can rename these forms via the Form Management section. Under Type and Subtype Management, users can add, edit, or delete record types and subtypes within each category. Each record type is automatically linked to the same form associated with its parent category.

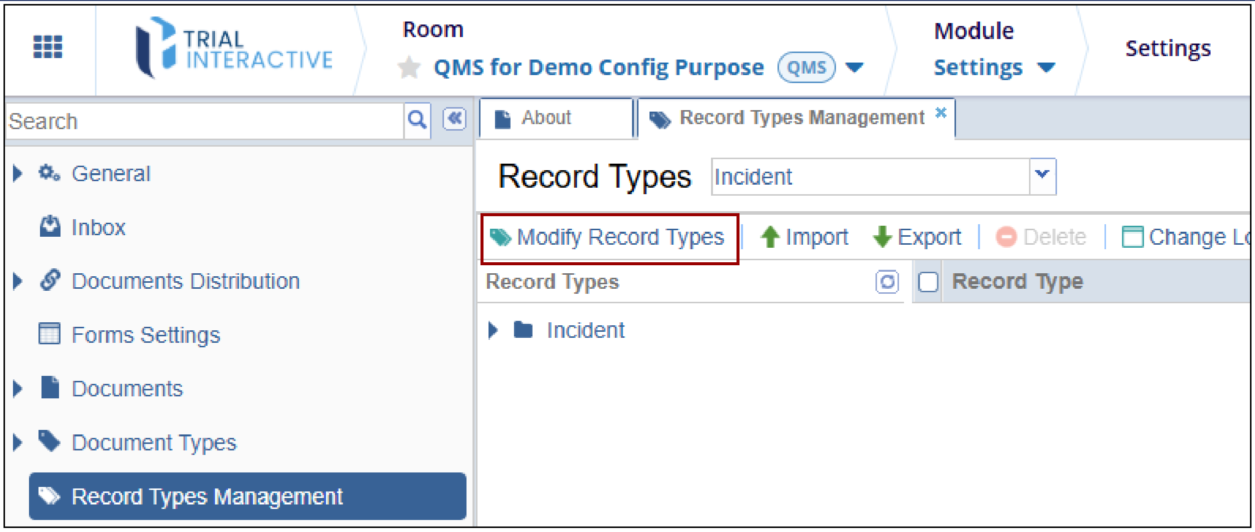
### Modify Record Types

To modify the record types, follow the steps below.

1. Navigate to the Settings module > Record Types Management and select a record type category, i.e., Incident, CAPA, or Action Item, from the dropdown.




2. Click on the 'Modify Record Types' button from the top menu bar.




3. On the 'Modify Document Types' tree window, select a record type category and click on the +Add button.


4. Provide a name to the new record type and click on the 'Save' button.


Note: Once the new record type(s) are successfully saved, users can associate the record types with teams and workflows.

5. To edit the record type, select the record and click on the 'Edit' button on the 'Modify Record Types' tree window.

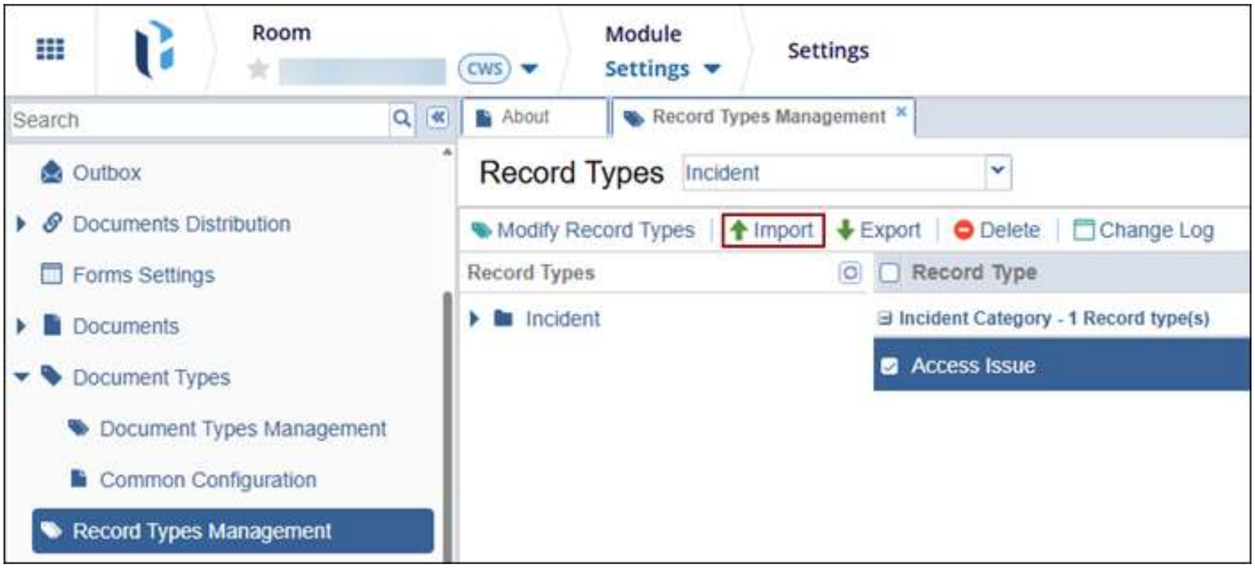

6. Modify the record type name and click on the 'Save' button.


7. To delete a record type, select the record and click on the 'Delete' button on the 'Modify Record Types' tree window.
8. Click on the 'OK' button on the confirmation pop-up to confirm the deletion and click on the 'Save' button to save the changes.

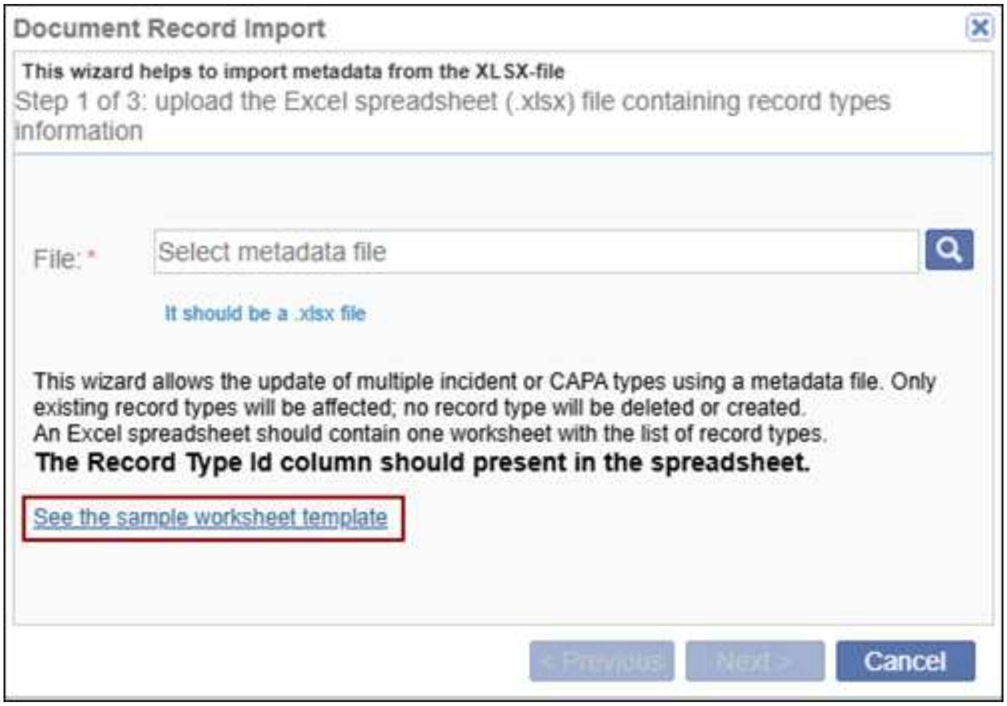
## Import

To import the record types, follow the steps below.

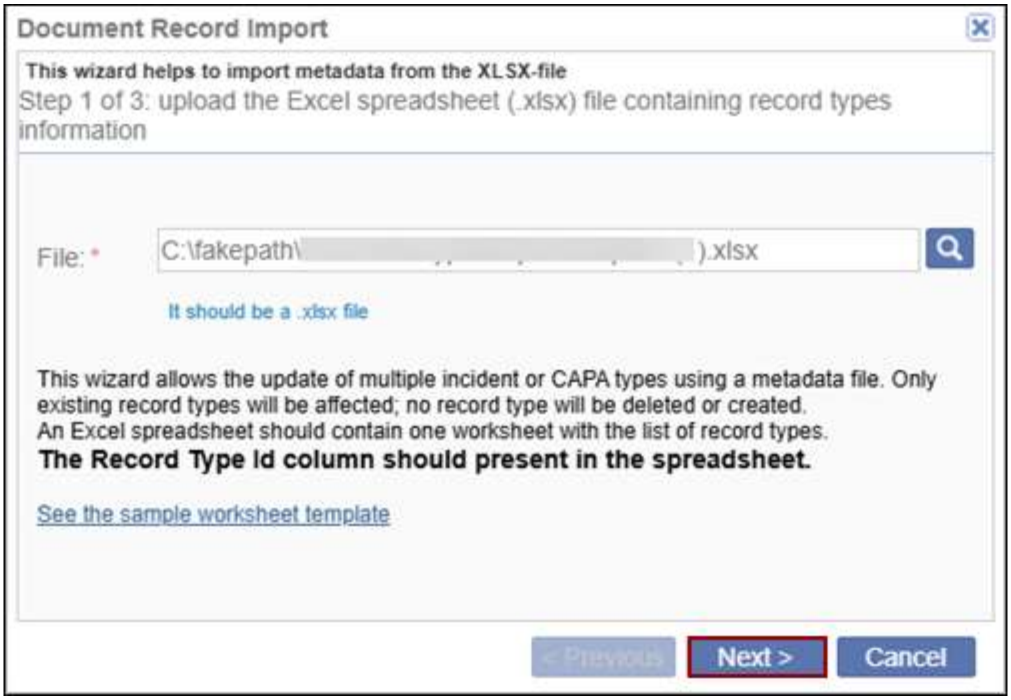
1. From the Settings module > Record Types Management, select a parent record type and click on the 'Import' button from the top menu bar.



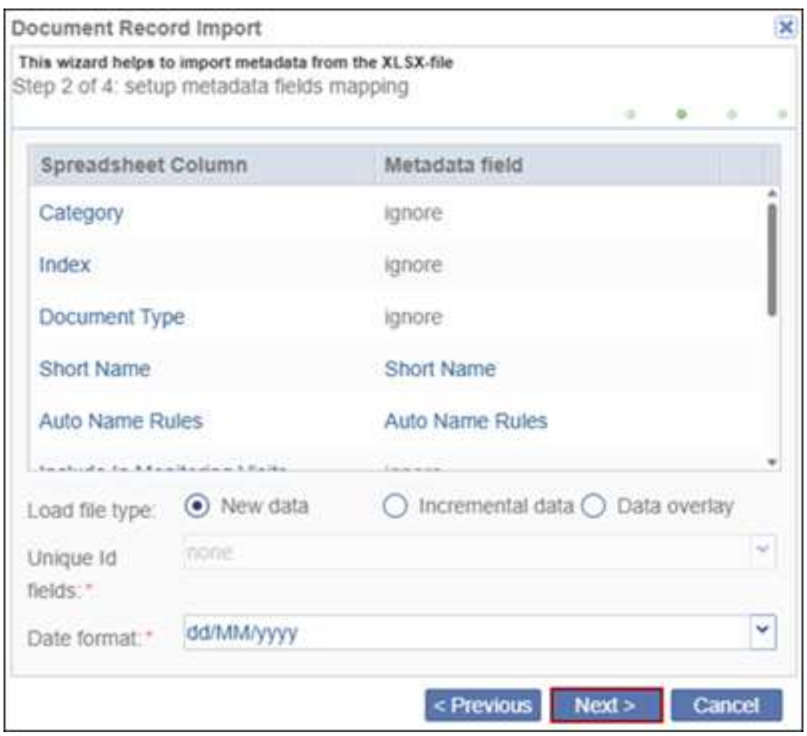

2. On the 'Document Record Import' window, download a sample worksheet template by clicking on the 'See the sample worksheet template'.



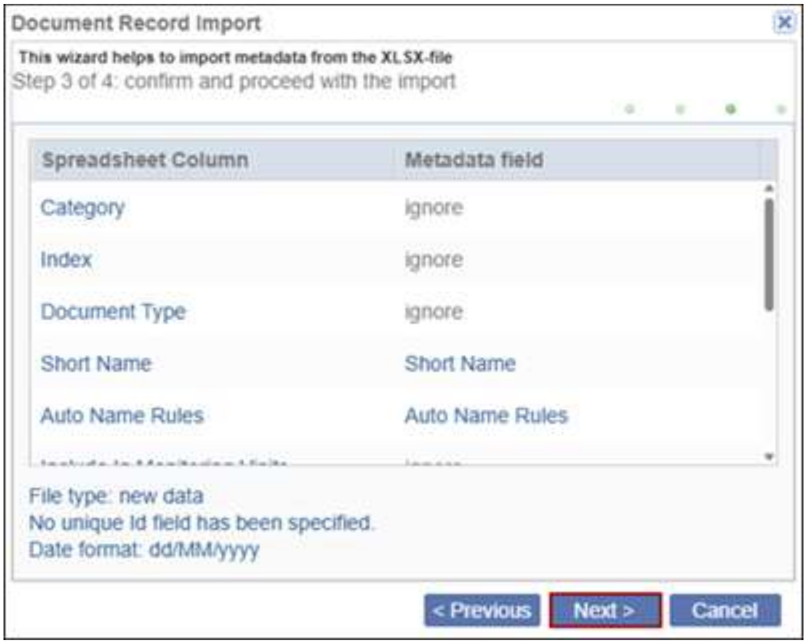
3. Fill in the necessary details in the worksheet template, upload the '.XLSX' file, and click on the 'Next' button.



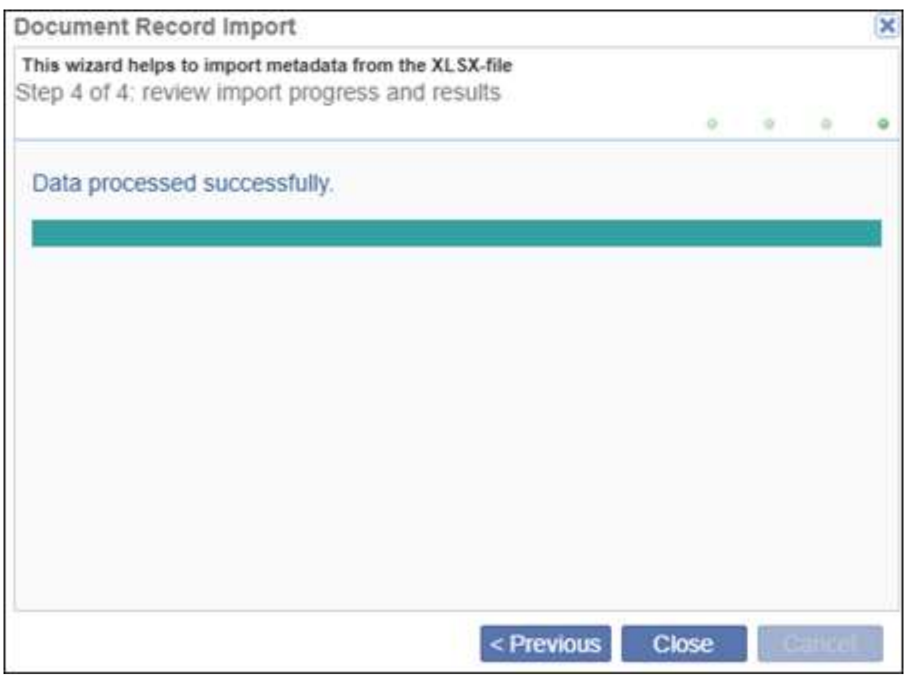

4. In the next step, set up the metadata fields mapping by configuring the Load File type, Unique Id fields, and Date format, and click on the 'Next' button.



5. In the next step, review the details and click on the 'Next' button.



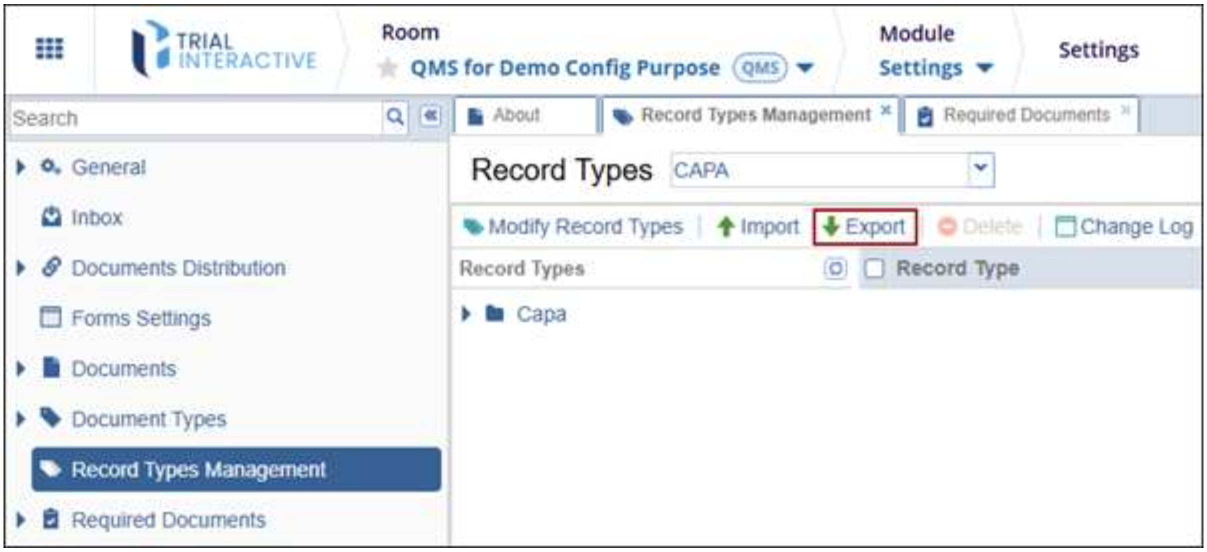

6. Once the data is successfully imported, the Import window displays the success message.



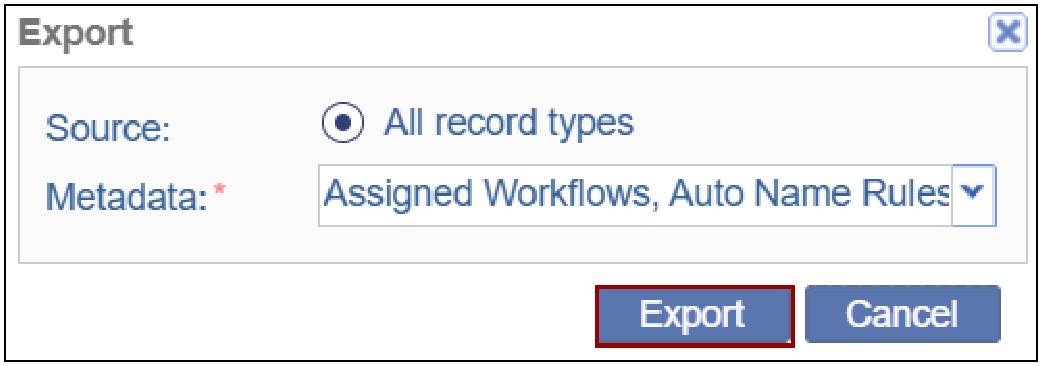
## Export

To export the record types, follow the steps below.

1. From the Settings module > Record Types Management, select a parent record type and click on the 'Export' button from the top menu bar.

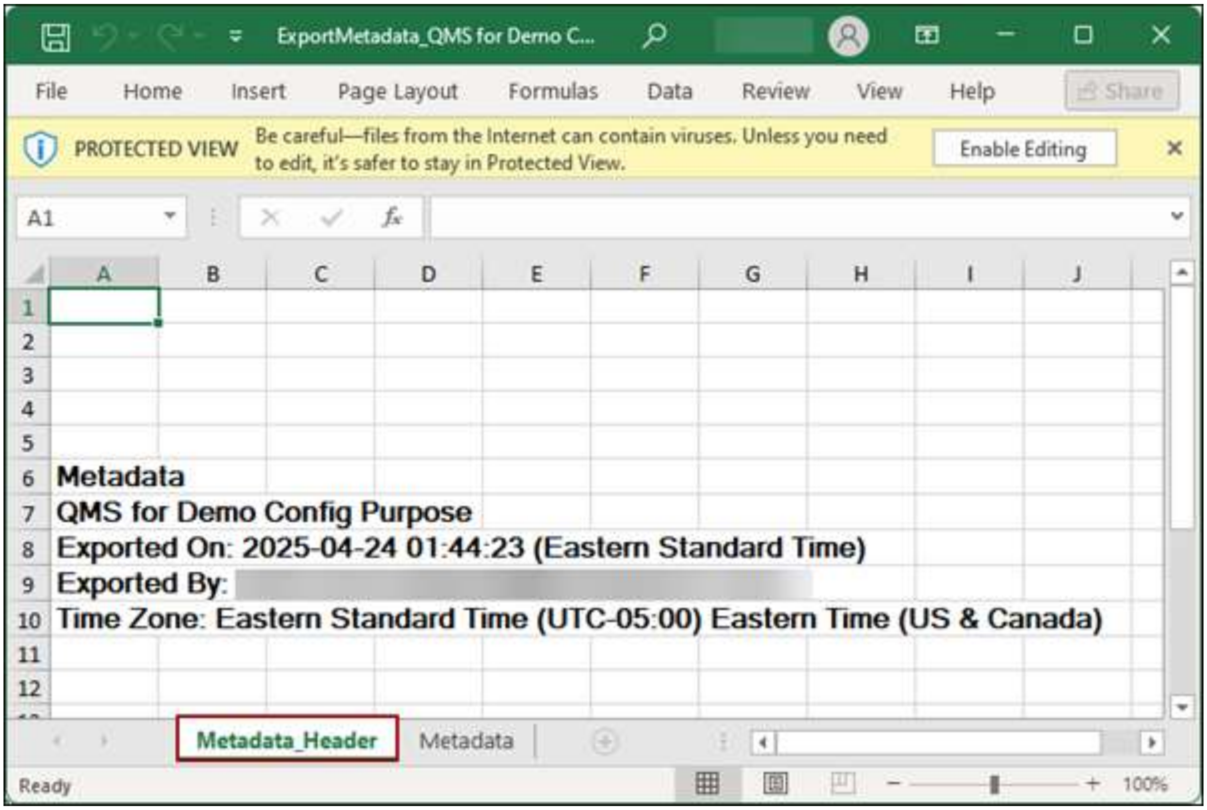


2. On the Export dialog box, add the metadata fields from the dropdown options and click on the 'Export' button.

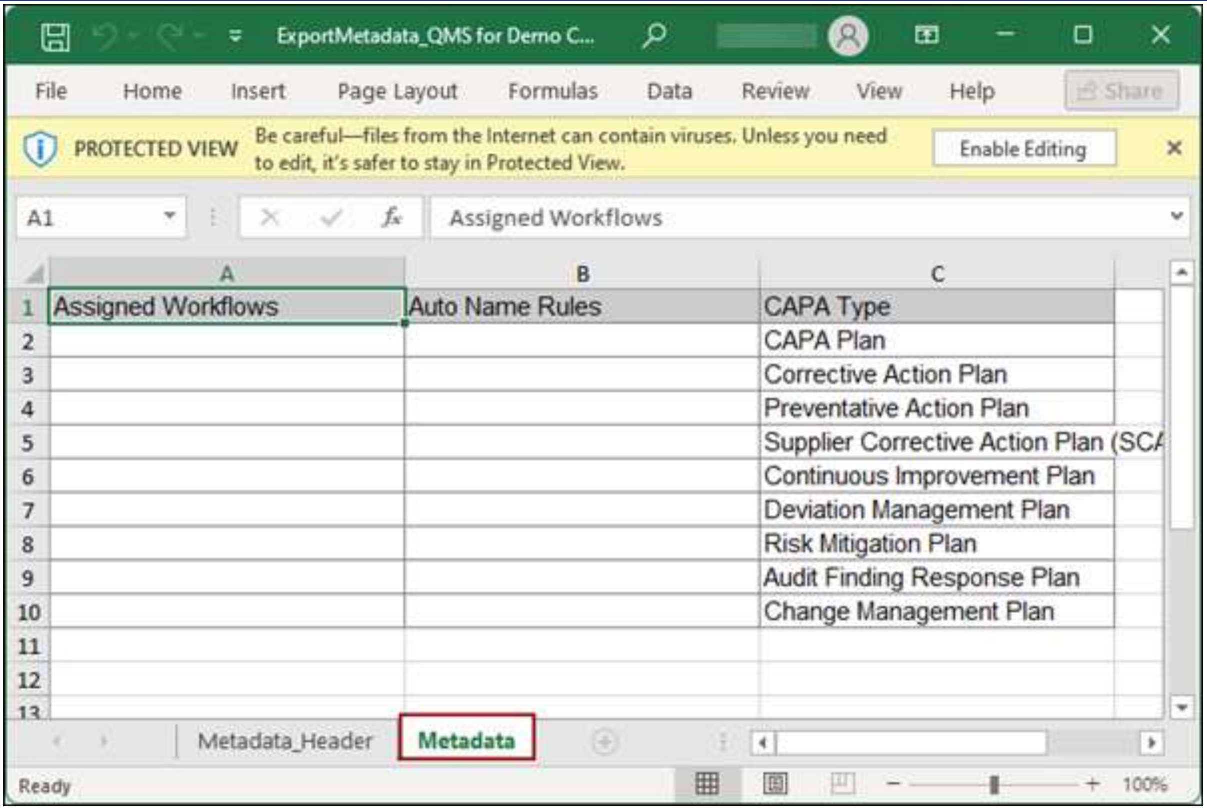


3. Click on the 'Get Job Result' button on the Exporting metadata dialog box and download the file into the local system.

4. On the downloaded file, click on the ‘Metadata_Header’ tab to view details like Room Name, Exported On, Exported By, and Time Zone.



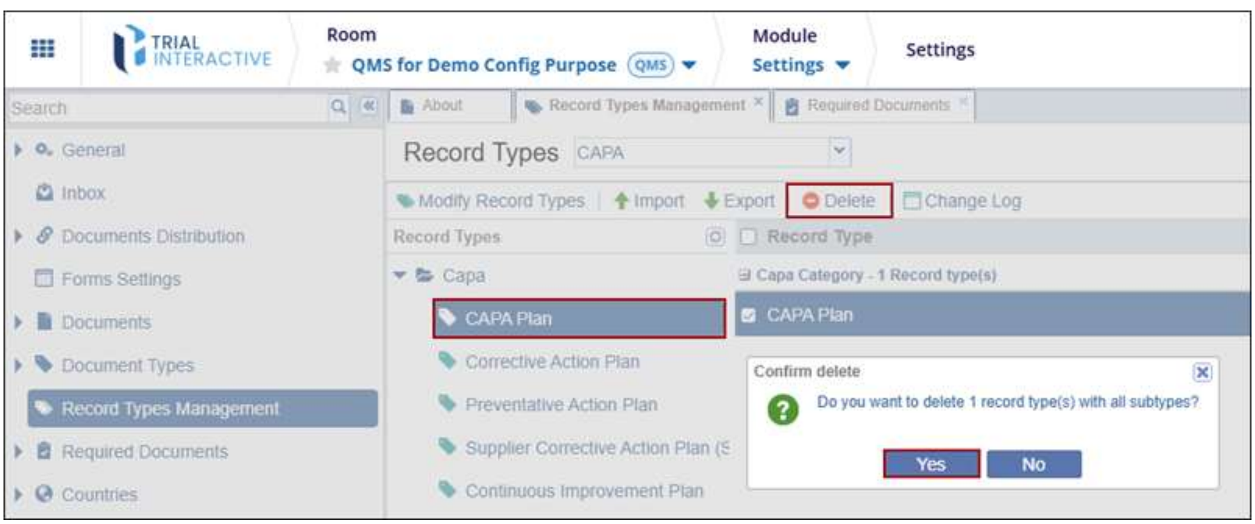

5. Click on the ‘Metadata’ tab to view the details about the record types.




## Delete

To delete a record type along with its sub-types, follow the steps below.

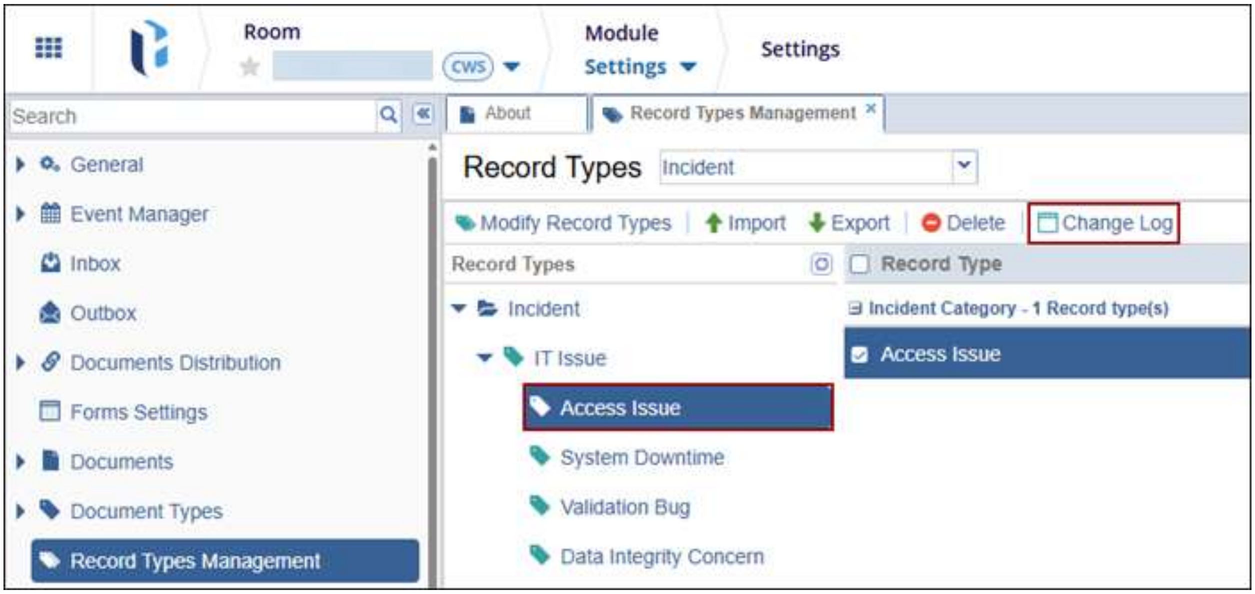
1. Select a parent record type and click on the 'Delete' button from the top menu bar.
2. Click on the 'Yes' button on the confirmation pop-up to confirm the record types and sub-types deletion.



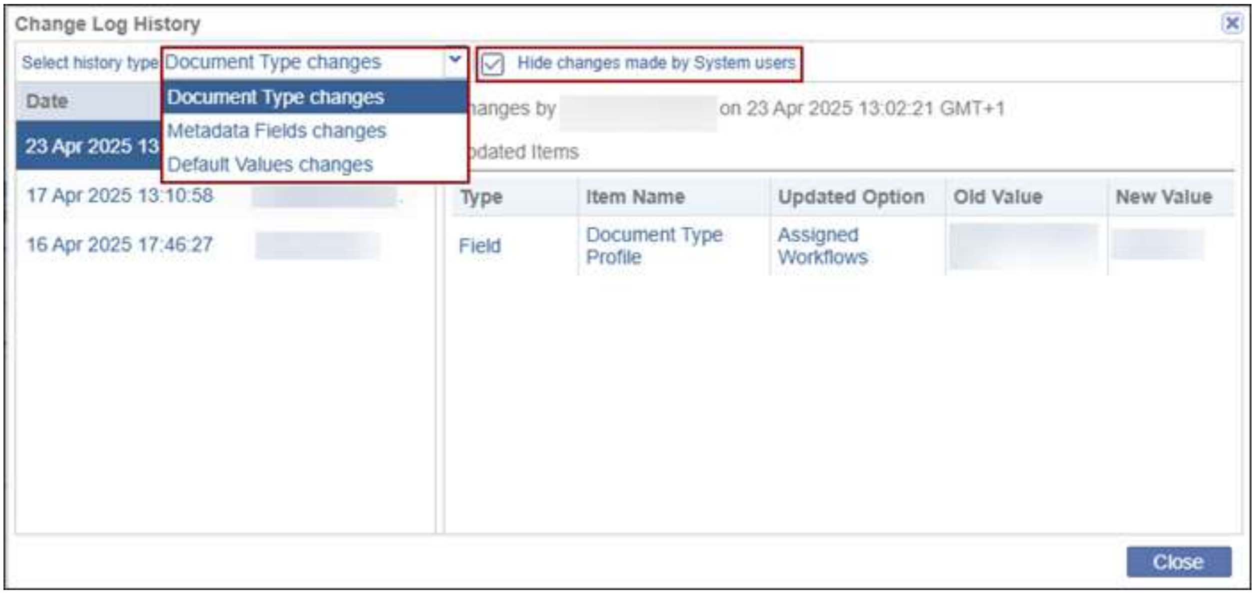
## Change Log

To view the change log history, follow the steps below.

1. Select a record type by expanding categories and associated sub-categories, and click on the 'Change Log' button from the top menu bar.



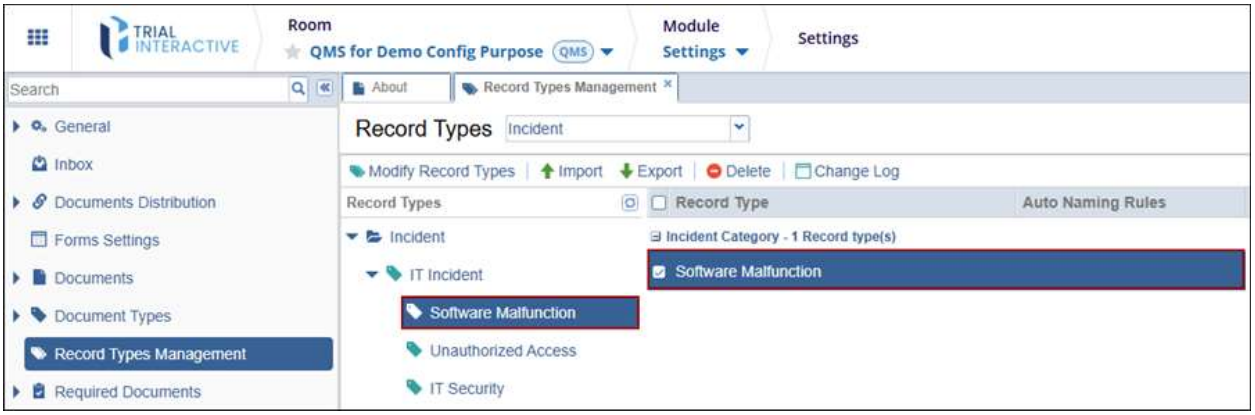
2. On the Change Log History window, select a history type from the available dropdown options.
3. Check or uncheck the 'Hide Changes made by System Users' checkbox to hide or display the changes made by Super Admins, respectively.



## Record Type Profile

To configure the record type profile, follow the steps below.

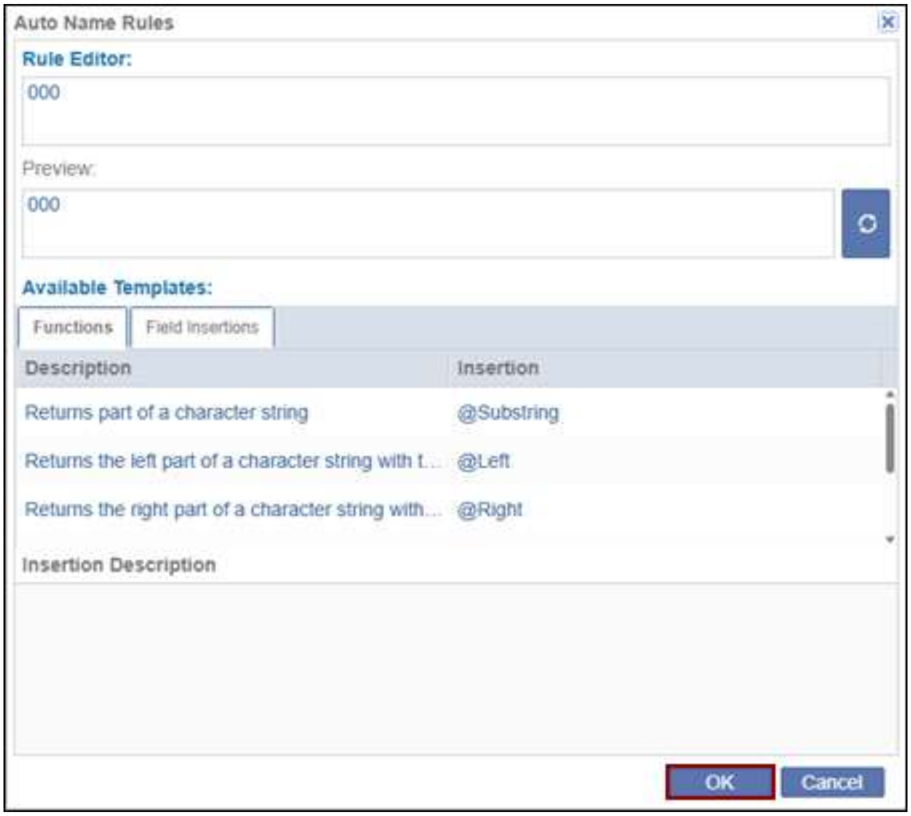
1. Select a record category i.e., Incident, CAPA and Action Item, etc., expand the parent and sub-folders, and select the desired record type.



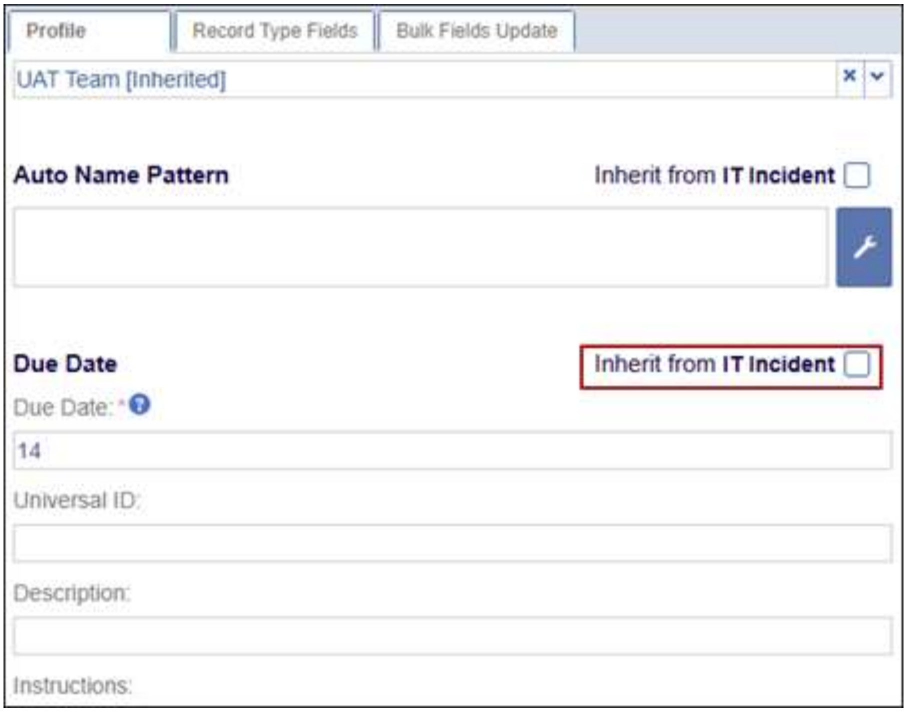

2. Click on the Profile tab, navigate to the Process Configuration section, and select a team from the available dropdown options.


3. Uncheck the parent record type checkbox to configure the Auto Name Pattern and click on the wrench icon.


4. On the Auto Name Rules window, add the necessary details in Rule Editor and select the required options from the Functions and Field Insertions from the Available Templates section.
5. Click on the 'OK' button once the necessary configurations are done.



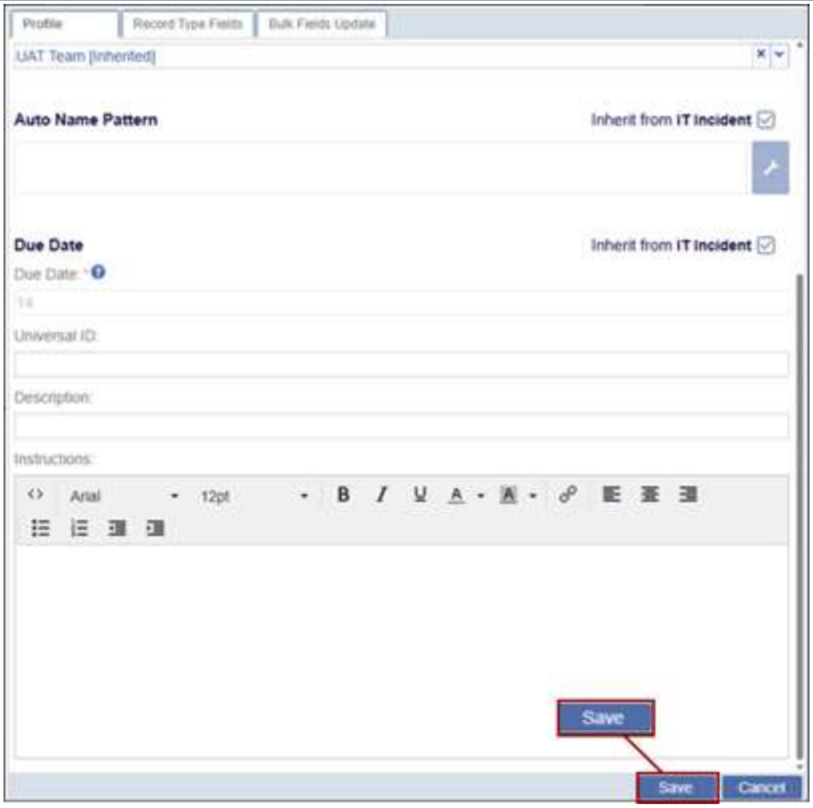
6. Uncheck the parent record type checkbox to configure the Due Date and enter the number of days in the field.




Note: If the checkbox is enabled, the record type will inherit the configurations from its parent record type.

7. Additionally, add the following details and click on the 'Save' button at the bottom.

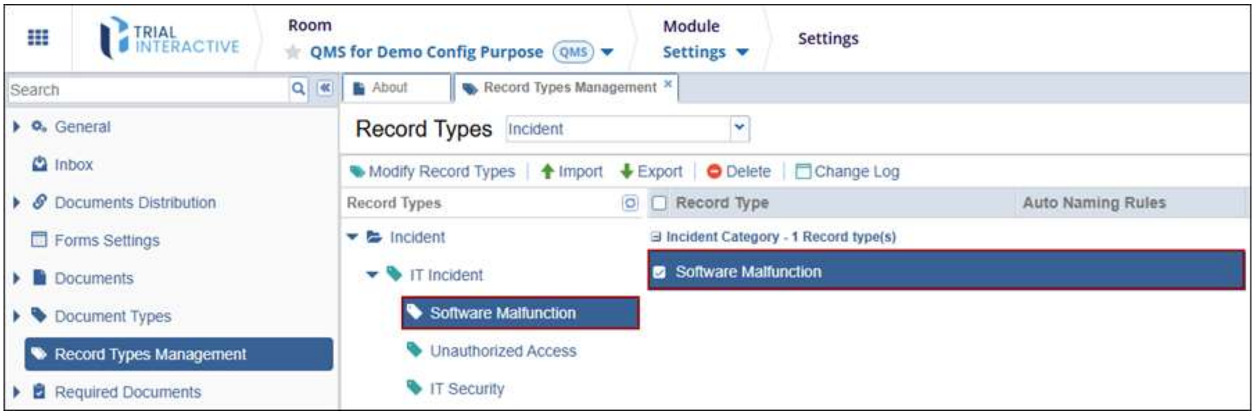
   a. Short Name
   b. Universal ID
   c. Description
   d. Instructions


Profile
Record Type Fields
Bulk Fields Update
UAT Team [Inherited]
Auto Name Pattern
Inherit from IT Incident
Due Date
Inherit from IT Incident
Due Date:
Universal ID:
Description:
Instructions:
Arial
12pt
Save
Save
Cancel

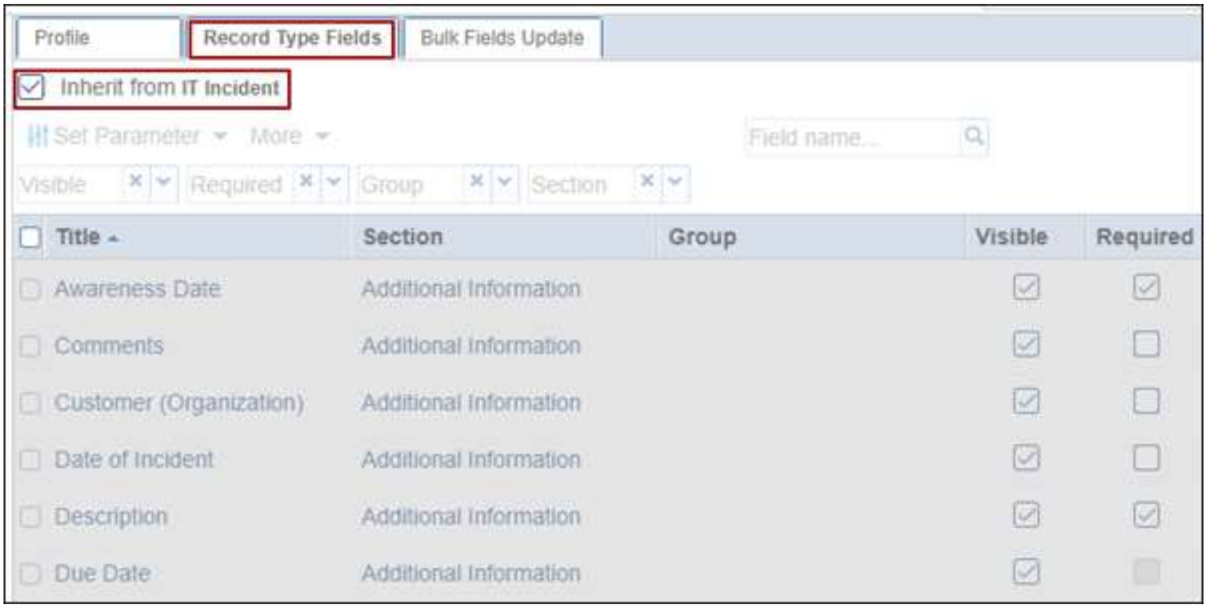
### Record Type Fields

To configure the record type fields, follow the steps below.

1. Select a record category i.e., Incident, CAPA and Action Item, etc., expand the parent and sub-folders, and select the desired record type.

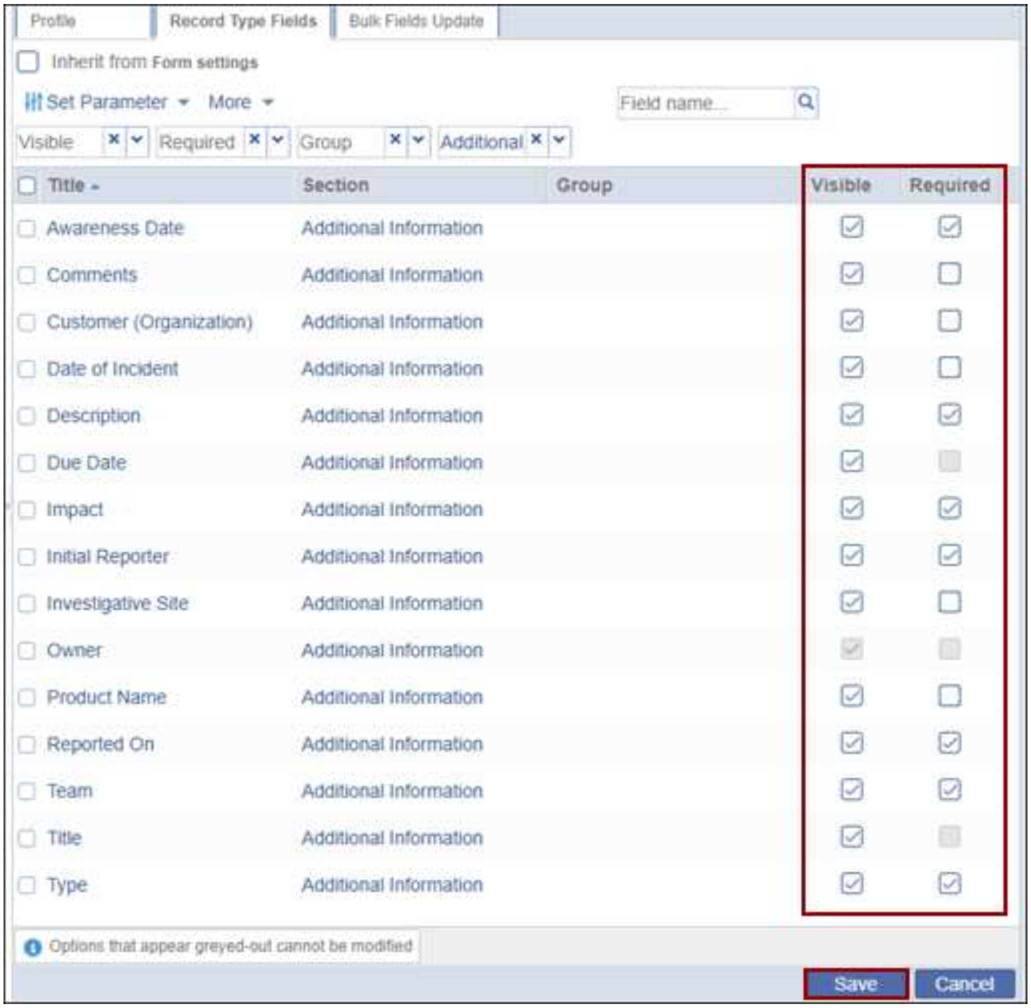


2. Click on the 'Record Type Fields' tab and uncheck the 'Inherit from (parent record)' checkbox.



Note: If the 'Inherit from (parent record)' checkbox is checked, the record type will inherit the same configurations of its parent record.

3. Check or uncheck the ‘Required’ and ‘Visible’ checkboxes to determine whether the field should be mandatory and/or visible, respectively and click on the Save button.



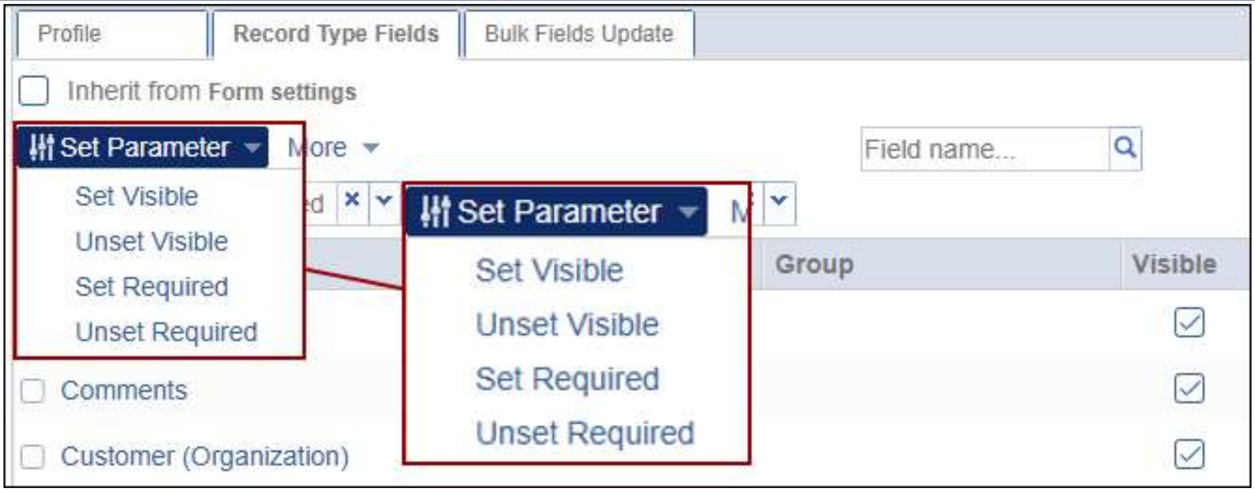

### *Additional Record Type Field settings*

Admin users can configure the following settings within the ‘Record Type Field Settings’ tab.

<u>Set Parameter</u>

To set a parameter, follow the steps below.

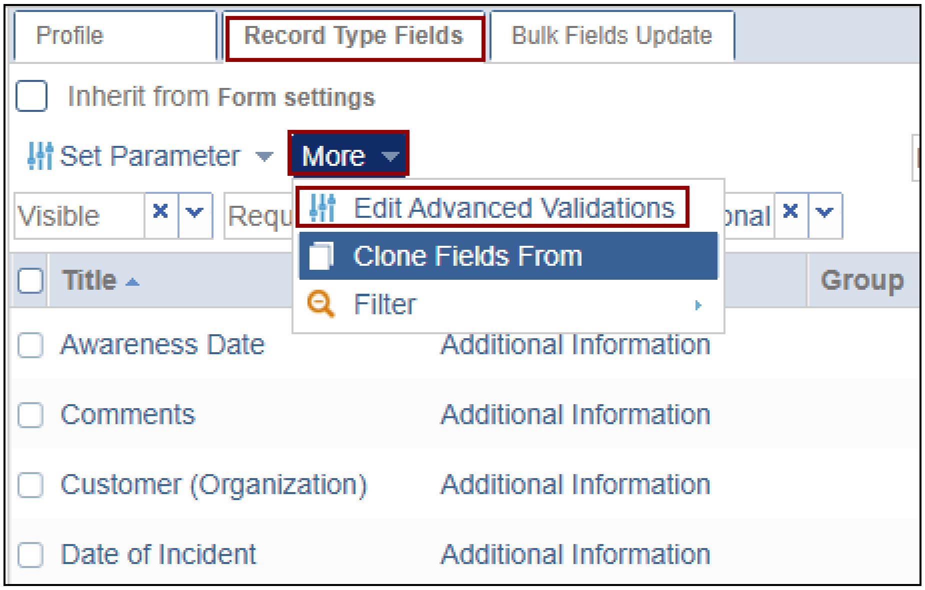
1. Within the ‘Record Type Fields’ tab, click on the Set Parameter dropdown.
2. Select the option from the available dropdown options.
    a. Set Visible
    b. Unset Visible
    c. Set Required
    d. Unset Required



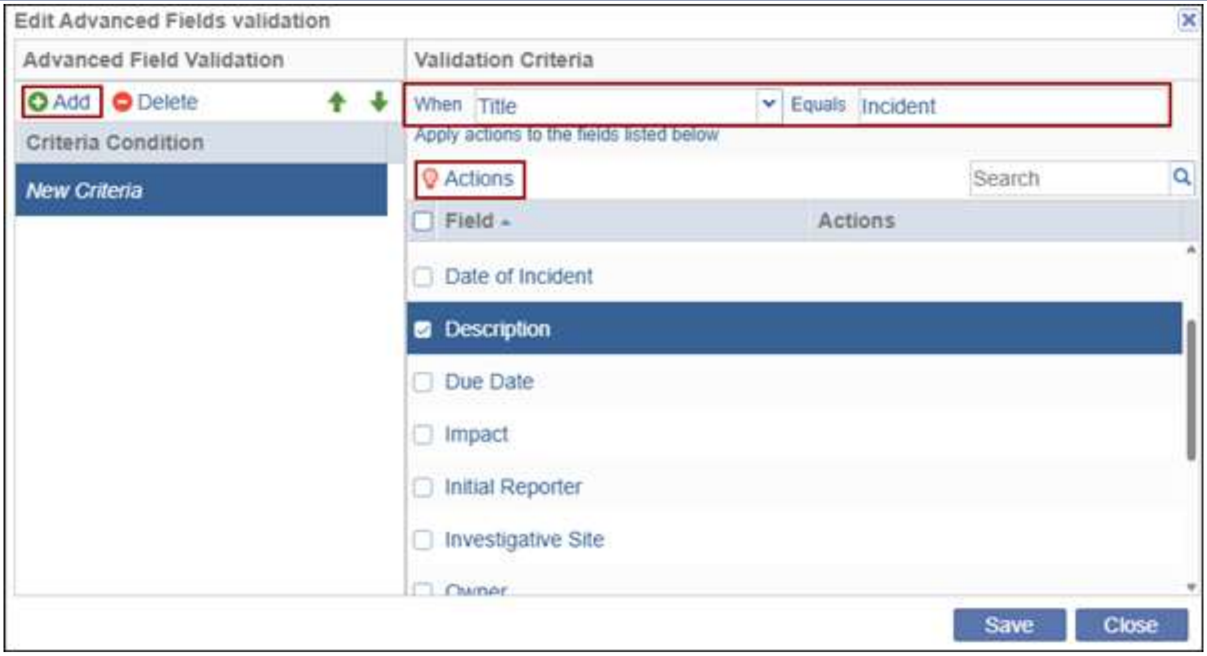

Edit Advanced Validations

To edit advanced validations, follow the steps below.

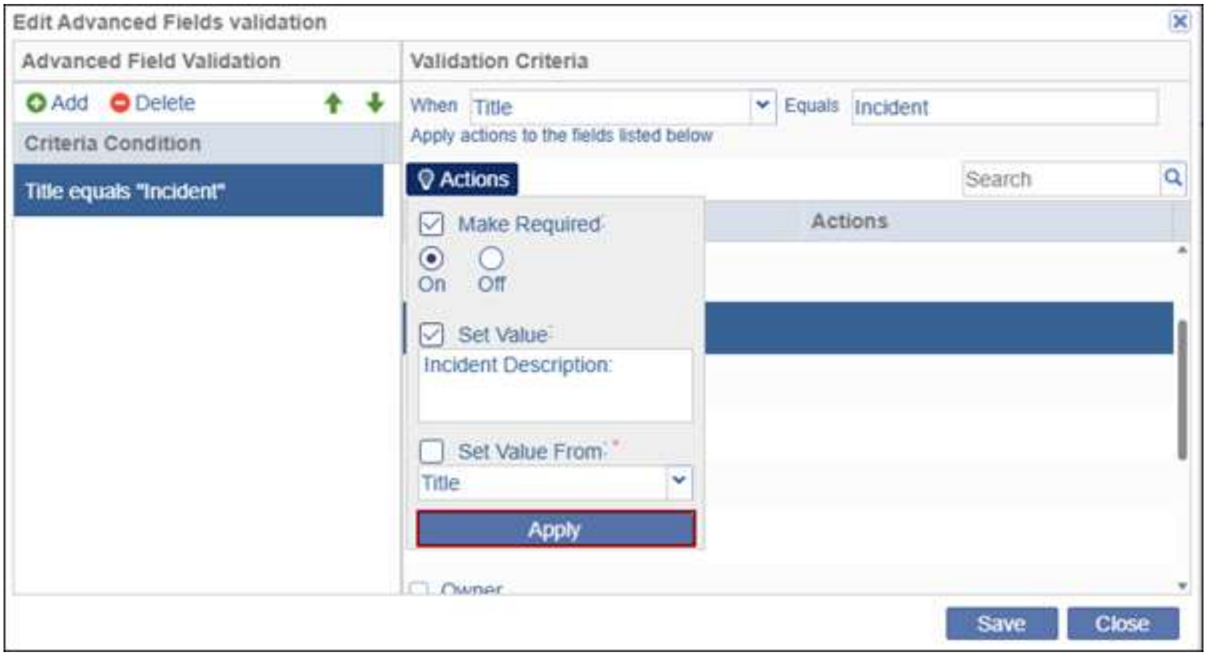
1. Within the 'Record Type Fields' tab, click on the 'More' dropdown and select the Edit Advanced Validations option.



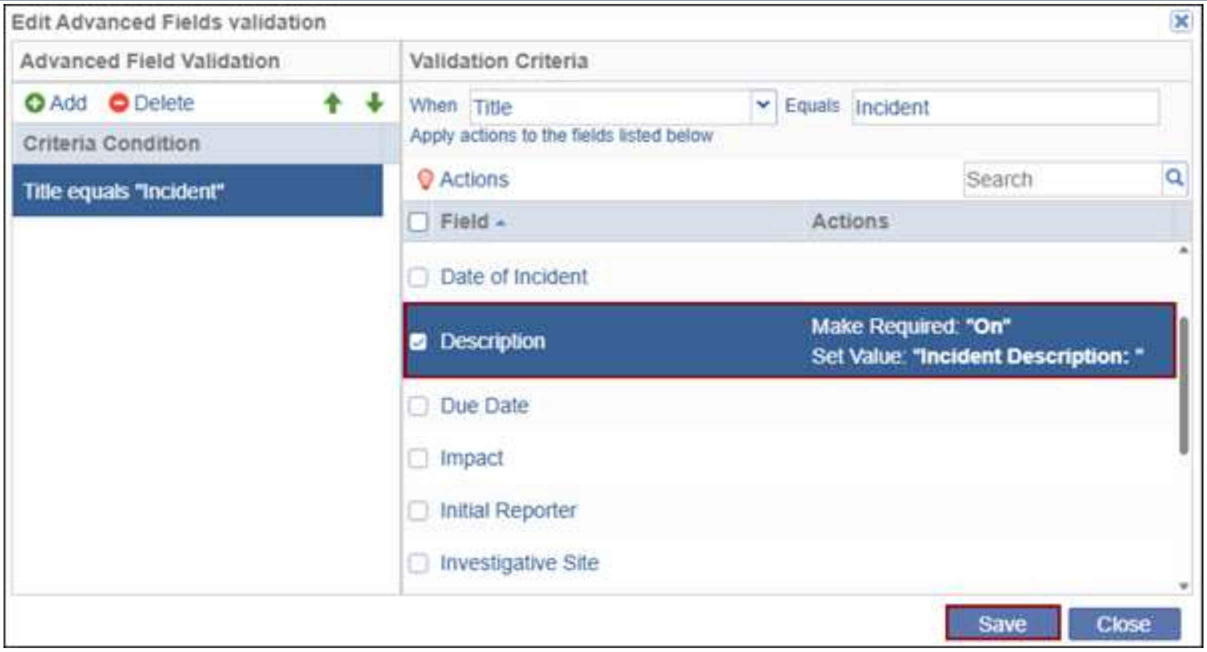

2. On the '**Edit Advanced Field Validation**' screen, click on the '**+Add**' button under the 'Criteria Condition' section.
3. Under the Validation Criteria section, add values for 'When' and 'Equals' criteria fields.
4. Select a field from the list.
5. Click on the '**Action'** button.




6. Configure the necessary actions and click on the Apply button.




7. Once the action is configured, click on the 'Save' button.



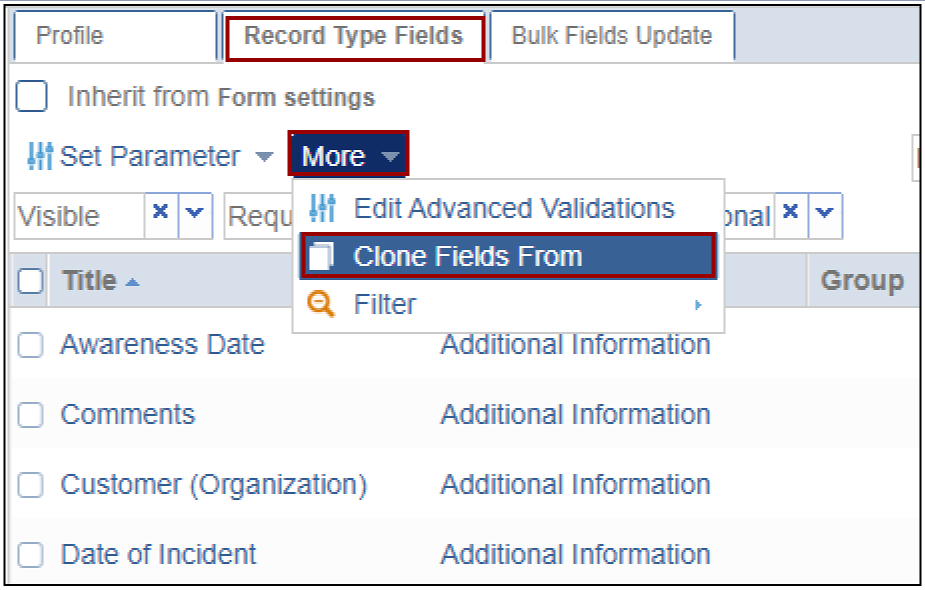

Important

- In the above example, the validation rule is defined as: 'When Title equals Incident, the Description field becomes required and value is set as Incident Description.'
- This means that when a user creates an Incident with the record type, where this validation is applied, the Description field becomes required along with the configured value.

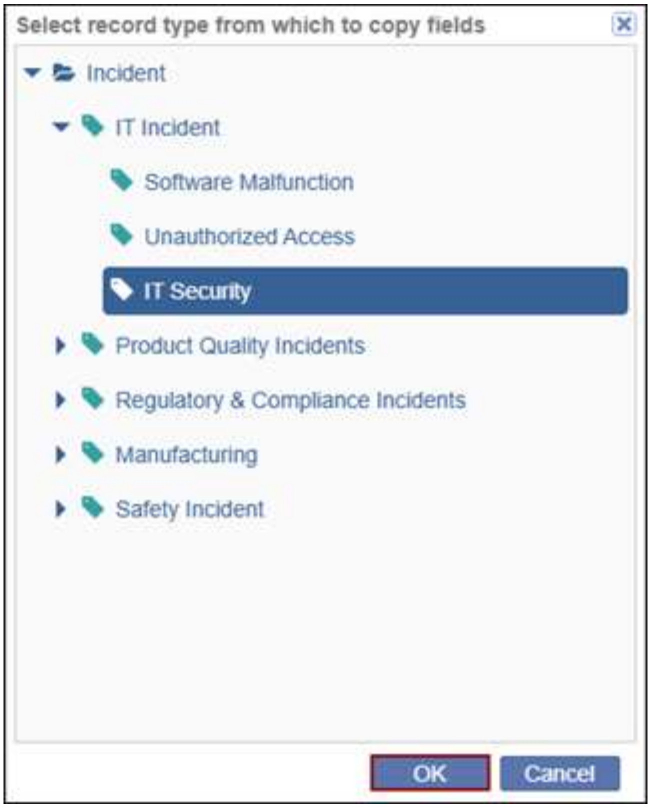
## Clone Fields From

To clone fields from another record type, follow the steps below.

1. Within the 'Record Type Fields' tab, click on the 'More' dropdown and select the 'Clone Fields From' option.




2. Select a record type to copy the fields from and click on the ‘OK’ button.

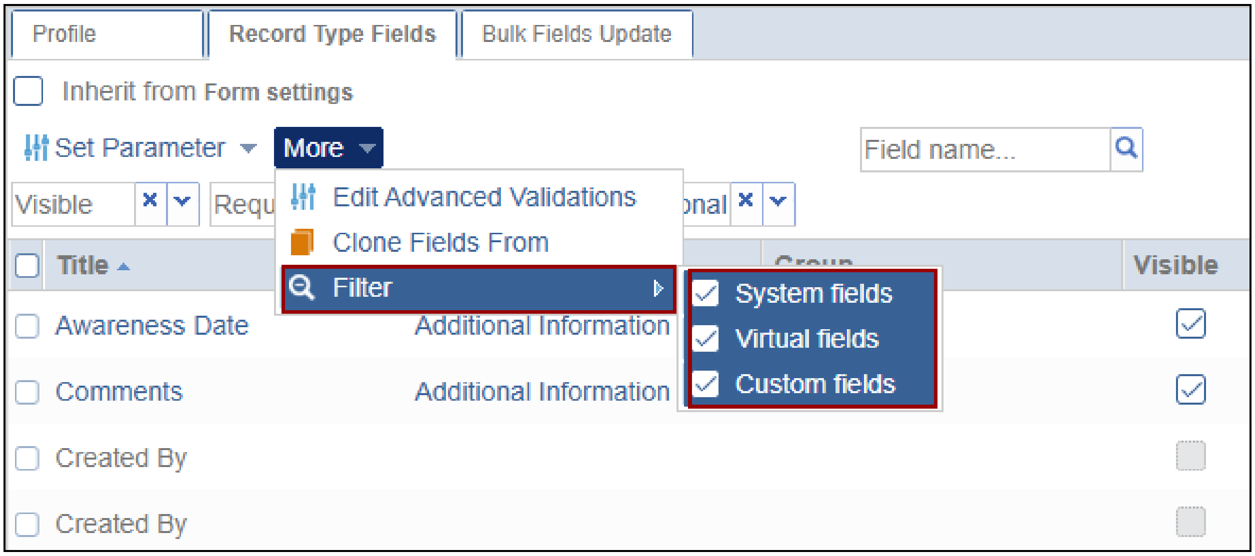


Filter

To configure filters, follow the steps below.

1. Within the 'Record Type Fields' tab, click on the 'More' dropdown and select the 'Filters' option.
2. Check or uncheck the checkbox for the following options.

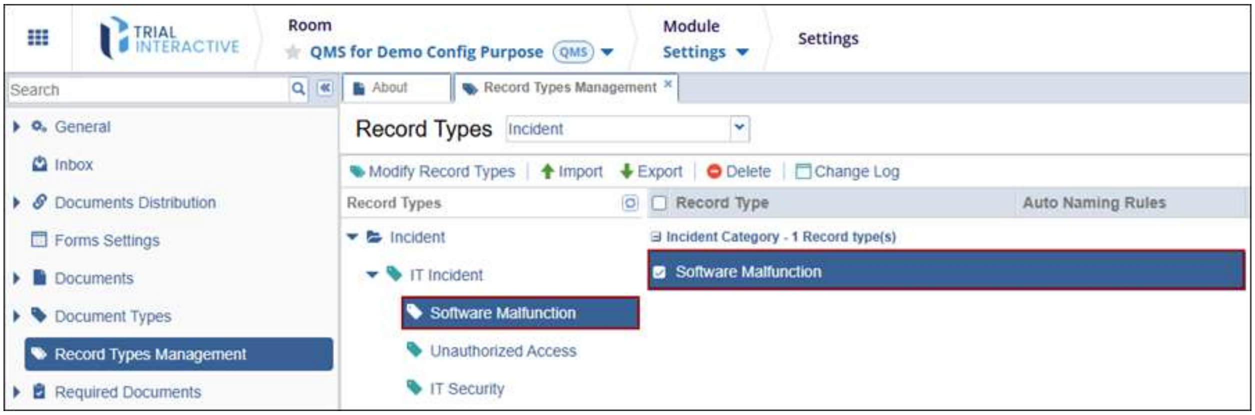
    a. System Fields
    b. Virtual Fields
    c. Custom Fields



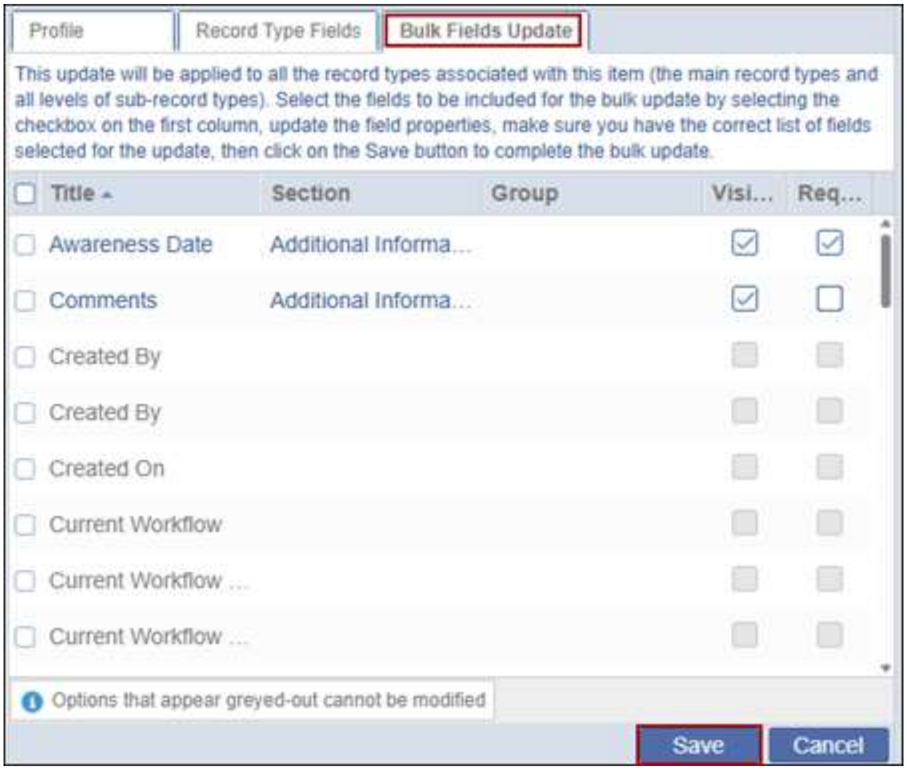

## Record Type Bulk Field Updates

To update the record type fields in bulk, follow the steps below.

1. Select a record category i.e., Incident, CAPA and Action Item, etc., expand the parent and sub-folders, and select the desired record type.



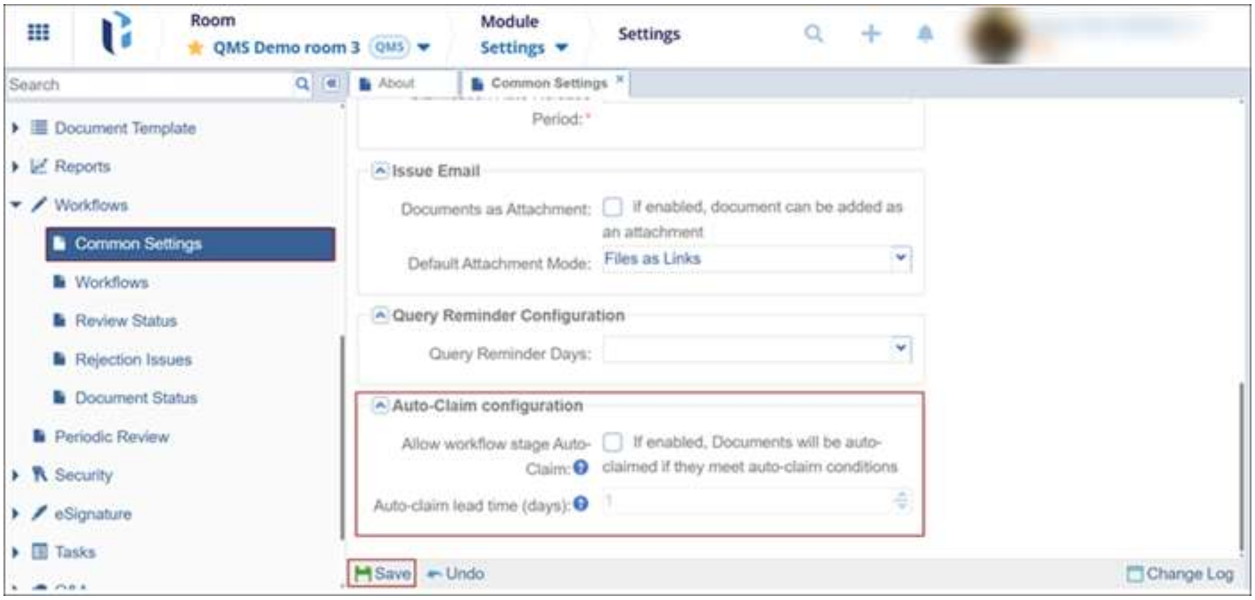
2. Click on the 'Bulk Fields Update' tab and check and/or uncheck the 'Required' or 'Visible' checkboxes to control the fields' visibility and click on the Save button.



## Auto-Claim Configuration

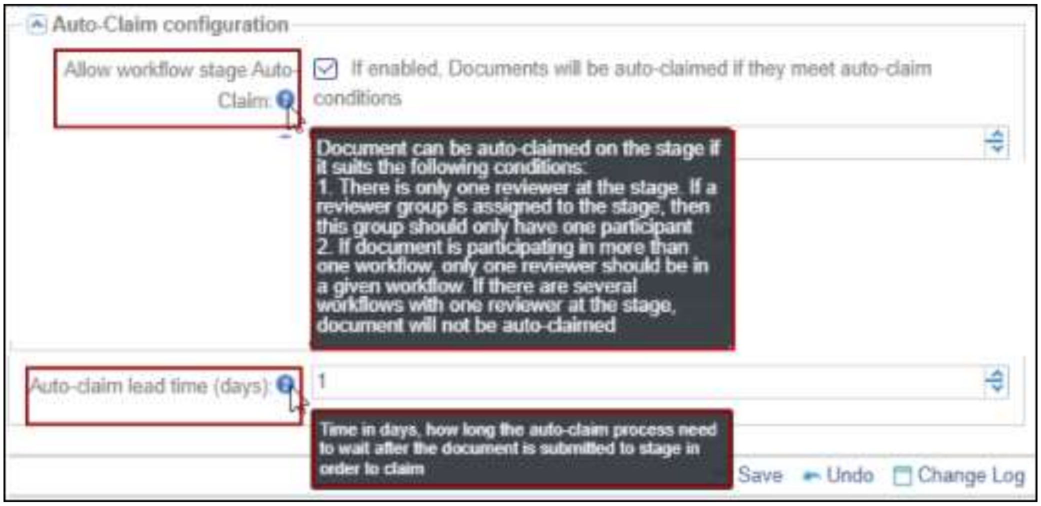
To configure the auto-claim configuration settings, follow the steps below.

1. Navigate to the Settings module > Workflows > Common Settings.
2. Check the checkbox next to the 'Allow Workflow stage Auto-Claim' setting.
3. Enter the number of days after which, if the reviewer has not claimed the documents, they will be auto-claimed by the system and assigned to the reviewer.
4. Click on the Save button.




Important

- If there is more than one authority in a particular stage, any one authority must manually claim the document irrespective of the Auto-Claim Configuration settings.
- Click on the tooltip to view the settings description.



# INCIDENT

This section outlines the complete lifecycle of an Incident, from initiation to closure. The Incident workflow is divided into three key stages:

1. Assessment Stage
2. Investigation Stage
3. Quality Approver Stage

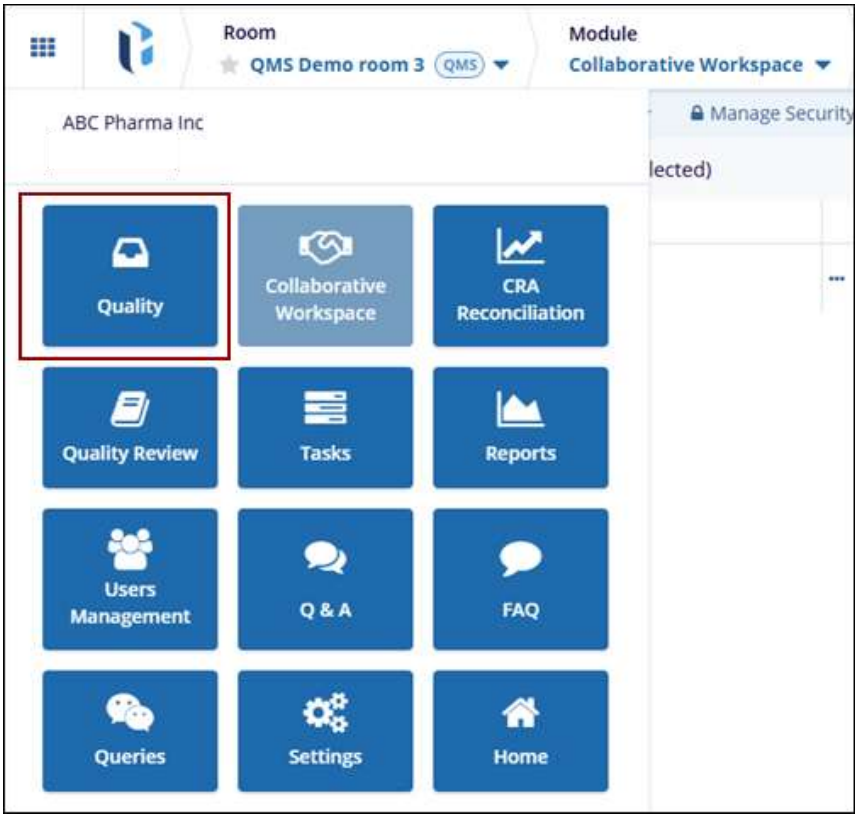
Note: The workflow configured for this Incident is a simplified version, intended to help users easily understand the basic process. In actual use, the workflow and process may vary based on workflow and configuration, and specific business requirements. To understand the Workflow Setting, click here.

## Create Incident

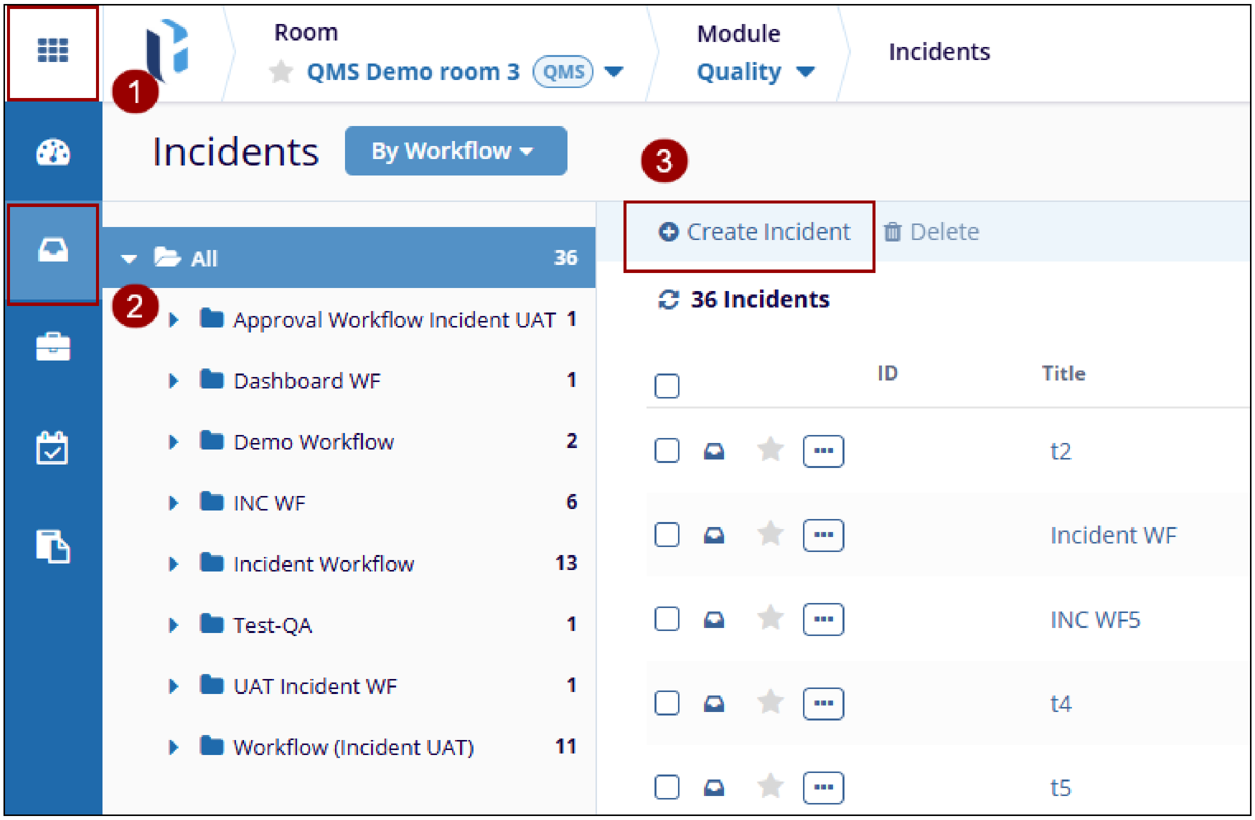
This section explains how to create an Incident in the Quality Module. To create an Incident, the 'Create Incident' Action should be added to the user in the User Management Module.

Steps to Create an Incident in the Quality Module:

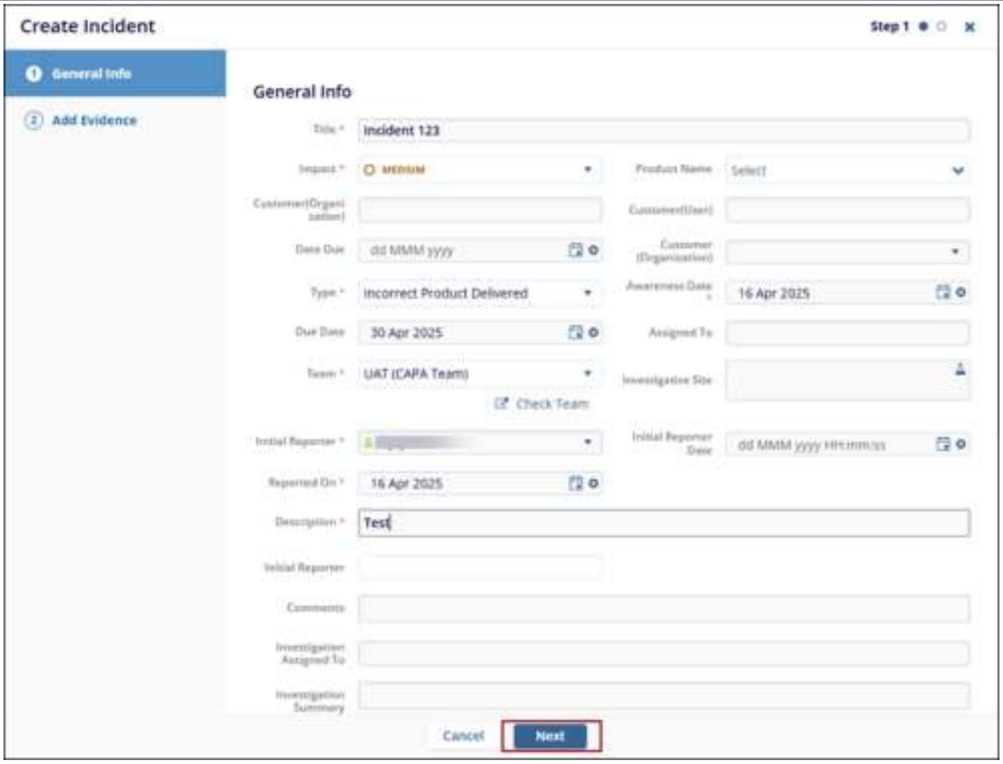
1. From the Home Page, navigate to the room where to perform this activity.
2. Click the Waffle Menu located at the top-left corner of the screen, then select Quality Module. The user will be redirected to the Quality Module's Dashboard screen.



3. In the left navigation panel, click the Incidents icon, which will open the Incident screen.
4. On the Incidents screen, click the + Create Incident button.

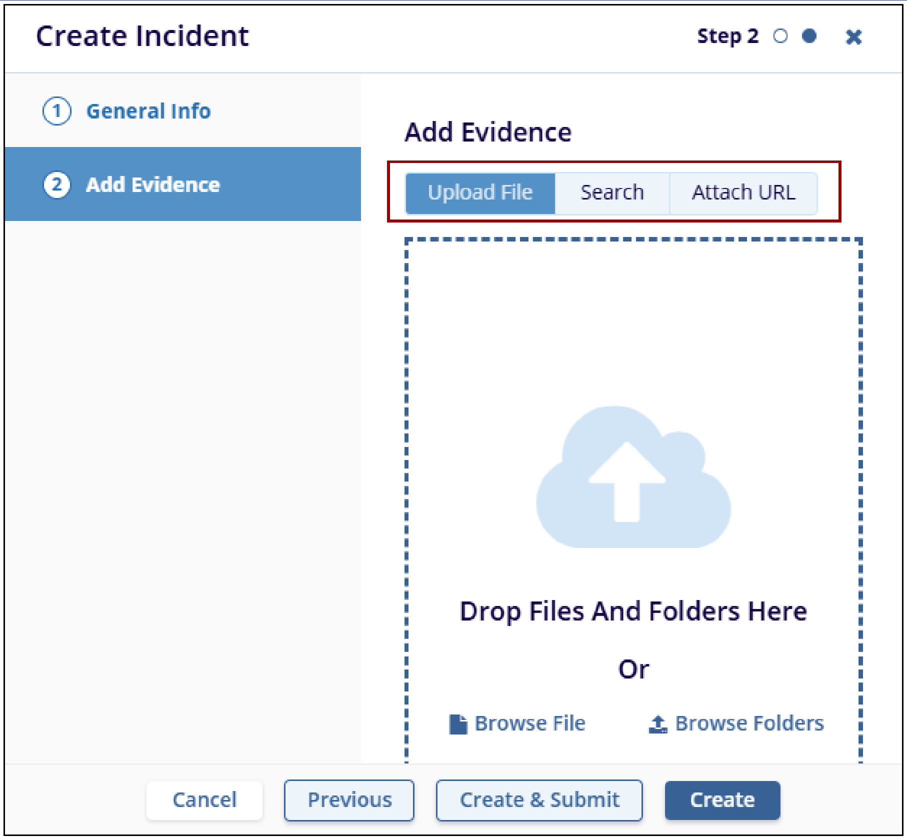



5. Fill in the mandatory fields such as Title, Impact, Type, Due Date, Team, Initial Reporter, Reported Date, Description and Awareness Date as shown in the screenshot below. After completing all required fields, click Next.

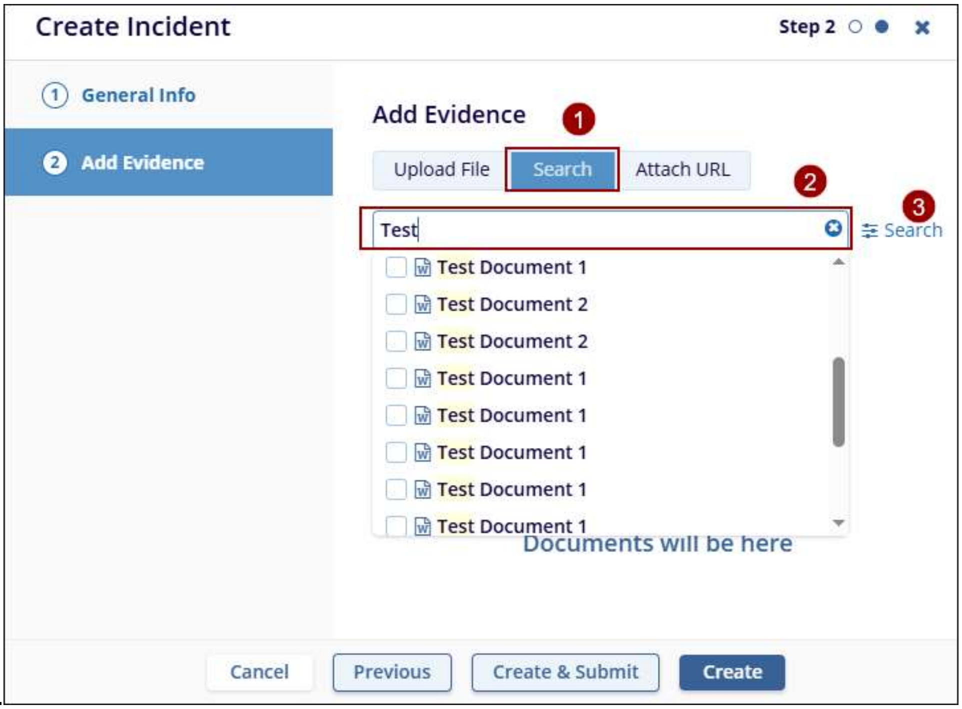


Note: Users can make the changes in the metadata and Evidence until it is submitted.

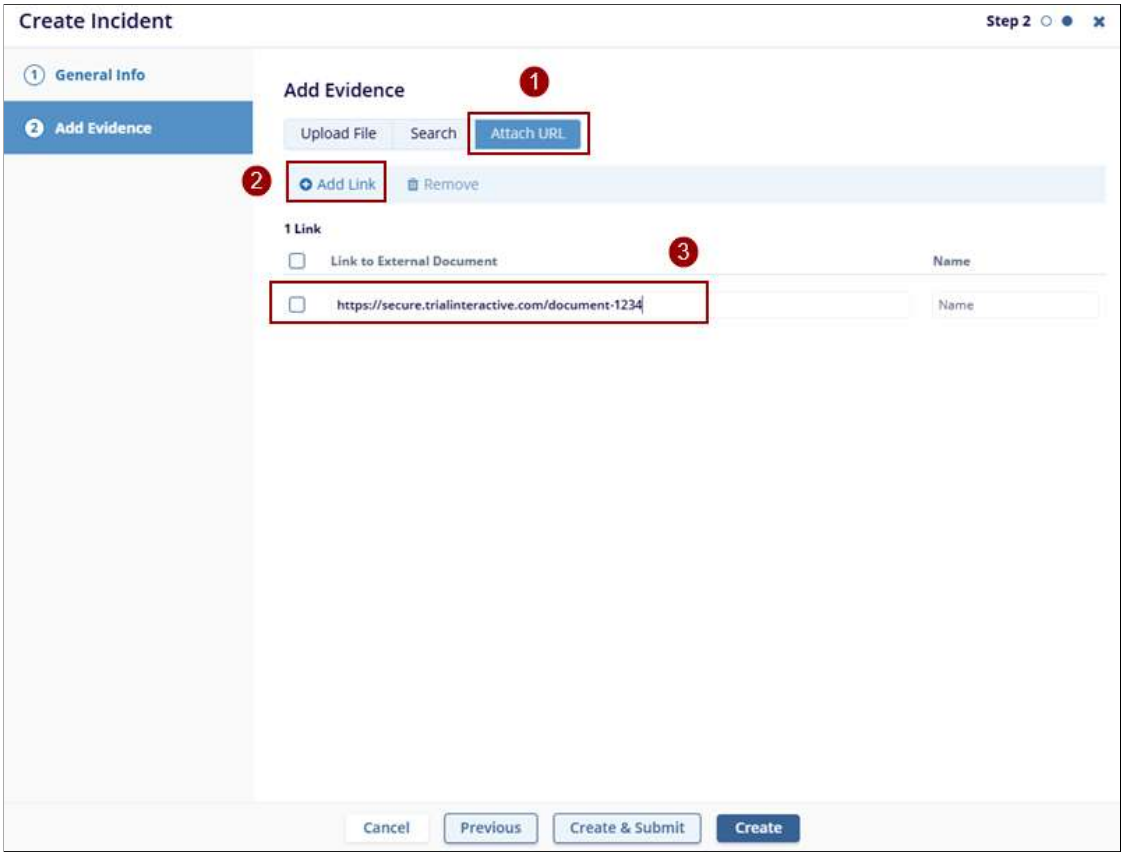
6. In the Add Evidence screen, users have three options to Add Evidence.
7. The First Option is Upload File. To use this option, click '**Upload File**' and drag and drop files or browse the folders to select the documents.




8. The second option is search. To use this option, click the Search tab.
9. Enter a minimum of 3 characters in the search bar (e.g., 'Test') and select the document(s) from the list of search results.

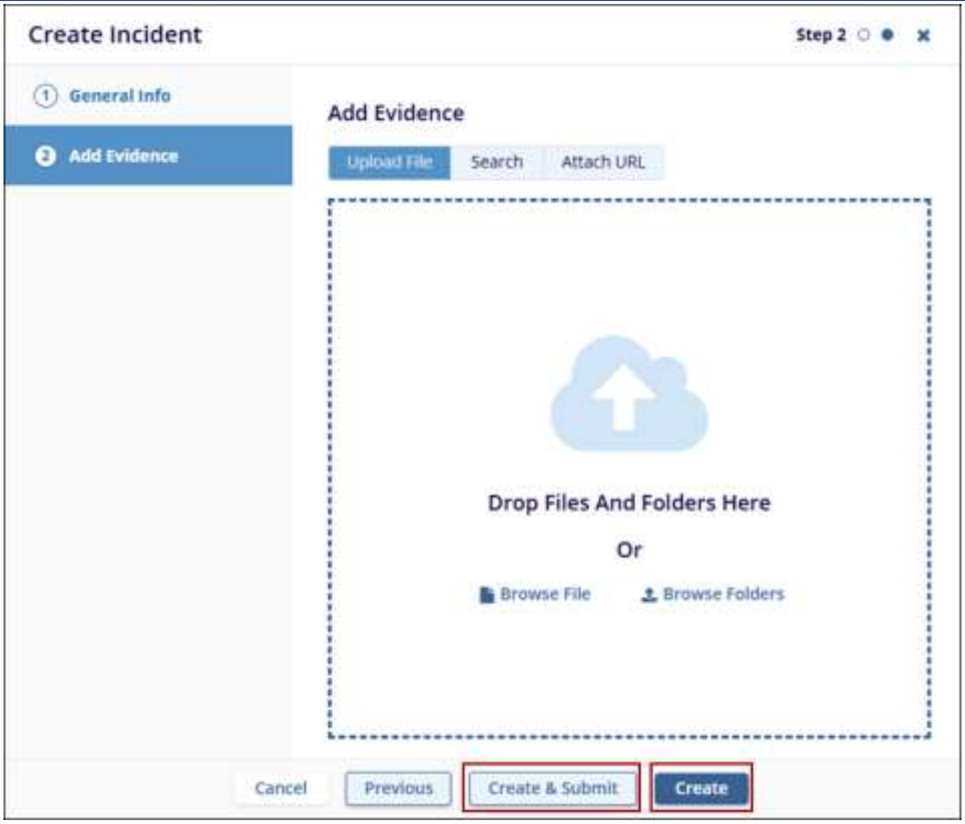


10. The third option is to '**Add a URL'** to this Incident. Click the Attach URL tab, click Add Link, paste the desired URL, and provide a name or description for the link.




11. Once evidence is added, click Create to save the incident. The user will receive the successfully created pop-up at the top right side of the screen, and the Incident will be saved in 'Draft' status in the grid.

Note: To directly submit the Incident after creation, click Create & Submit. This will bypass the intermediate steps. To continue from the submission step, click here to navigate to the *Incident Submission* section.




## Submit Incident

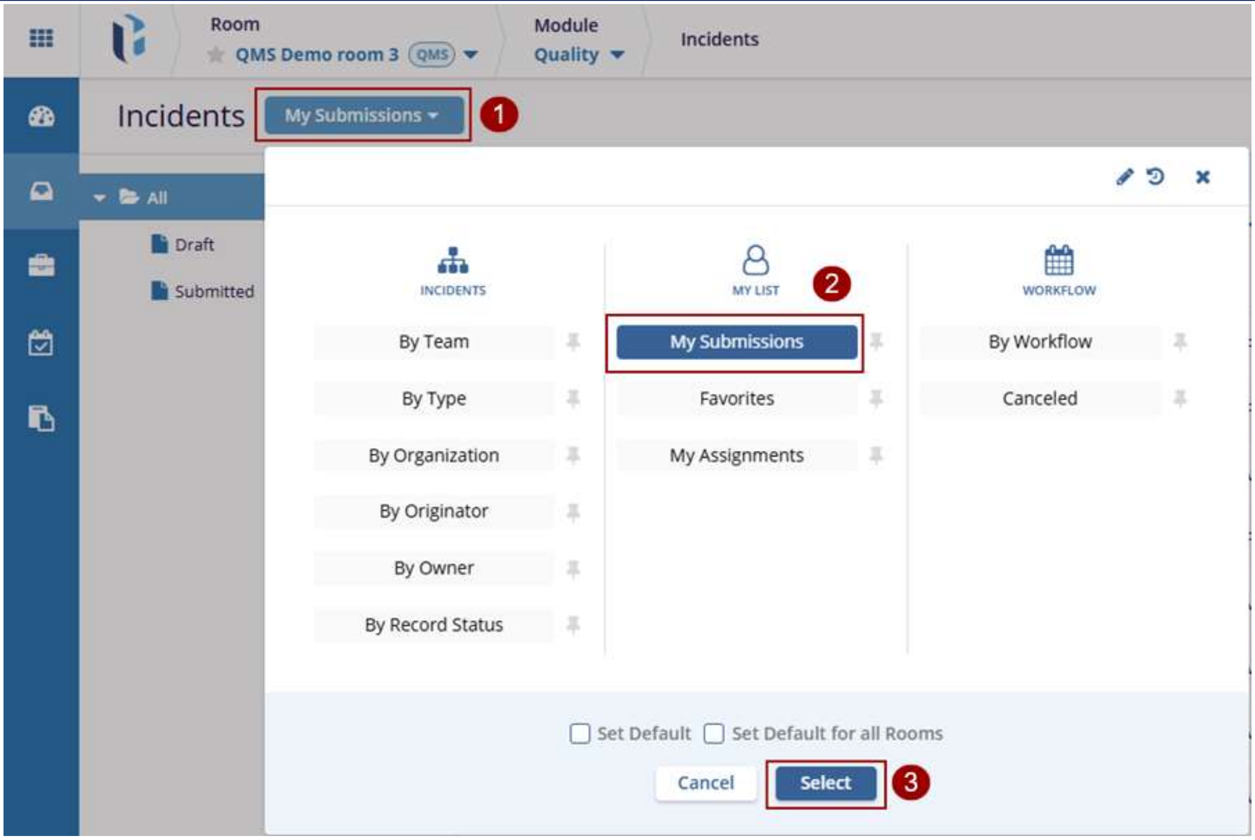
Once the Incident is created, it will appear under the assigned Team in Draft status within the grid.

To submit the Incident for review (Draft to Submitted), follow the steps below.

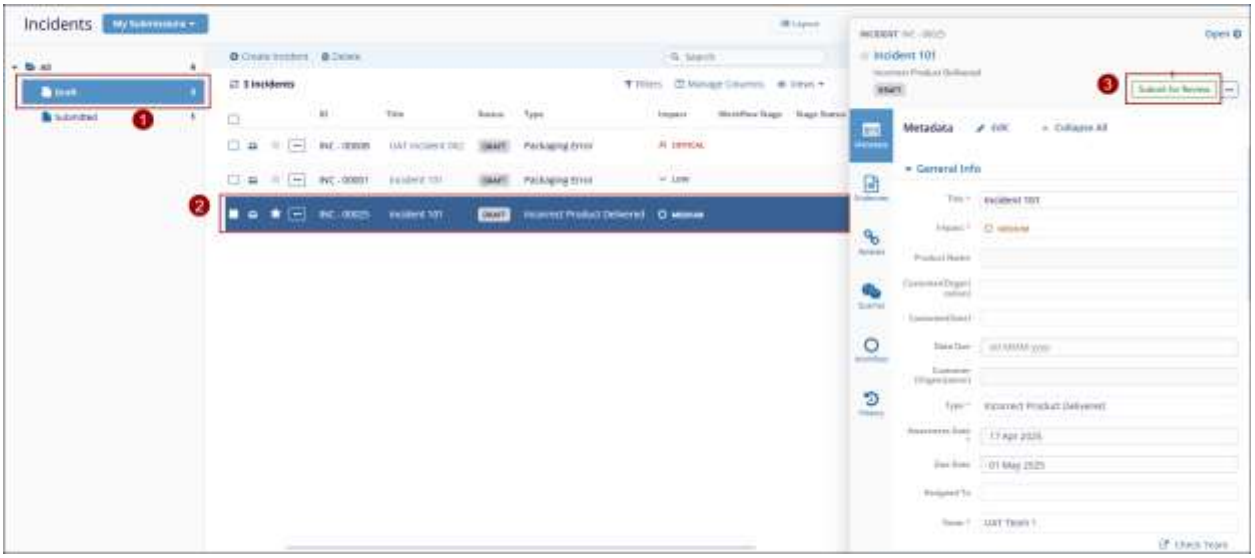
1. On the Incidents screen, click the dropdown next to the current view (e.g., *My Submissions*) to open the view selection panel.
2. In the view selection panel, go to the My List section and click on My Submissions to filter incidents created by the particular user.

   Note: This process can also be performed using the Team View. Here we are using the 'My Submission' view to cover the '**View by'** Functionality.

3. Click the Select button at the bottom to apply the chosen view.



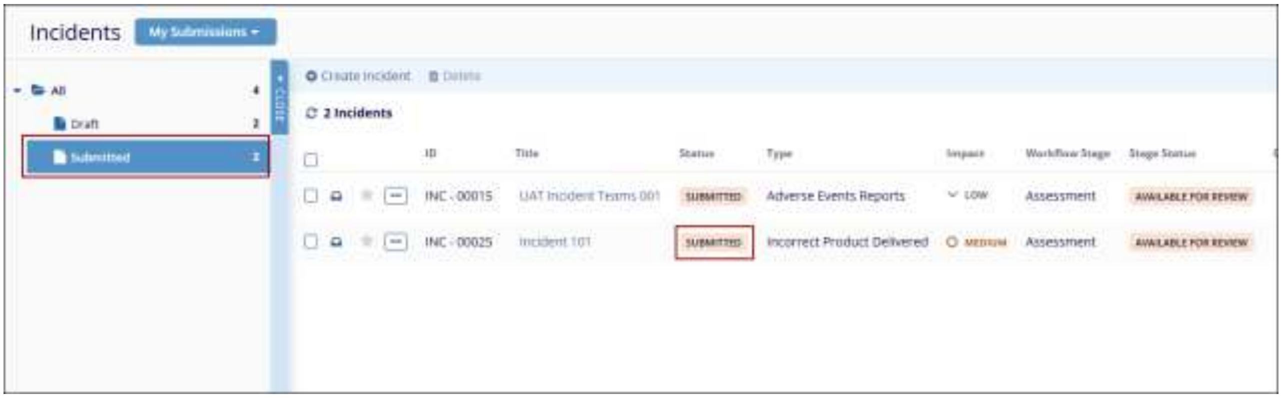

4. From the left sidebar, click Draft to display all incidents currently in draft status.
5. In the grid, locate and click on the specific draft incident to submit for review.
6. The incident details will open on the right panel. Click the Submit for Review button.




7. In the pop-up that appears, optionally add a comment to provide context or additional information.
8. Click the Submit button to confirm, after which the record will be locked for editing and sent for review.


9. After clicking the Submit button, a pop-up window will appear asking the user to select a workflow for the incident.
10. Choose the appropriate workflow from the list and click the Select button to proceed.


11. A success message will appear at the top-right corner of the screen confirming the incident has been submitted.
12. To verify submission, go to the Submitted folder from the left panel under the selected view.
13. The incident will now appear in the list with the Status marked as ‘Submitted’ and a corresponding workflow stage (e.g., *Assessment*).



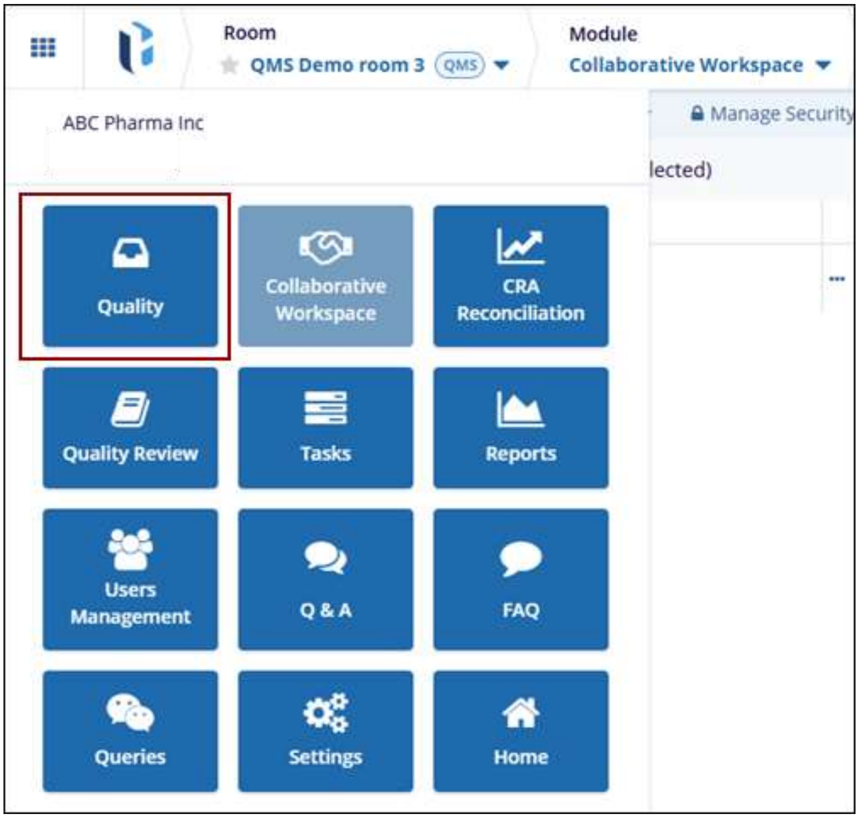
## Claiming the Incident

Once the user (Originator) submits the incident for review. It will proceed further and will be sent to the Process. Once an Incident is submitted by the Originator, it proceeds to the Assessment Stage, where it is assigned to the Process Owner or Supervisor for further action. At this stage, users can perform multiple actions depending on the workflow configuration, such as Claim, Clarify, Approve for Investigation, or Close.

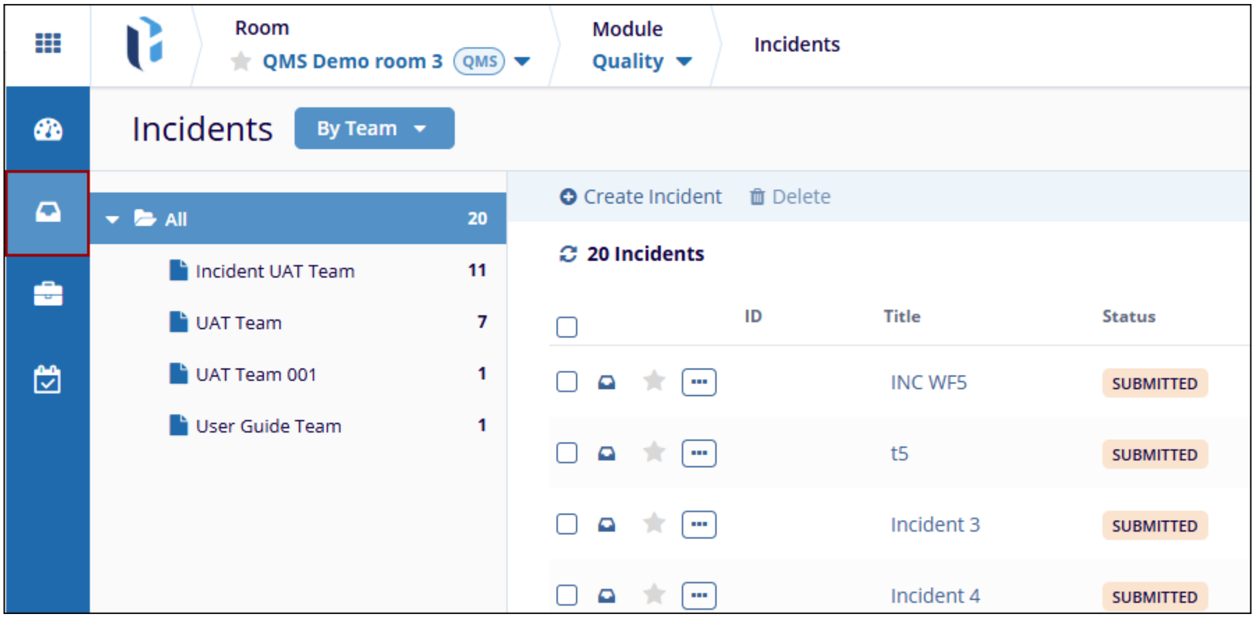
To understand in detail the workflow, please refer to this section: QMS Workflow Settings.

Follow the steps below to claim the incident.

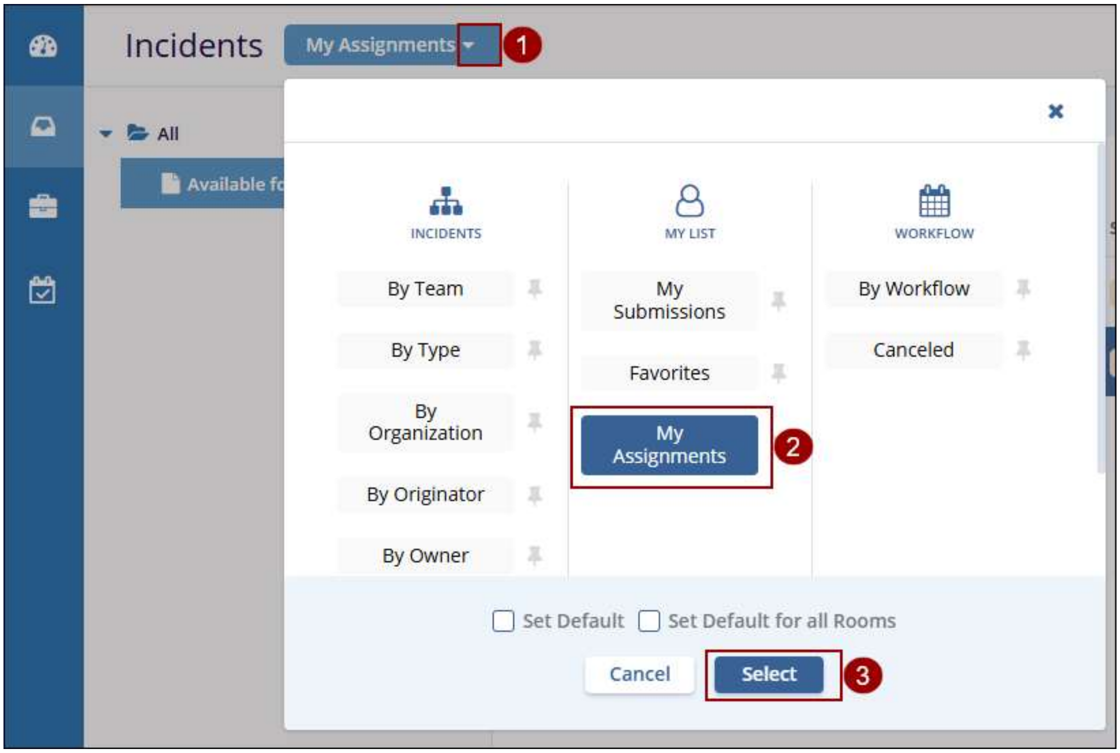
1. To check the Incident that has been Available for Review user (Process Owner) needs to navigate to the Incident in the Quality Module.
2. Click the Waffle Menu located at the top-left corner of the screen, then select Quality Module. The user will be redirected to the Quality Module's Dashboard screen.



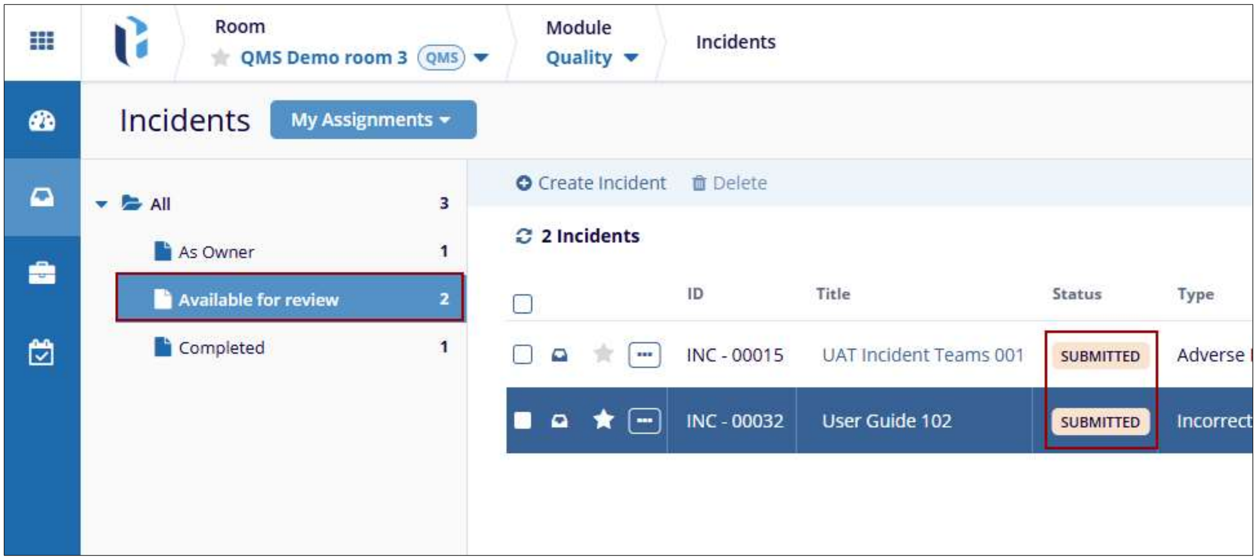
3. In the left navigation panel, click the Incidents icon, which will open the Incident screen. To check the Incident that has been '**Available for Review'**, the user (Process Owner) has multiple options using the view by functionality. By default, it is selected '**By Team'**.



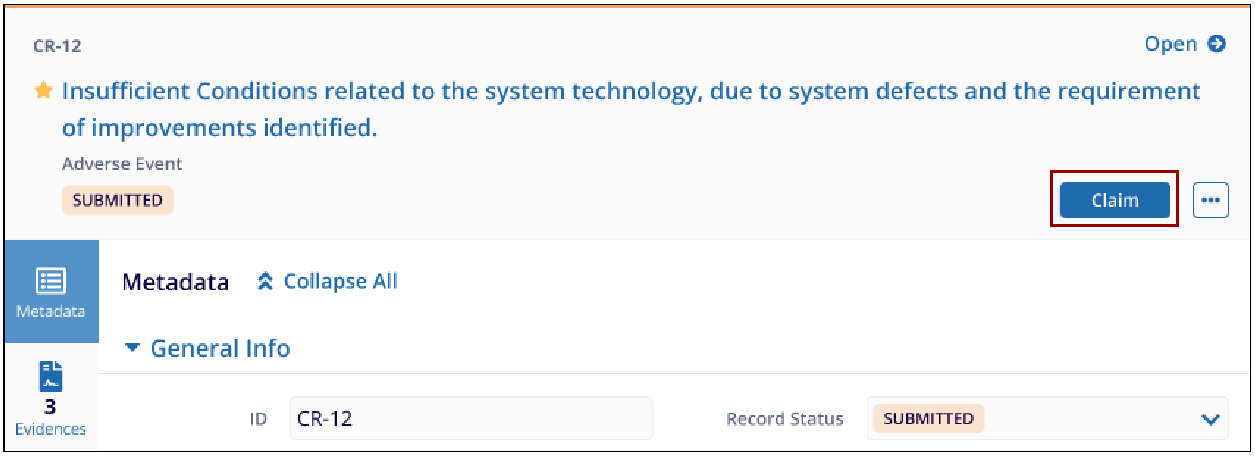

4. Select the My Assignments view and click on the Select button.




5. It will display the My Assignment view from the folders. Click on the Available for Review folder. It will display all incidents with a stage status of Available for Review.



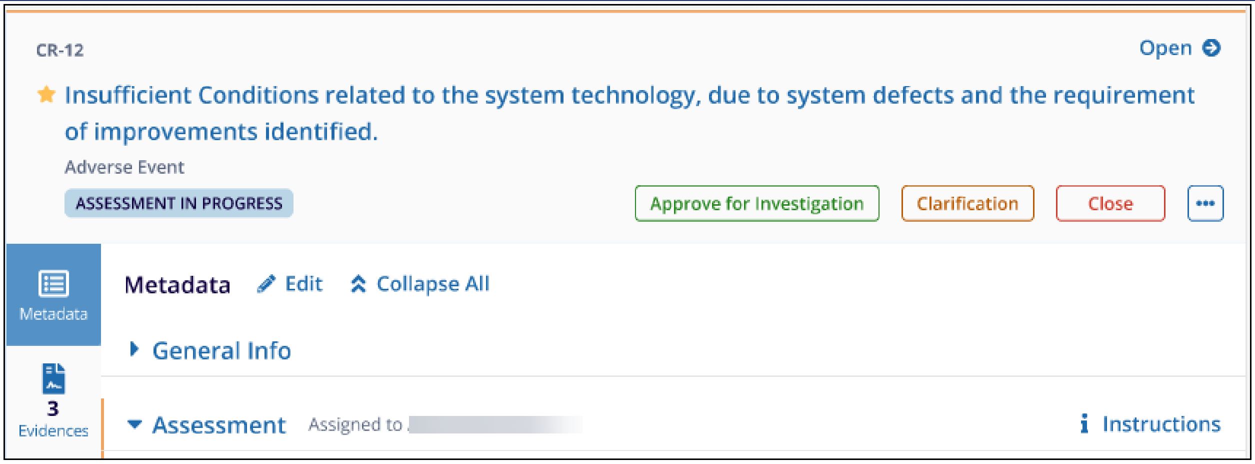

6. Click on the Incident title, and the metadata page will appear on the right side of the screen.
7. To claim the incident, click on the Claim button.




8. After clicking on the claim button. A successful message will display at the top right side of the screen. The Incident is in the 'Assessment In Progress' stage.

Note: Users can see options in the screenshot below: 'Approve for Investigation', 'Clarification', and 'Close', which depend on the configuration in the workflow.

9. If the Process Owner wants to proceed further. Click on the 'Approve for Investigation'.




10. Now the Incident Assessment process is completed, and from 'Assessment In Progress' to the 'Investigation Pending' stage.

## Incident Clarification

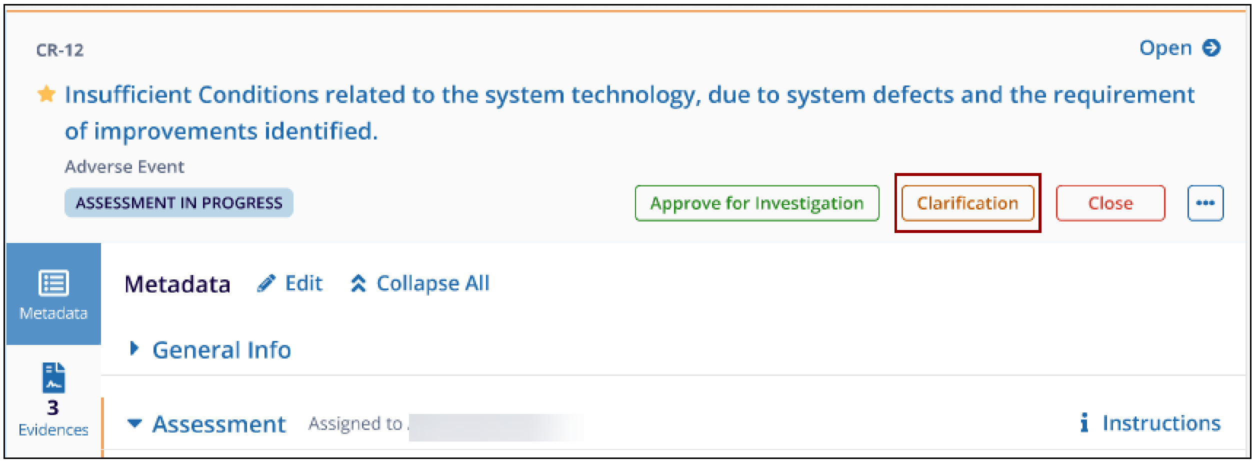
This scenario occurs when a user needs clarification on the incident before sending it to the next stage. Incident Clarification can be done at any stage, depending on the workflow configuration.

This section covers the following.

- How to Create a Query
- How to Respond.

### Requesting Clarification

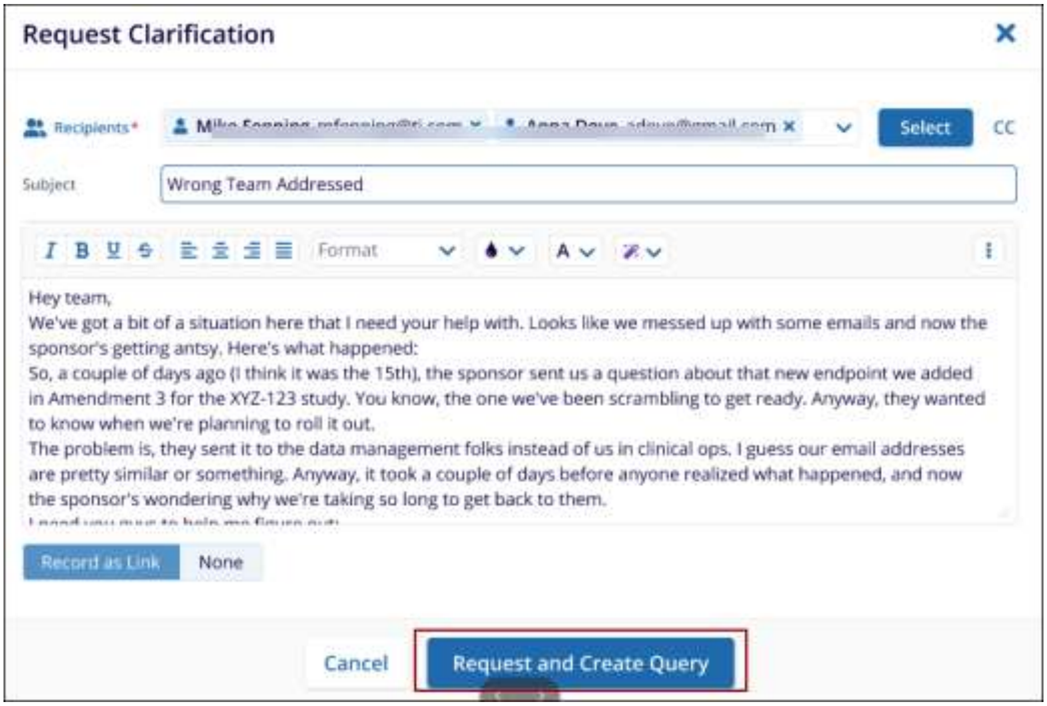
1. From the Incident tab, select the View by drop-down.
2. Click on My Assignments view from the list view, select the Incident that needs clarification.
3. The Metadata panel will display.
4. On the metadata panel, click the Clarification button.



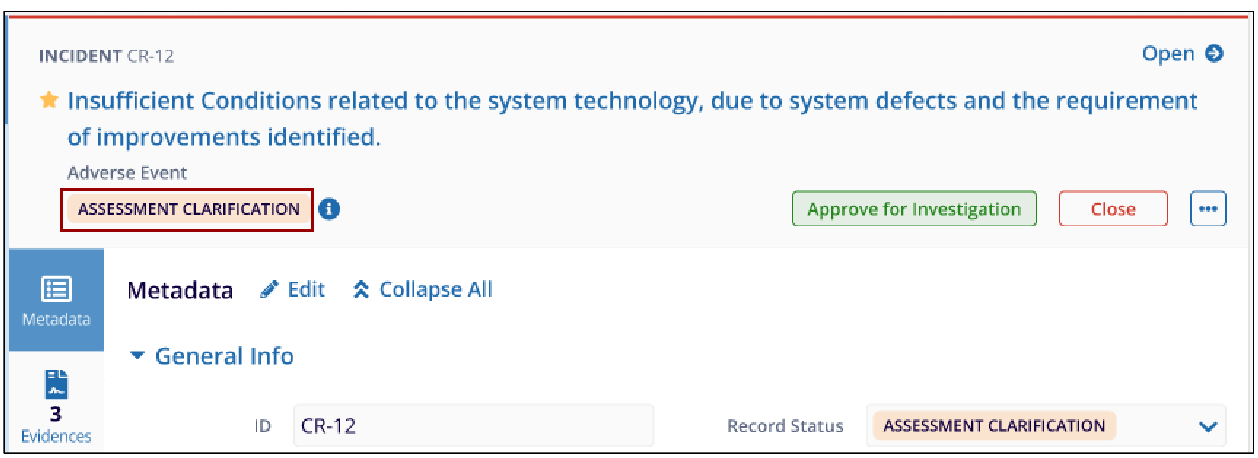

5. The Request Clarification pop-up window appears.

6. Enter the required information:
   - Recipients: Select one or multiple recipients.
   - Subject: Provide a concise subject line.
   - Message: Type a detailed message describing what clarification is needed.

7. Click Request and Create Query.




8. After sending the clarification, the Incident status changes to Assessment Clarification. Please note that the user can still edit the incident if necessary.



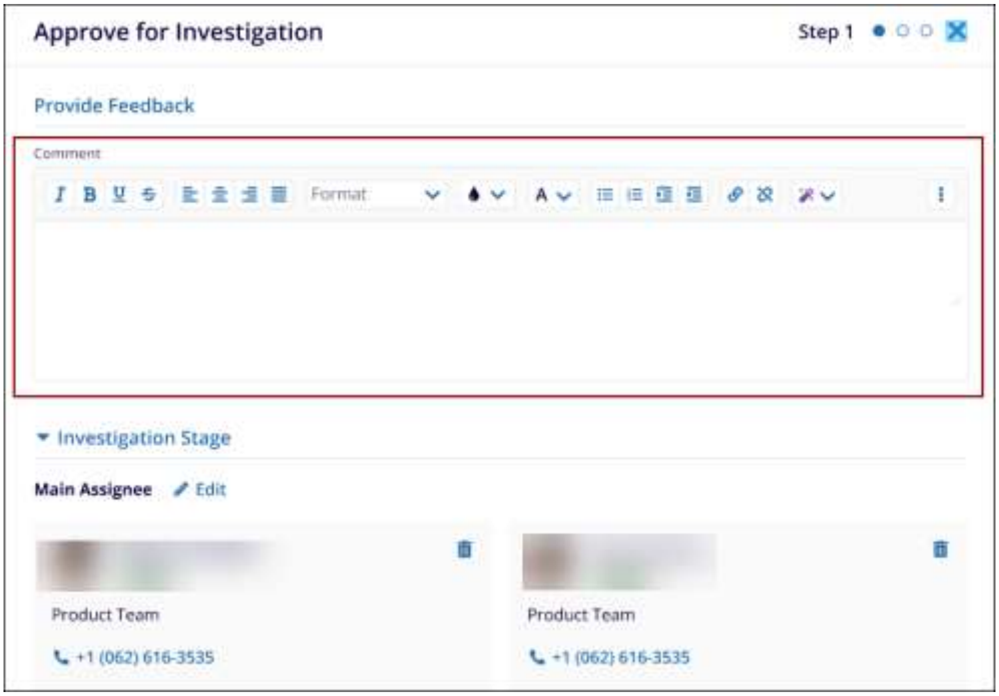

Note: In this example, the Process Owner will raise a query seeking clarification on the incident, and the Originator will provide a response to that query.

## Originator's Response

9. The Originator receives an email notification prompting them to address the clarification request.
10. The Originator:
    a. Reviews the query.
    b. Updates the missing information or evidence as needed.
    c. Clicks Respond in the query window.
11. After the Originator responds, the Supervisor will receive an email notification about the response.

## Completing the Clarification process

12. The Supervisor reviews the updated Incident metadata and the response.
13. After verification, the Incident moves back to Assessment in Progress status.
14. To continue, the Supervisor clicks Approve for Investigation.
15. The Approve for Investigation window appears. Supervisor can provide comments (feedback is optional but recommended).
16. Review or update the Investigation Stage assignees if needed.
17. Click Submit to approve the incident for investigation.
18. The Incident progresses to the Investigation Pending stage.




Note: If the Originator does not provide sufficient clarification, the Supervisor has the option to Cancel the incident.

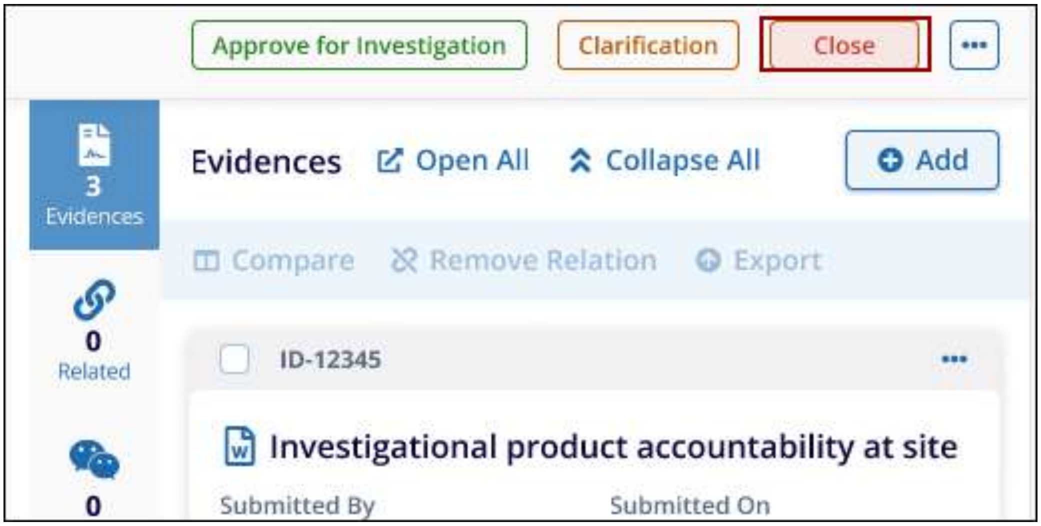
## Cancel Incident

Incidents can be canceled at any stage, depending on the configuration of the workflow. Once an authority cancels a CAPA, the record is removed from the workflow.

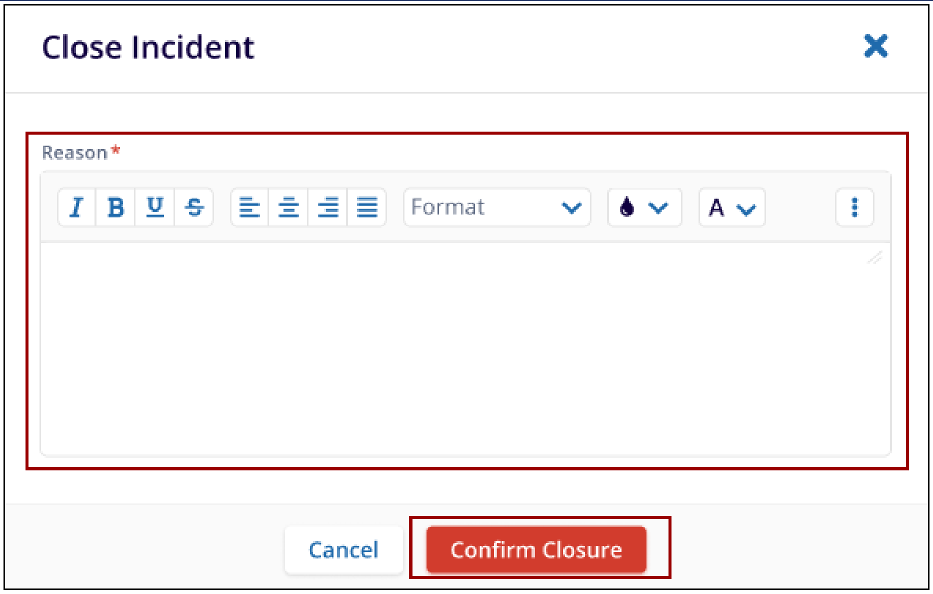
Follow the steps below to cancel an Incident:

1. Navigate to the My Assignments view and select the Incident to cancel.
   Once selected, the Incident metadata panel will appear on the right side of the screen.
2. On the metadata panel, at the top-right side, click the Close button.

(Refer to Screenshot - The 'Close' button appears along with other action options like 'Approve for Investigation' and 'Clarification.')




3. A Close Incident pop-up window will appear.
4. In the pop-up window. Enter the Reason for closing the Incident in the provided text area.




5. Provide the reason for closing the incident and click on the confirm closure button to complete the cancellation.
6. Once confirmed, the Incident will be closed, and a success message will appear at the top-right of the screen.

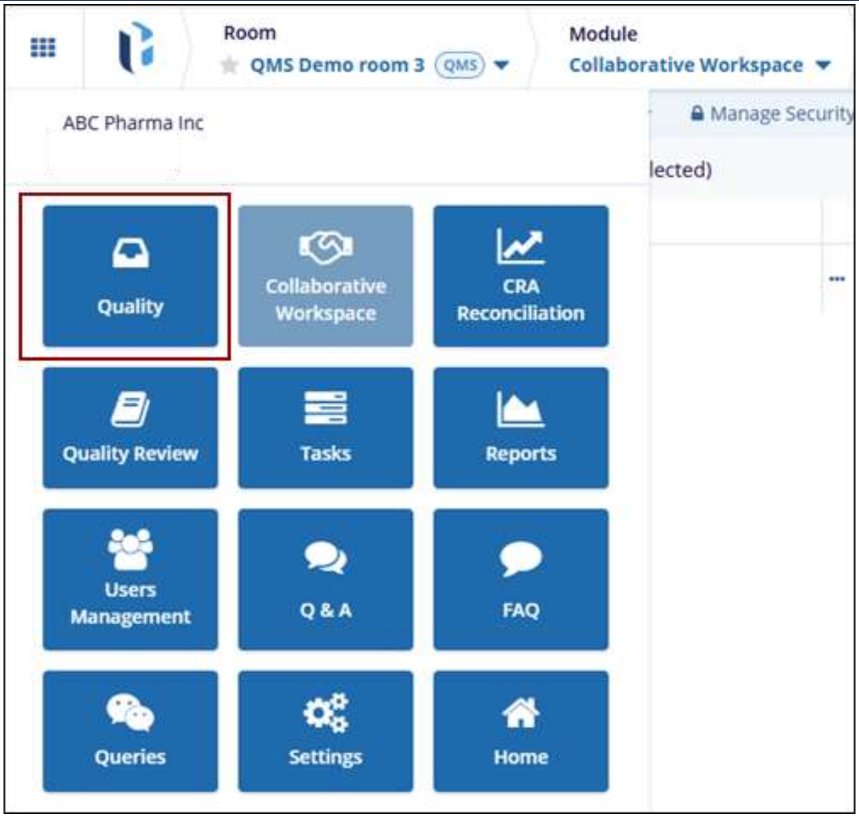
## Start Investigation

After an Incident is claimed and completed by the assigned Process Owner during the Assessment Stage, it transitions to the Investigation Stage.
At this point, the assigned Main Investigator receives an email notification informing them of the new assignment.

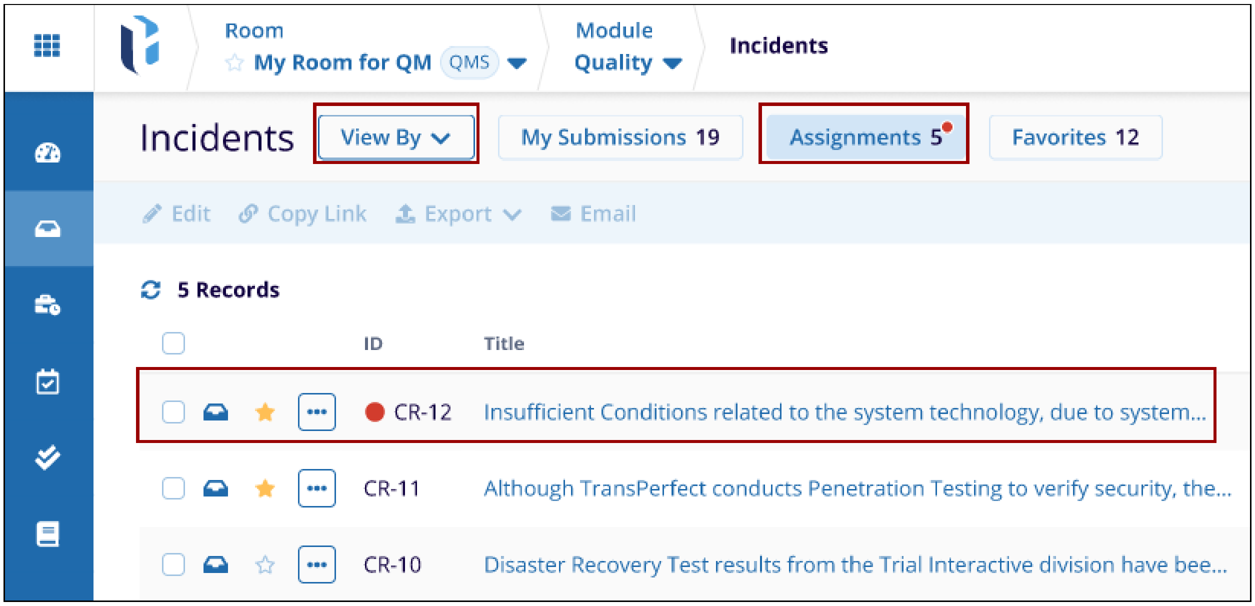
Note: Actions like Clarification, Cancellation, and other modifications are configured within the system's workflow settings.

Follow the steps below to start the Investigation

1. From the Home Page, navigate to the room where to perform this activity.
2. Click the Waffle Menu at the top-left corner of the screen and select Quality Module. The user will be redirected to the Quality Dashboard.

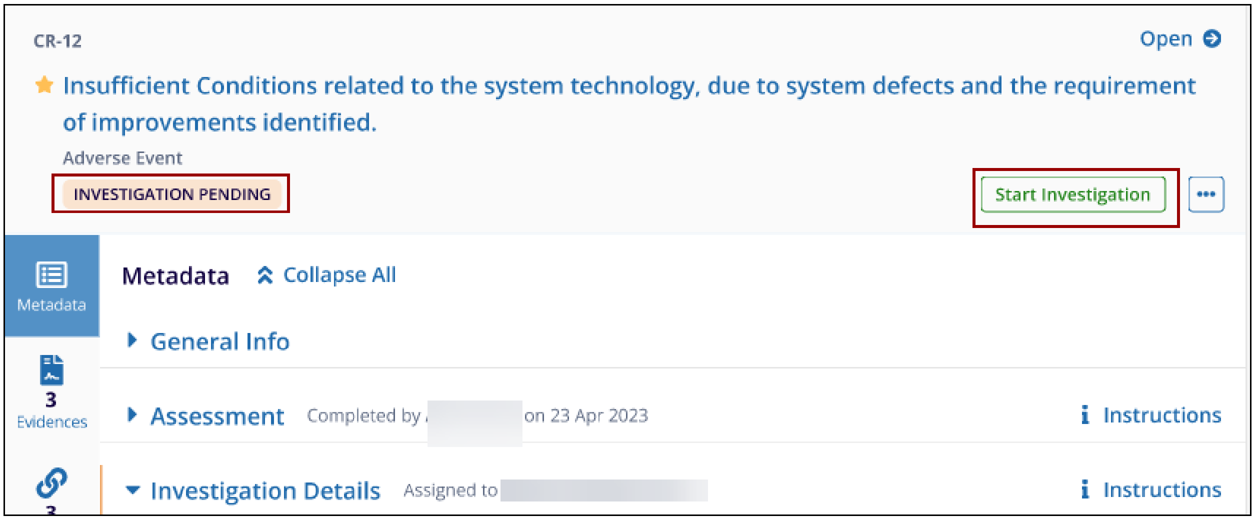



3. Click the Incidents icon in the left navigation panel to open the Incident screen.
4. From the View by options, select the My Assignment option. All incidents will be displayed as shown in the screenshot below.

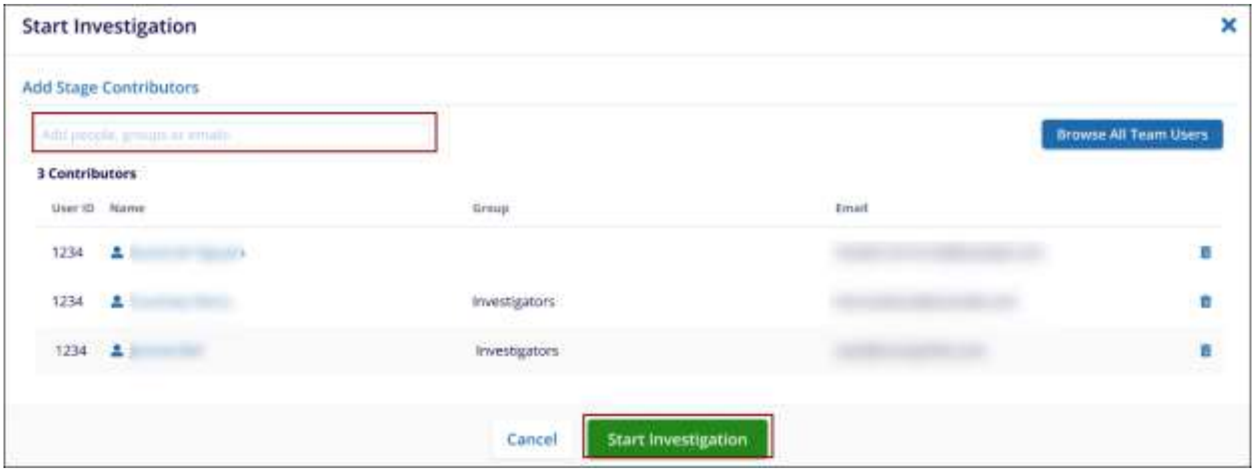



5. Select the Incident received in the email notification.
6. Check that the Incident status is displayed as Investigation Pending.

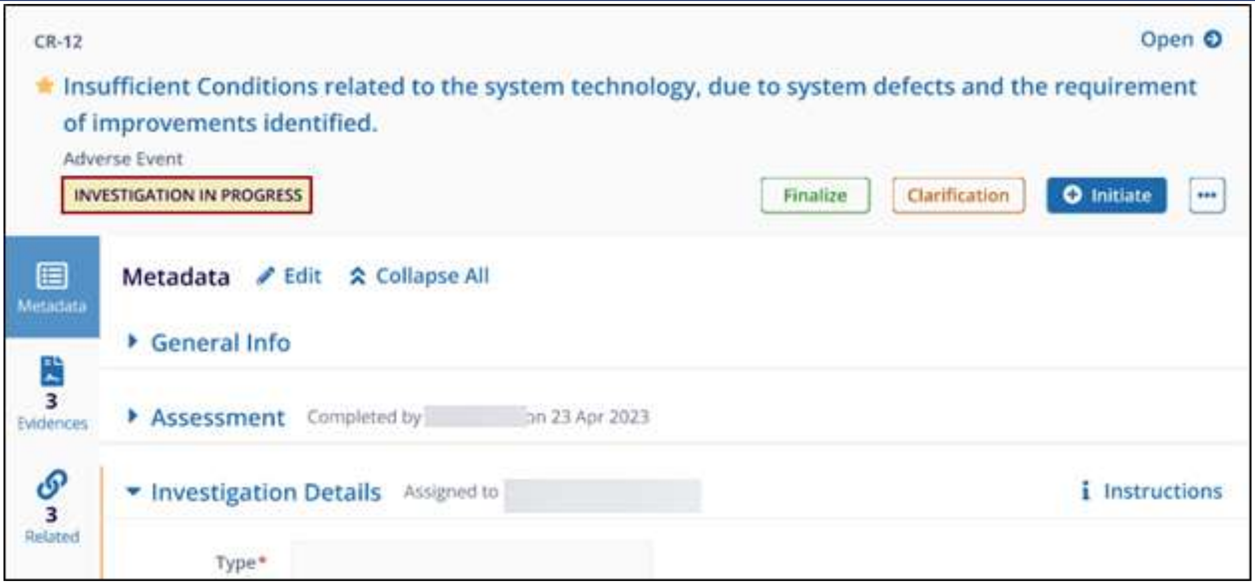
7. Click the Start Investigation button located at the top-right corner of the Incident metadata panel.




8. After clicking Start Investigation, the Start Investigation pop-up window will appear.




9. In the Add Stage Contributors field, enter the name, group, or email address of the Sub-Investigator to add to the Investigation.
10. Select the Sub-Investigator from the dropdown list.
11. Click the Start Investigation button at the bottom of the pop-up window to initiate the Investigation.
12. Once the Investigation is started, the Incident status will change to Investigation in Progress.



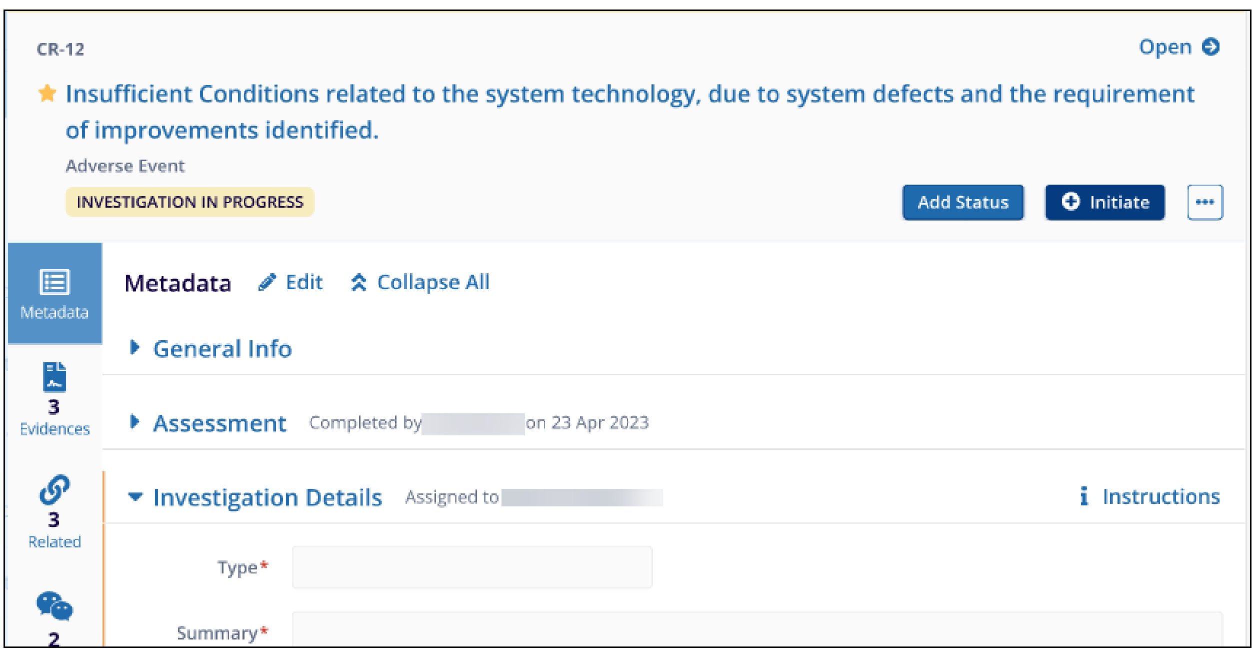

13. After the Investigation is initiated, Sub-Investigators will receive an email notification informing them of their assignment to the Incident and the Main Investigator who assigned it.


## Investigation in Progress

Once the email notification is received that the investigation has started with the Record ID, Record Link, Assignee Name, and the Incident Name, as shown in the screenshot below.


Follow the steps to start working on the investigation:

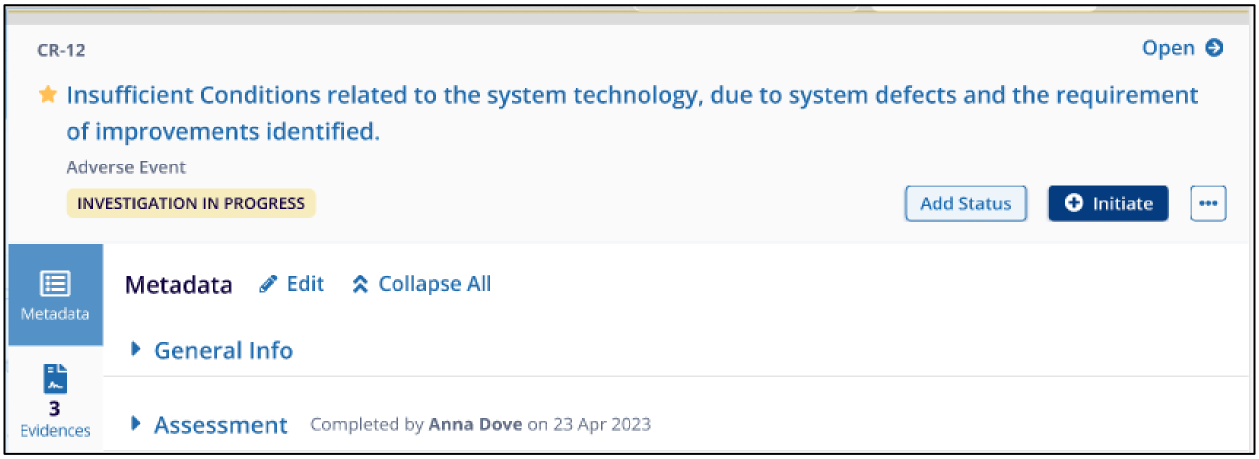
1. In this stage, the investigation is in Progress. The sub-investigator can review and check the investigation in MY assignment.
2. When an investigator investigates the incident, he will include all additional information to cover all bases.
3. The sub-investigator should click on the '+ Initiate' button to create and CAPA and an Action Item.



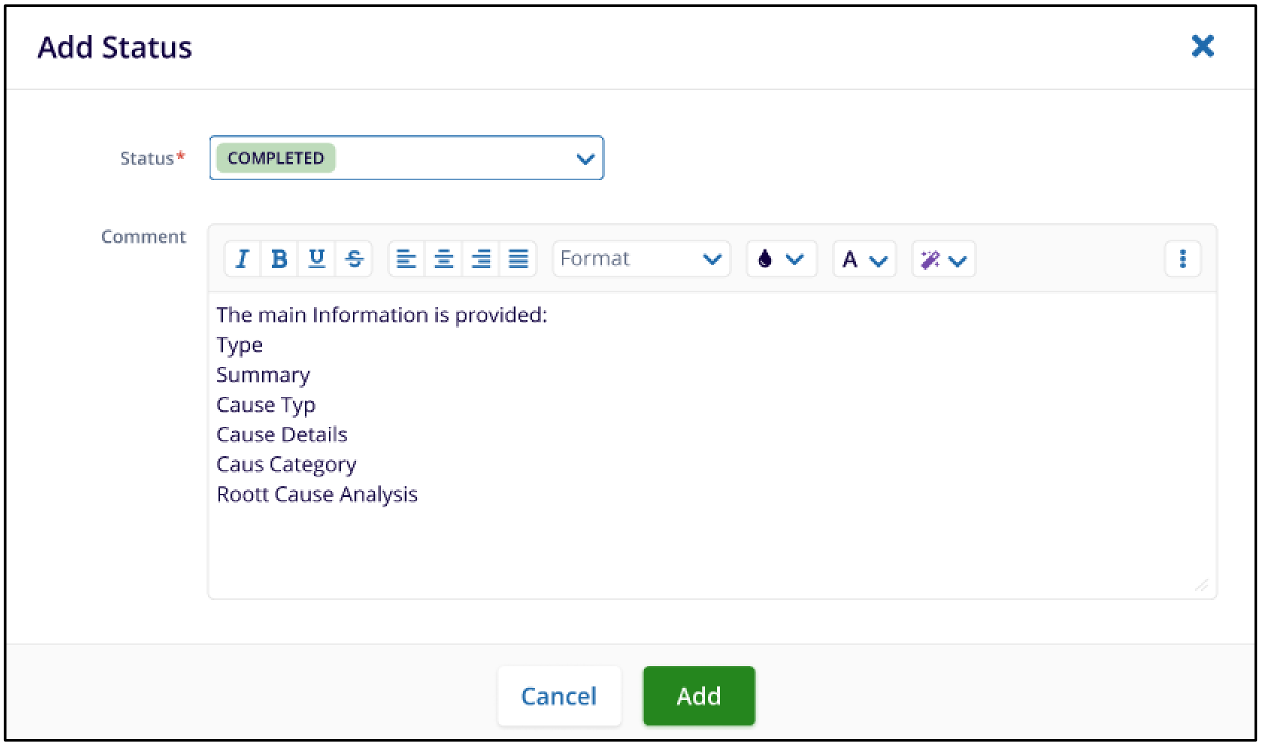

4. After clicking on the button, it will open the window to create CAPA and Action Item.

5. Please refer to the CAPA and Action Item sections to learn how to create the CAPA and Action Item.


6. Once the investigation is completed, the sub-investor will click on add status.



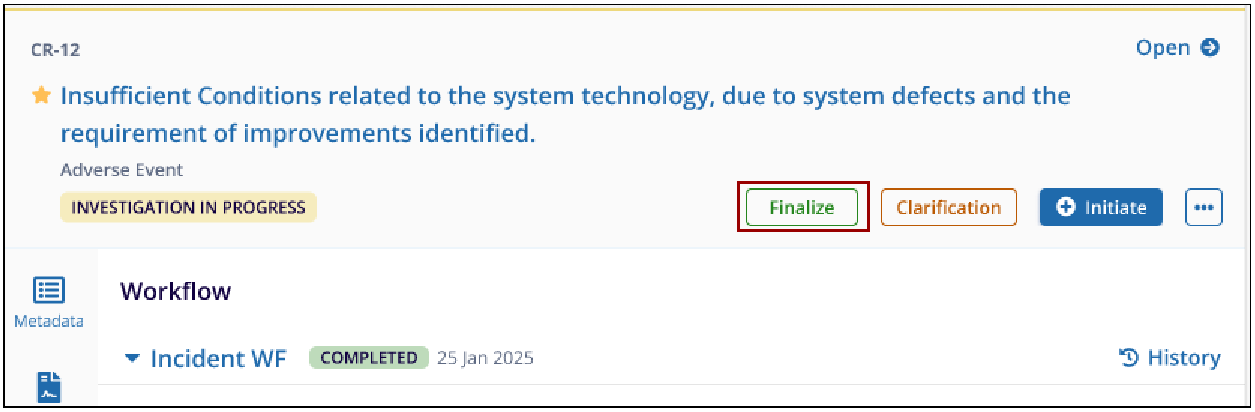

7. Keep the status as completed and provide the comments.




8. The Main Investigator will check the details and finalize the Incident.

   Follow the steps to finalize the incident.

   1. Once the Incident is completed, investigate. The main investigator can finalize the incident.
   2. To finalize the incident, the user has to select the incident that needs to be finalized.
   3. Once the Incident is selected, the metadata panel will appear.
   4. Click on the Finalize button at the top of the metadata screen.



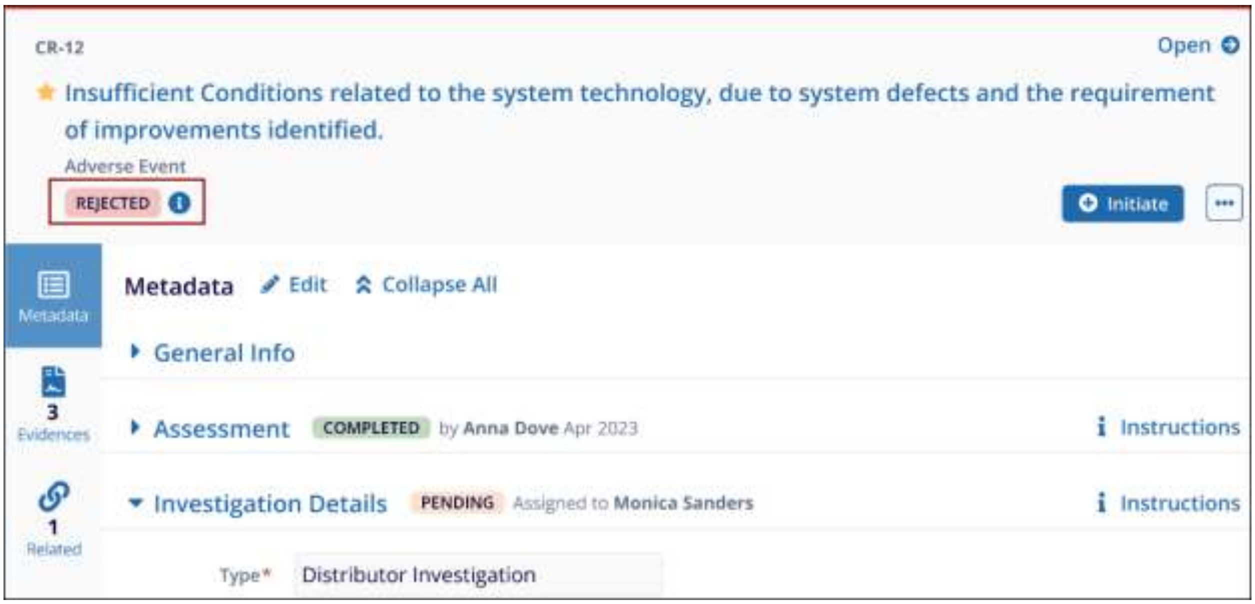

   5. The Finalize investigation Page will appear. Fill out the missing information and click on the finalize button.
   6. Once it is finalized, the stage will change to Investigation In progress – Investigation Finalized – 'Approval Pending'.

## Reject Investigation

Once the incident is finalized and sent to QA for approval. The QA will receive an email notification

Follow the steps to reject the Incident:

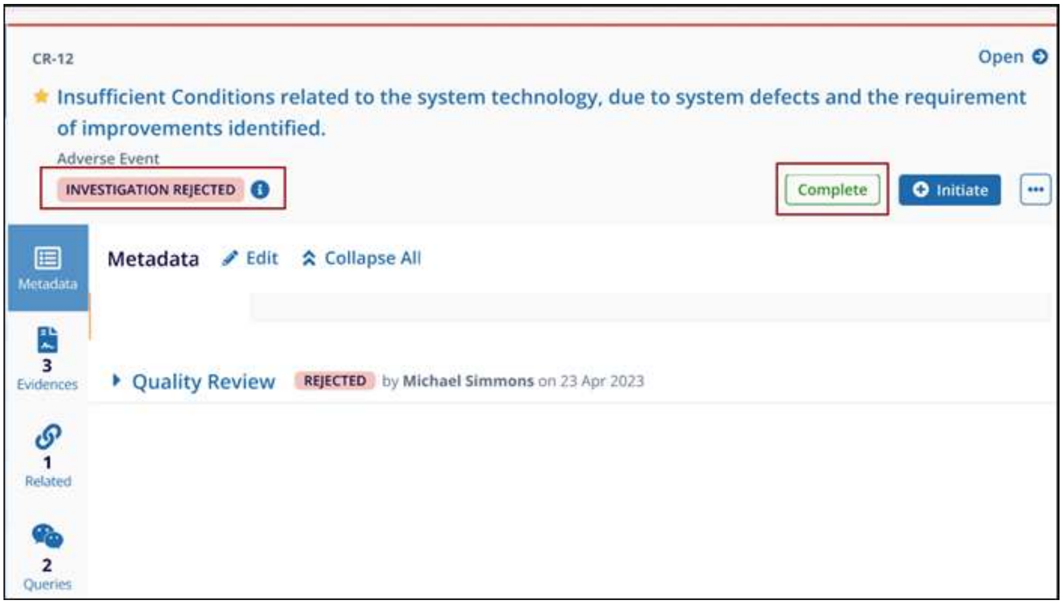
1. Select the Incident that the user wants to reject from the '**My Assignment'** grid view.
2. After selecting the incident, the metadata panel will appear.
3. Click on the Reject Investigation. It will display a pop-up window for rejecting the incident.
4. Provide the reason for the rejection and click on the reject button to proceed further.
5. The Incident status will change to '**Reject'**. Refer to the screenshot below.




### Revise Investigation

1. The main investigator will receive the Investigation Rejected email notification.
2. To revise the Incident, locate the rejected incident from the My Assignment view.
3. Select the incident, the metadata screen will appear, and the status is displayed as Investigation Rejected.

4. To proceed further, the user needs to check the QA feedback and update the incident with the required evidence.
5. Once all Information is filled, click on the completed button at the top right corner of the metadata panel.




6. The Complete pop-up window will appear with the comment box. Enter the information, such as what was revised, explanation, and so on, as per the requirement.
7. Once all information is filled, click on the Complete button.
8. The status will change to Approval is Pending.


## Incident Approval

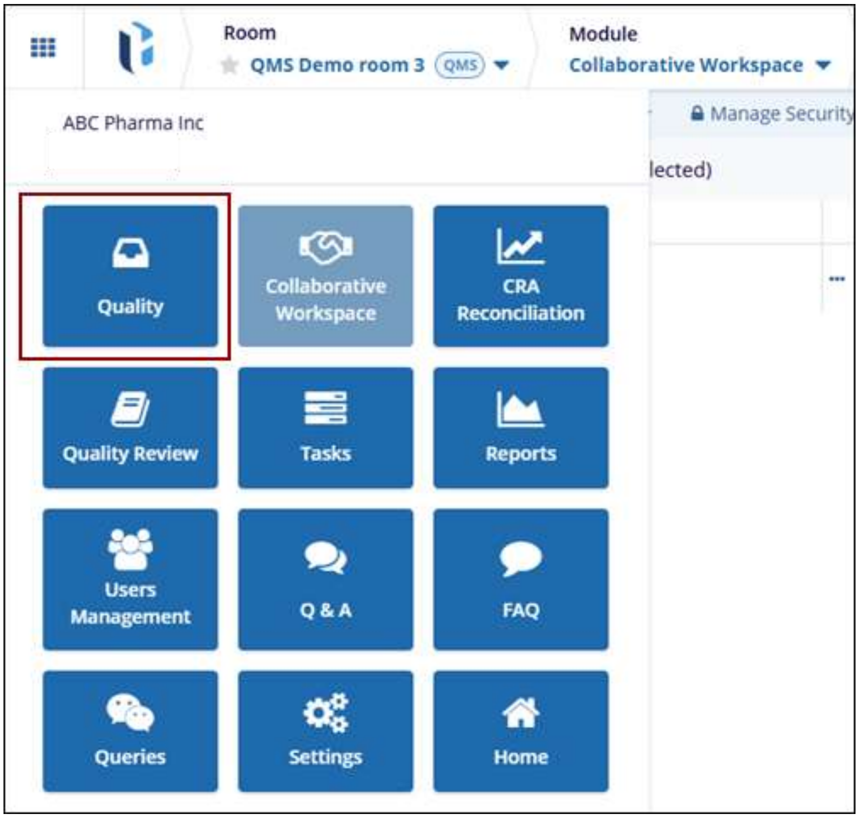
Once the Investigation is completed and sent for approval, a QA will receive an email notification.

Please note that the Approval process is explained in this section. All modifications, such as Clarification, Cancellation, and other related actions, must be configured through the workflow settings.

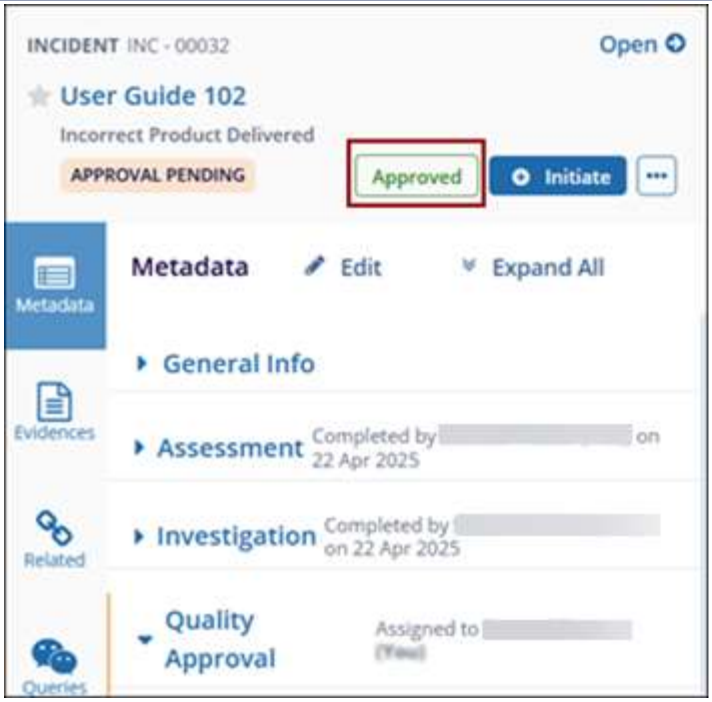
To create and learn more about CAPA, click here.

To create and learn more about an Action item, click here.

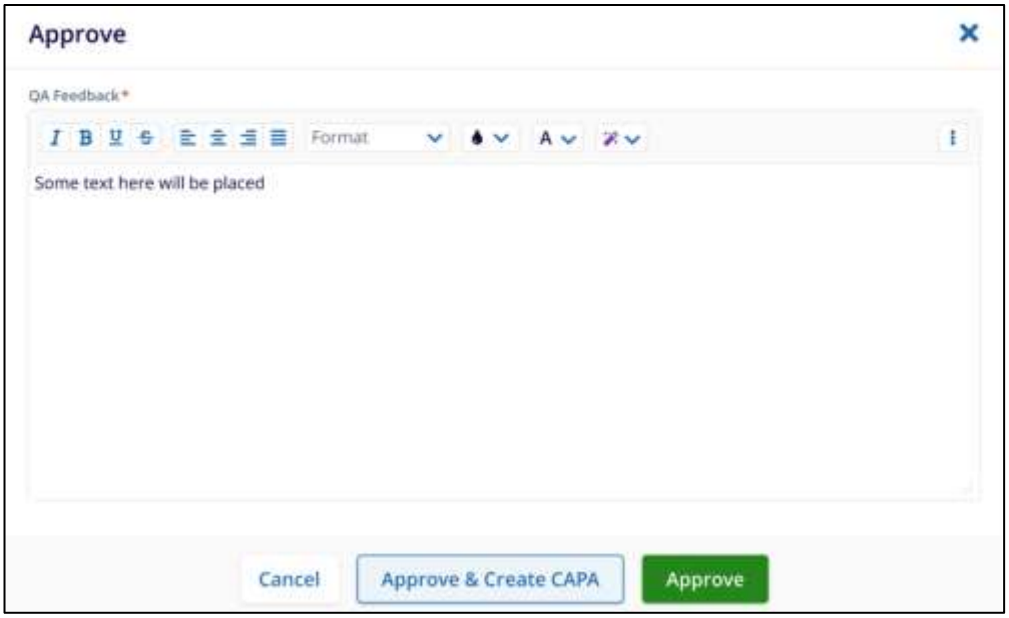
1. From the Home Page, navigate to the room to perform this activity.
2. Click the Waffle Menu located at the top-left corner of the screen, then select Quality Module. The user will be redirected to the Quality Module's Dashboard screen.




3. In the left navigation panel, click the Incidents icon, which will open the Incident screen.
4. From the grid, select the incident to view its metadata panel. The incident is in the Approval Pending Stage.
5. To proceed further with the approval process. Click on the Approve button. Refer to the screenshot below.




6. The Approve window will appear with a feedback box. Provide feedback as per the requirement.
7. Click on the Approve button to approve the Incident.



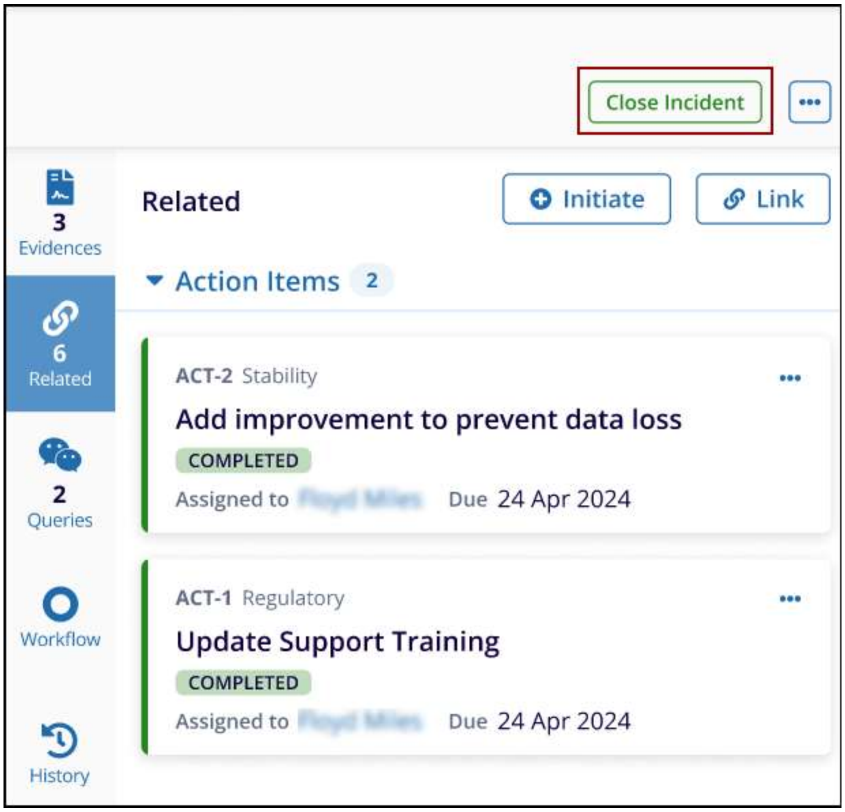

8. The status of the incident will change to Resolved.

## Close Incident

Closing incident must be configured from the workflow setting.

Follow the steps to close the Incident:

1. To close the incident, locate the incident that user need to close.
2. From the view by menu select the MY ASSIGNMENT view and select the Incident.
3. After select the Metadata will appear, from the top right side of the metadata panel. Click on the Close Incident.




4. The Close Incident pop window will appear with the Closure comment.
5. Provide the closure comment and click on the close incident button.

# CAPA

In Quality Management, CAPA stands for Corrective and Preventive Action, which refers to a process of identifying and addressing the root causes of non-conformities, incidents, or other quality issues to prevent their recurrence.

A CAPA process typically involves the following stages.

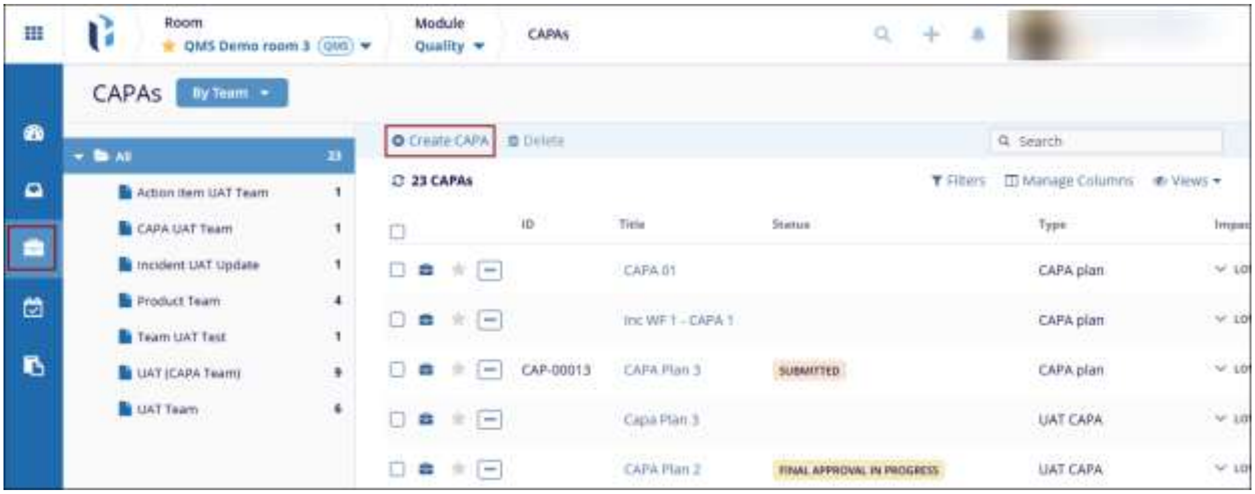
- Implementation
- Implementation Approval
- Execution
- Execution Approval

## Create CAPA

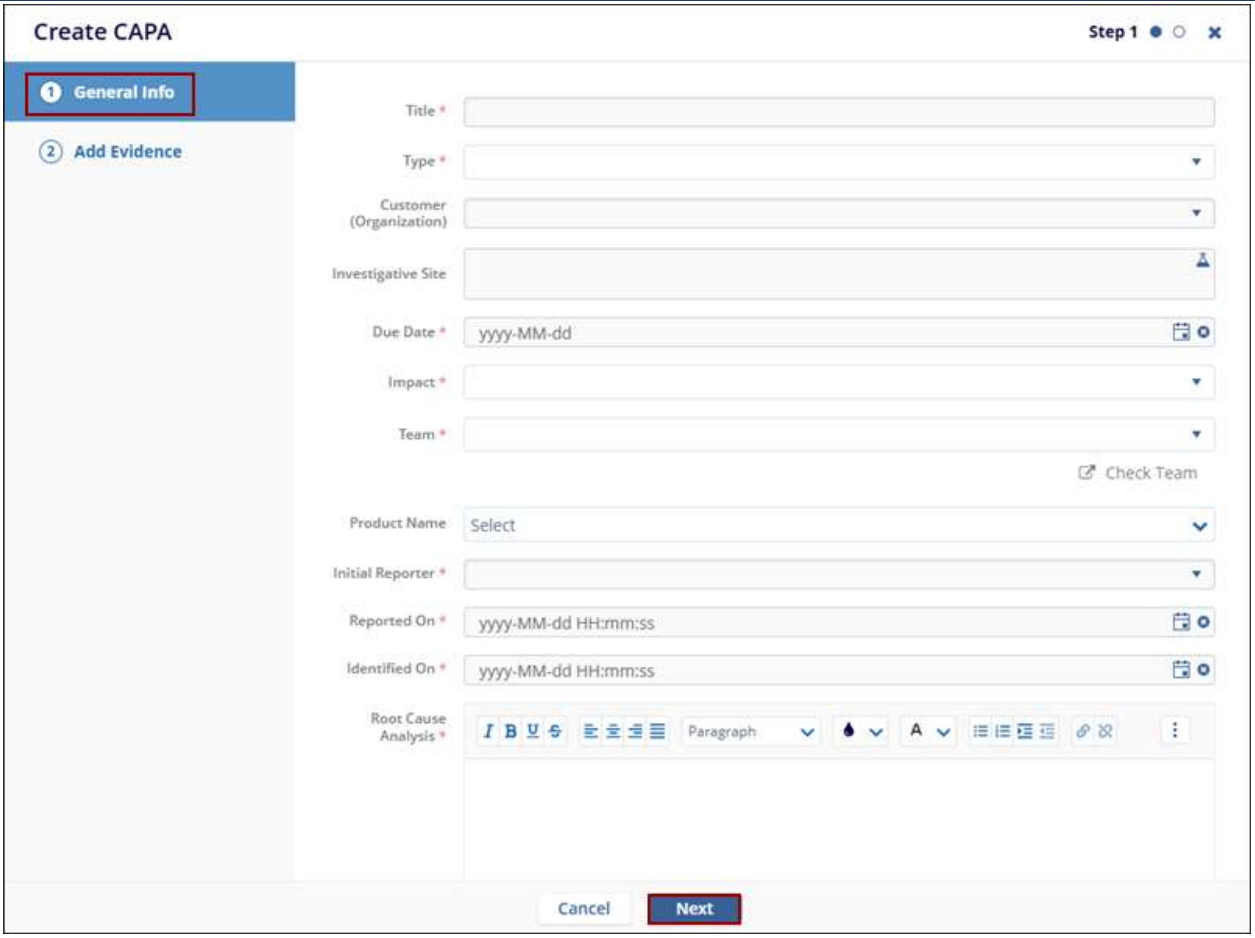
This section explains the process of creating a CAPA record from the Quality module. For creating a CAPA record, the originator user must have the 'Create CAPA' action added from the User Management module.

To create a CAPA, follow the steps below.

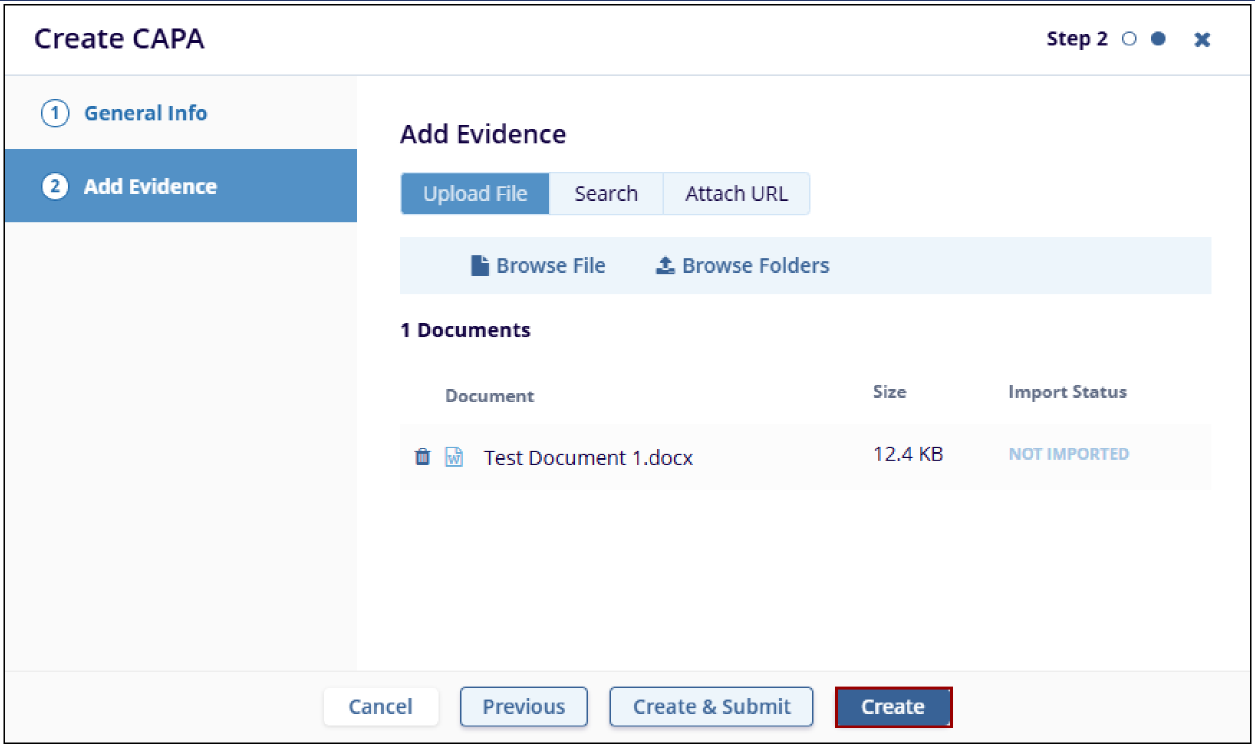
1. Within the 'Quality' module, click on the CAPAs modal from the left-hand navigation pane.
2. Click on the +Create CAPA button from the top menu bar.



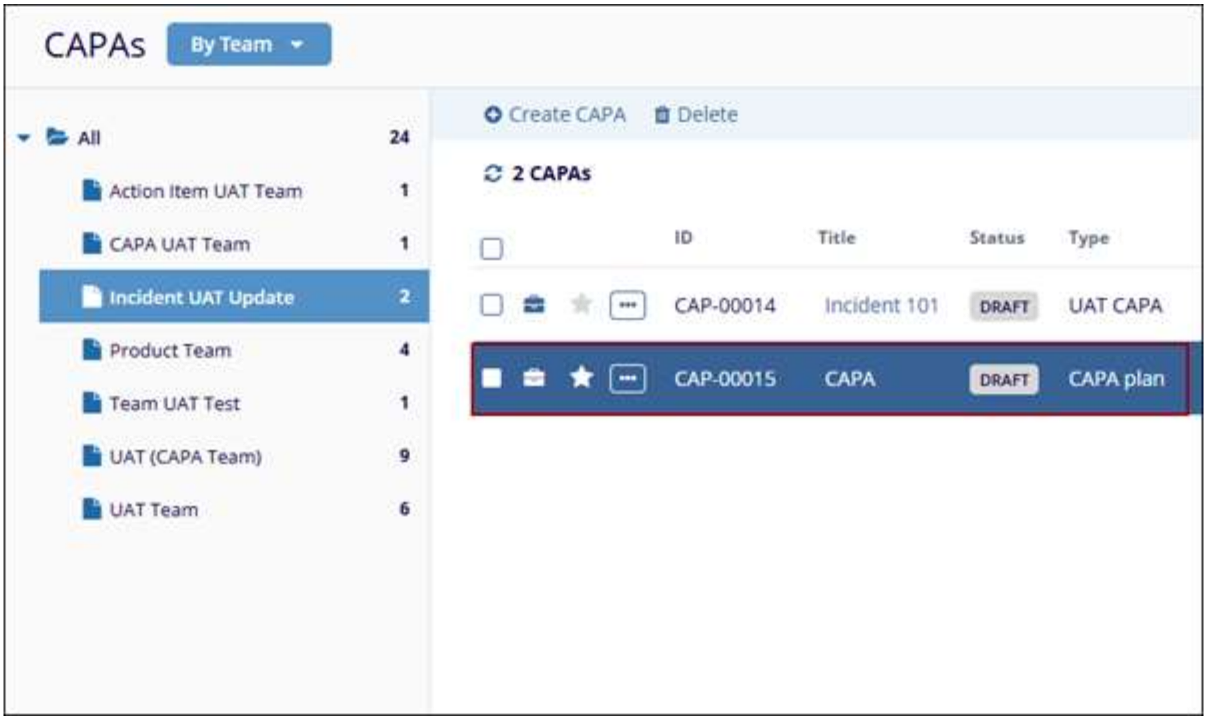

3. On the 'Create CAPA' form, fill in the mandatory details within '**Step 1: General Info'** and click on the 'Next' button.



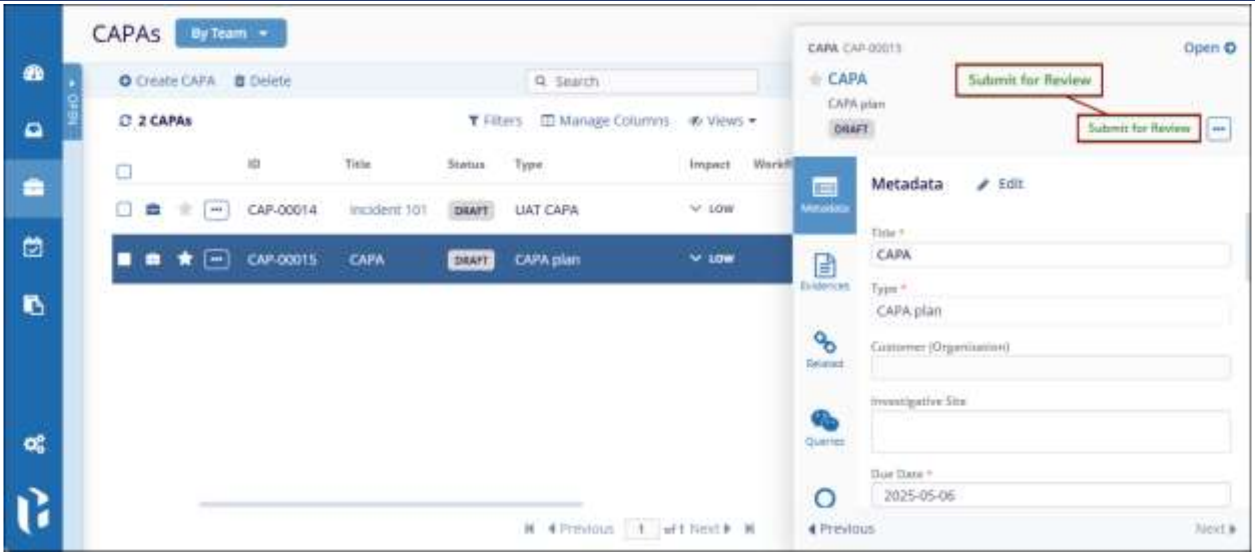

4. Upload a file or folder as evidence and click on the 'Create' button.



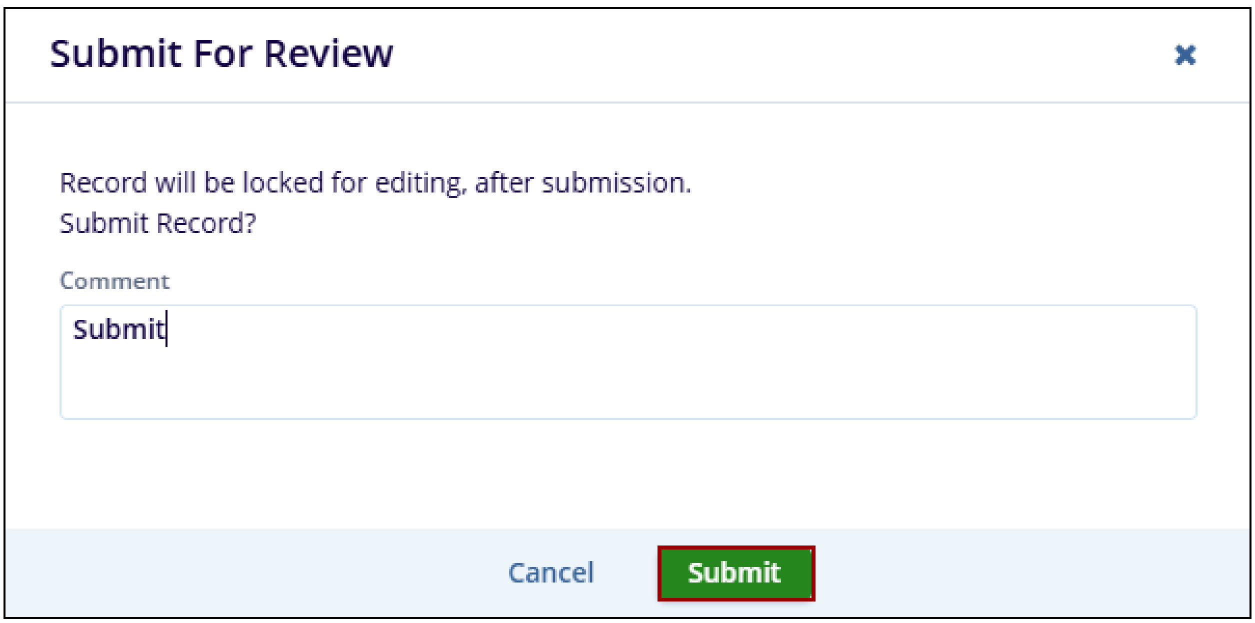

5. Once the CAPA is created, it is saved in the 'Draft' status.



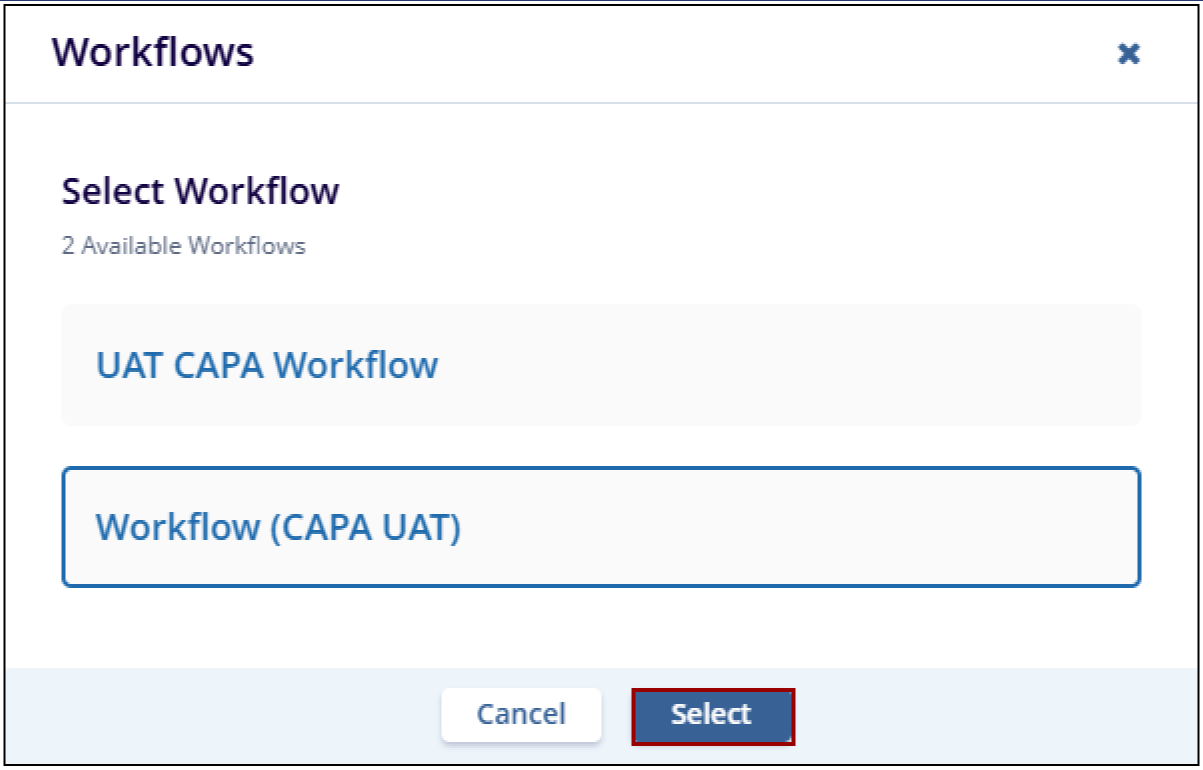

6. Click on the CAPA title and click on the 'Submit for Review' from the metadata panel.




7. On the ‘Submit for Review’ popup, enter a comment and click on the ‘Submit’ button.

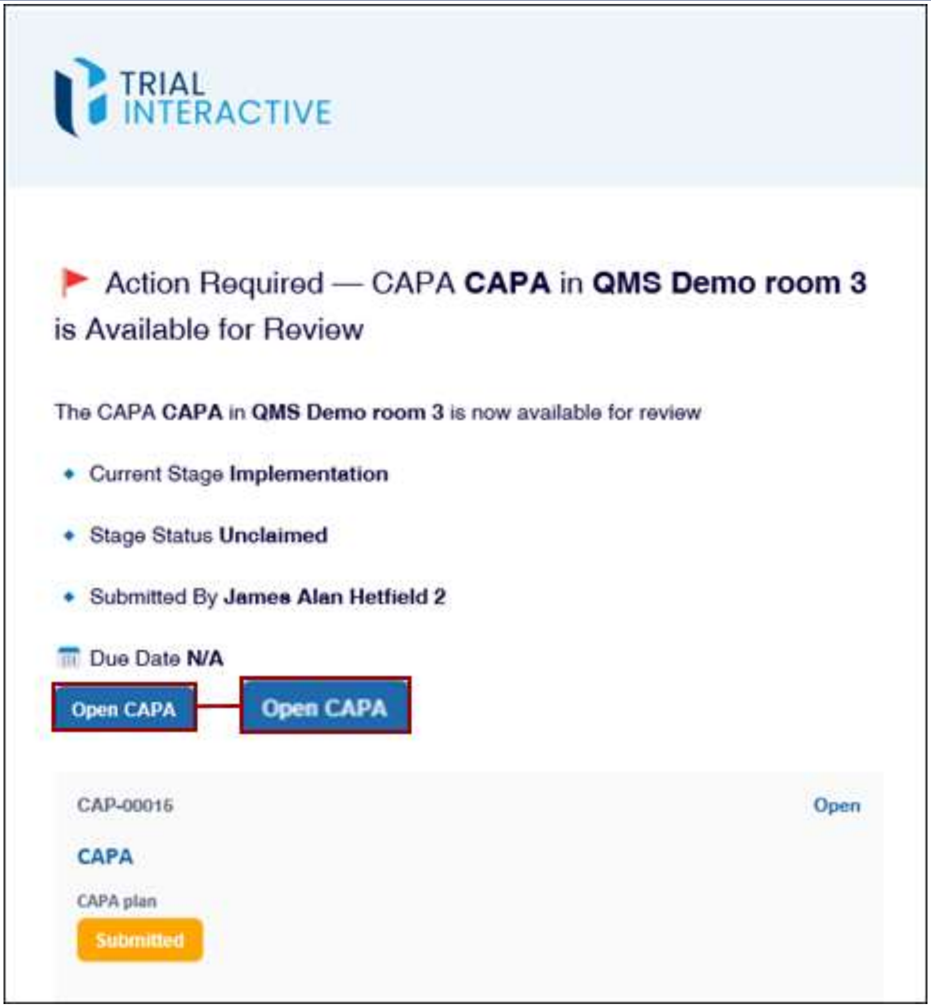



8. Choose the appropriate workflow from the ‘Workflows’ wizard and click on the ‘Select’ button.




9. Once the CAPA record is successfully transitioned to the first stage of the workflow. The ‘Record Status’, ‘Workflow Stage’, and ‘Stage Status’ display statuses as configured in the workflow.


10. Once the record enters the first stage of the approval workflow, the authority receives an email notification about the CAPA record with CAPA details and a clickable ‘Open CAPA’ button to open the record.




Note

- Email notifications about record transitions are sent to the relevant authority types based on the Approval Workflow configuration.
- The number of stages a CAPA record progresses through, along with its record and stage statuses, is determined by the configured Approval Workflow.

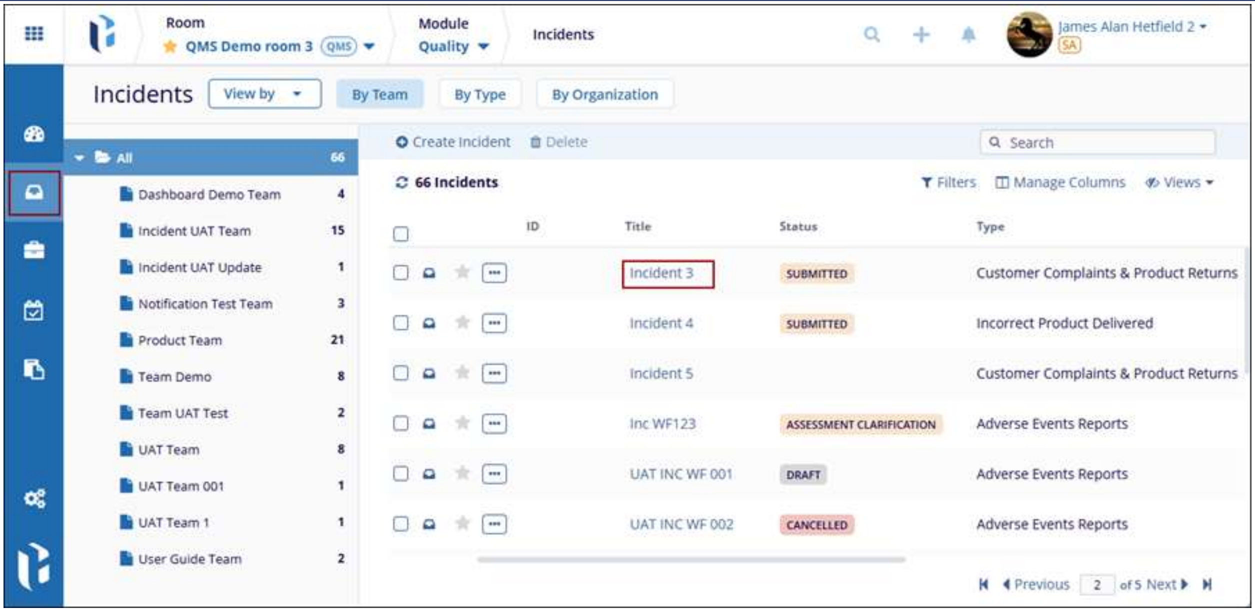
## Create CAPA through an incident

In addition to creating a CAPA record through the CAPA's modal, originator users can create a CAPA through an incident.

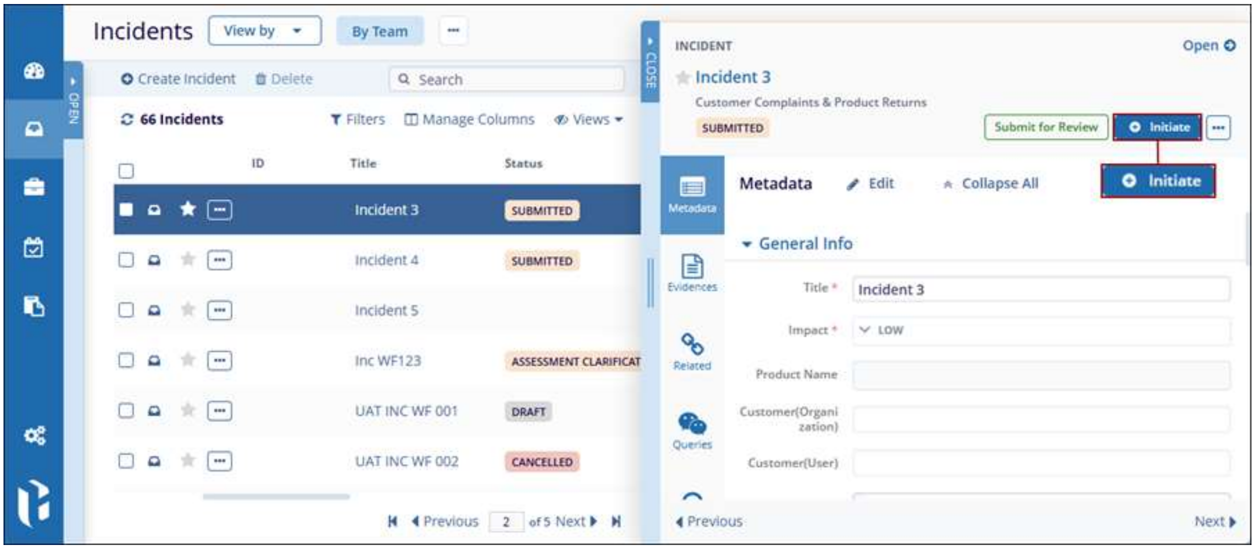
Note: Additionally, the originator must be an Admin user. If the CAPA is being created by an editor user, they must belong to the assigned team and hold the necessary authority.

To create a CAPA through an incident, follow the steps below.

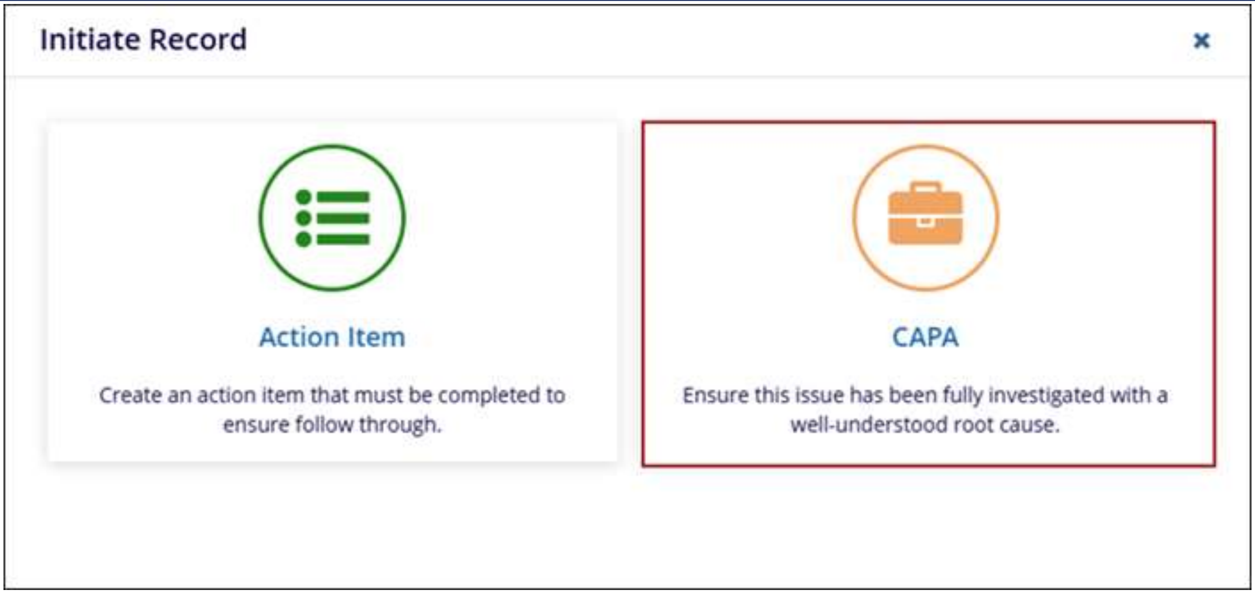
1. Navigate to the Quality module > Incidents tab and click on an incident's title.




2. From the incident's quick view panel, click on the 'Initiate' button.




3. On the 'Initiate Record' dialog box, select the CAPA option.



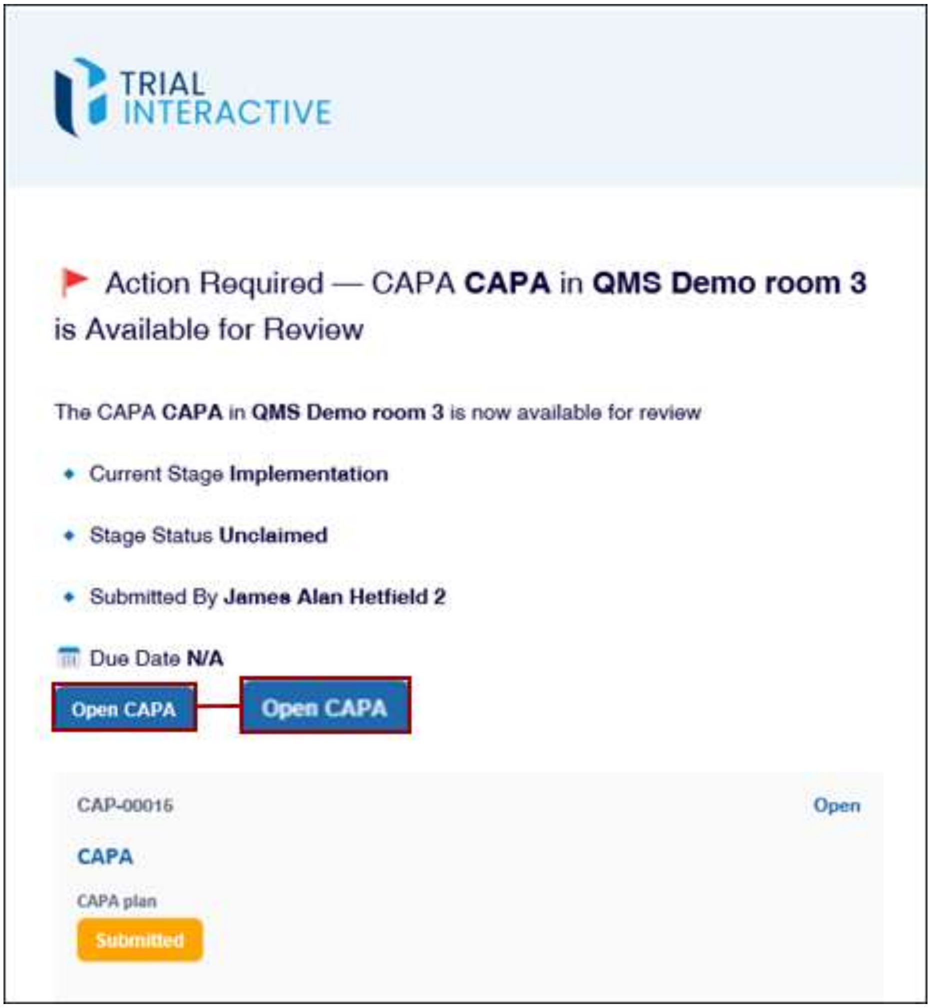

4. To create a CAPA record and submit for review, follow 'STEPS 3 to 10' from the Create CAPA section.

## Approve CAPA

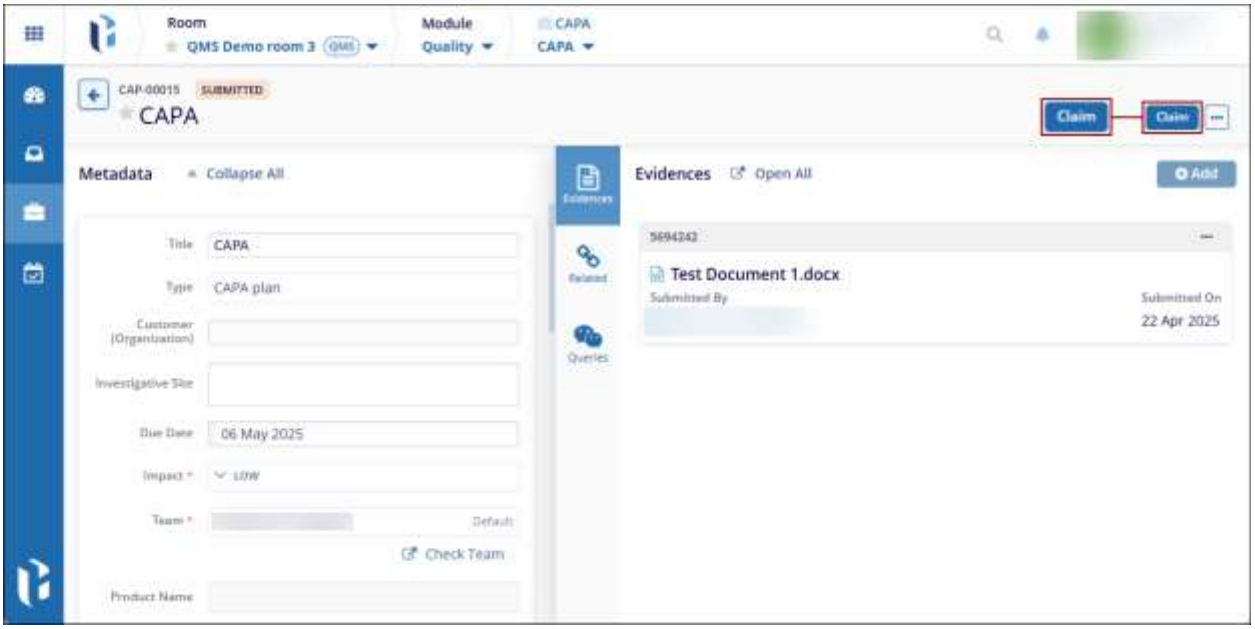
When a CAPA record enters the approval workflow, the designated authorities are responsible for advancing the record through each stage until it reaches the final stage. At the final stage, a user (typically an Approver) reviews and approves the record, thereby resolving it.

To approve and resolve a record, follow the steps below.

1. Login as a user who is assigned as an authority in the first stage of the workflow and click on the 'Open CAPA' button from the email notification.



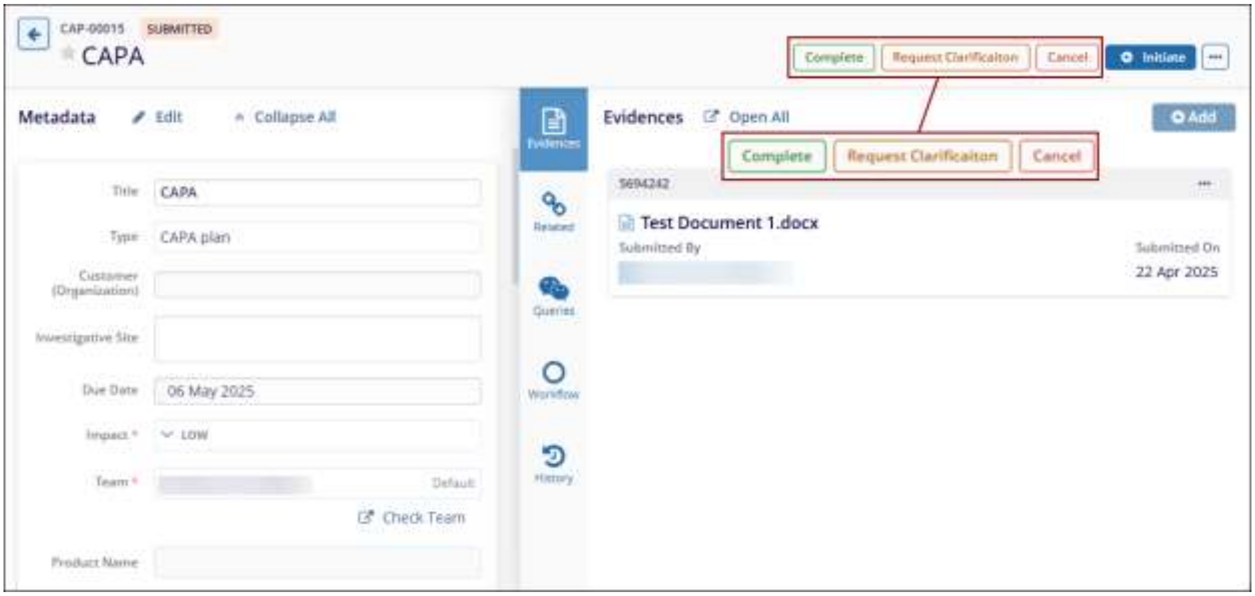

2. Additionally, users can access the CAPA record assigned to them by setting the My Assignments view from the dropdown at the top.
3. On the CAPA records screen, click on the 'Claim' button.



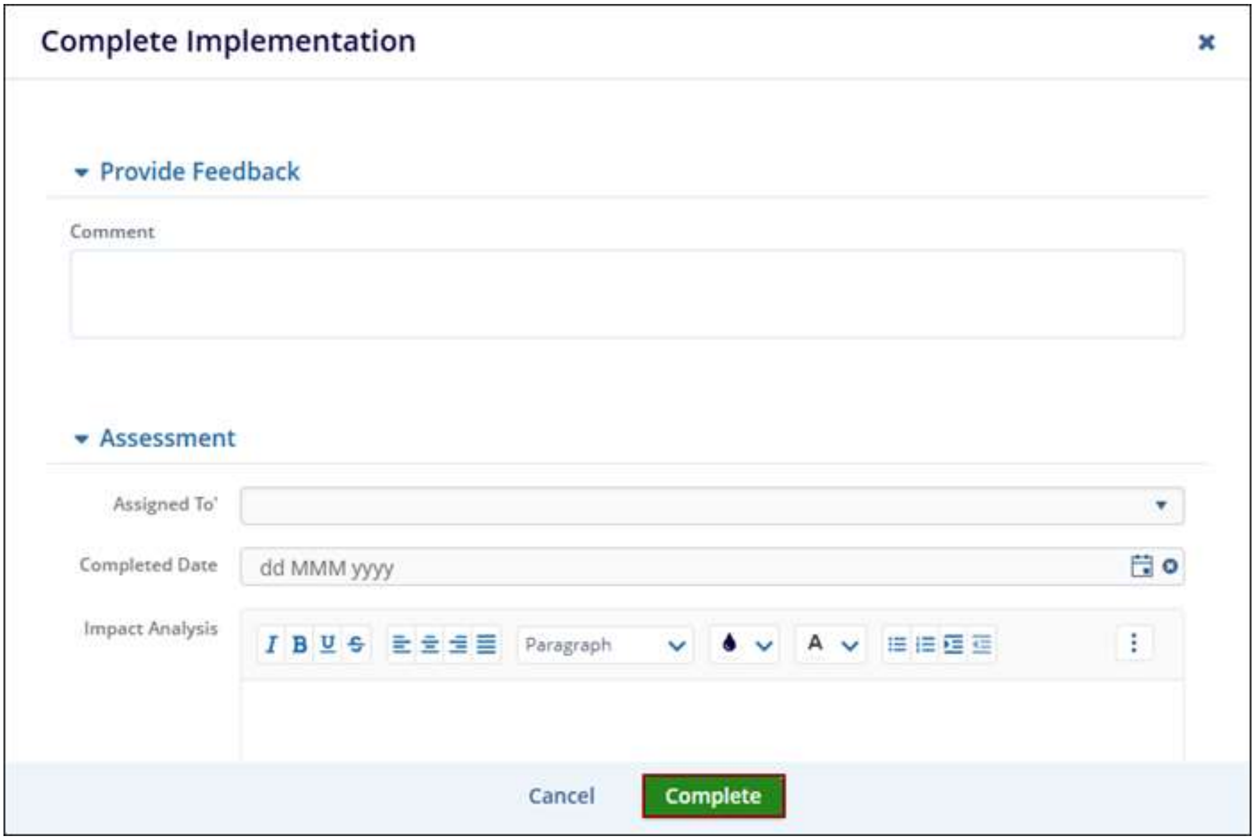

Note:

- The ‘Claim’ button appears when there are multiple authority types in the workflow stage, and any one of the authorities should manually claim the record.
- If there is only one user in a stage, the record is auto-claimed.

4. Once the assigned authority clicks the ‘Claim’ button, the record is claimed by that authority and the action buttons appear as configured in the workflow.

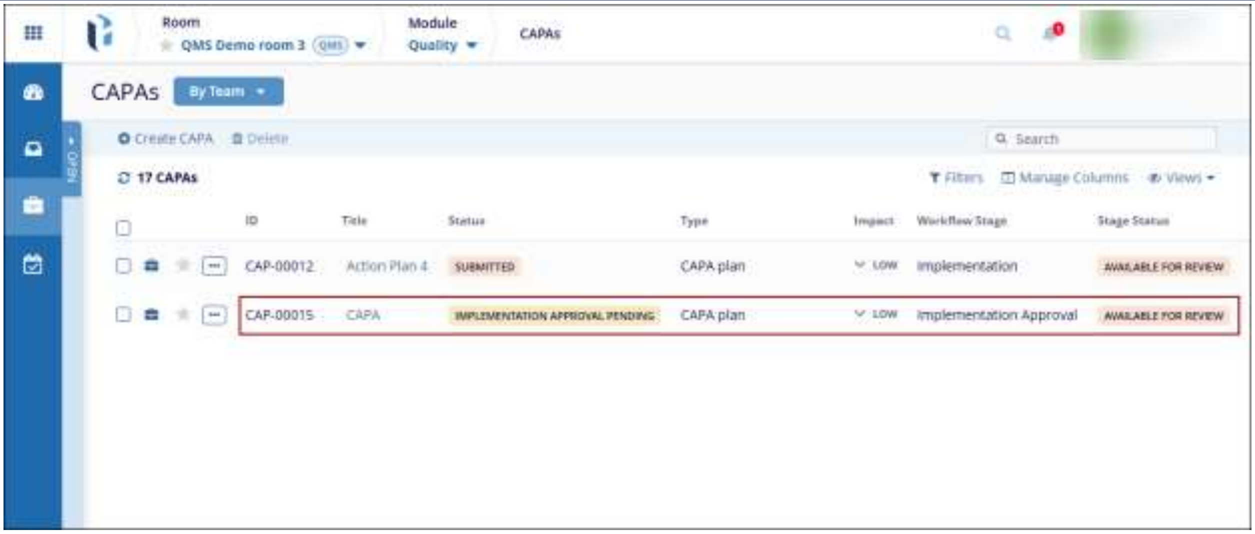


5. Click on the ‘Complete’ button, fill in the necessary details in the ‘Complete Implementation’ form, and click on the ‘**Complete’** button.



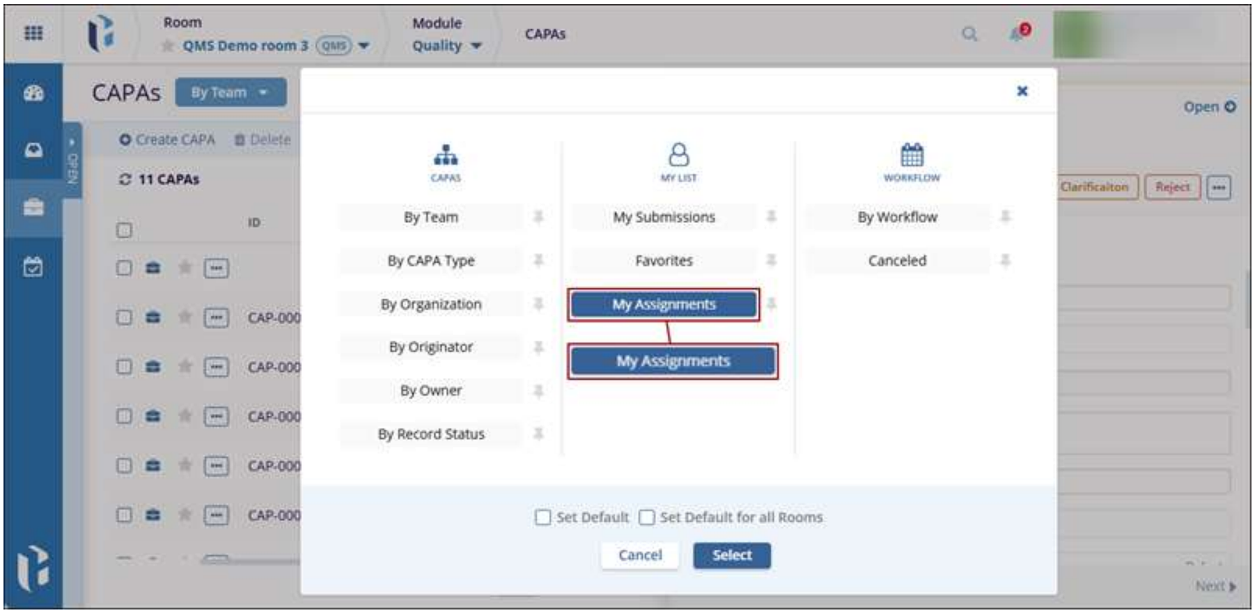

Note: The display of forms and other sections, upon clicking an action button, depends on the ‘Triggers’ configured within the workflow.

6. Once the record is completed, it is transitioned into the next stage, i.e., Implementation Approval, and the record displays the statuses as configured in the workflow.

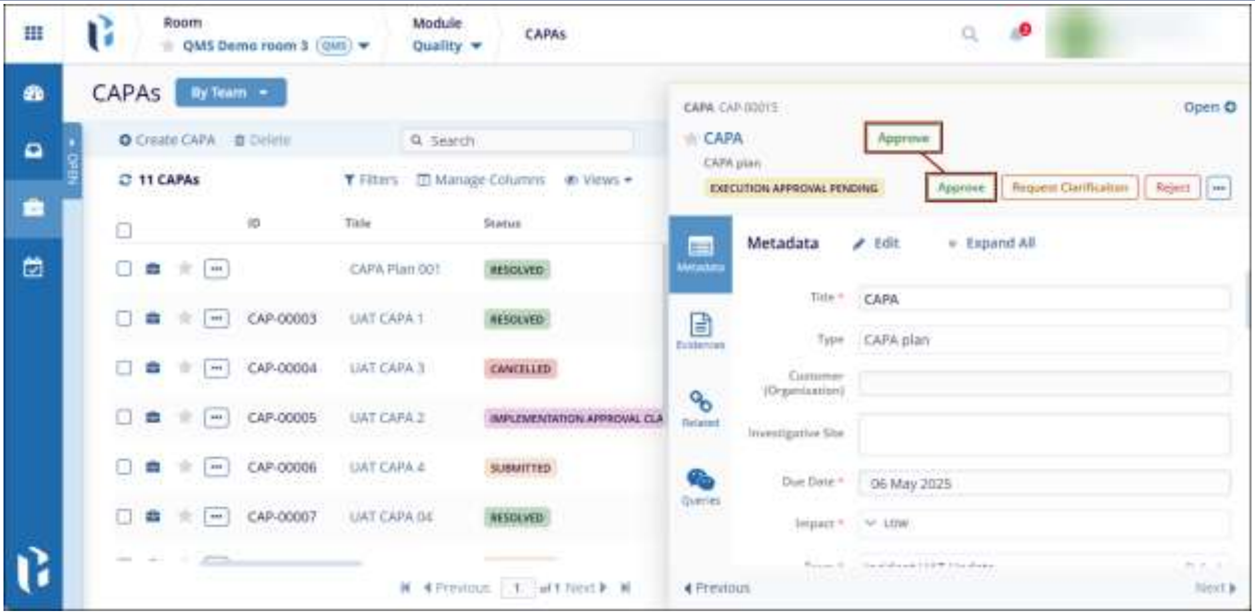



Note: Follow the steps from STEP 1 to STEP 6 to complete the record transition to the last stage.

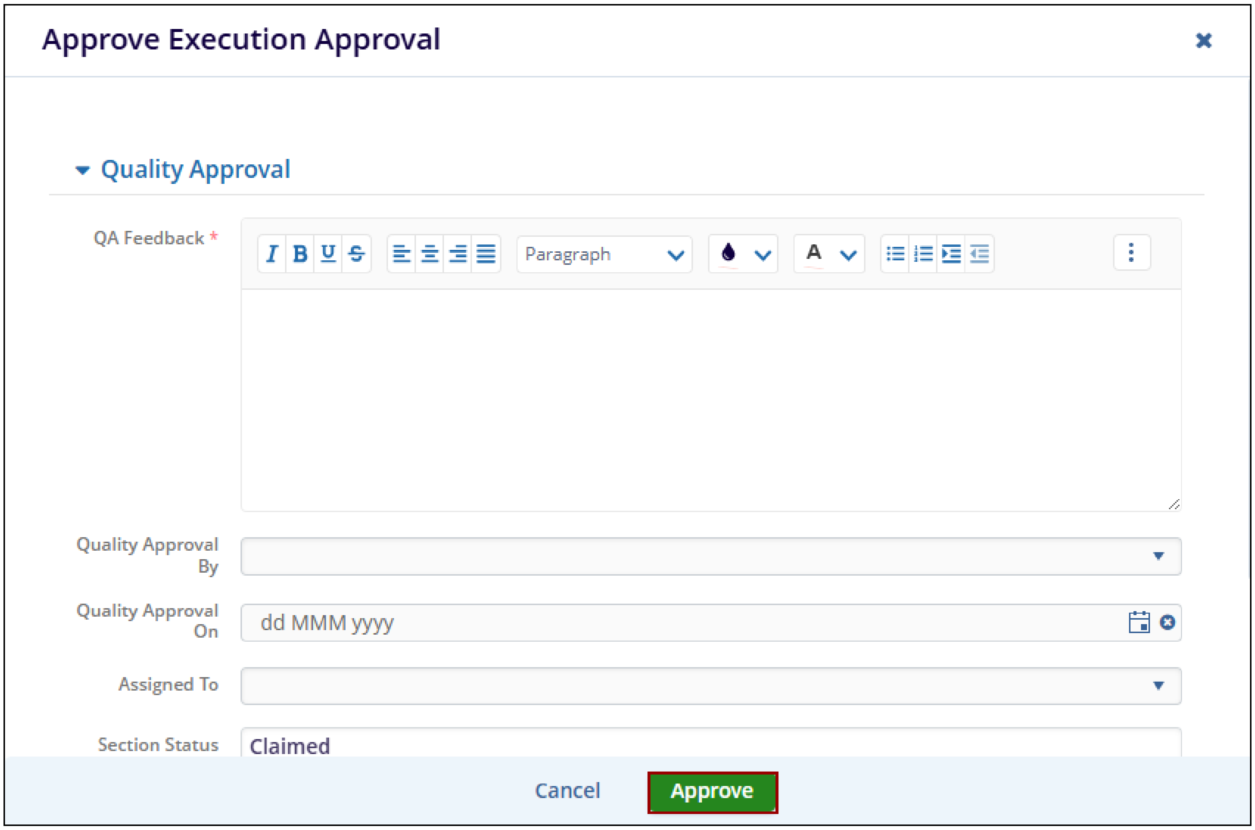
7. As the assigned authority in the last stage, access the CAPA record through the email notification or the 'My Assignments' view.



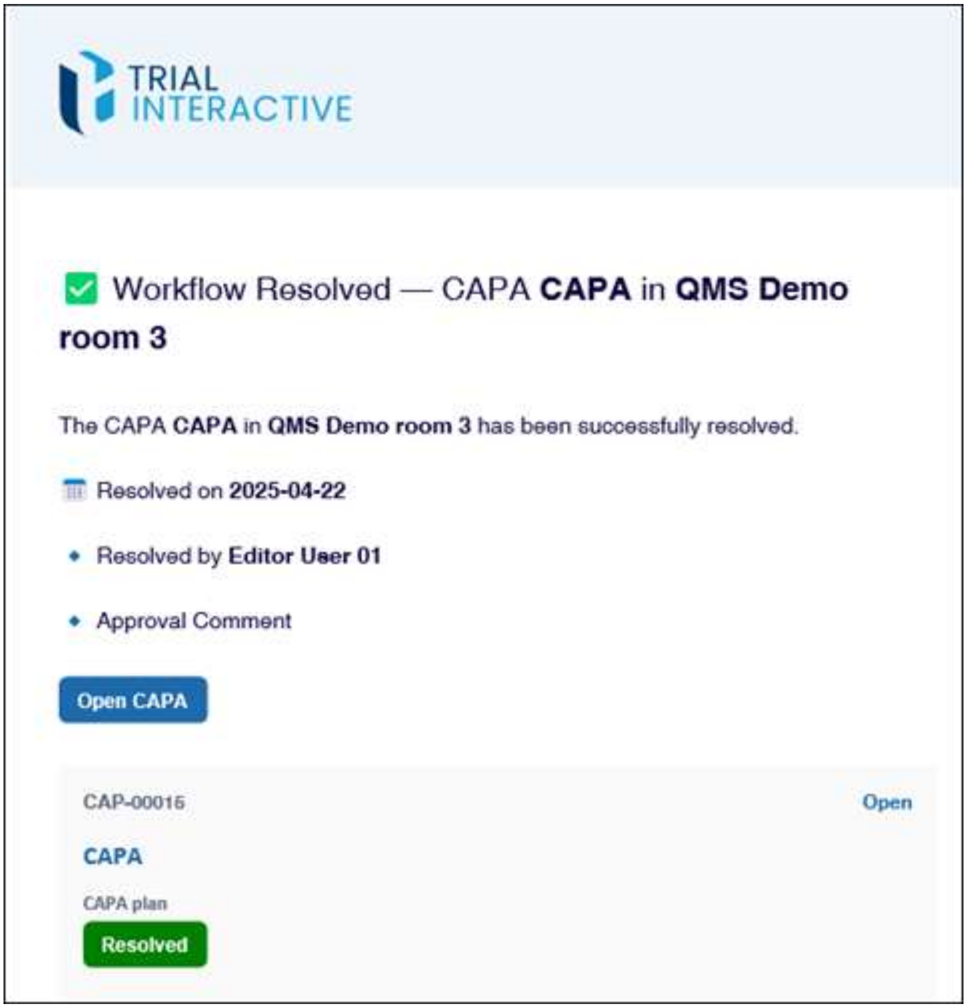

8. Click on the 'Approve' button above the Quick View panel.



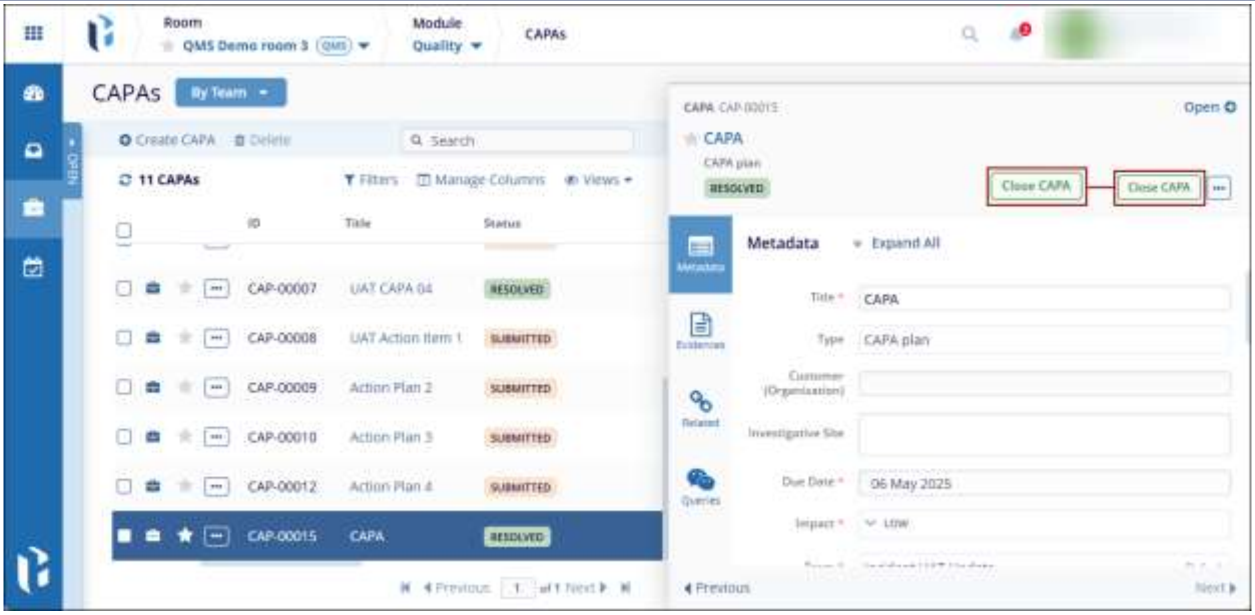
9. Enter the required details in the 'Approval Execution Form' and click on the Approve button.



10. Once the CAPA is successfully resolved, all the authorities for whom the notifications are enabled, receive an email stating the CAPA is resolved.




11. On the CAPA records page, click on the ‘Close CAPA’ button above the Quick View panel.




12. On the 'Close CAPA' popup, mandatorily add a comment and click on the 'Close CAPA' button.

## Request Clarification

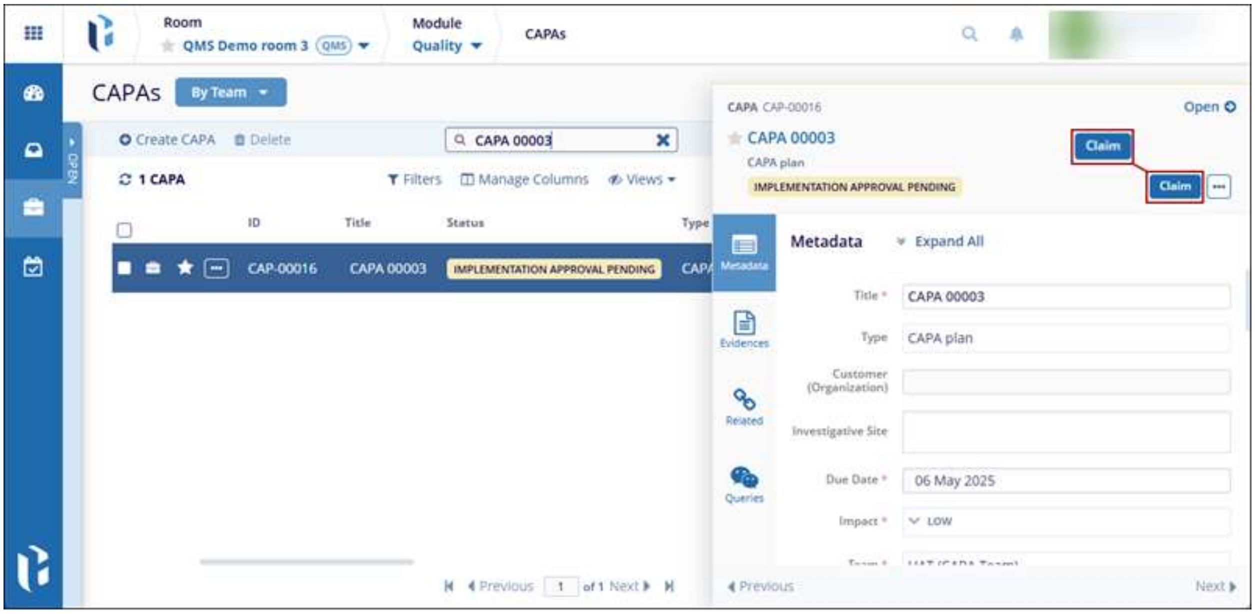
When a CAPA record progresses through the workflow stages, the assigned authorities at each stage can request clarification or create a query for the CAPA record, based on the workflow stage configuration.

To send a CAPA record for clarification, follow the steps below.

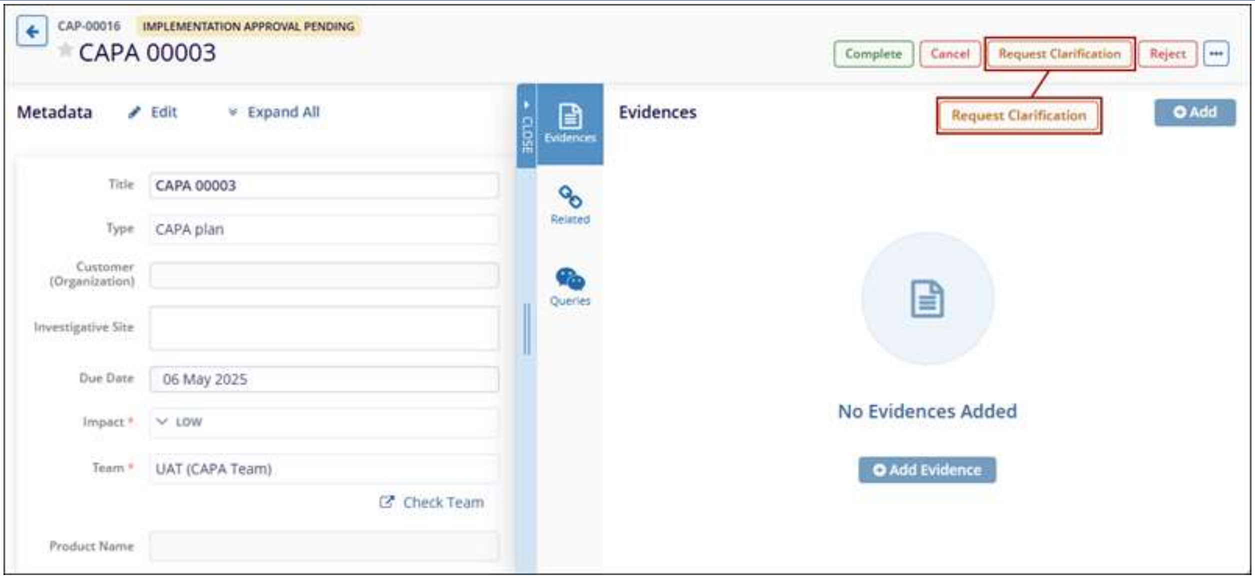
1. Create a CAPA record as an originator user and send it to the first stage of the approval workflow by following the steps detailed in the Create CAPA section.

2. As the authority in the first stage of the approval workflow, send the CAPA record to the second stage of the workflow, i.e., Implementation Approval by following the STEP 1 to STEP 6 from the Approve CAPA section.

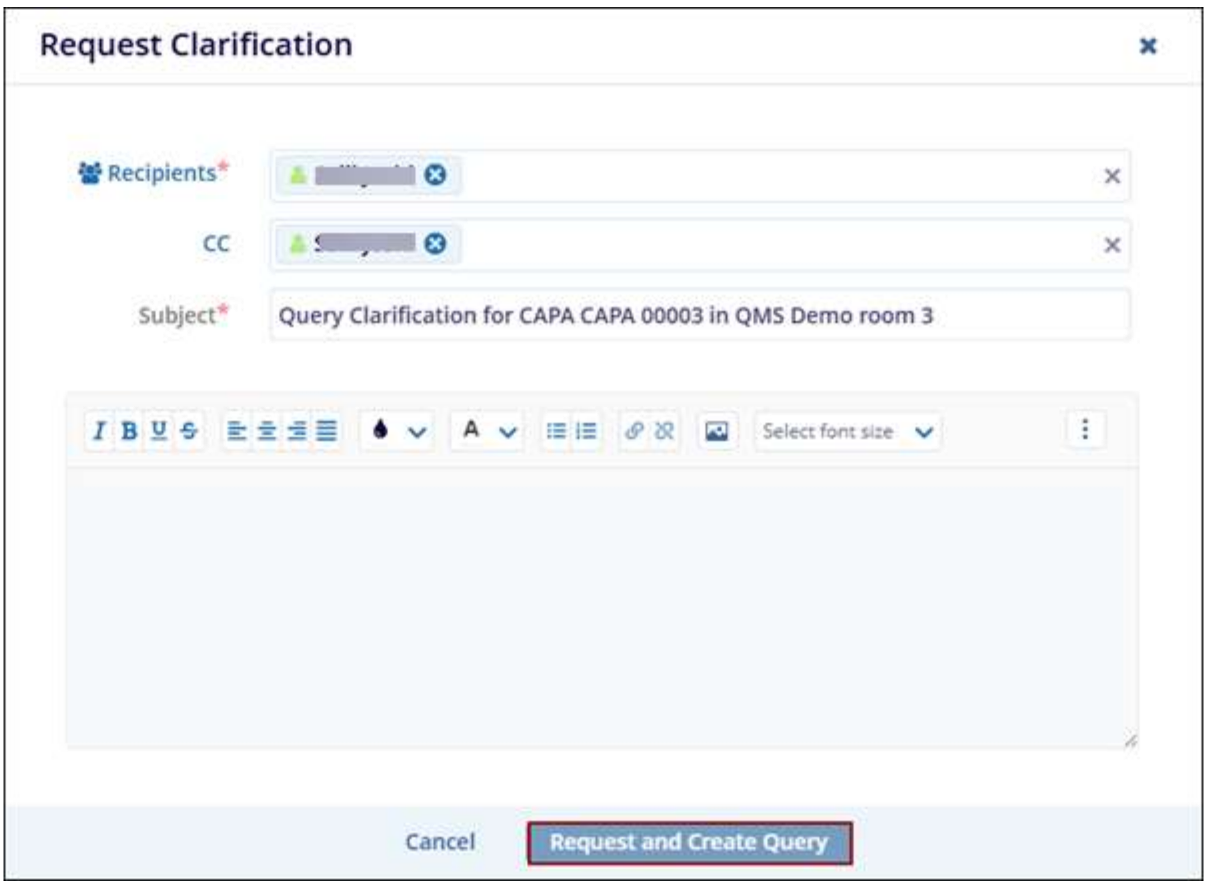
3. As the authority in the Implementation Approval stage, open the CAPA record and click on the Claim button.



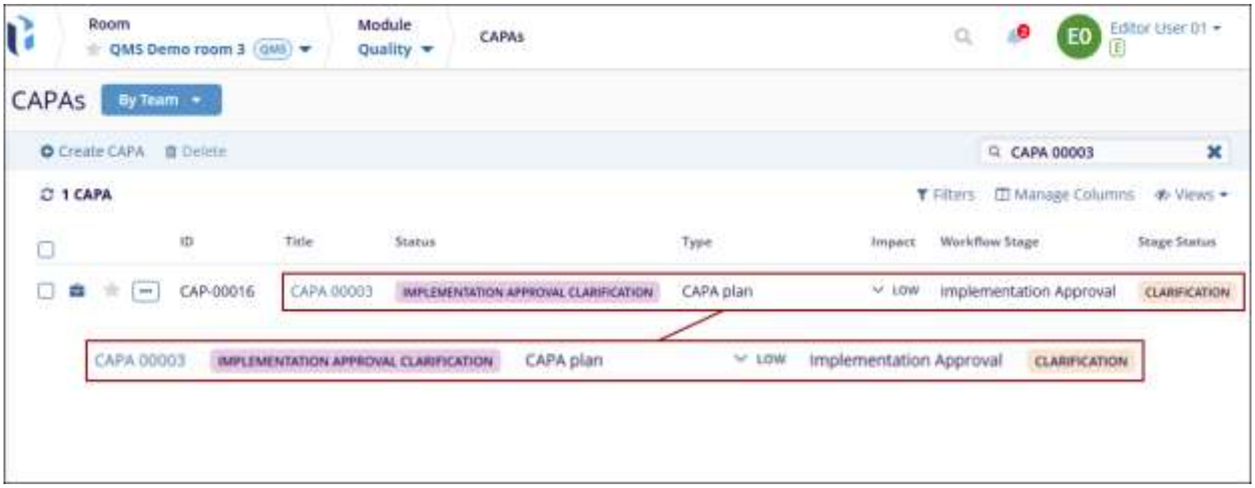

4. Click on the 'Request Clarification' button above the top of the quick view panel.




5. On the ‘Request Clarification’ screen, mandatorily specify the recipients, add a description, and click on the ‘Request and Create Query’ button.

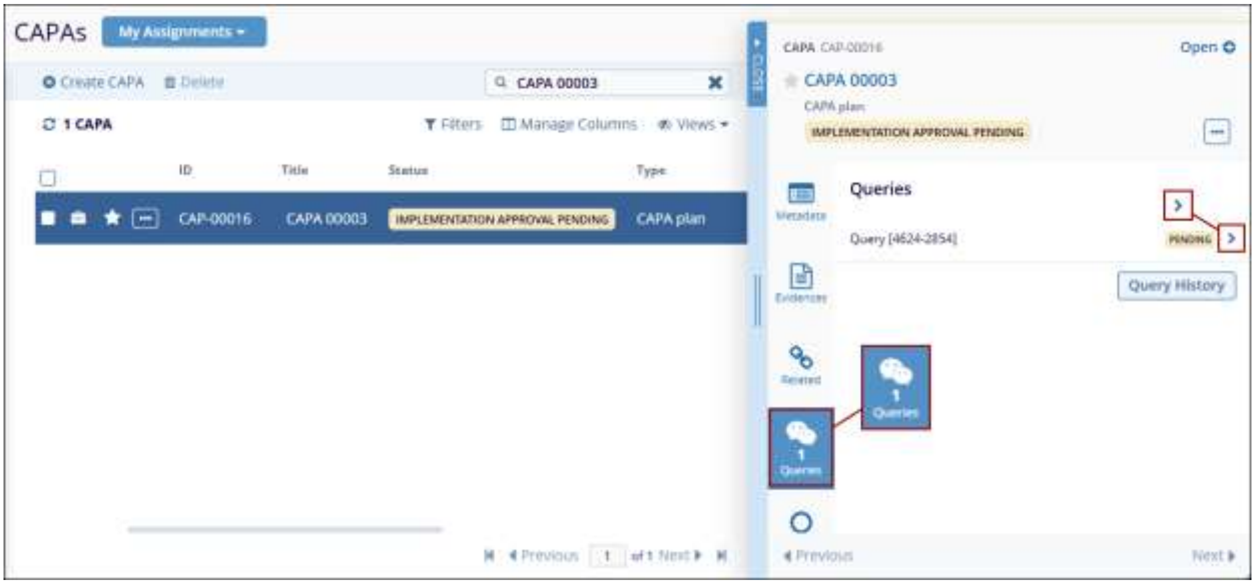


6. Once the record is successfully sent for clarification, the CAPA record displays the statuses as configured in the workflow.

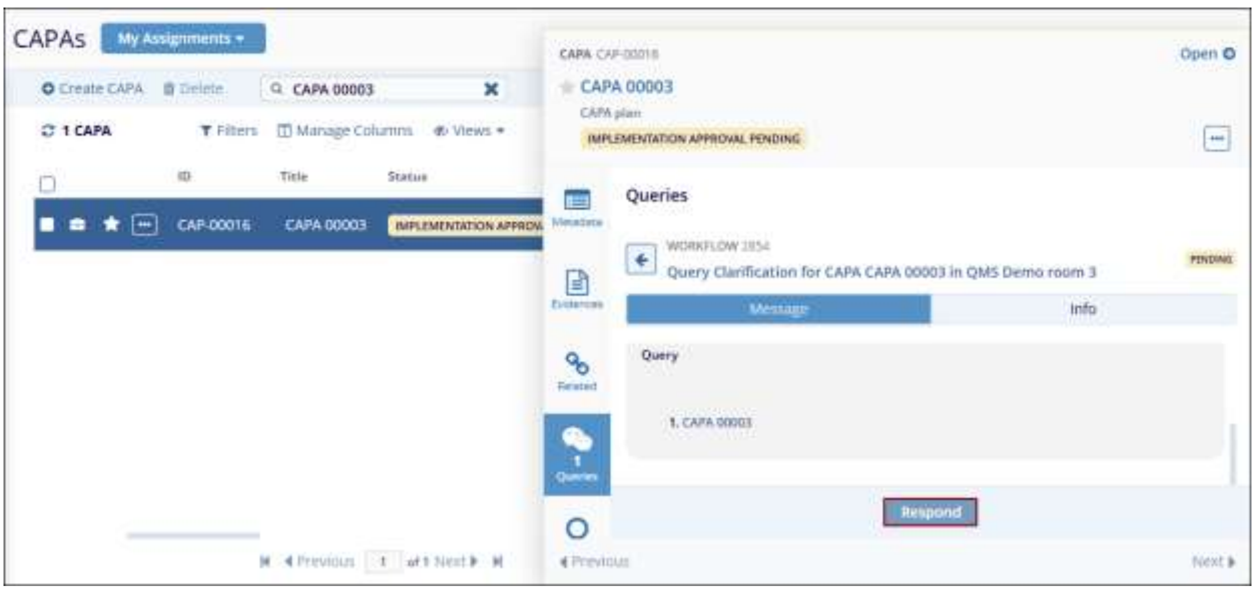


7. Additionally, the authority in the previous stage, i.e., Implementation, receives an email notification stating that a clarification is required on the CAPA record.

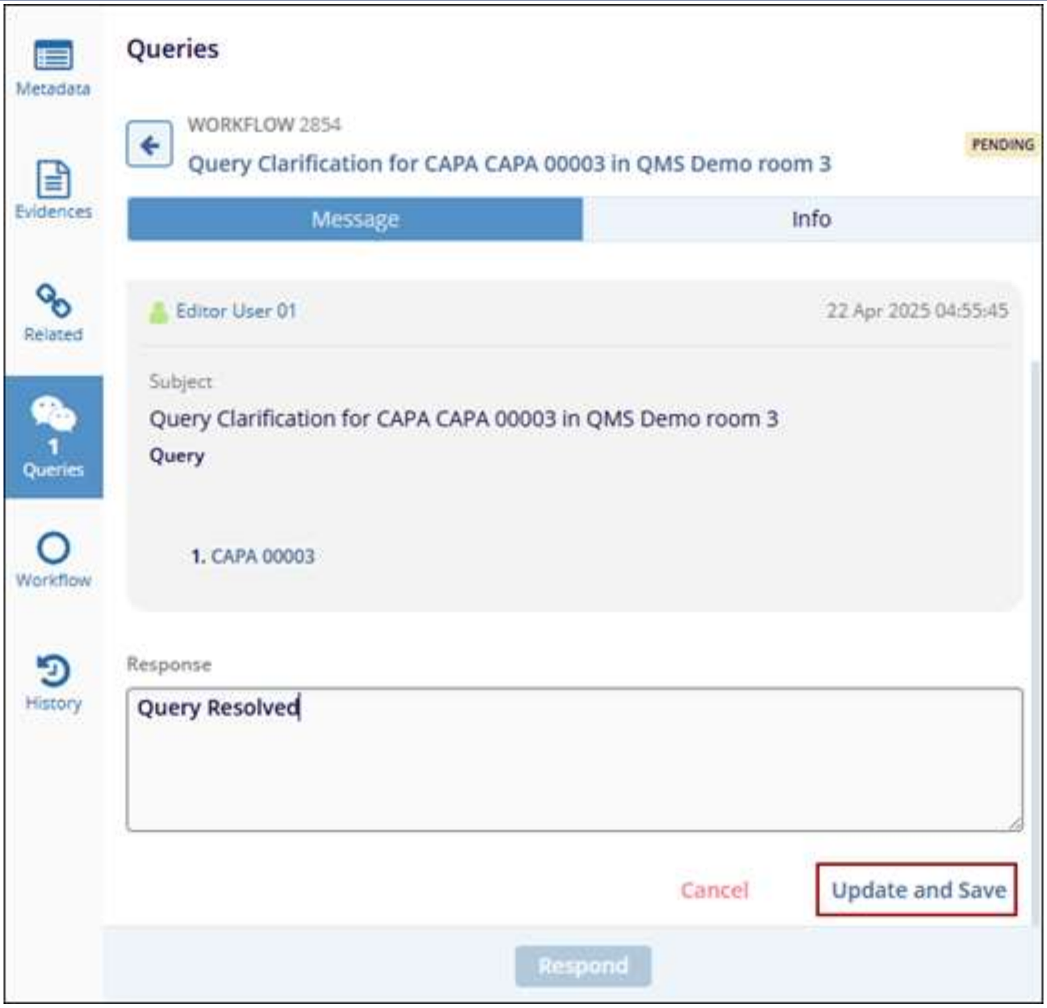
8. As the authority in the Implementation stage, open the CAPA record and navigate to the ‘Queries’ tab in the quick view panel and click on the ‘>’ arrow.



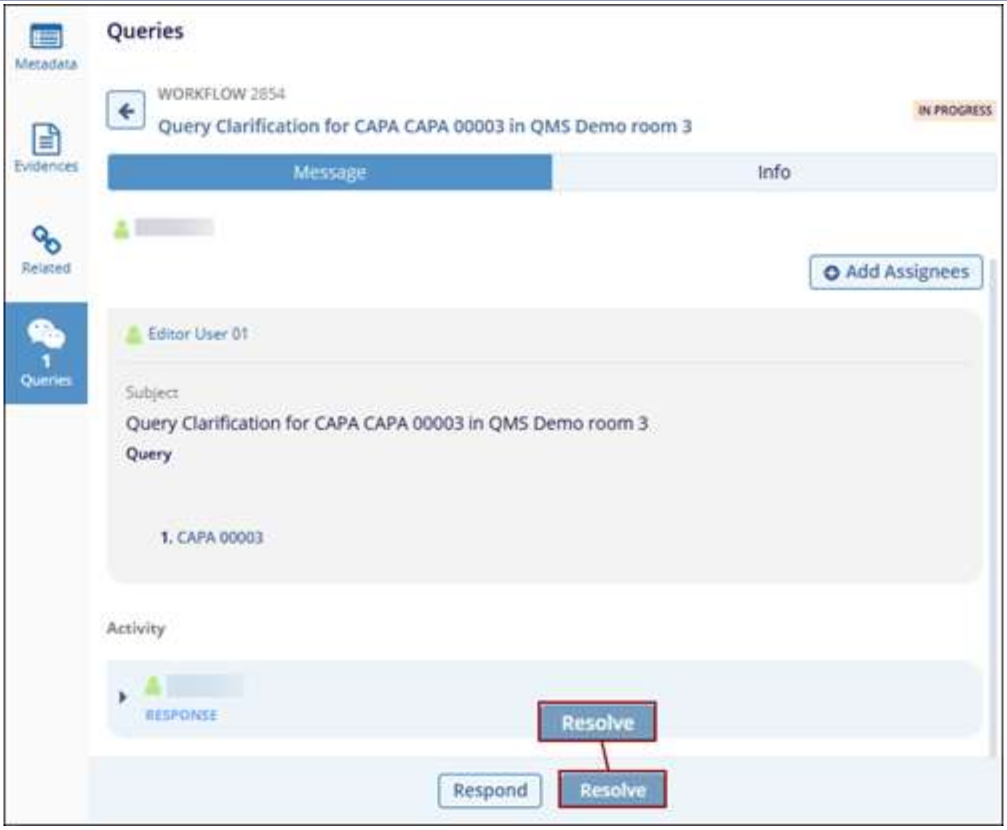

9. Click on the ‘Respond’ button.



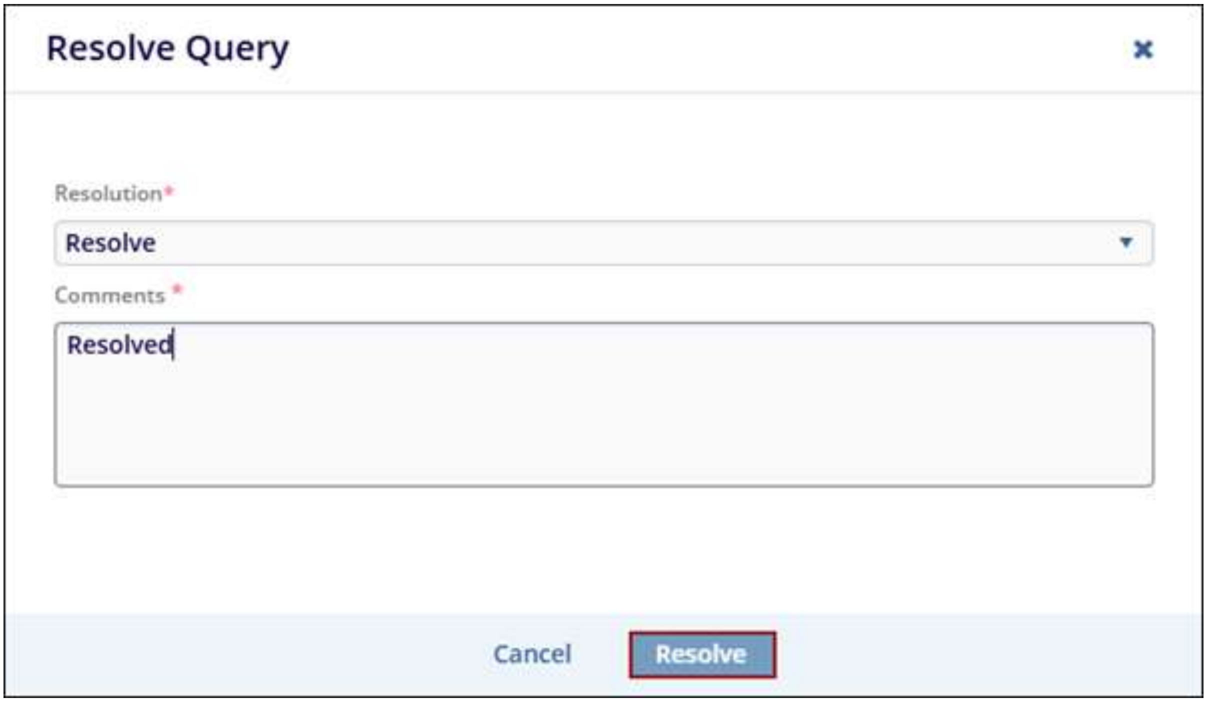

10. Enter the necessary response and click on the ‘Update and Save’ button.



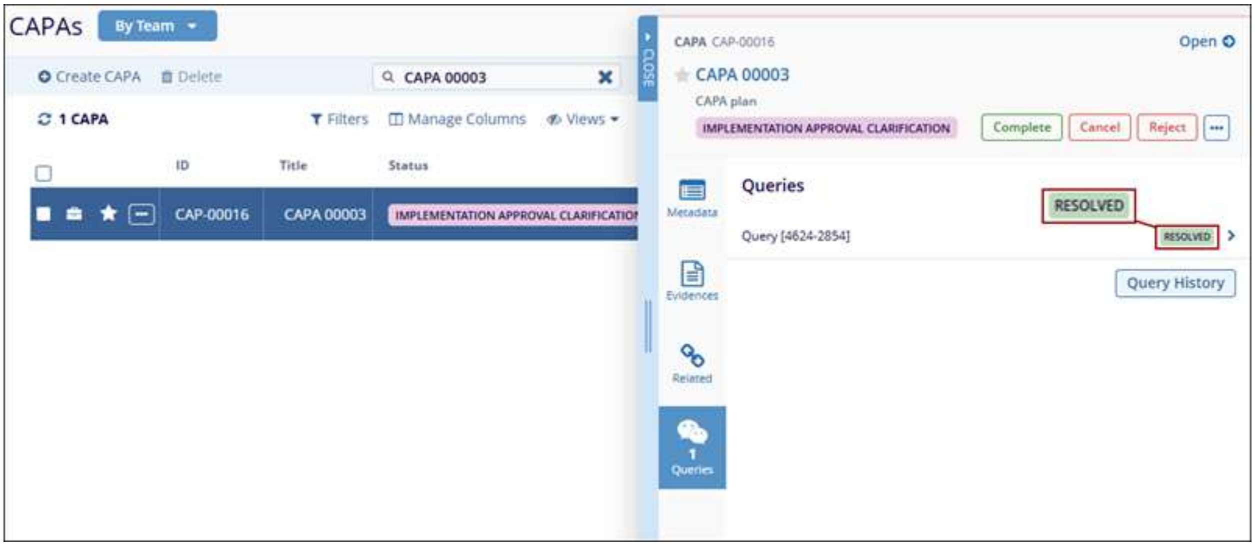

11. As the query initiator, i.e., assigned authority in the Implementation Approval stage, navigate to the Queries tab and click on the 'Resolve' button.



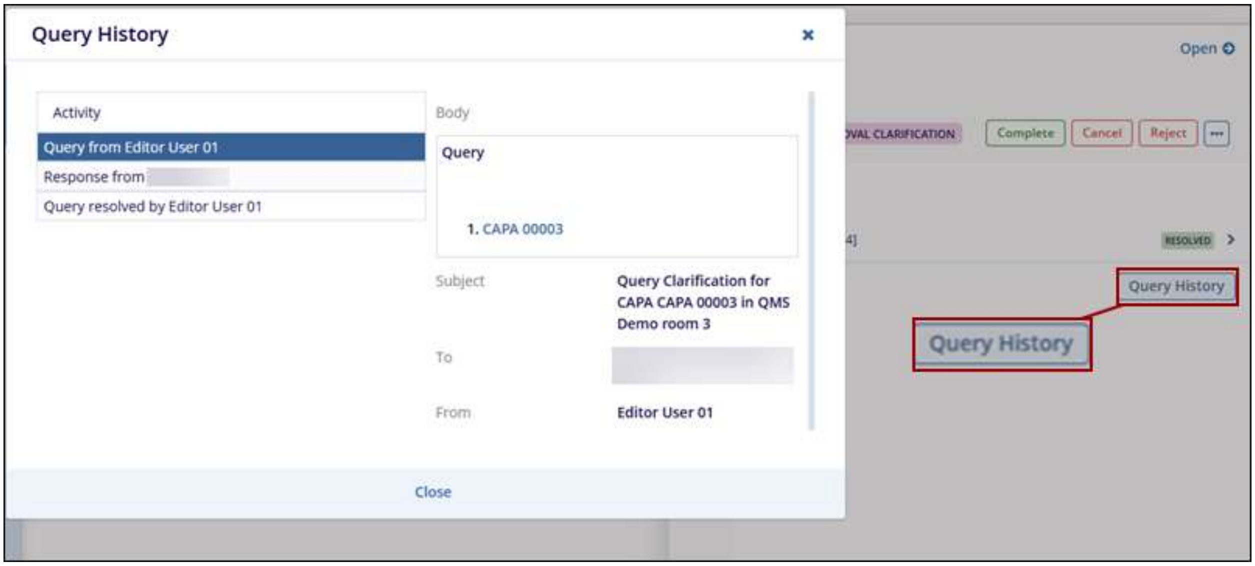

12. On the 'Resolve Query' modal window, mandatorily enter comments and click on the 'Resolve' button.



13. Once the Query is successfully resolved, the 'Queries' tab displays the status as resolved.




14. Click on the 'Query History' button to view the activities related to the Query.




15. Complete the record approval by following STEP 7 to STEP 12 detailed in the [Approve CAPA] section.

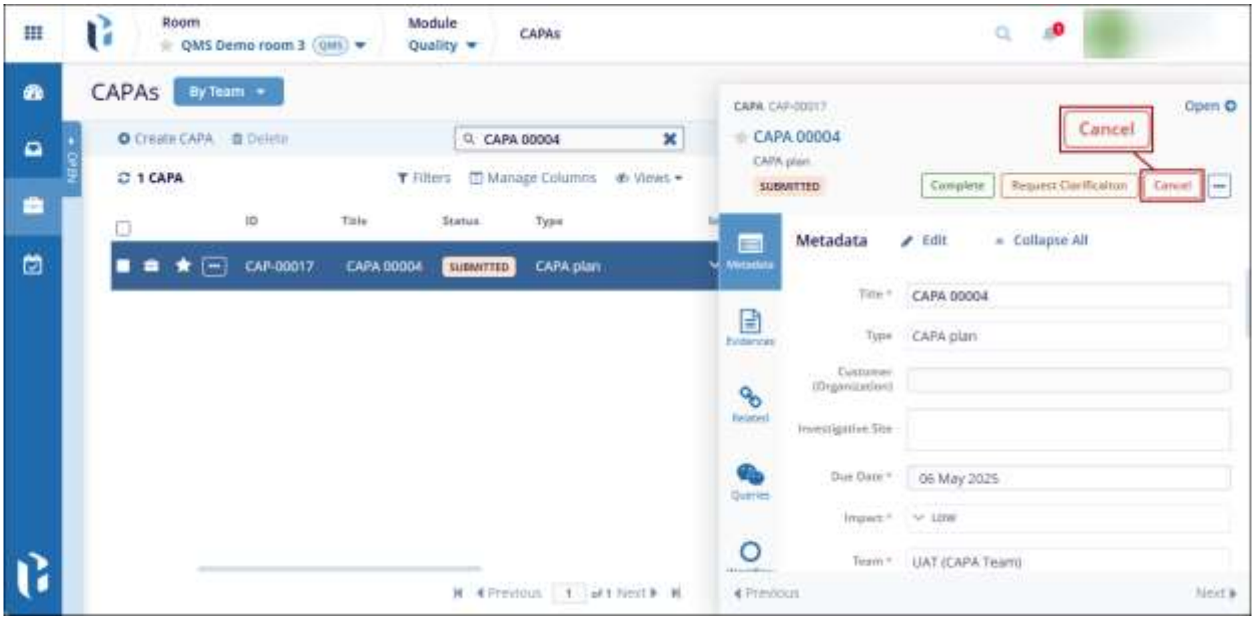
## Cancel CAPA

Authorities in the workflow stages can cancel a CAPA record depending on the configurations in the workflow stages. Once an authority cancels a CAPA, the record is removed from the workflow.

To cancel a CAPA, follow the steps below.

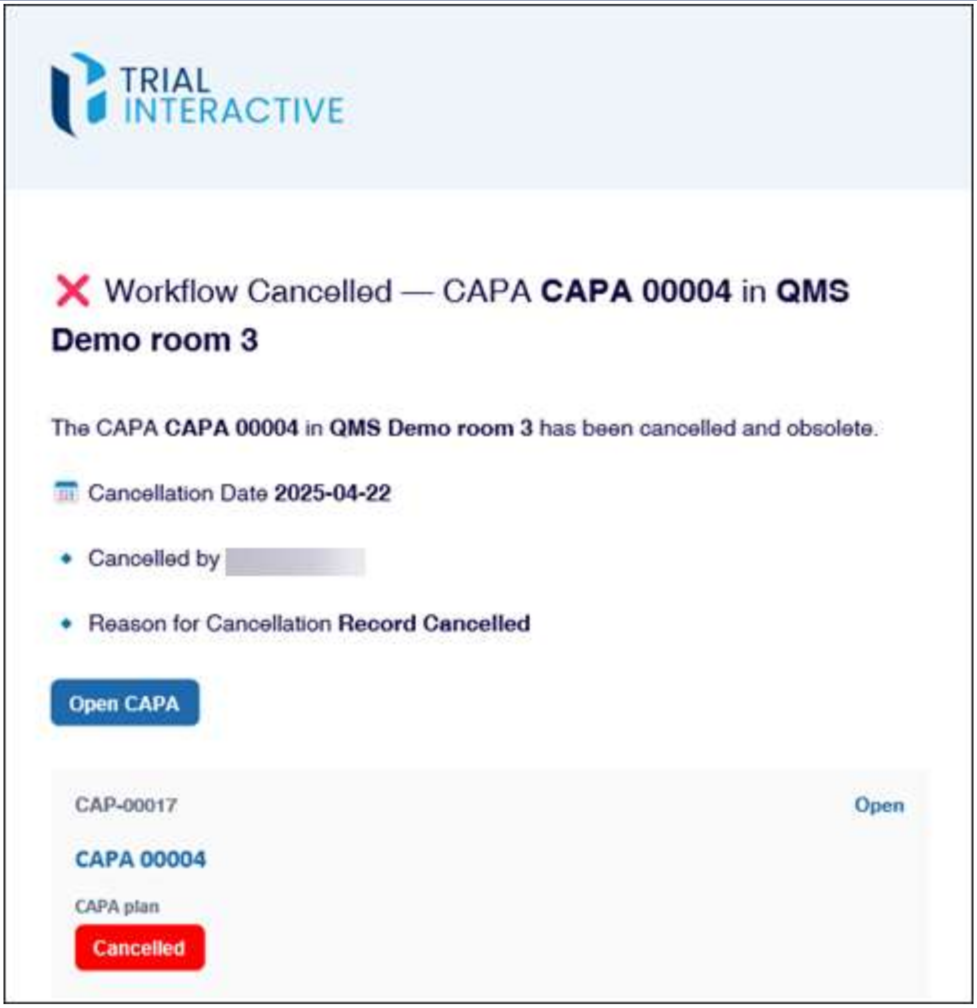
1. Create a CAPA record as an originator user and send it to the first stage of the approval workflow by following the steps detailed in the Create CAPA section.

2. As an authority in the first stage, open the CAPA record, claim the record, and click on the Cancel button.




3. On the ‘Cancel Implementation’ dialog box, enter the necessary comments and click on the Cancel button.


4. Once the record is successfully cancelled, it is removed from the workflow and displays the statuses as configured in the workflow.
5. Additionally, depending on the notification's configuration in the approval workflow, the authorities receive an email notification stating that the record was canceled.


TRIAL INTERACTIVE
Workflow Cancelled — CAPA CAPA 00004 in QMS Demo room 3
The CAPA CAPA 00004 in QMS Demo room 3 has been cancelled and obsolete.
Cancellation Date 2025-04-22
Cancelled by
Reason for Cancellation Record Cancelled
Open CAPA
CAP-00017
Open
CAPA 00004
CAPA plan
Cancelled

## Reject CAPA

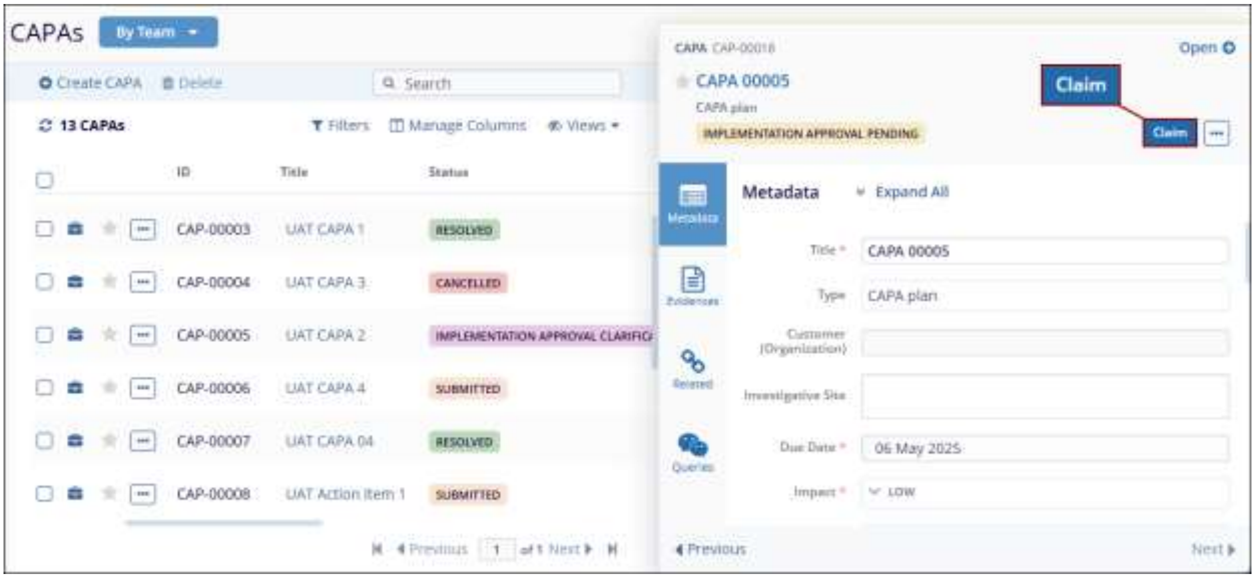
Authorities within the workflow stages can reject a CAPA record based on the stage-specific configuration. Rejections typically occur during the Approval stage by the designated Approver. When a CAPA record is rejected, it is sent back to the previous stage. For instance, if a record is rejected at the Implementation Approval stage, it will return to the Implementation stage.

To reject a CAPA record, follow the steps below.

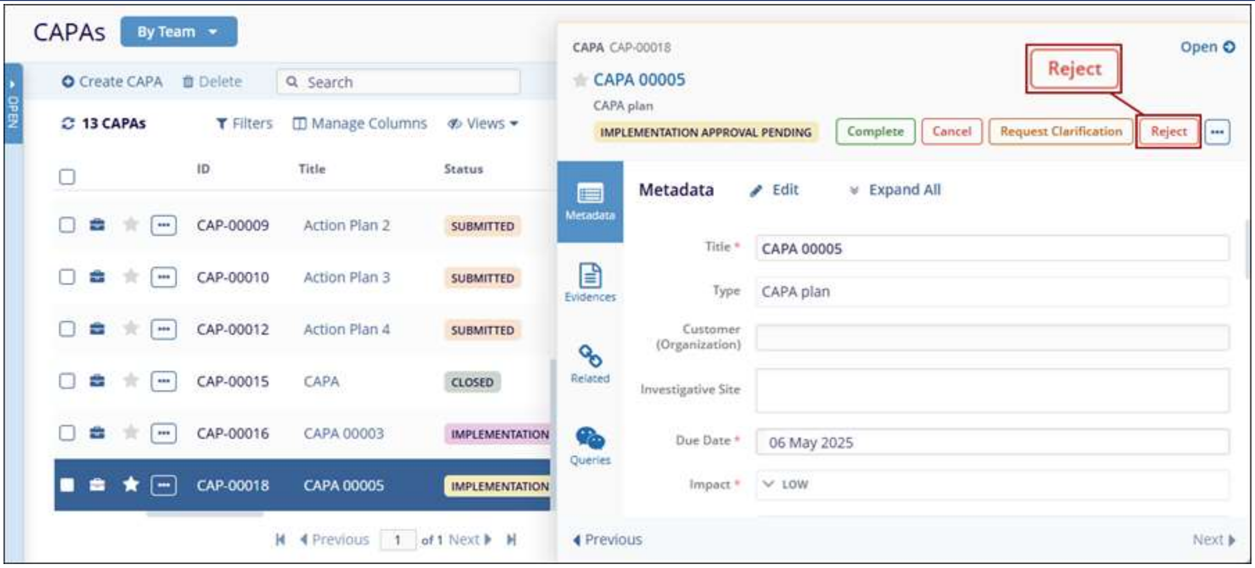
1. Create a CAPA record as an originator user and send it to the first stage of the approval workflow by following the steps detailed in the Create CAPA section.

2. As the authority in the first stage, complete the record and transition it to the next stage by following 'STEP 1 to **STEP 6'** detailed in the Approve CAPA section.

3. As the assigned authority in the 'Implementation Approval' stage, open the CAPA record and click on the Claim button.

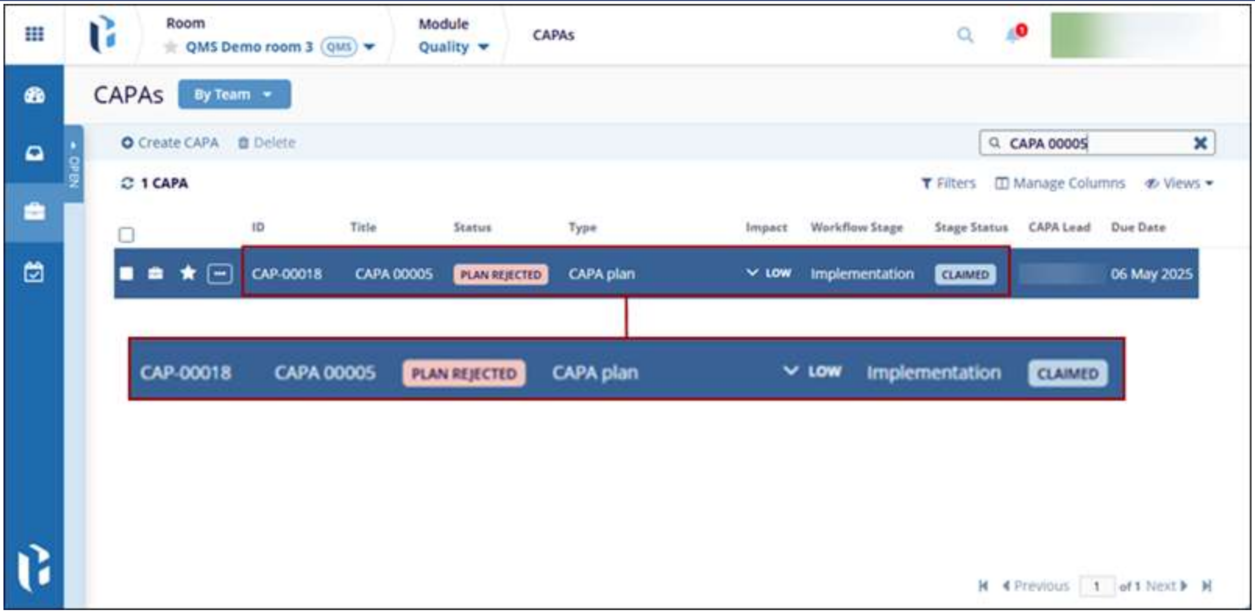



4. Click on the 'Reject' button situated above the quick view panel.

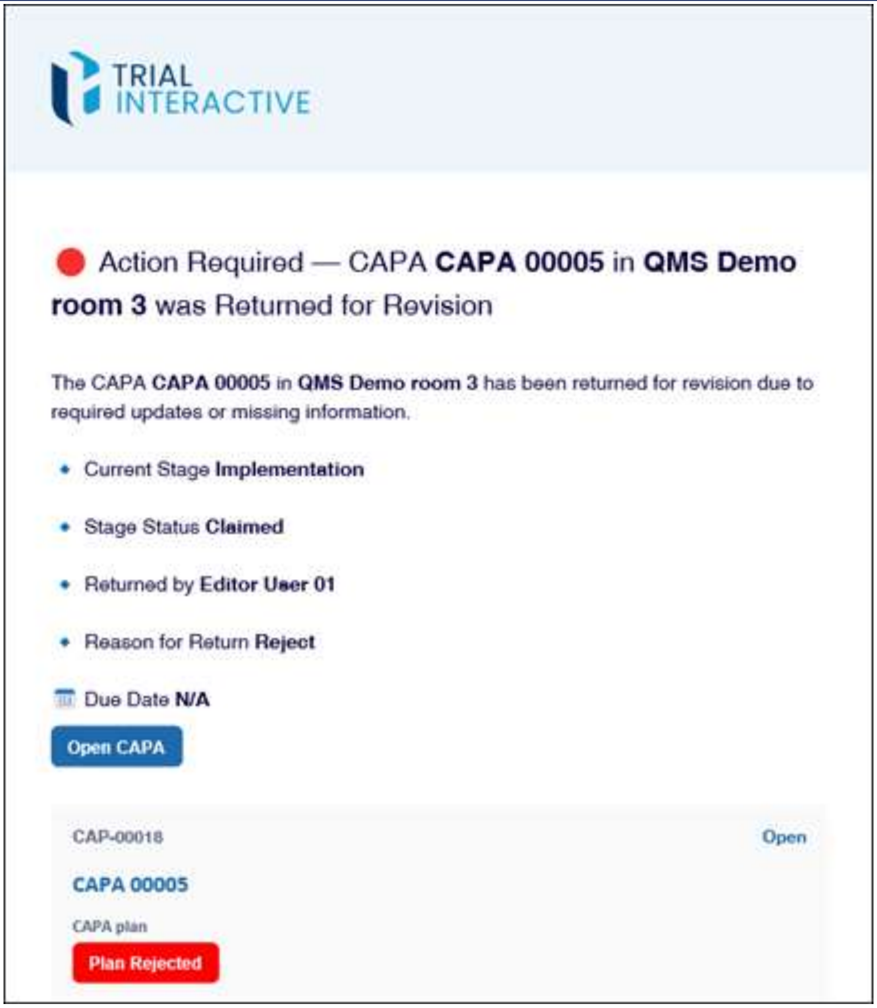



5. On the ‘Reject Implementation Approval’ dialog box, enter the necessary comments and click on the ‘Reject’ button.


6. Once the record is successfully rejected, it is transitioned back to the previous stage and displays the statuses as configured in the workflow.




7. Additionally, the authority in the previous stage of the workflow receives an email notification stating the record is returned for revision, depending on the notification's configuration in the workflow.




8. As the authority in the previous workflow stage, make the necessary revisions and transition the record to the next stage.

9. Approve the record in the last stage by following the steps detailed in the [Approve CAPA](#) section.

Important

- The display of forms, workflow status, record status, and available action buttons are determined by the configurations set in the QMS Workflow settings.
- If a stage has multiple assigned authorities, the record must be manually claimed by one of them to proceed.

# ACTION ITEMS

In Quality Management, Action Items are created during the CAPA, Audit, or Non-Conformance process, Action Items help organizations implement corrective, preventive, and immediate actions efficiently. These tasks can trigger related processes such as Change Management, Training, or additional risk assessments to ensure comprehensive issue resolution.

An Action Item typically involves the following workflow stages

- Implementation
- Implementation Approval

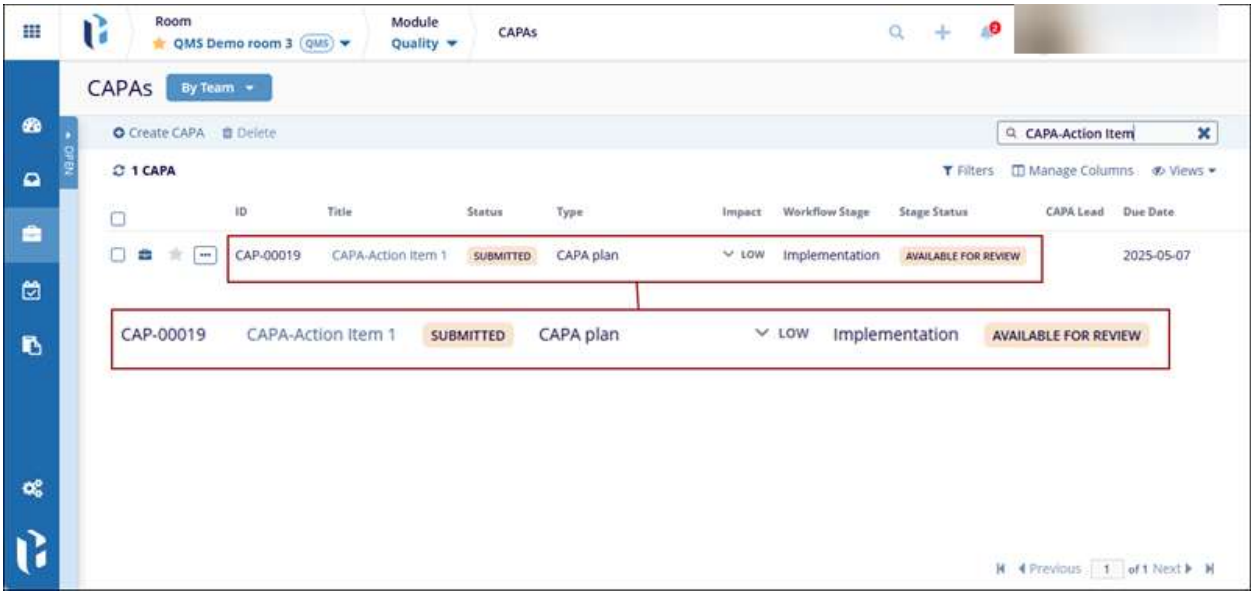
## Create Action Item

This section describes the process of creating an Action item from a CAPA record within the Quality module. To initiate an Action item from a CAPA, the originator must have the 'Create CAPA' action enabled in the User Management module.

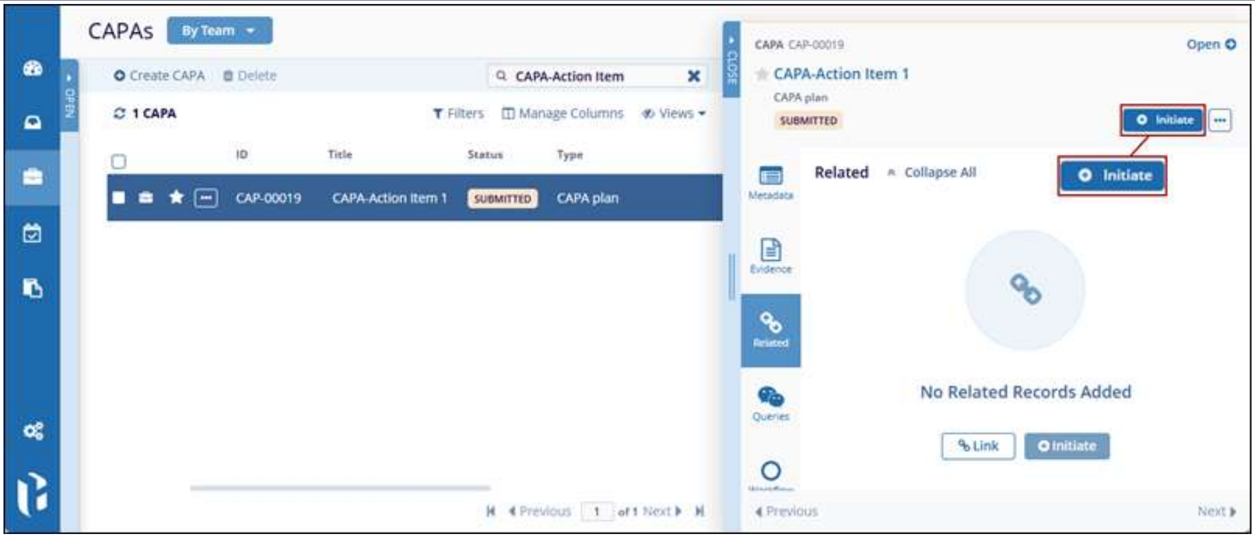
Note: Additionally, the originator must be an Admin user. If the Action item is being created by an editor user, they must belong to the assigned team and hold the necessary authority.

To create an Action Item from CAPA, follow the steps below.

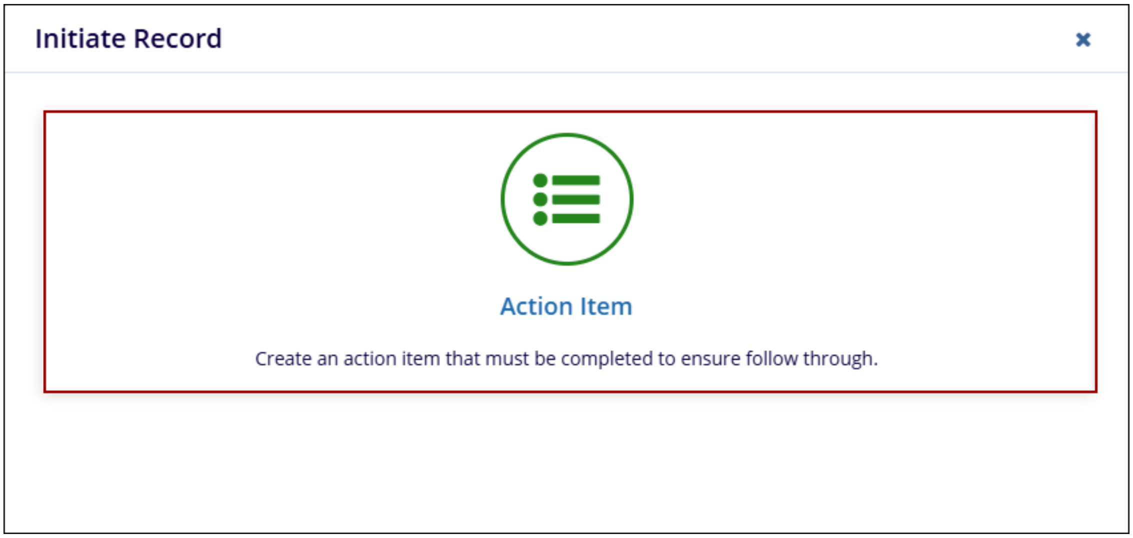
1. Create a CAPA record and submit it for review by following the steps, i.e., STEP 1 to STEP 8, detailed in the Create CAPA section.



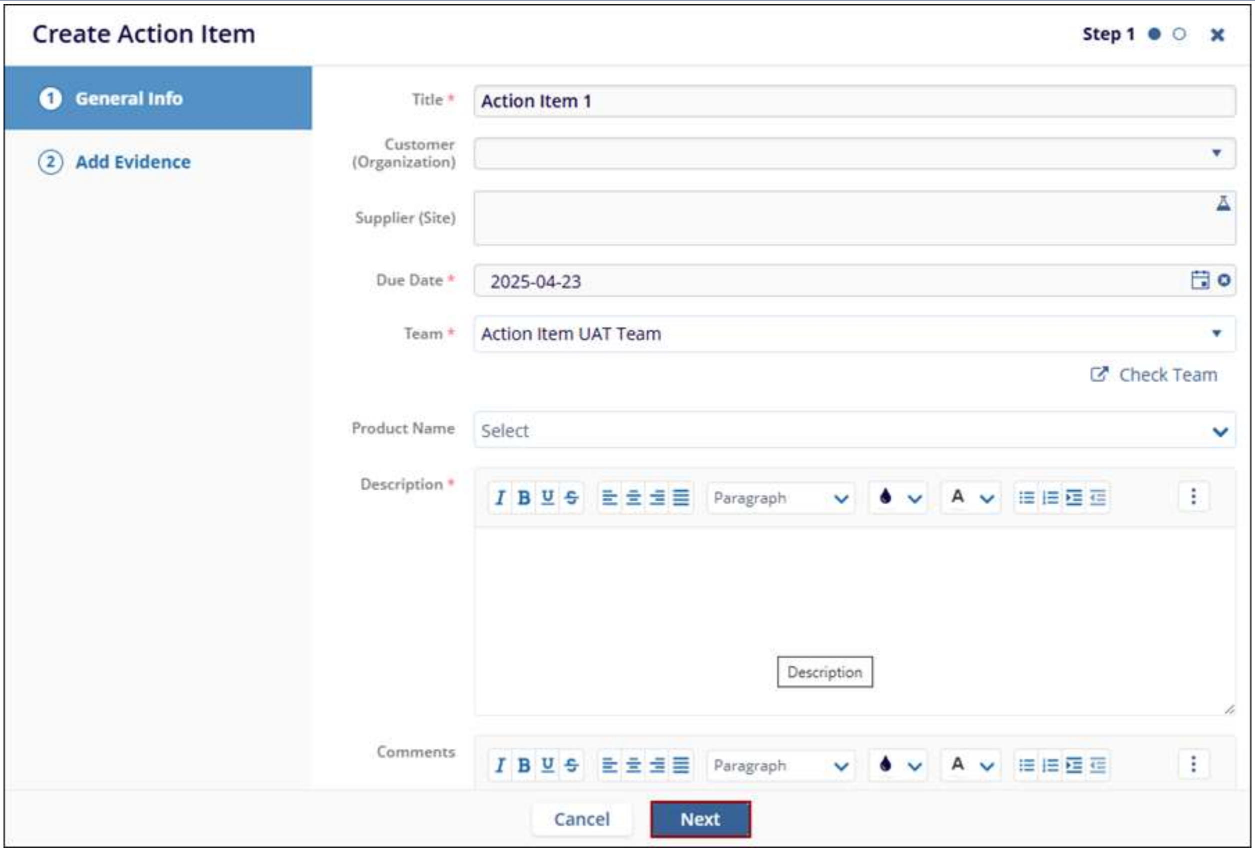

2. Click on the CAPA title, navigate to the 'Related' tab in the quick view panel and click on the 'Initiate' button.



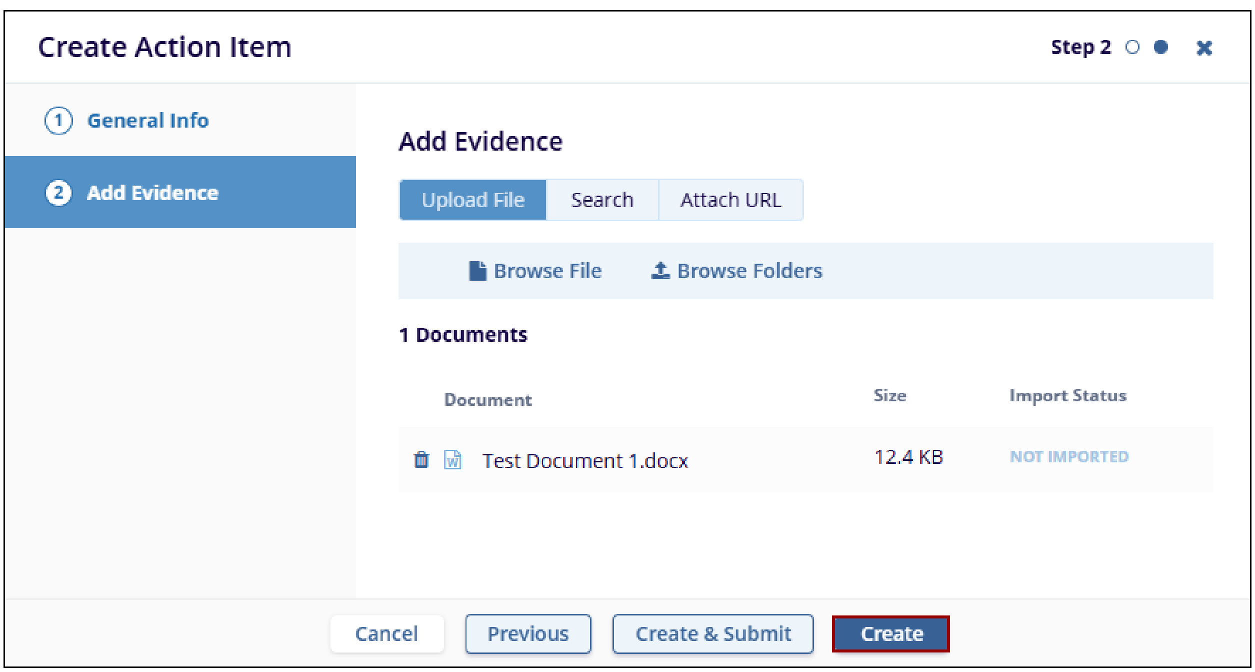

3. On the ‘Initiate Record’ modal window, select the ‘Action Item’ option.



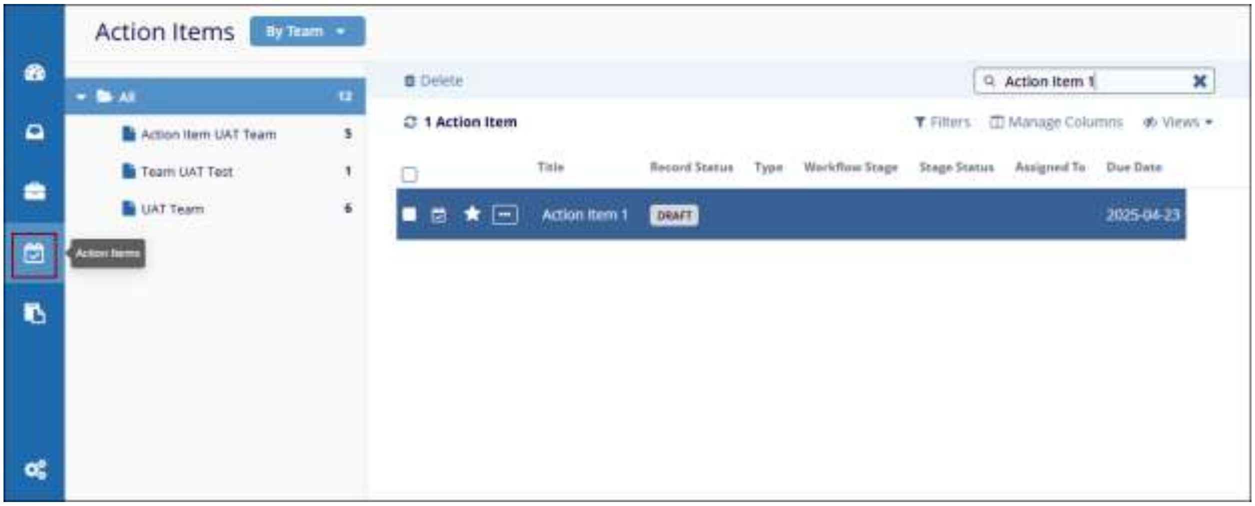

4. On the ‘Create Action’ form, fill in the mandatory details within ‘**Step 1: General Info’** and click on the ‘Next’ button.



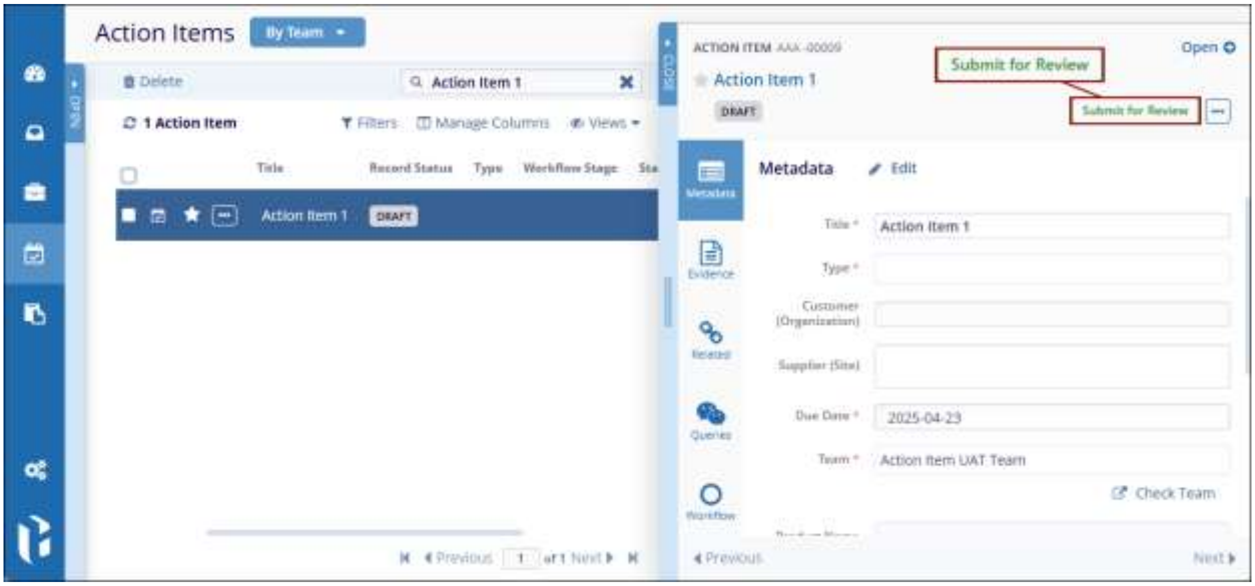

5. Within ‘Step 2: Add Evidence’, upload a file or folder as evidence and click on the ‘Create’ button.



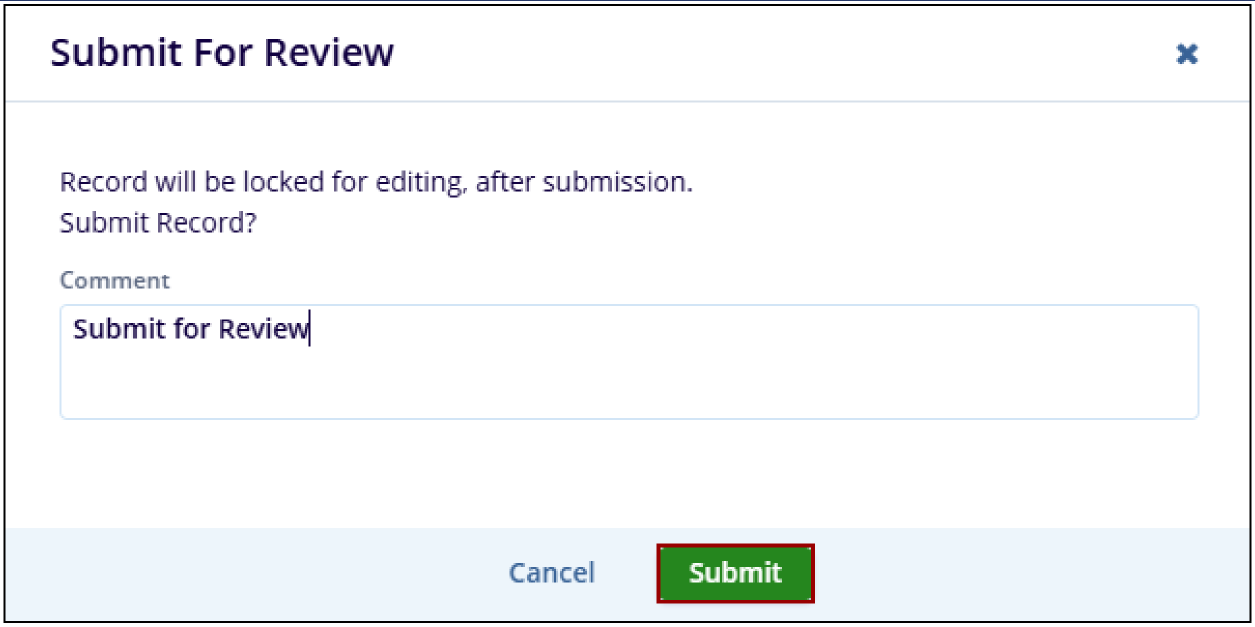
6. From the left-hand navigation pane, click on the ‘Action Items’ modal and select the item by setting the appropriate view.



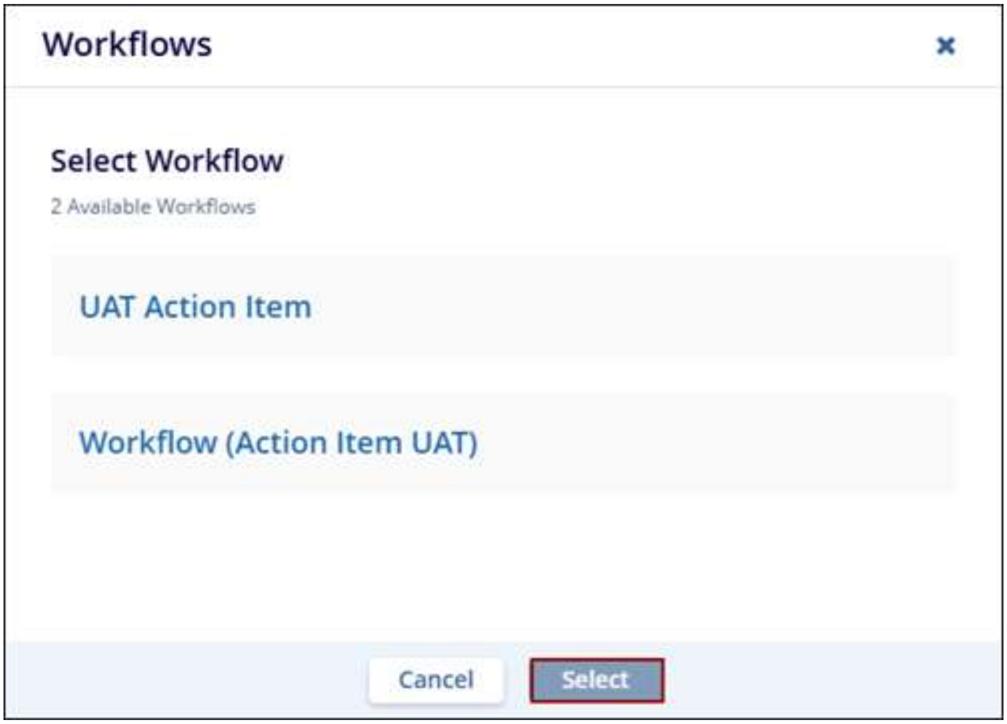

7. Select the Action Item and click on the ‘Submit for Review’ button from the quick view panel.



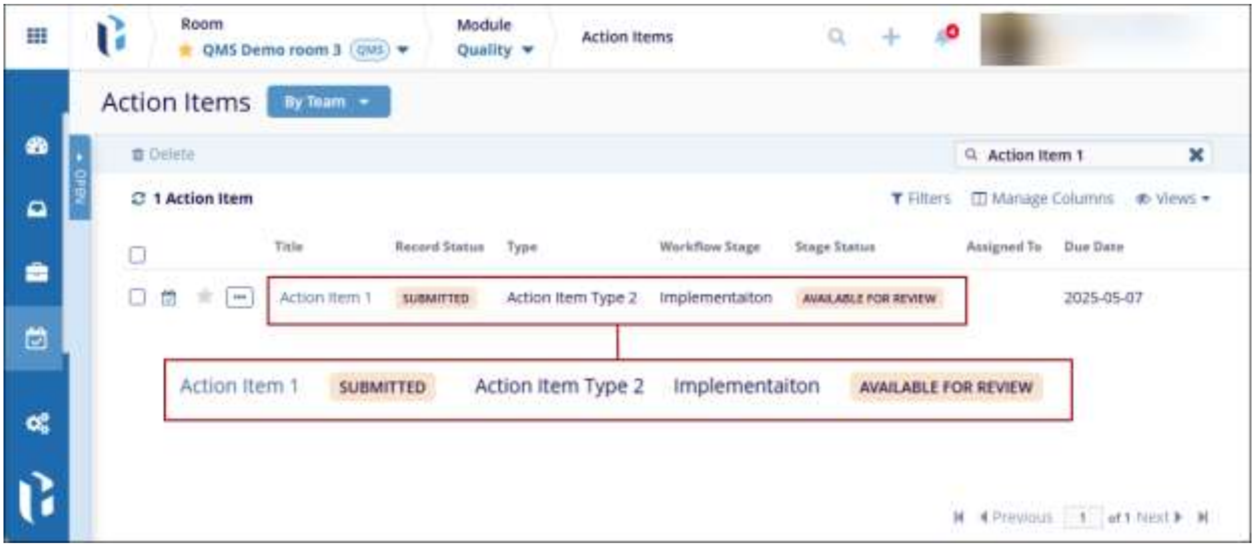

8. Enter the necessary comment in the ‘Submit for Review’ popup and click on the ‘Submit’ button.



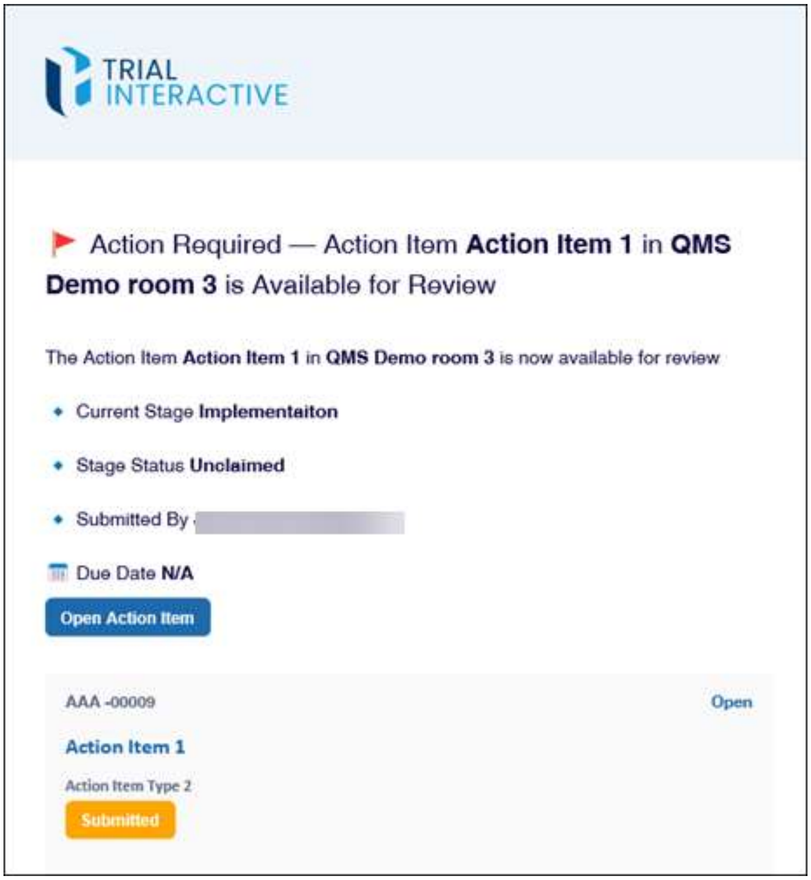

9. Choose the appropriate workflow from the ‘Workflows’ wizard and click on the ‘Select’ button.




10. Once the Action Item is successfully transitioned to the first stage of the workflow. The ‘Record Status’, ‘Workflow Stage’, and ‘Stage Status’ display statuses as configured in the workflow.




11. Once the record enters the first stage of the approval workflow, the authority receives an email notification about the CAPA record with CAPA details and a clickable 'Open CAPA' button to open the record.



Note

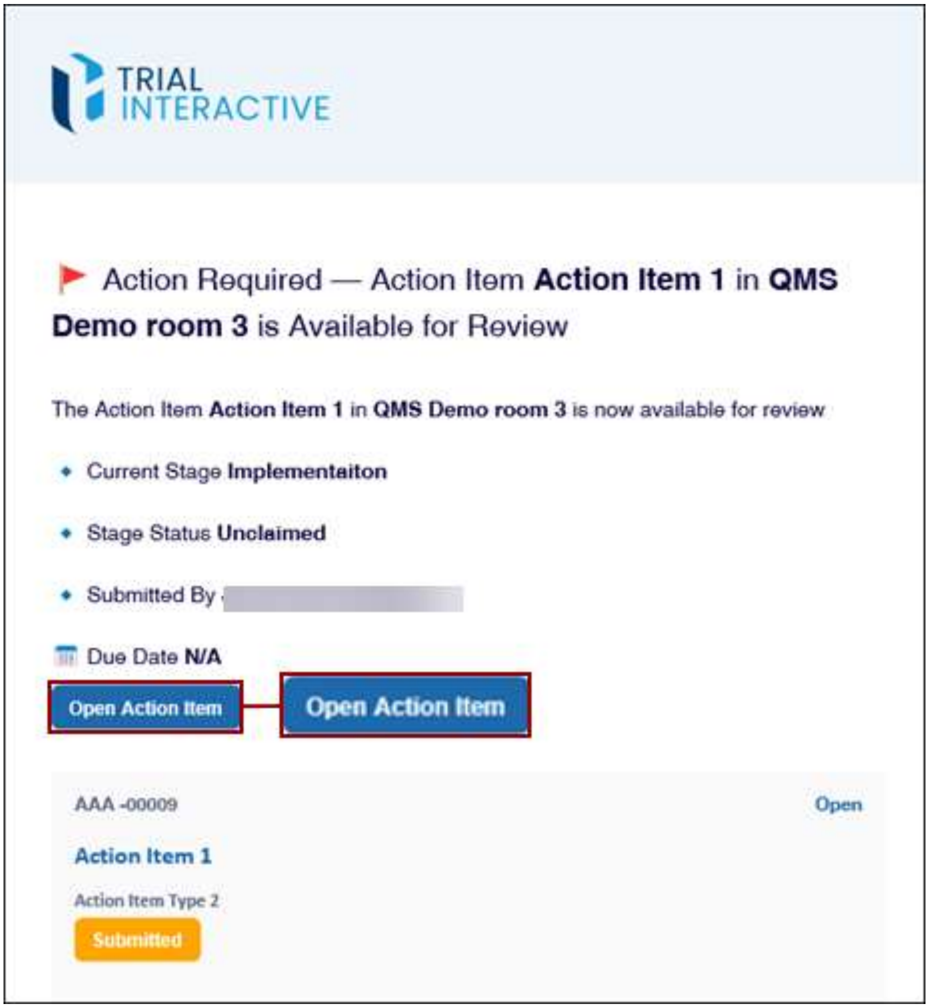
- Email notifications about record transitions are sent to the relevant authority types based on the Approval Workflow configuration.
- The number of stages an Action item progresses through, along with its record and stage statuses, is determined by the configured Approval Workflow.
- If more than one workflow is identified based on the record types, users can choose from the available workflows list.
- If only one workflow is identified based on the record types, the records automatically enter that workflow without displaying the selection wizard.

## Approve Action Item

When an Action item enters the approval workflow, the designated authorities are responsible for advancing the record through each stage until it reaches the final stage. At the final stage, a user (typically an Approver) reviews and approves the record, thereby resolving it.

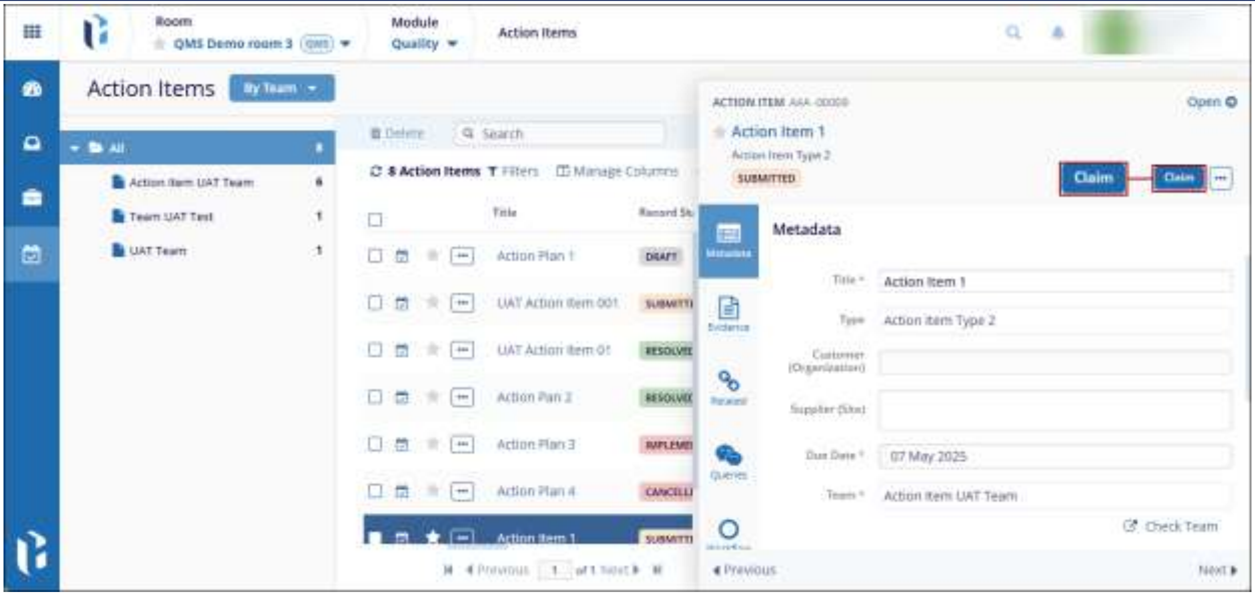
To approve and resolve a record, follow the steps below.

1. Login as a user who is assigned as an authority in the first stage of the workflow and click on the ‘Open Action Item button from the email notification.




2. Additionally, users can access the Action Item assigned to them by setting the My Assignments view from the dropdown at the top.

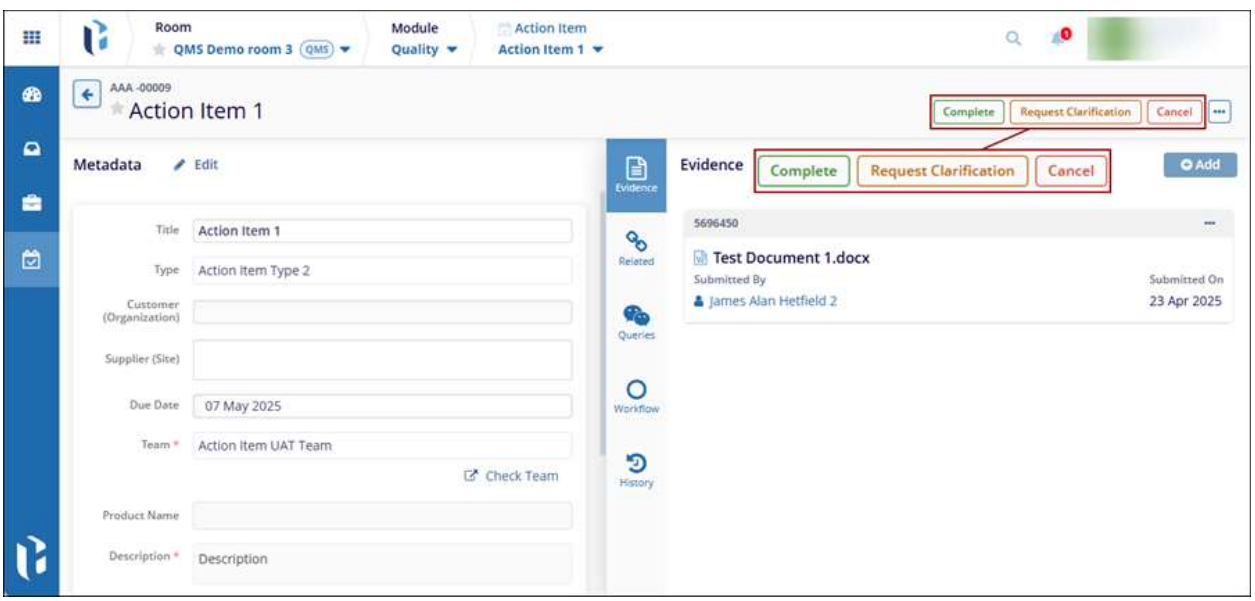
3. On the Action Item records screen, click on the ‘Claim’ button.




Note:

- The ‘Claim’ button appears when there are multiple authority types in the workflow stage, and any one of the authorities should manually claim the record.
- If there is only one user in a stage, the record is auto-claimed.

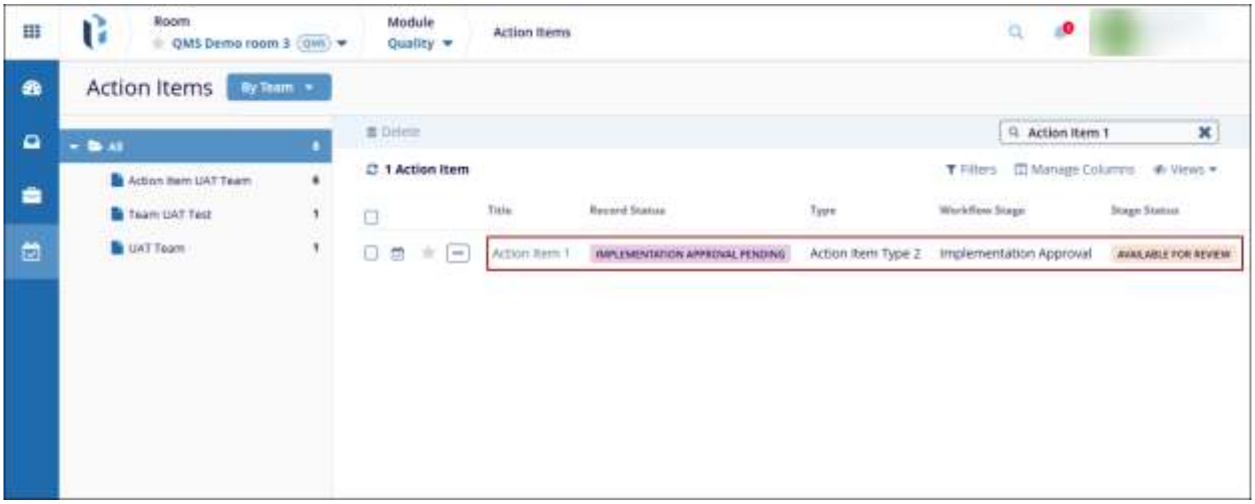
4. Once the assigned authority clicks the ‘Claim’ button, the record is claimed by that authority and the action buttons appear as configured in the workflow.



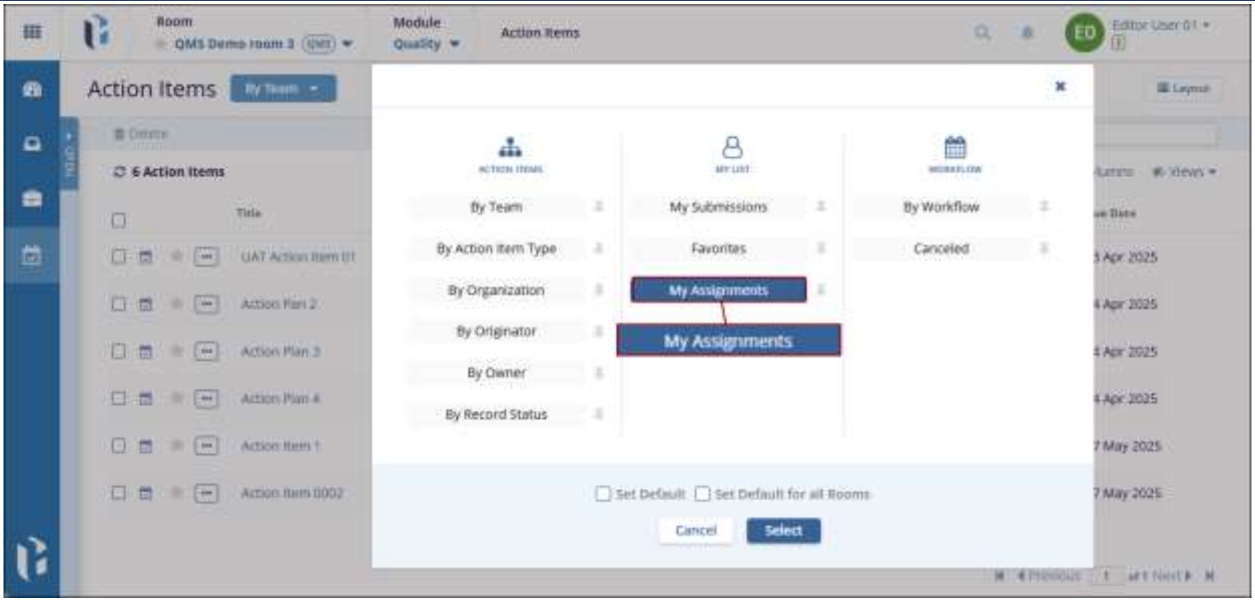
5. Click on the ‘Complete’ button, fill in the necessary details in the ‘Complete Implementation’ form, and click on the ‘**Complete’** button.


Note: The display of forms and other sections, upon clicking an action button, depends on the ‘Triggers’ configured within the workflow.

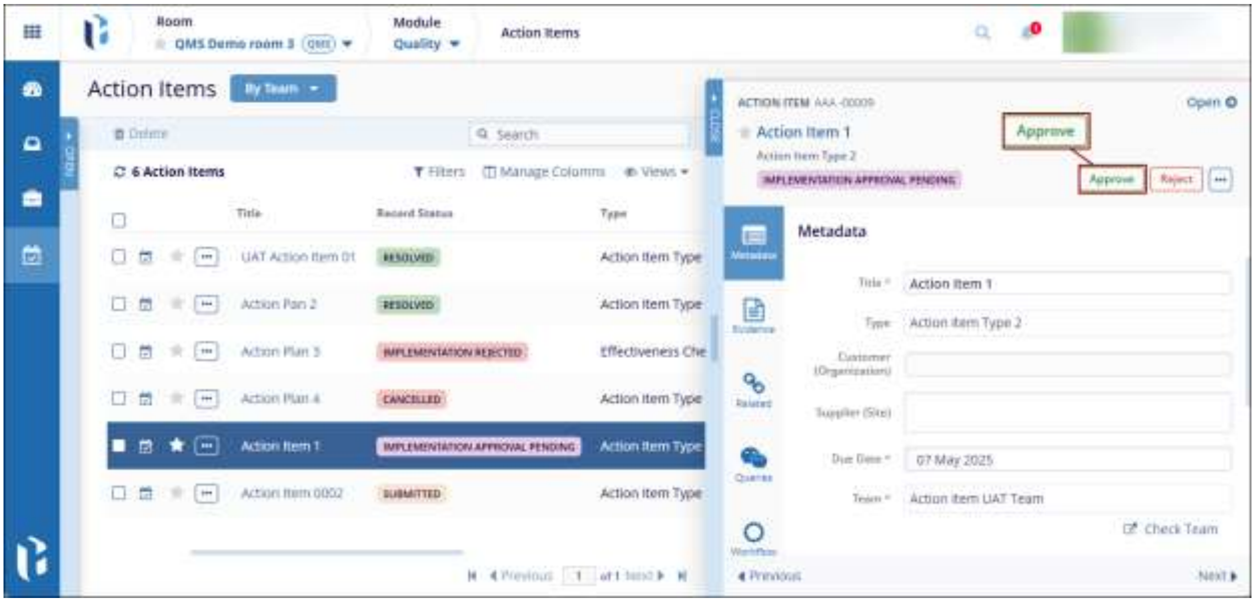
6. Once the record is completed, it is transitioned into the next stage, i.e., Implementation Approval, and the record displays the statuses as configured in the workflow.



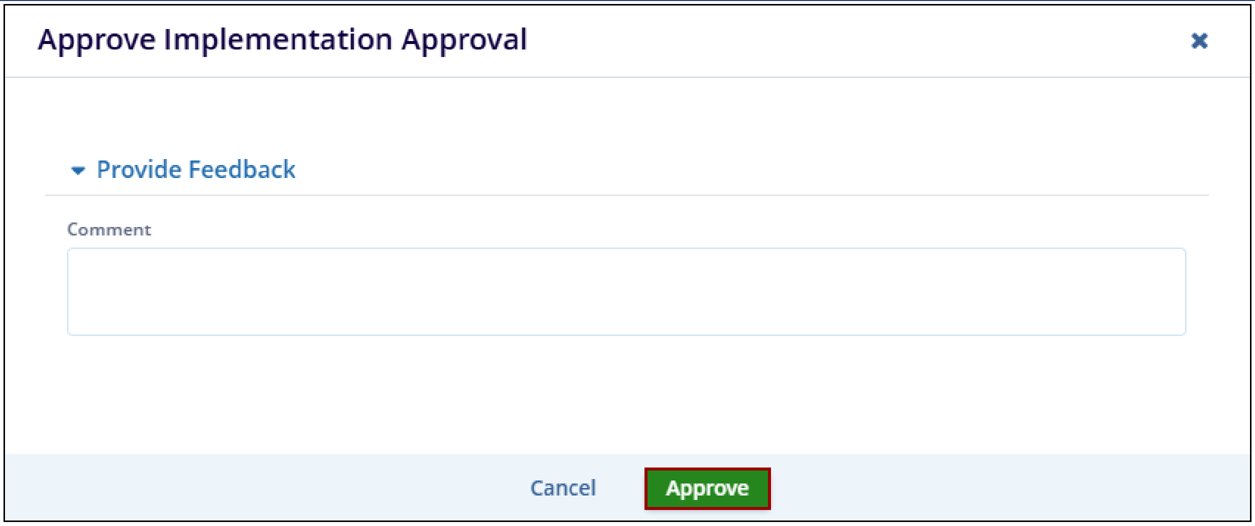

7. As the assigned authority in the last stage, access the Action Item through the email notification or the ‘My Assignments’ view.



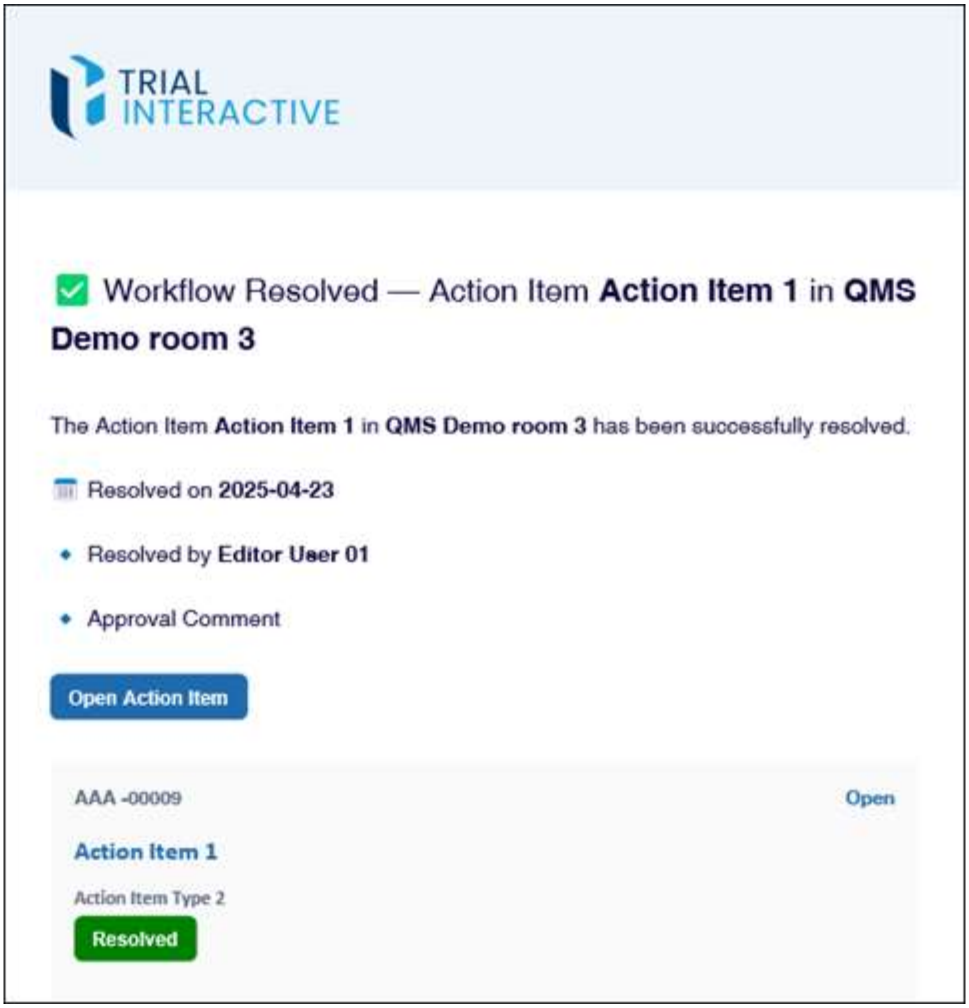
8. Open the Action item, claim the record and click on the 'Approve' button above the Quick View panel.



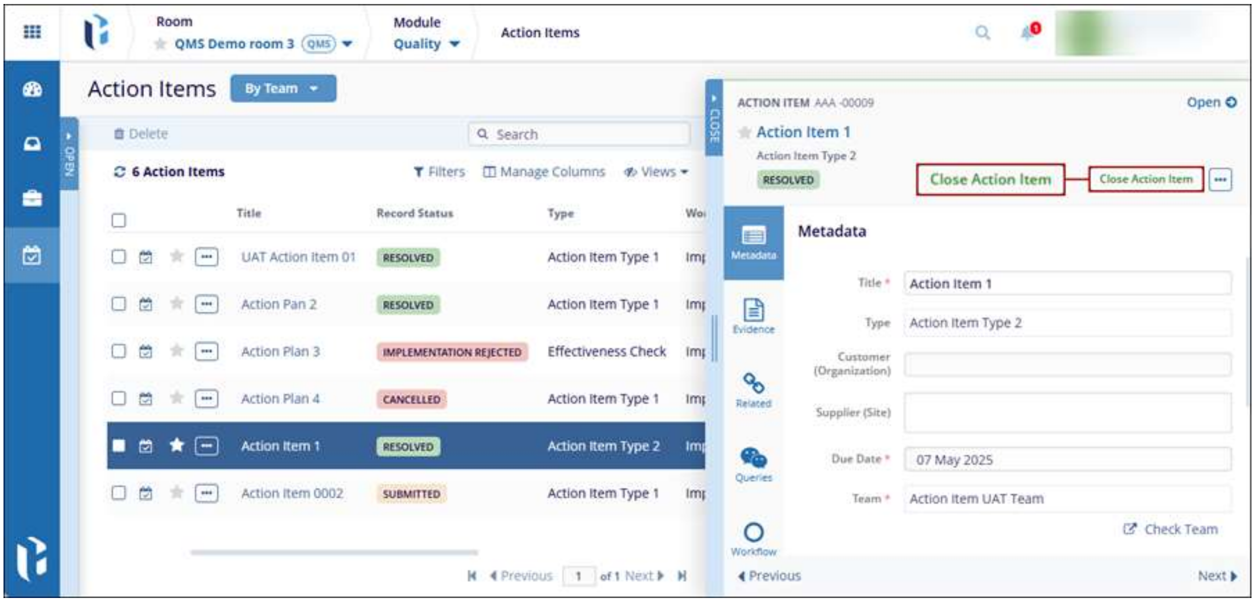
9. Enter the required details in the 'Approval Form' and click on the Approve button.



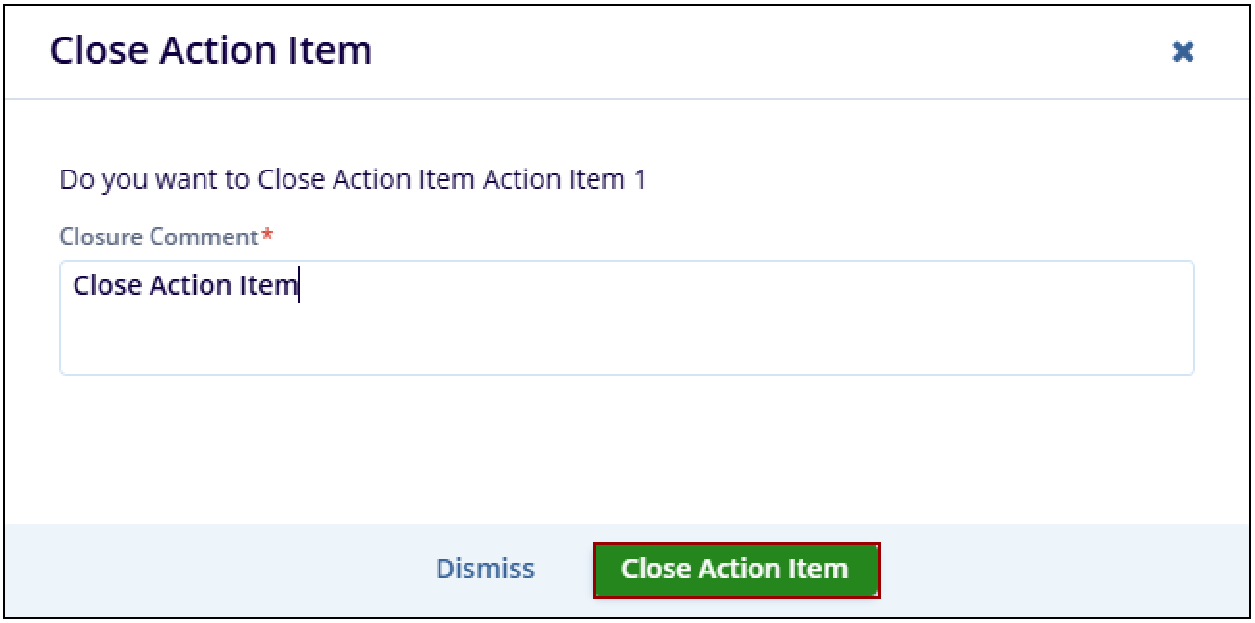

10. Once the Action Item is successfully resolved, all the authorities for whom the notifications are enabled, receive an email stating the Action Item is resolved.



11. On the Action Item record page, click on the ‘Close Action Item’ button above the Quick View panel.




12. On the ‘Close Action Item’ popup, mandatorily add a comment and click on the ‘Close Action Item’ button.

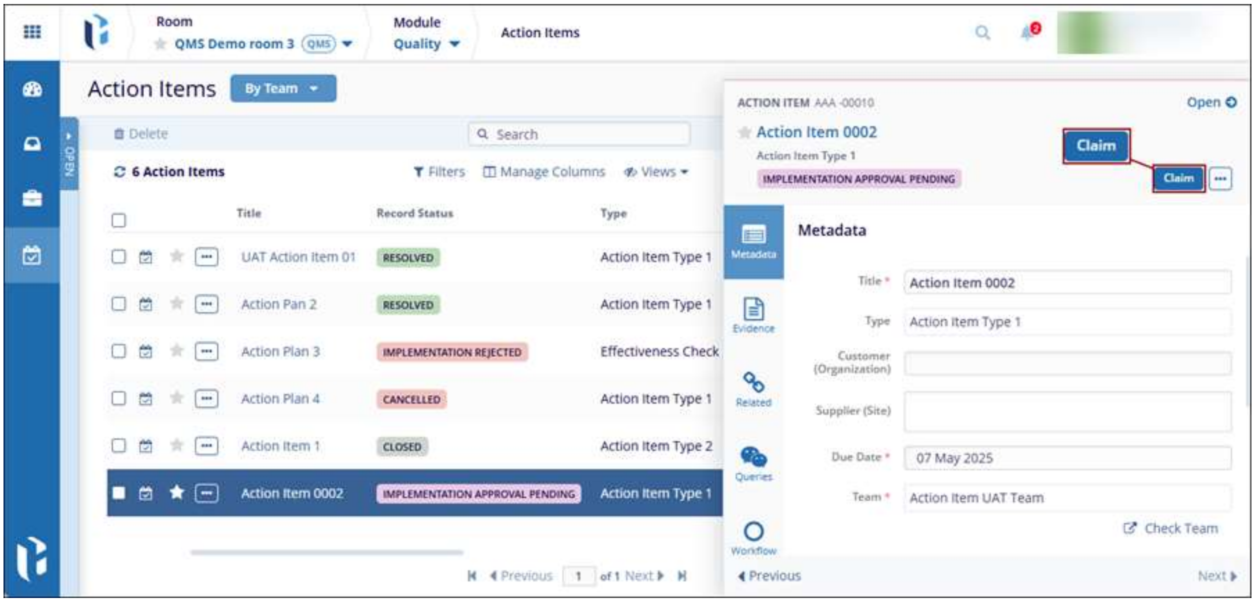


## Request Clarification

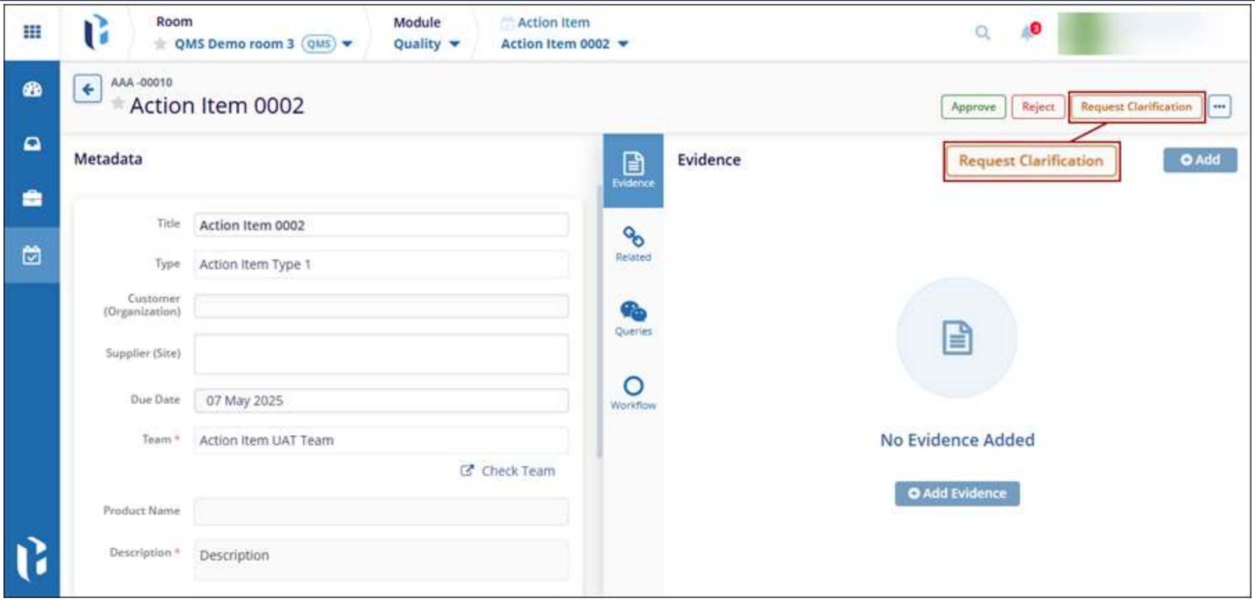
When an Action Item progresses through the workflow stages, the assigned authorities at each stage can request clarification or create a query for the CAPA record, based on the workflow stage configuration.

To send an Action Item record for clarification, follow the steps below.

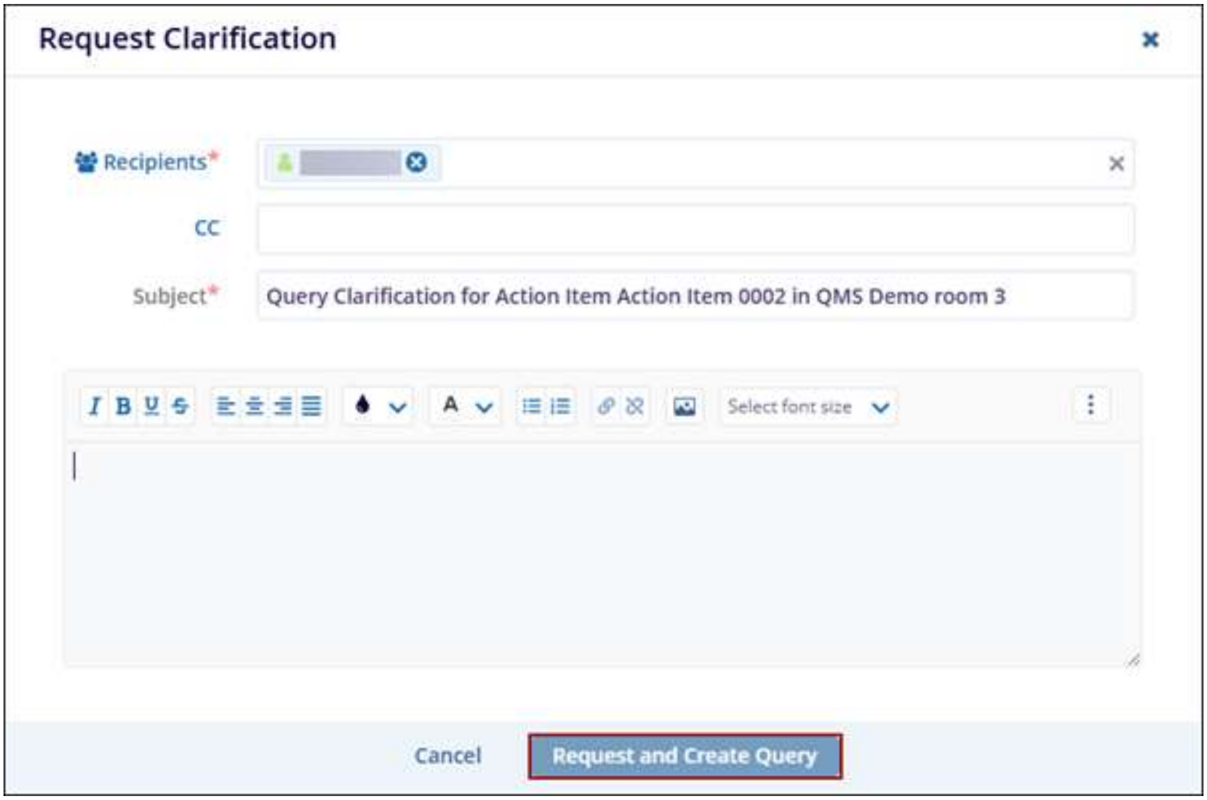
1. Create an Action Item as an originator user and send it to the first stage of the approval workflow by following the steps detailed in the Create Action Item section.
2. As the authority in the first stage of the approval workflow, send the Action item to the next stage of the workflow, i.e., Implementation Approval by following the STEP 1 to STEP 6 from the Approve Action Item section.
3. As the authority in the Implementation Approval stage, open the Action Item and click on the 'Claim' button.



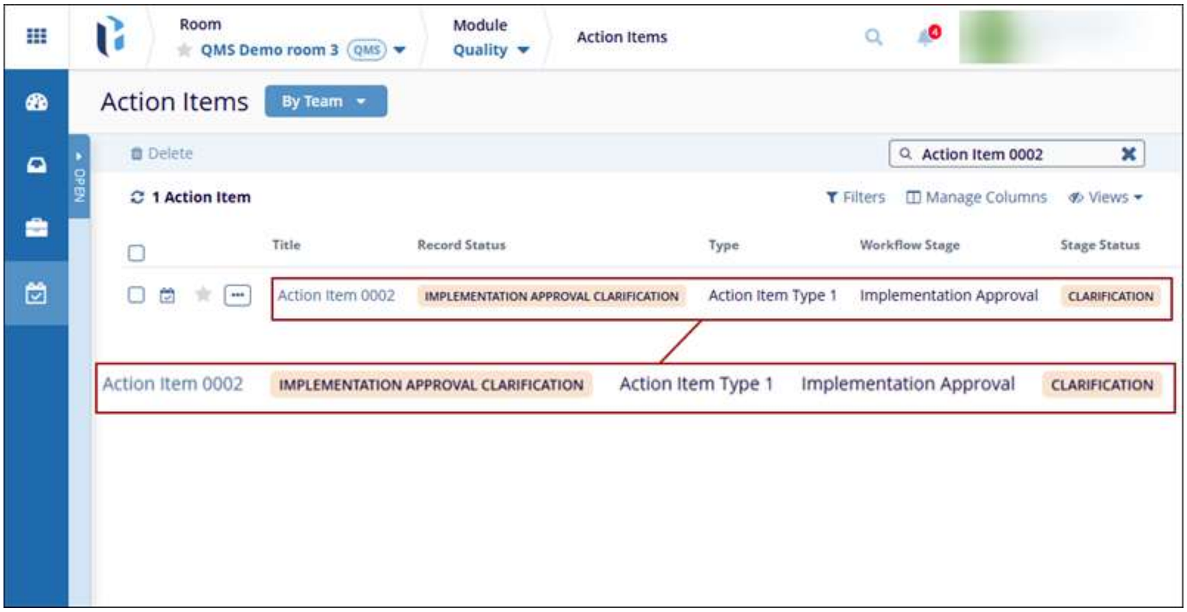

4. Click on the 'Request Clarification' button above the top of the quick view panel.



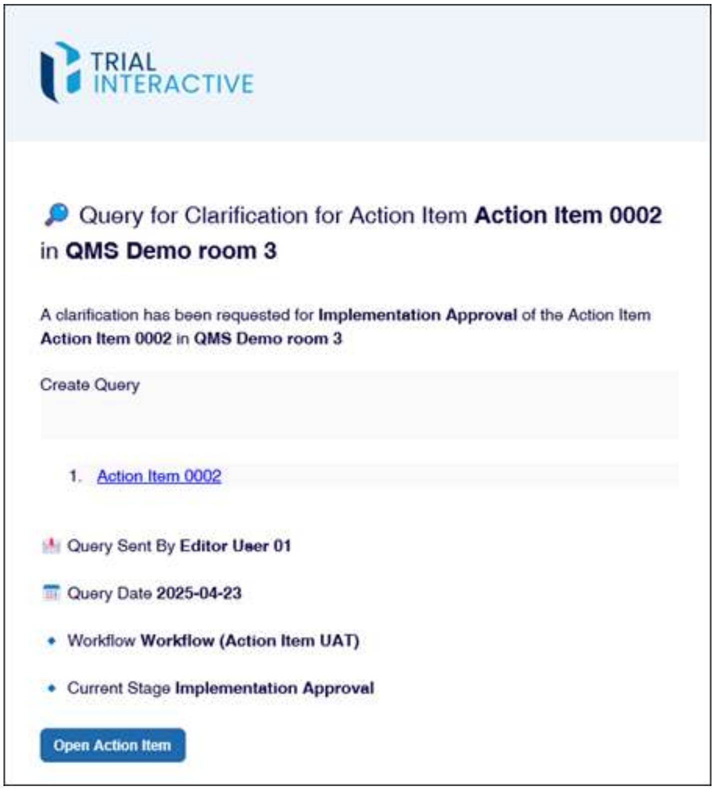

5. On the 'Request Clarification' screen, mandatorily specify the recipients, add a description, and click on the 'Request and Create Query' button.



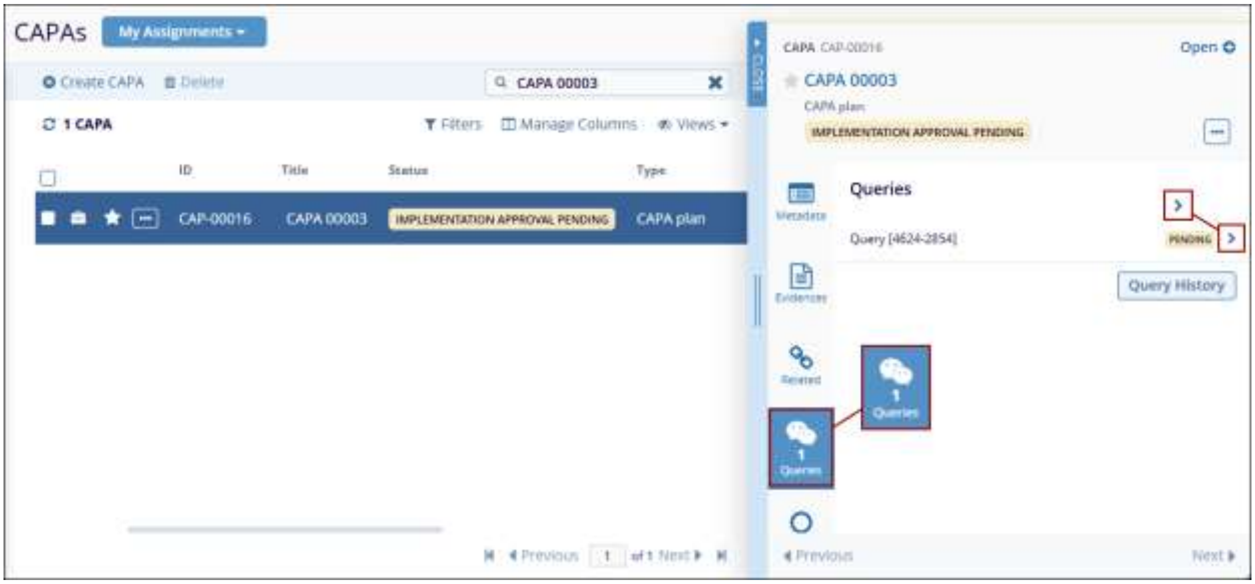
6. On the record is successfully sent for clarification, the CAPA record displays the statuses as configured in the workflow.



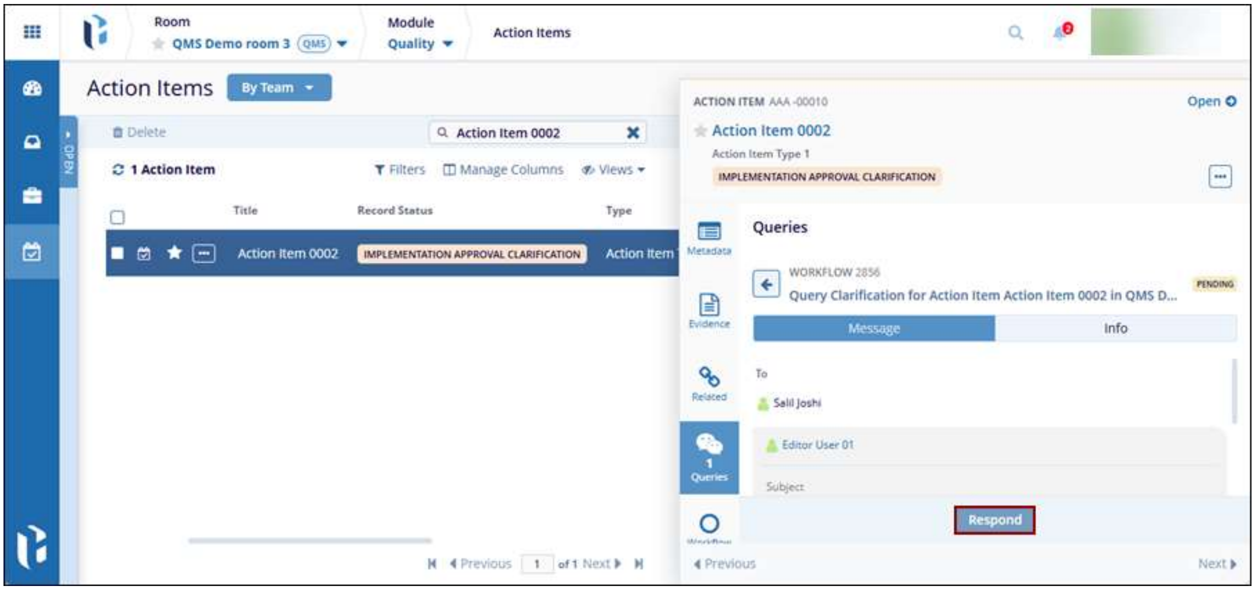

7. Additionally, the authority in the previous stage, i.e., Implementation, receives an email notification stating that a clarification is required on the CAPA record.



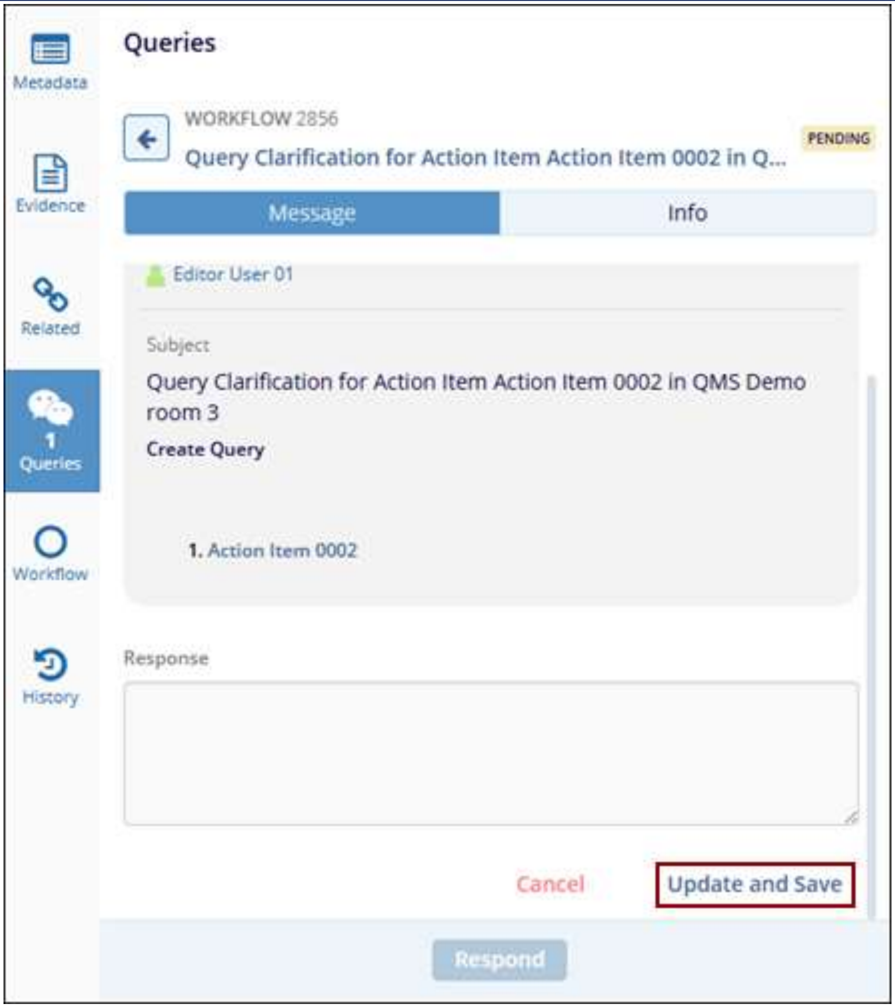
8. As the authority in the Implementation stage, open the Action Item and navigate to the ‘Queries’ tab in the quick view panel and click on the ‘>’ arrow.



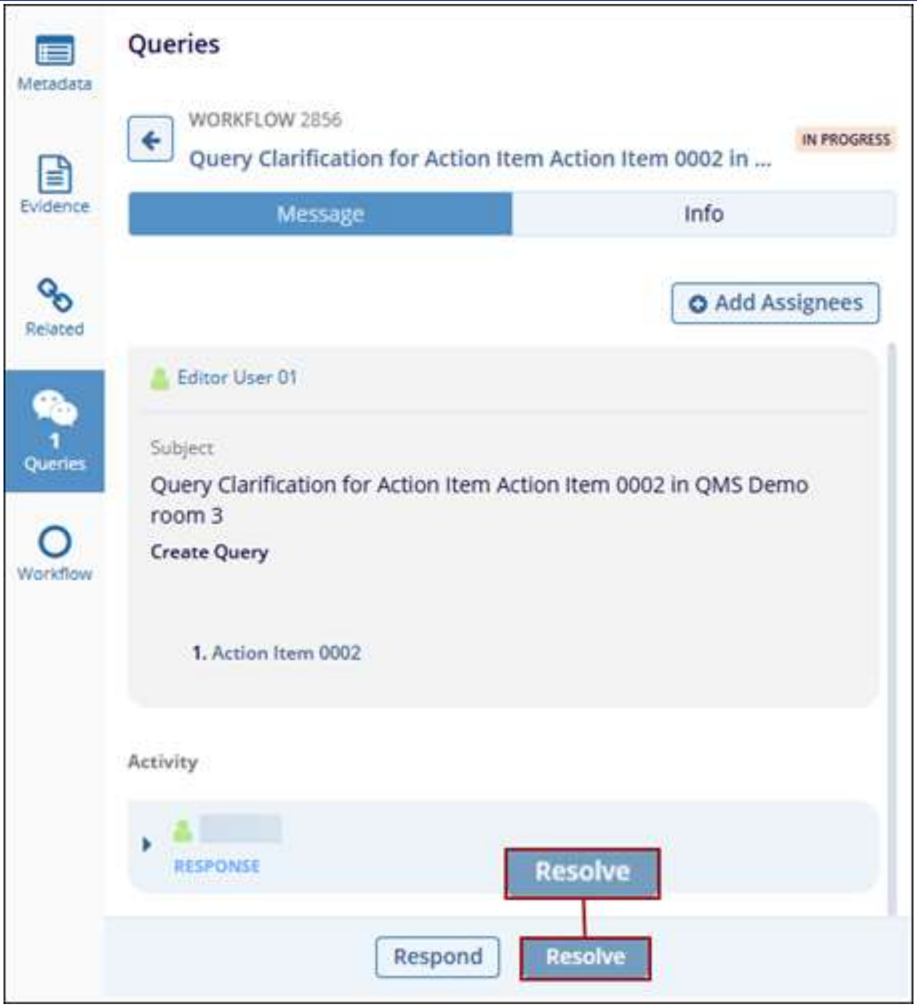

9. Click on the ‘Respond’ button.



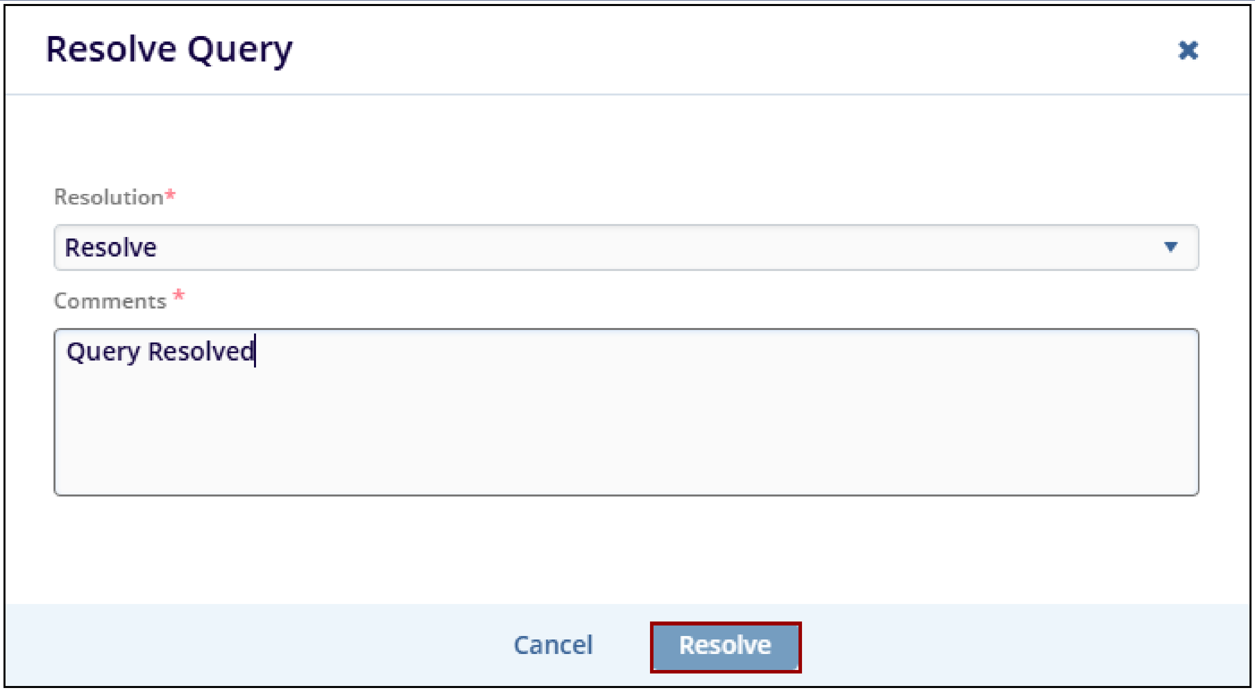

10. Enter the necessary response and click on the ‘Update and Save’ button.



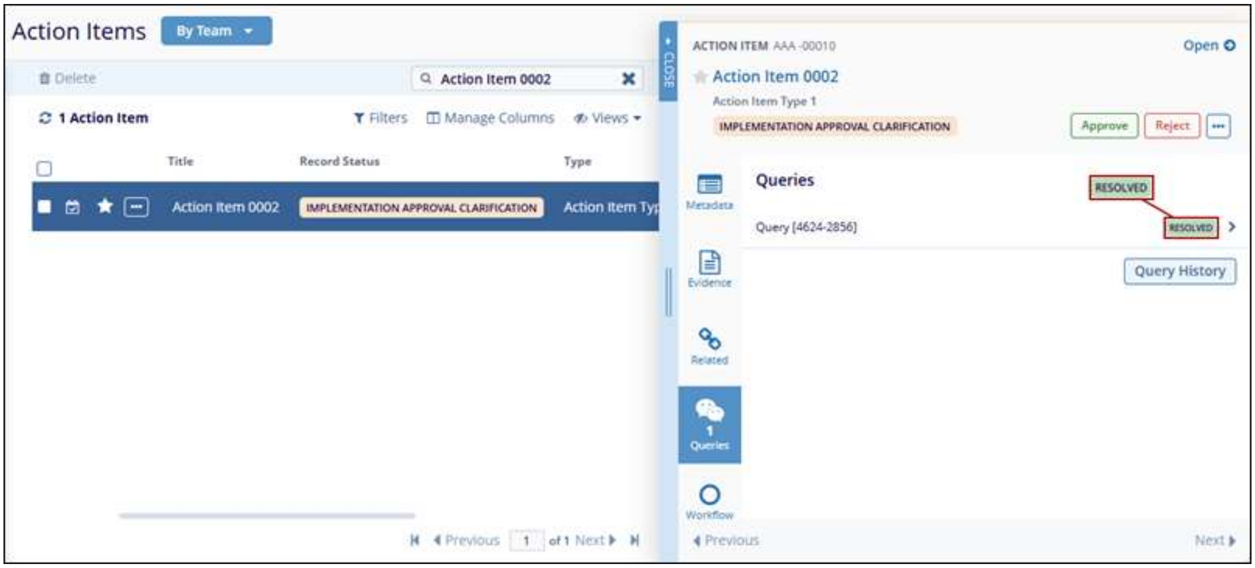

11. As the query initiator, i.e., assigned authority in the Implementation Approval stage, navigate to the Queries tab and click on the 'Resolve' button.



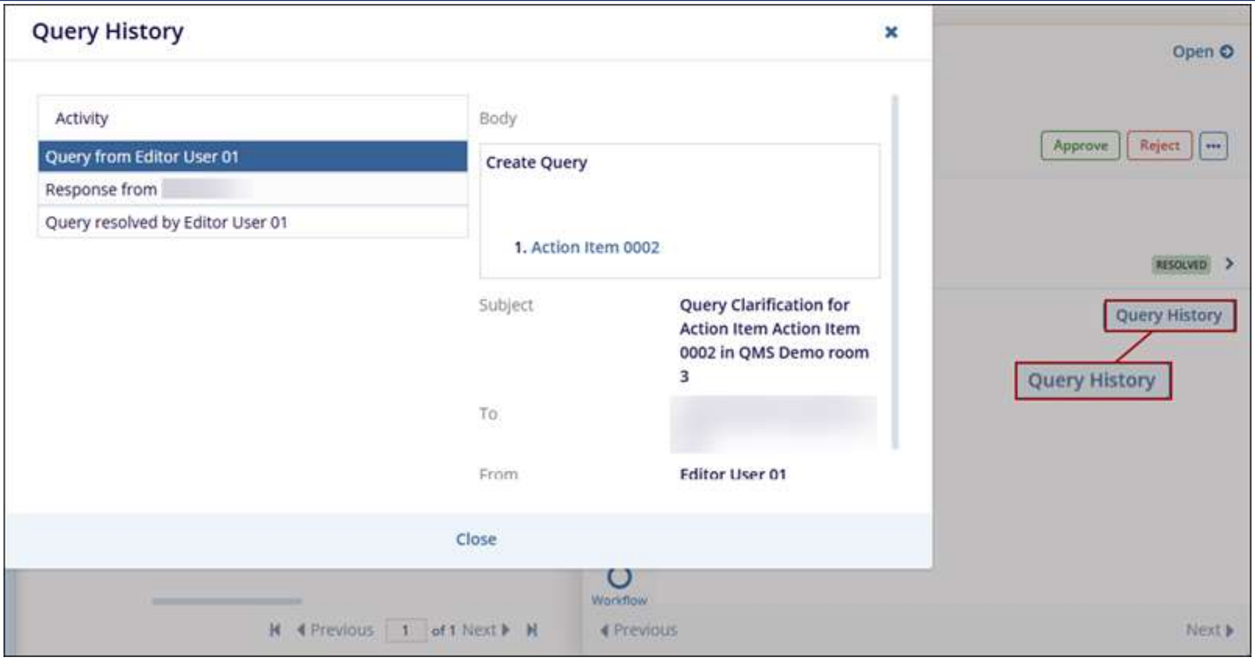

12. On the 'Resolve Query' modal window, mandatorily enter comments and click on the 'Resolve' button.




13. Once the Query is successfully resolved, the 'Queries' tab displays the status as resolved.




14. Click on the 'Query History' button to view the activities related to the Query.




15. Complete the record approval by following the steps, i.e., STEP 7 to STEP 12, detailed in the [Approve Action Item](#) section.

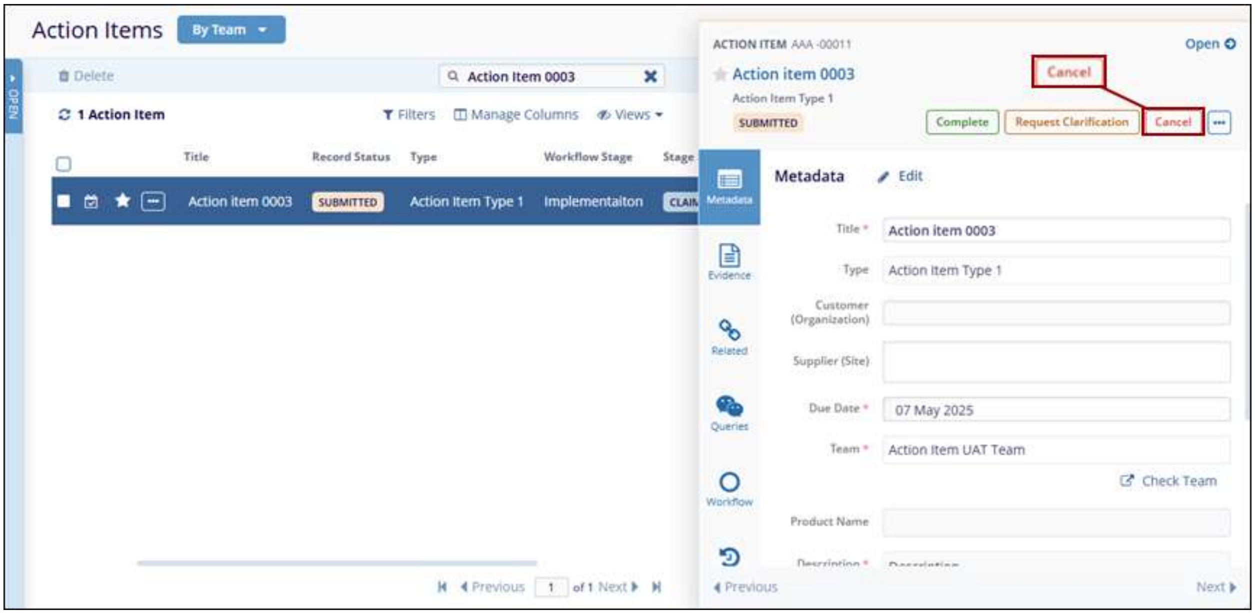
## Cancel Action Item

Authorities in the workflow stages can cancel an Action Item record depending on the configurations in the workflow stages. Once an authority cancels an Action Item, the record is removed from the workflow.

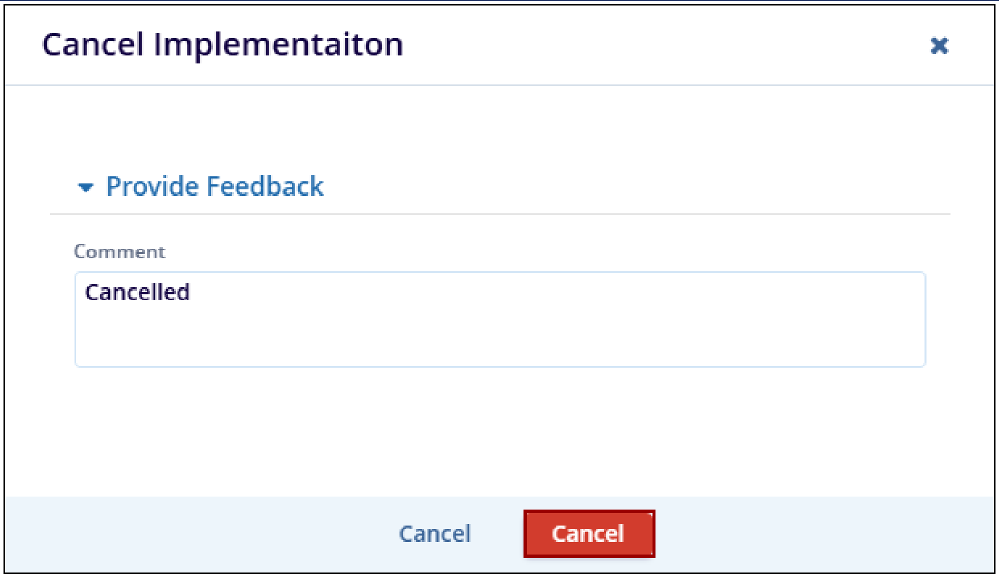
To cancel an Action Item, follow the steps below.

1. Create an Action Item record as an originator user and send it to the first stage of the approval workflow by following the steps detailed in the Create Action Item section.

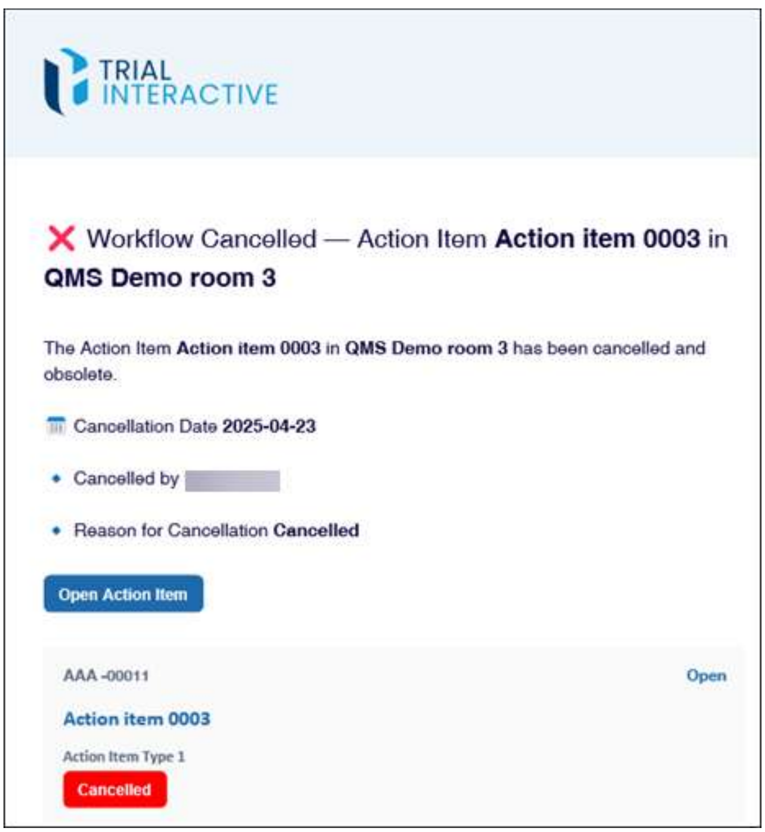
2. As an authority in the first stage, open the Action Item record, claim the record, and click on the Cancel button.



3. On the 'Cancel Implementation' dialog box, enter the necessary comments and click on the Cancel button. Once the record is successfully cancelled, it is removed from the workflow.




4. Additionally, depending on the notification's configuration in the approval workflow, the authorities receive an email notification stating that the record was canceled.



## Reject Action Item

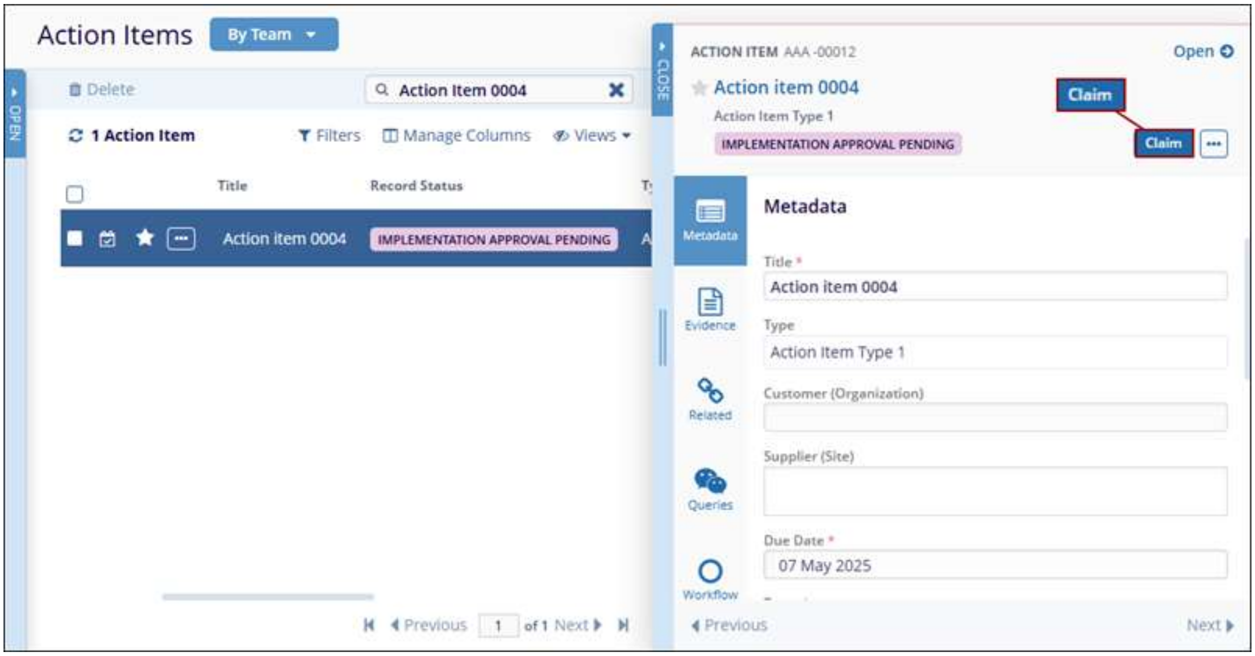
Authorities within the workflow stages can reject an Action Item record based on the stage-specific configuration. Rejections typically occur during the Approval stage by the designated Approver. When an Action Item is rejected, it is sent back to the previous stage. For instance, if a record is rejected at the Implementation Approval stage, it will return to the Implementation stage.

To reject an action item, follow the steps below.

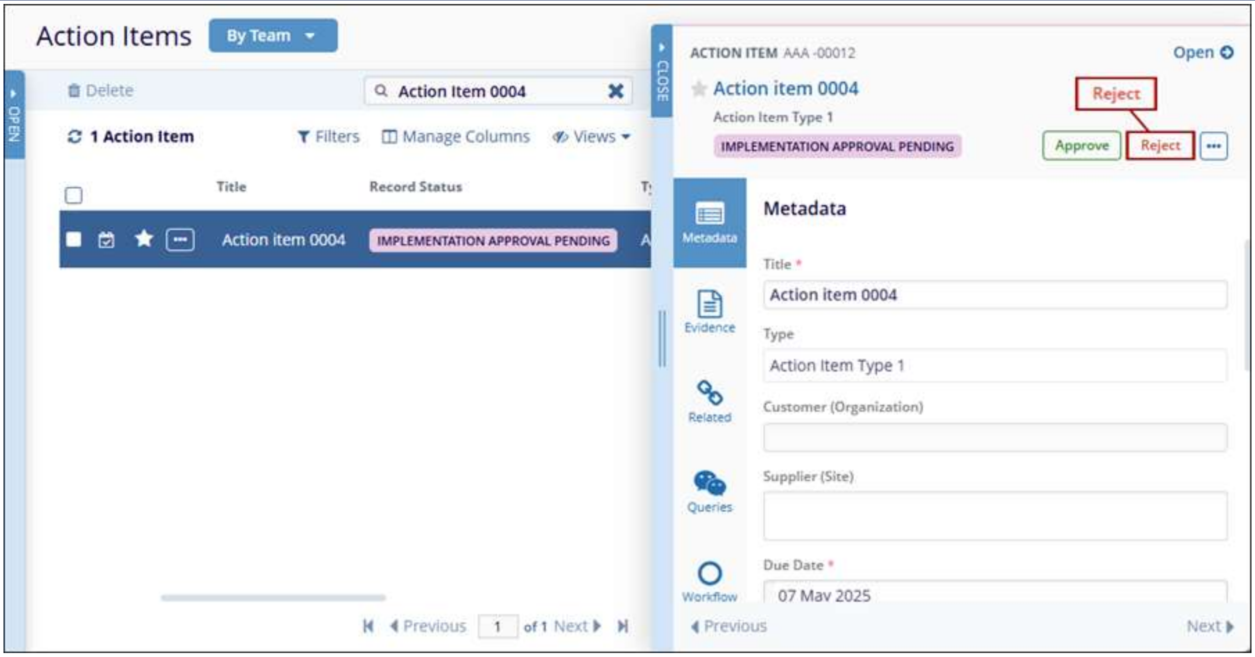
1. Create an Action Item as an originator user and send it to the first stage of the approval workflow by following the steps detailed in the Create Action Item section.

2. As the authority in the first stage of the approval workflow, send the Action item to the next stage, i.e., Implementation Approval by following the STEP 1 to STEP 6 from the Approve Action Item section.

3. As the assigned authority in the 'Implementation Approval' stage, open the Action Item record and click on the Claim button.

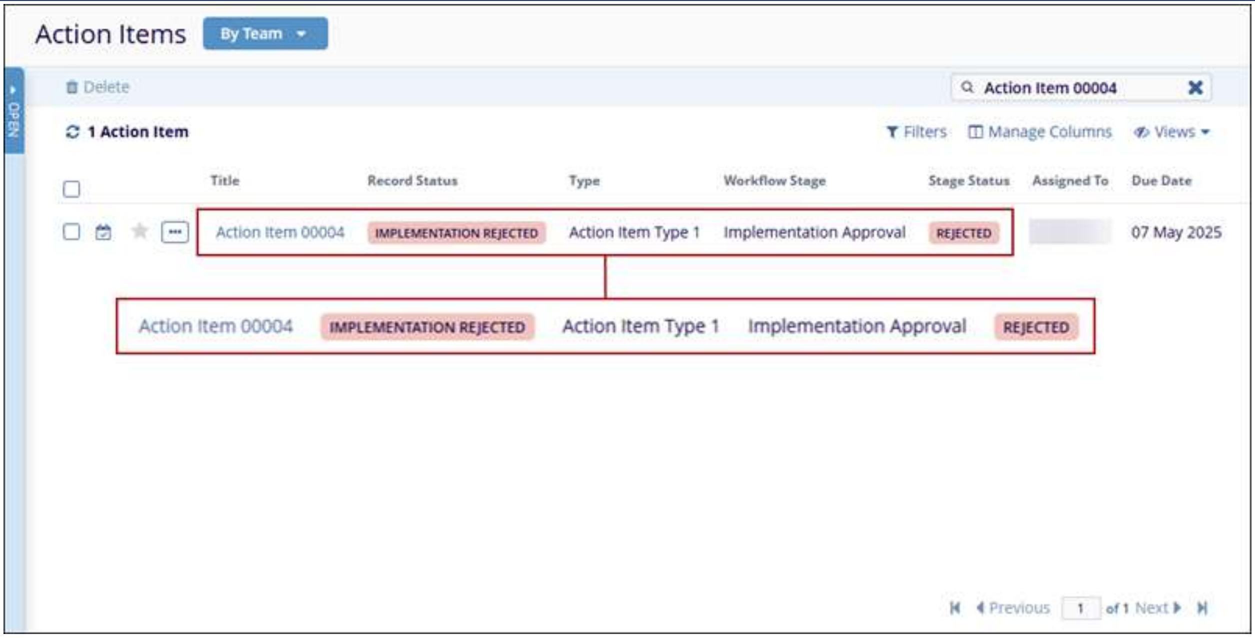



4. Click on the 'Reject' button situated above the quick view panel.




5. On the ‘Reject Implementation Approval’ dialog box, enter the necessary comments and click on the ‘Reject’ button.


6. Once the record is successfully rejected, it is transitioned back to the previous stage and displays the statuses as configured in the workflow.




7. Additionally, the authority in the previous stage of the workflow receives an email notification stating the record is returned for revision, depending on the notification's configuration in the workflow.

8. As the authority in the previous workflow stage, make the necessary revisions and transition the record to the next stage.

9. Approve the record in the last stage by following the steps detailed in the Approve Action Item section.

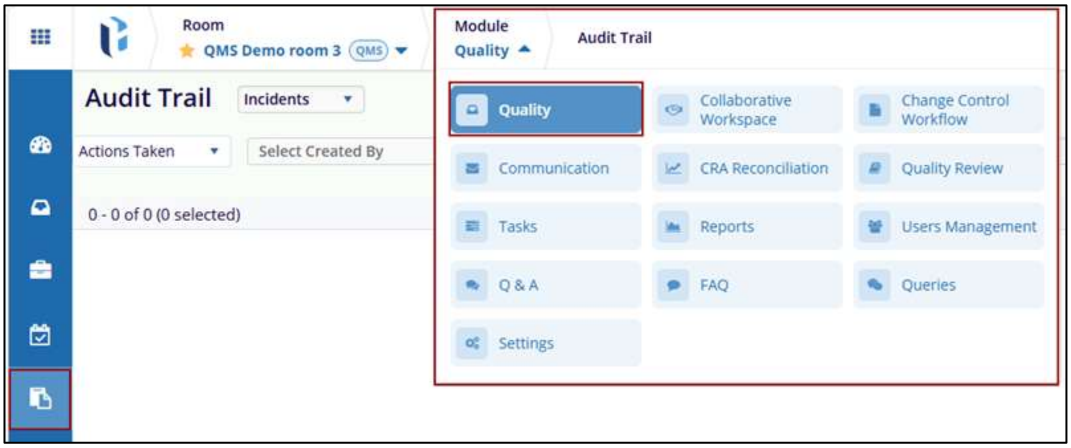
# AUDIT TRAIL

An Audit Trail is a chronological, security-relevant record that captures and displays the actions performed on a document. It provides evidence of all changes made by all users. The following section outlines the available filters for viewing and analyzing the audit trail.

Note: By default, the audit trails grid pane is empty, and the documents are displayed only after entering and applying certain parameters and criteria.

To access the Audit Trail modal within the eTMF module, follow the steps below.

1. Navigate to the Quality module within the QMS room, or click the Module dropdown and select the Quality module option.
2. On the eTMF screen, navigate to the left-hand menu and select the Audit Trail modal.




3. The Audit Trail screen displays options to apply certain filter criteria and export the audit trail details.

## Audit Trail Process

To retrieve the audit trail detail, follow the steps below.

1. On the Audit Trail screen, specify a parameter from the available dropdown options.
    - Incidents
    - CAPAs
    - Action Items
2. Click on the ‘Actions Taken’ dropdown and select or deselect actions by clicking on their respective checkboxes.
3. Specify one or multiple users in the Select Created By box.
4. Add the From and To dates by clicking on the calendar icon.
5. Add Document IDs separated by commas to retrieve data restricted to the specified document IDs.
6. If the user wants to add the Subform created within the particular parameter, click the check box of the Include Subform option.
7. Click on the Apply button.


8. The Audit Trail screen displays data based on the applied filters and parameters.

Note: Refer to the sections below to understand filters, parameters, and other actions within the Audit Trail modal.

## Audit Trail Parameters

Users can retrieve the audit trail based on selected parameters. The options in the 'Actions Taken' dropdown are displayed according to the chosen parameter.

- Incidents
- CAPAs
- Action Items


Follow the steps below to view the audit trail for all the parameters:

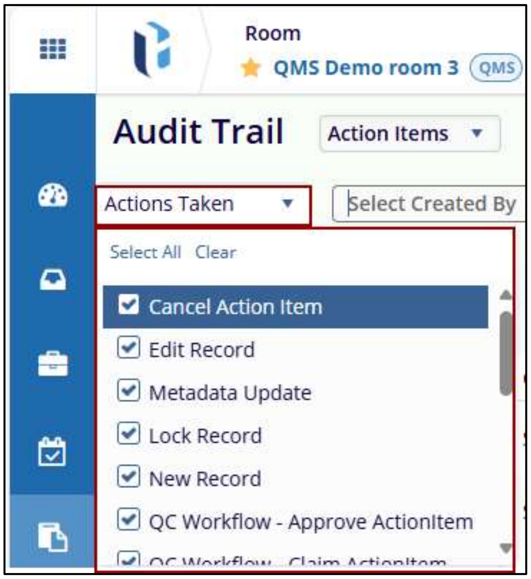
1. Click the drop-down menu displayed next to the Audit Trail page Title.
2. Select the Incidents option to search documents.
3. Select the appropriate option from the Actions Taken dropdown menu.
4. Enter name(s) in the Select Created By field.
5. Click the Calendar icon to select the Start Date and End Date for the documents.
6. Enter the Document ID in the document ID field if needed/available.
7. Check the box of Include Subform if the user wants to include the Subform along with the created incident.
8. Click the Apply button.

The audit trail information will be presented as shown below, based on the selected parameters:

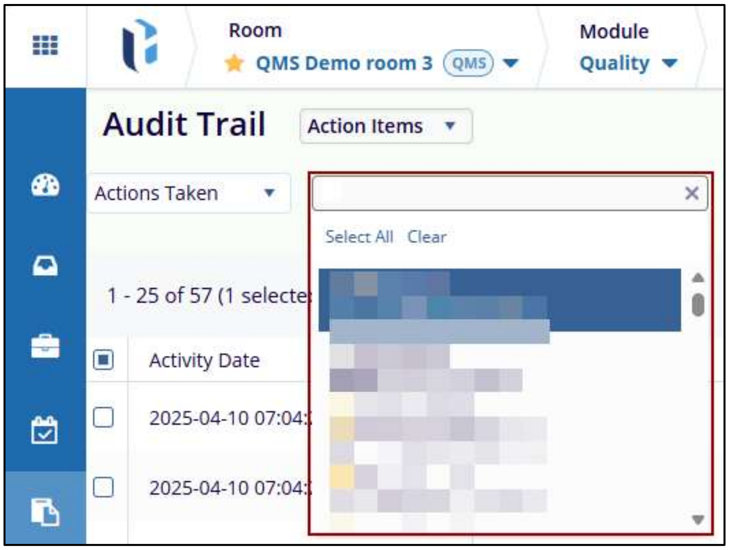
## Audit Trail Filters

Users can apply additional filters to the selected parameter. The following filters are available in the Audit Trail modal, allowing users to retrieve specific data.

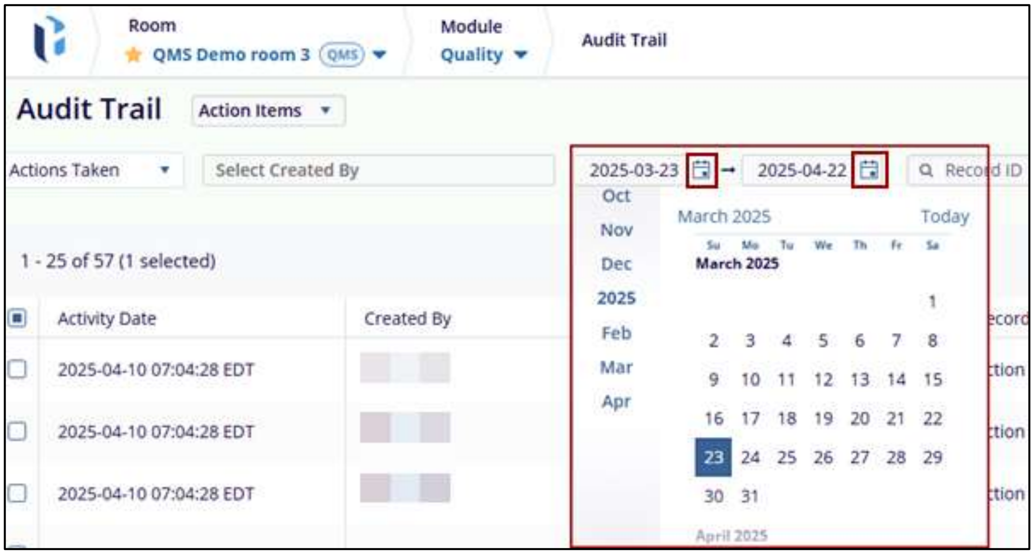
1. Actions Taken: This dropdown displays a list of actions to be selected from the dropdown menu for filtering the audit trail as per the selected parameter. The Actions Taken dropdown populates and displays actions depending upon the parameter selected. Users can either select all actions or select specific actions by clicking on their respective checkboxes. Select Created By: In the Select Created By field, users can specify one or more usernames associated with document creation in eTMF. When a username is selected, the Audit Trail screen filters and displays records corresponding to the specified user.




2. Select Created By: In the Select Created By field, users can specify one or more usernames associated with document creation in eTMF. When a username is selected, the Audit Trail screen filters and displays records corresponding to the specified user.




3. Date Filters: Users must enter start and end dates in their respective fields to search for a document. By default, the start date is set to the previous month, and the end date is set to today. To select dates, click on the calendar icon. Once the dates are chosen, click the Apply button on the right side to view the search results. Users can also select dates from the previous year by scrolling up in the Months field.




4. Record ID Filter: The Record ID field allows users to retrieve audit trail for a specific document by entering its ID number, separated by commas. After entering the document ID, users must click the Apply button on the right side to view the search results. As per the selection of the parameters the Record ID gets changed.

5. Include Subform: The Include Subform checkbox is used when the activity has a Subform along with it.
   Example: QC Workflow - Claim CAPA, QC Workflow - Return Document Back, etc.

6. Apply: The Apply button display the data related to selected parameters or the criteria that is set by the user.

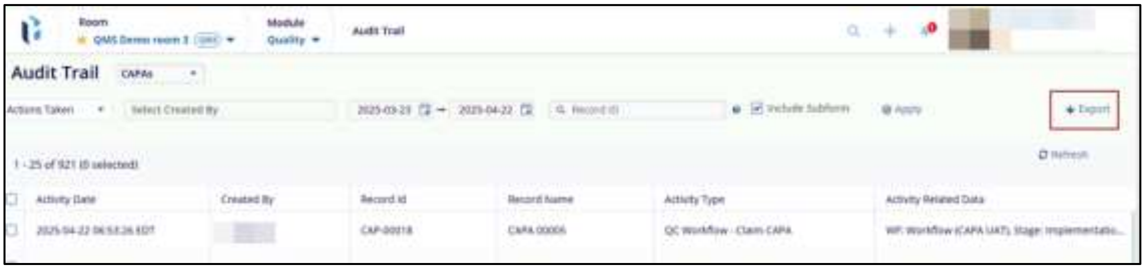
7. Refresh: The Refresh button is visible and accessible when the audit trail results are displayed. When a parameter or a filter is updated, users need to click the Refresh button to update the audit trail records as per the newly applied filters and parameters.


Room
QMS Demo room 3
Module
Quality
Audit Trail
Audit Trail
CAPAs
Actions Taken
Select Created By
2025-03-23
2025-04-22
Record ID
Include Subform
Apply
Export
Refresh
1 - 25 of 921 (0 selected)
Activity Date
Created By
Record Id
Record Name
Activity Type
Activity Related Data
2025-04-22 06:53:26 EDT
CAP-00018
CAPA 00005
QC Workflow - Claim CAPA
WF: Workflow (CAPA UAT), Stage: Implementatio...
2025-04-22 06:53:26 EDT
CAP-00018
CAPA 00005
Lock Record

## Export Audit Trail

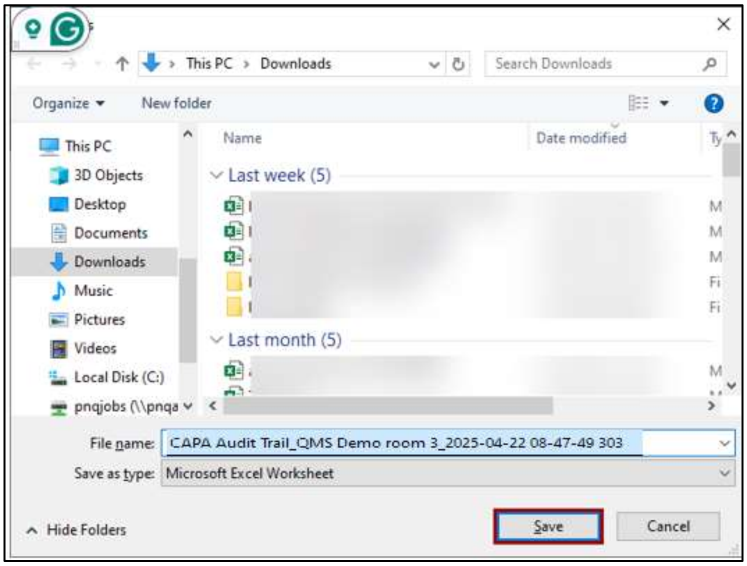
To export the Audit Trail data, follow the steps below.

1. On the Audit Trail screen, click on the Export button.

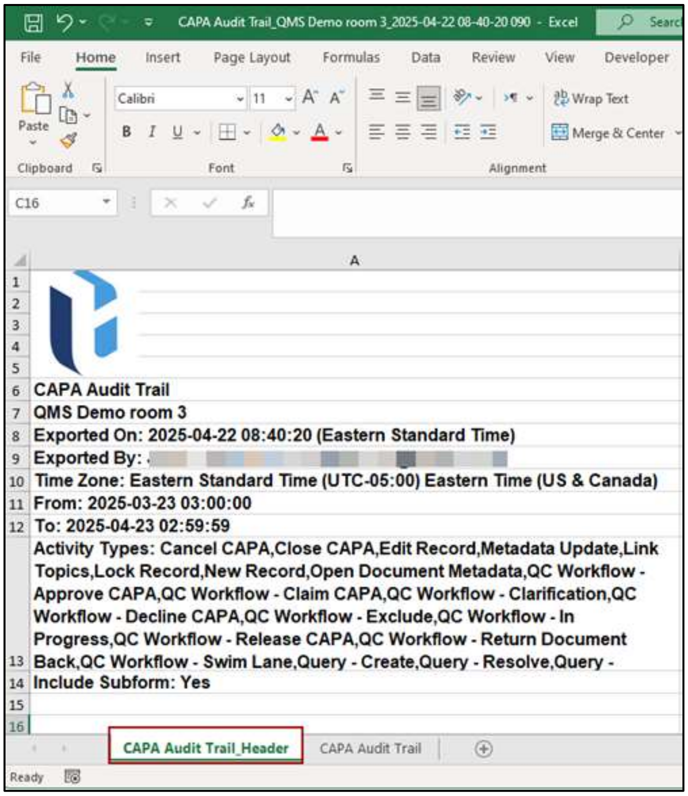



2. On the Audit Trail, Export pop-up displaying the success message, click on the Get Results button.


3. Download the Microsoft Excel Worksheet containing the export data into the local system.




4. On the downloaded file, click on the CAPA Audit Trail Header tab to view the header related details.




5. Click the CAPA Audit Trail tab to access audit trail details.