

How to Create a CAPA

TI version 10.7

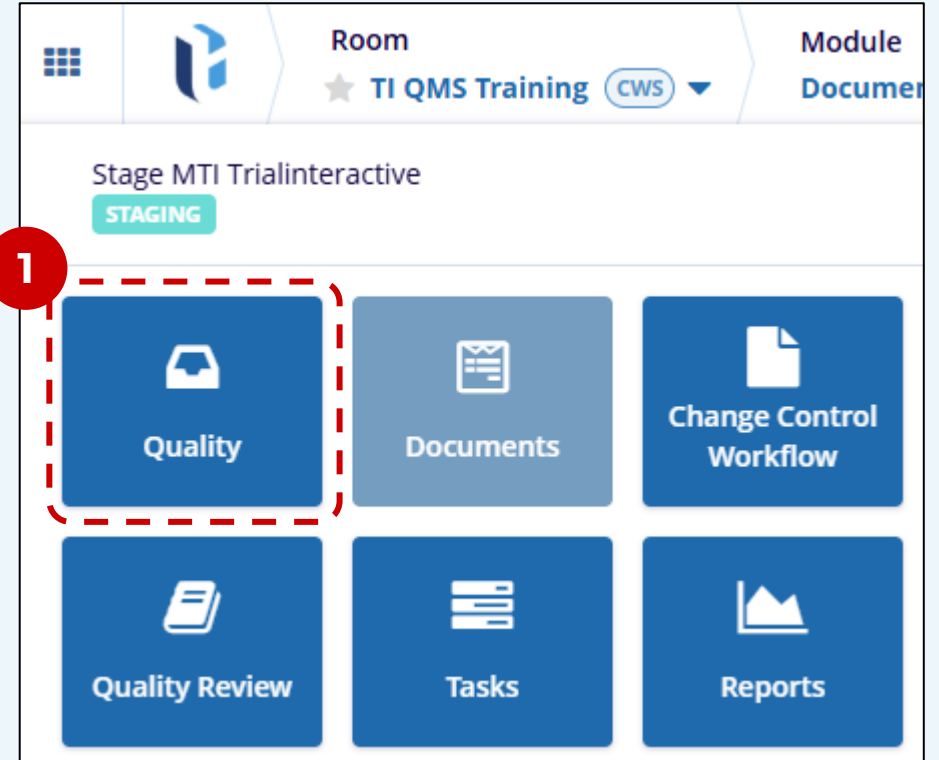
APPLICABLE TO:

- Admin
- Manager
- Editor
- Reader
- QMS
- eISF

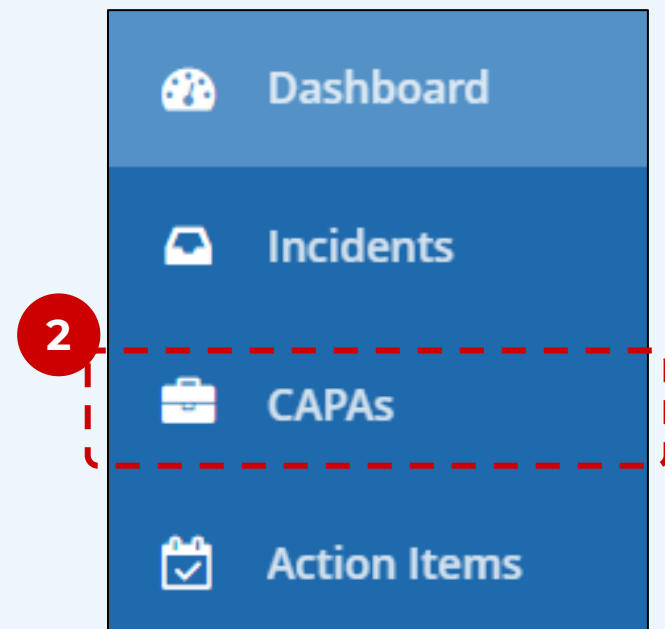


Due to the flexible configuration of TI QMS, variations from the example shown should be expected . For example, different datafields may be required or displayed.

1 Enter a QMS-Enabled Collaborate room. Via the waffle or the module selector, navigate to the **Quality** module (the name may vary).



2 Select the option for **CAPAs** from the navigation sidebar.



3 Click on **Create CAPA**.



4 Give a **Title** to the CAPA.

A screenshot of a CAPA form. The 'Title *' field is highlighted with a red dashed box and contains the text 'Review All Templates for Default Dates'. The 'Type *' field is empty. A red circle with the number '4' is in the top left corner.

5 Select the Type of CAPA from the **Type** dropdown.
This will also auto-select the Team assigned to that type, if any.

A screenshot of the CAPA form showing the 'Type *' dropdown menu open. The menu lists four options: 'Systemic Improvement', 'Root Cause-Based CAPA', 'Long-Term Resolution Plan', and 'Supplier-Driven CAPA'. The 'Long-Term Resolution Plan' option is highlighted with a mouse cursor. A red circle with the number '5' is in the top left corner.

6 The **Check Team** button allows you to review what users are members of the selected Team.

A screenshot of the CAPA form showing the 'Type *' dropdown set to 'Long-Term Resolution Plan' and the 'Team *' dropdown set to 'CAPA Team'. A 'Check Team' button with a magnifying glass icon is highlighted with a red dashed box. A red circle with the number '6' is in the bottom right corner.

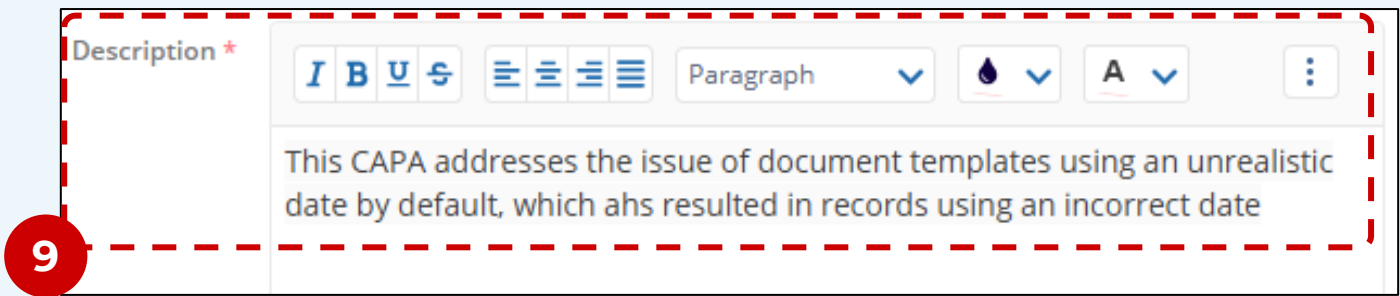
7 Populate the 'Action' text fields. Required fields are marked with a red asterisk.
Text boxes like these support rich text, including pictures and Tables.

A screenshot of the CAPA form showing the 'Immediate Action *' text field. The field contains the text 'Identify any templates that have a default date set before the current year'. Above the text is a rich text editor toolbar with options for bold, italic, underline, link, bulleted list, numbered list, paragraph, and other formatting options. A red circle with the number '7' is in the top left corner.

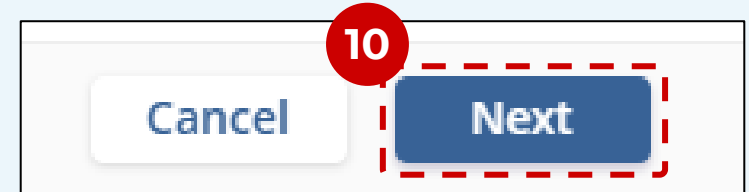
8 Set the Reporting fields. You can use the **calendar** buttons to select day and time.

A screenshot of the CAPA form showing the reporting fields. The 'Initial Reporter *' field is empty. The 'Reported On *' and 'Identified On *' fields are empty and each has a calendar icon button to its right. A red circle with the number '8' is in the top left corner.

9 Complete any other fields as required.



10 Click on **Next** to move to the second part of CAPA setup, which is adding evidence.



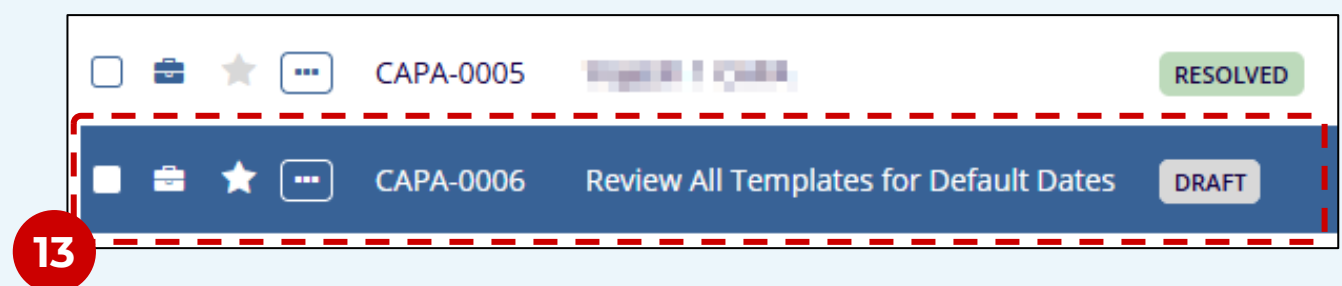
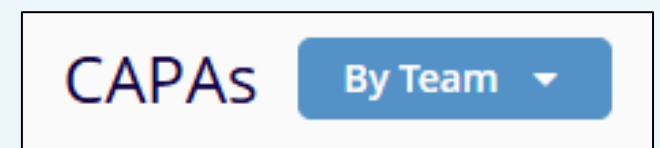
11 Choose how you'll add evidence. You may Upload files, Search for existing content in the current room, or type/paste URLs.



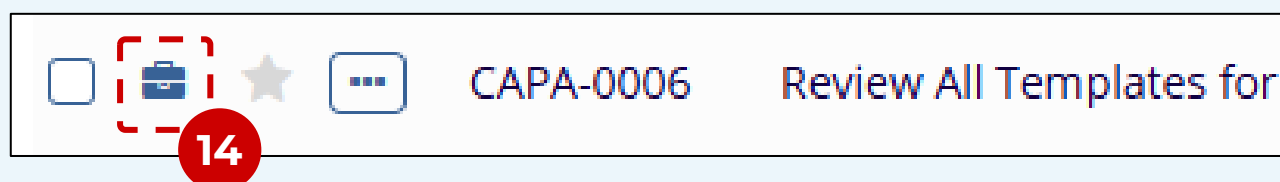
12 Complete Adding Evidence as chosen, then click **Create** to generate a Draft CAPA, or **Create & Submit** to send the record to the first contributor.



13 Once Created, a CAPA can be found in the CAPAs browser with its current status.



14 Click on the **Inbox Icon** to display a full page view of the CAPA – or click on the record name to display details in the side panel.



15 Only if you chose Create in step 12, the CAPA can be advanced from Draft to active status by clicking the **Submit for** button above the side panel.

