QLIMS

Laboratory Information Management

QLIMS - Laboratory Information and Management System

CAPA (Corrective and Preventative Actions) Manager

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OnQ software

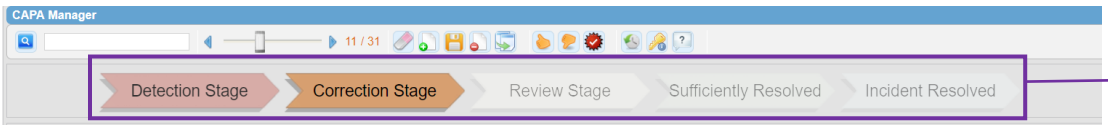
Overview

In today's highly regulated research and manufacturing environment, identifying the cause of a quality failure or a nonconformity as well as having a comprehensive and structured investigation process to prevent recurrence has become a mainstay. This is where a **Corrective and Preventive Actions (CAPA)** manager comes into play.
Many see CAPA's as an arduous task that only needs to be completed in order to remain compliant, rather, the CAPA manager should be viewed as an end-to-end system that provides the tools necessary for identifying, evaluating and investigating incidents as well as implementing and checking the effectiveness of a resolution, for quality control and regulation.

The **QLIMS CAPA** manager is designed to maintain Corrective and Preventative procedures for general incidents, sample parameters breaching specification and Instrument failure incidents, while also integrating with the extensive capabilities of the QLIMS platform.

How it works

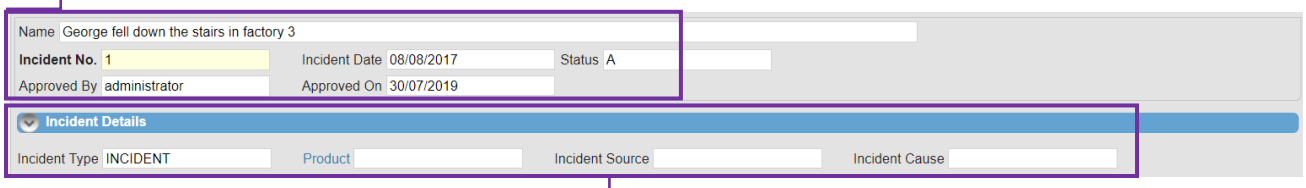
The QLIMS CAPA Manager includes a progress meter which provides a visual representation of the viewed record's current status, as well as a tool allowing for quick links to useful features of the CAPA record, including returning a search for all records of a specific type and updating the viewed record's status



CAPA Progress Meter

Recording an Incident

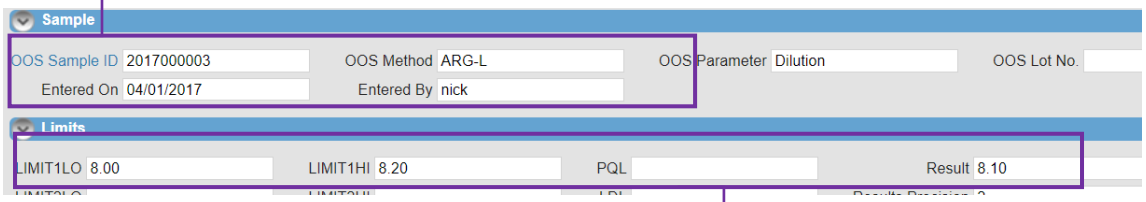
- Provide a brief description of the incident
- A unique ID and approval details are autogenerated for auditing purposes
- Record additional details such as the date



- Record Incident Type
- Select Product/sample type if the incident is product related
- Select a source and cause

If the Incident is Sample related:

- Based on the product selected, QLIMS automatically populates the OOS Sample ID
- QLIMS Filters for the method and parameter that were OOS

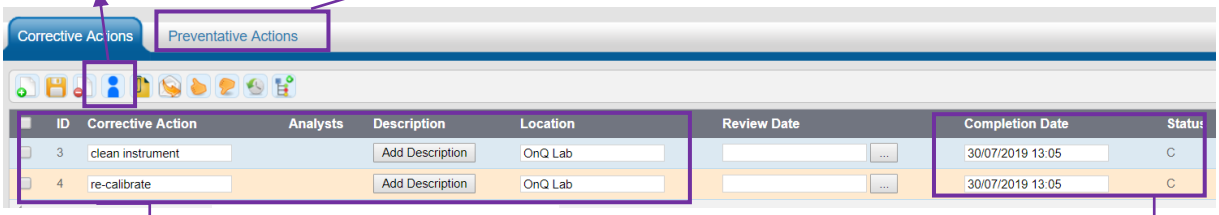


Limits and results associated with that record are auto-populated for the user to review if the limits require adjustment or if there is a fault with the sample/testing

Recording the Corrective and Preventative Actions

Assign specific analysts (QLIMS Address Book) to an action

Similar to corrective actions, a preventative action can be defined and description provided to prevent reoccurrence of the CAPA record



- Define all corrective actions
- Highlights the analyst assigned to each action
- Provide detailed description and location

- Select a date for when the action should be performed
- Select a date for when completed
- Authorised user can then approve of completion

Key Benefits:

- ✓ Recording and managing incidents/conflicts (intentional and unintentional)
- ✓ Record the findings of an investigation of the incident
- ✓ Record the actions that must be undertaken to resolve a conflict
- ✓ Users can review which stage the incident/problem is in currently with the help of a progress meter
- ✓ Email alerts to those associated with the incident

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