Qualityze

Datasheet

Qualityze CAPA Management Solution Document, Plan, Investigate, Implement And Review Your CAPA

Corrective Action and Preventive Action (CAPA) is a systematic investigation to find the root cause of identified defects/problems and any associated risks to prevent their recurrence (corrective action) or to prevent the occurrence (preventive action). Qualityze CAPA management software (QCA) complements your established CAPA process and enables your organization to take a more holistic approach.

Document and Plan your CAPA

With Qualityze's CAPA module, this can be achieved by completing the Initiation steps. Within the Initiation step, you can capture key information such as:

- Title, Problem Statement
- CAPA Source and Source Number
- Reported Date, Reported By
- Criticality, CAPA Owner
- Risk Assessment and others

You also have an option to perform an initial risk assessment to help further plan the course and level of investigation. The extent of the investigation depends on the several criteria such as criticality, the risk to a customer, risk to the company, extent of the defect etc.

You can choose the CAPA workflow or close out the CAPA with no further action. Additionally, if the CAPA workflow is selected, you have the flexibility to select/deselect the task, define the task owner and the task due date that is necessary for each CAPA record.

Investigate, identify root cause and risk assessment.

Use the Investigation task to document the investigation result or outcome. Investigation task is where you document the multiple root cause(s) and perform the risk assessment. Additionally, you can also document the results of investigation.

Implement Action Plan

You can categorize multiple action plans as Correction, Corrective, Preventive or Risk Based to address the root cause that was identified during the investigation task. Additionally, you have an option to document the verification plan in this task to help monitor the effectiveness of the implemented action plan.

Verification & Effectiveness Review

In Qualityze, you use the Effectiveness Review task to document the verification plan and objective evidence to validate the success of the action plans implemented. Additionally, in the Closure Review, you as a CAPA owner can make the determination whether the CAPA was effective in eliminating or minimizing the cause of the quality issue based on the analysis of the objective evidence collected in the Effectiveness Review task.

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Qualityze CAPA Management Solution
Ensuring ISO 9001 & Regulatory Compliance

Capabilities	Benefits
Industry Best Practices	Implement your CAPAs with industry-proven best practices to improve your product and process quality
Centralized CAPA Database	Track all your quality CAPA records in a validated system with detailed audit trail for a regulatory environment
Risk Assessment	Assess the risk of the event and evaluate the need for root cause analysis and investigation using system driven Risk Priority Value (RPV)
Electronic or Digital Signature	An electronic signature for every action and decisions performed. Includes the name of the signatory, the date and time of signature execution
Iconic Color Code Managed Workflow Process	The color-coded icons quickly help the user know “WHERE AM I” in the managed workflow process.
Dashboards & Reports	Users can create any number of Dashboards and reports.
File Attachments	Multiple files of any type can be attached to a CAPA and files are identified by steps of the process
Automated Dynamic Workflows	Dynamic workflow configuration allows user to create variations of workflow for every CAPA record.
Follow or subscribe to your important quality records	Follow feature allows user to keep track on progress of the CAPA that they are interested in, even though they do not own or have any active task. The system will create an alert on the dashboard anytime the CAPA records that they are following is updated.
Notes for important reminders	Allows user to create a ‘sticky note’ to the self in the portal. Use it as a personal reminder or to remind yourself of work that needs to be done for a CAPA record or a specific task.
Alerts & Notifications	A content change notification service that provides information in the homepage anytime any type of updates occurs to an CAPA records that the user own.
Portal Page	Dynamic portal page provides a quick overview of all the tasks for a user to complete. Approval, Task Completion, Alerts, Notes, Followed CAPAs and CAPAs that the user owns are all displayed in the portal page.
Task List Approval	With task list approval, approver will have the capability to approve right from the task list without having to go into the details of the CAPA record.
Outlook Email Approval	With this feature, approver do not have to sign into the application to approve. User can simply reply back with words like ‘APPROVE’, ‘APPROVED’, ‘REJECT’, or ‘REJECTED’, as a response.
Chronology	Every CAPA record has a timeline of an event which tells the user what happened when. In other words, a very high level audit trail that allows user to quickly understand the sequence of activities that occurred in the life cycle of CAPA record.

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Qualityze Inc.

3903 Northdale Blvd Suite 100E Tampa FL 33624
Phone: +1-877-207-8616 Email: info@qualityze.com

www.qualityze.com