

Qualityze Change Management Solution Identify, Evaluate, Assign, Implement, Ensure Document Compliance



As new regulations emerge and existing regulations become more stringent, the effort to minimize the poor quality and manage ongoing changes is very challenging. Keeping up with the different changes for processes, SOP's, Work instructions, design spec's, training plans, formulations and others becomes a compliance headache for all companies. Qualityze Change Control Management Software Solution leverages the latest cloud technologies to complement your established change management processes.

Initiating and Documenting Change

The information related to the change request must be documented clearly and concisely. With Qualityze's Change Management module, this can be achieved first by creating a change request. Within the Initiation step of a change request, you can capture key information such as

- Date of change request
- Change request type, title, and description,
- Change request scope and justification
- Priority (High, Medium, or Low).
- Change requester, Change Owner

Review & Approve Change

A Change request can be initiated by anyone in the organization. However, it needs to be properly reviewed and confirmed for the validity of the request.

In Qualityze's Resolution step, you have an option to start the approval process to complete this step. If you feel that the change request is not valid you can close out the request. If further processing is required, you can start the change workflow to complete the request.

Notification of Change

Once the change request is verified and approved. The document owner and the relevant users get a notification about the upcoming change. This early notification will help them to plan things accordingly.

Qualityze built-in capability provides a real-time notification to impacted users and owners. Even if the change request is opened, the change owner, the document owner(s) and the task owner get notified about that change request.

Reducing Change Implementation Cycle Time

It is necessary to implement the change in timely manner by reducing the cycle time. The timeliness of change implementation is critical to its success as well as being compliant. In Qualityze change workflow, every change task is generated with a due date. The built-in notification and dashboard capability allow you to monitor the request progress. In addition, the escalation rule helps to auto escalate the pending and delayed activities to appropriate users while reducing the cycle time.

Automatic Archiving of Old Revisions

Archiving of old change request is required as a part of the change management process. The archived record is your window to the past for changes that were implemented or rejected.

Once the change request is closed, it cannot be reopened. Every change request will contain the revision of a document that was impacted by the change. Similarly, every document that was changed per the change request(s), will also have the reference back to the change request. This built-in, auto reference feature allows you to easily manage and maintain the historical data related to change request.

Ensure Regulatory Compliance

The ever-changing regulatory environment makes it difficult for any organization to follow the compliances. In most of the organizations, a standard template is used to standardize the change management process. The standardization of the process helps the organization to strive for the compliance.

Qualityze's feature-packed module has streamlined and standardized the change request process than before. Its built-in workflow, notifications, escalations and monitoring capability makes it easy for you to track the process and take required action. With all of these out-of-the-box features, Qualityze change control management software strives to help your organization to remain compliant with industry regulatory standards.



Qualityze Change Management Solution Ensuring ISO 9001 & Regulatory Compliance

| Capabilities | Benefits |
|---|--|
| Industry Best Practices | Implement your Change Management with industry-proven best practices to improve your product and process quality |
| Centralized Change Request(s) Database | Track all your quality changes in a validated system with detailed audit trail for a regulatory environment |
| 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 |
| Dashboards & Reports | Users can create any number of Dashboards and reports. |
| Iconic Color Code Managed Workflow Process | The color-coded icons quickly help the user know "WHERE AM I" in the managed workflow process. |
| Proactive Input Validation | Proactive input validation helps guide the user while reducing errors on later steps |
| File Attachments | Multiple files of any type can be attached to a change record and files are identified by steps of the process |
| Automated Dynamic Workflows | Dynamic workflow configuration allows user to create variations of workflow for every Change. |
| Follow or subscribe to your important quality records | Follow feature allows user to keep track on progress of the Change 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 change 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 an Change or a specific task. |
| Alerts & Notifications | A content change notification service that provides information in the homepage anytime any type of updates occurs to a Change 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 Change Records and the Change Records 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 change 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 Change 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 Change record. |

