Qualityze

Qualityze Nonconformance Management Solution
Document, Manage, Track Your Deviations

Datasheet

A Nonconformance means that a problem has occurred and it needs to be addressed. It happens when something does not meet the specification or requirements in some way. Qualityze Nonconformance Management Software (QNC) solution complements your established Nonconformance process.

Identify and Document the problem

With Qualityze's non-conformance module, this can be achieved by completing the Initiation and Product Information steps. Within the Initiation step you can capture key information such as:

- Defect Statement and Code
- Occurrence Date
- Reported Date, Reported By, Location
- Products and Lot/Batch number and Quantity, NC Owner and others

You have an option to create additional custom fields to capture information that your business needs.

Evaluate/Review the problem

Once the problem is identified and documented, the next step in the process is to quickly evaluate and review the problem to determine the extent of investigation of the nonconforming material(s) utilizing Risk Assessment.

Segregate Non-Conforming Material

The nonconforming material must be identified and segregated in a controlled area to prevent nonconforming material from being used inadvertently until the material review board (MRB) makes the final disposition.

Dispose Non-Conforming Material

Once the non-conforming material is identified, tagged and segregated in a controlled area, the MRB or authorized management person makes the final decision on disposition. A written rationale or justification for disposition decision needs to be documented and signature of those approving the disposition.

Investigate non-conforming material on need of further corrective actions

The investigation of a nonconformance is an important part of the quality system. In Qualityze, you use the combination of Investigation and Implementation task to document the investigation with all root causes of the nonconformance. The flexibility of the system allows you to document multiple root causes and defect associated. Whereas, in the Implementation task you document and implement the actions such as correction, corrective, preventative, Risk based as appropriate.

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Qualityze Nonconformance Management Solution Ensuring ISO 9001 & Regulatory Compliance

Capabilities	Benefits
Industry Best Practices	Implement your Nonconformance with industry-proven best practices to improve your product and process quality. Capture Defect Data and Risk Assessment, Reduce Nonconformance Cycle Time, Integrate Document, Nonconformance and CAPA Management. Integrate with Core Business Systems and make Compliance-Driven Decisions
Centralized Deviation Database	Track all your quality deviation 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 CAPA 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 NC and files are identified by steps of the process.
Automated Dynamic Workflows	Dynamic workflow configuration allows user to create variations of workflow for every NC record.
Follow or subscribe to your important quality records	Follow feature allows user to keep track on progress of the NC 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 NC 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 NC 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 NC 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 NCs and NCs 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 NC 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 NC 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 NC record.

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