



The ever-changing regulatory landscape, potential product liability issue and cost of compliance are making organizations adjust the way they process, manage, resolve and report customer complaints. Managing customer complaints and regulatory reporting are the new headache for any regulatory industry.

Documentation

Customer complaints and regulatory reporting are an inevitable part of the regulated industry. When it occurs, you should be able to document the problem quickly and clearly that can be assessed for regulatory reporting.

With Qualityze complaints management software system, this can be achieved by completing the Initiation step. Within the Initiation step, you can capture key information such as:

- Complaint Description and complaint Code
- Occurrence Date and Location
- Aware Date
- Product Information
- Reported Date and Reported By
- Complaint Owner and Others

Besides this information, you have an option to create additional custom fields to capture information that your business needs. Once the record is saved, a unique number will be assigned by the system for you to keep track of the customer complaints.

Root Cause Investigation

The root cause investigation of a complaint plays a very important role in the functioning of the complaint system. The extent of the investigation depends on the several criteria such as criticality, a risk to the patient or end user, the risk to the company, extent of the defect, etc. In Qualityze, you use the combination of different tasks to document the investigation result or outcome. You can perform two types of investigation to identify the cause:

Customer Investigation and Product Investigation. The flexibility of the system allows you to document multiple root causes. Additionally, you can also document the results of the investigation.

Customer Investigation is related to the information that you want to collect for understanding the root cause. Product Investigation is performed internally to check for any existing nonconformance during the manufacturing process that may have contributed to the complaint.

Managing Customer Response

Customer Response is an activity that an organization uses to respond to a customer who has filed a formal complaint about the products or services. Timely response to the customer is very critical to show an organization's commitment to resolve the issue.

In Qualityze, you can generate a customer letter with using a predefined response template. You also have an option to update or change the template based on your organization's requirement. Having a template provides a format, structure, and style that can be used to write a formal response to a customer complaint.

Regulatory Reporting and Submission

Some of the complaints need to be reported to the regulatory agency of the country where the incident occurred. There is always a specific timeframe that needs to be followed to complete the regulatory reporting and submission. The determination of reportable event and a timeline is based on the outcome of a decision tree.

With Qualityze complaints management software, you can create your decision tree based on the region for the complaint's management. For a reportable event/incident, the system auto-generates a task with a timeframe auto-calculated by the system. Using the pre-configured forms provided by FDA (MedWatch FDA MDR 3500), European Medical Devices Directive (93/42/EEC) (MEDDEV 2.12-1), Health Canada (MDPR), Therapeutic Goods Administration (TGA) etc., you can quickly and promptly generate the submission report.

Capabilities	Benefits
Industry Best Practices	Implement your customer complaints management with an industry-proven processes to improve your product and process quality.
Centralized Complaints Database	Track all your customer complaints in a validated system with detailed audit trail for a regulatory
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 complaint 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 customer complaint.
Follow or subscribe	Follow feature allows user to keep track on progress of the complaint record 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 complaint 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 Complaint 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 the complaint 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 Complaint Records and the Complaint 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 Complaint 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 Complaint record has a timeline of an event which tells the user what happened when. In other word, a very high-level audit trail that allows user to quickly understand the sequence of activities that occurred in the life cycle of a Complaint record.