



Ever changing regulatory landscape, potential product liability issues and cost of compliance are making organizations to adjust the way they handle, manage, settle, and report customer complaints. Effective management of customer complaints and regulatory reporting are an inevitable part of the regulated industry.

Document Customer Issues

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.

Perform 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.

Manage Customer Responses

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.

Conduct Global Regulatory Reporting and Submissions

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
CEM Type	Customer Experience Type is a predefined template where information such as Numbering Scheme, Task Model, Section Names can be predefined to be used in the records created under this type.
Complaint Initiation	Complaint Initiation is the first step in the Complaint management process. Once initiated, a unique number will be assigned which can be used to track the complaint as it goes through various steps of complaint lifecycle. It provides detailed information about the Type of Complaint, Type of Event, Product information, Reporter information, Facility and Service Provider information, Adverse Event Codes, Product Code and User information.
Security	In this step the user can modify or enable the security per complaint record. Security can be enabled to setup authorized entities and view only entities specific to individual record. Entities can be added as an individual user or as a group.
Reference	In this tab, Complaint owner can add a reference documents for this Complaint from different modules like NC, CAPA, Document, CR, Audit and other Complaint records.
Electronic/Digital Signature	An electronic signature is enabled by default when a Complaint is initiated and updated. The procedure for electronic signatures records the name of the signatory, the date and time of signature execution.
Complaint Workflows	Dynamic workflow configuration allows user to create variations of workflow for every Complaint record.
Proactive Input Validation	Validation on input from the user is performed as early as possible. Proactive input validation helps guide the user while reducing errors on later steps.
Complaint Approval	Complaint owner has an option to use an approval process as a part of the Complaint creation process prior to making InProgress.
File Attachments	Multiple files of any type can be attached to a Complaint record while it is open. Once the Complaint is expired the attachments cannot be attached or deleted.
Follow	Follow feature allows user to keep track on progress of the 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 the user is following gets updated.
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 detail of the 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 Complaint record.