



Controlling product safety incidents/failures/recalls is imperative to avoid serious implications on customers' health especially when the product is already available for use in market. It is the responsibility of the manufacturer to take a timely action to mitigate the issue as soon as it is discovered. It can only be possible with the help of a powerful, next-generation Field Safety Action and Recall Management Software. It will also provide greater visibility and traceability to analyze recall trends and make intelligent business decisions.

Achieving Safety Excellence is all about having a Proactive Post-Market Surveillance Program!

Monitoring product safety after its release in market is difficult. However, keeping a track of customer feedback is important for product quality and safety improvements. The best way to manage post-market surveillance activities is through automation and standardization. And Qualityze Field Safety Action and Recall Management along with Qualityze Complaint Management easily facilitates that. It keeps you and your teams' updates with the status of post-market activities, so you proactively mitigate risks. It integrates with your existing quality management system to connect all your critical data in one closed-loop system. You can further analyze the data to track recall/failure trends and make intelligent business decisions to prevent their recurrences.

With Qualityze Field Safety Action and Recall Management, you can enforce standardized processes to:

- Capture, manage, and track all the FSA or recall details on a centralized platform.
- Assess health hazards to identify the impact to consumer's health.
- Document, verify and investigate the product's Lots/Batches impacted.
- Improve communication to ensure faster response times.
- Efficiently manage FSA or recall records and regulatory reporting.
- Integrate with enterprise-level quality systems for improved product safety

Capture, Manage, And Track All the FSA or Recall Details on a Centralized Platform

Qualityze Field Safety Action and Recall Management is a configurable solution that enables enterprises to capture the necessary details in the desired format. It comes with pre-defined templates and forms to gather distribution data. You can also modify them as per your business needs. In addition, the standard design of the solution allows you to capture detailed information about the recalls initiated, including the Title, Scope, Nature, Vendor, Source, and much more.

The Qualityze Field Safety Action and Recall Management software helps businesses document their communication plans for specific records. You can print the records or directly email them to the concerned authorities without any hassles. This cloud-based solution is highly secure, scalable, and accessible, as opposed to legacy systems.

Assess Health Hazards to Identify the Impact to Consumer's Health

With the advanced integration capabilities of Qualityze Field Safety Action and Recall Management, you can evaluate the risk threshold of the product issues identified in post-market surveillance. It will further help you understand the need for product recall. You can then investigate and mitigate the product safety issues effectively by combining the post-market activities with Complaints and CAPA management in a closed-loop system.

Therefore, Qualityze Field Safety Action and Recall Management can help improve product quality, effectiveness, and safety.

Verify and Investigate the Product's Lot/Batch Impacted

Once you have tracked the product issue, it is essential to determine the lots or batches of the product impacted before it reaches customers. Qualityze Field Safety Action and Recall Management makes it simple for you. You can use the distribution data to verify the lot/batch impacted. Further, you can identify its root cause, assess its impact, and develop a plan of action to mitigate it effectively.

A tightly knitted system improves cycle times so that you can resolve quality issues quickly without any delays. In addition, the electronic signature validation ensures that all the data available in the system is correct and up to date. It enables you to track the exact quantity or lot of products.

Assess Your Materials For Compliance With Different Regulatory Requirements

You can use Qualityze Material Compliance Management to perform regular material compliance assessments for different regulatory requirements to identify risks and gaps that need to be addressed immediately. These assessments are usually done at varying intervals according to different regulations. For instance, conflict minerals regulations require an annual assessment. In contrast, REACH and RoHS compliance requires ongoing assessments, audits, and tests to respond to any updates and changes in the regulations. Qualityze makes it easier to manage all such compliance evaluations as per applicable regulations, including California Proposition 65, FDA Latex, EU Medical Device materials restrictions, Health Canada materials restrictions, and US Ozone Depleting Substances.

The Qualityze Material Compliance Management Solution can provide products and supply chains with a holistic compliance assessment program to meet your growing business requirements.

Improve Communication to Ensure Faster Response Times

Qualityze Field Safety Action Management enables you to develop an effective communication plan to manage FSA or Recall with ongoing operations. You can select the team responsible for managing and reporting the FSA or Recall to the concerned authorities and customers. Under the communication plan, you can also

choose the medium you want to communicate with your customers. For example, you can run a campaign on social media which will have a better reach than any other medium.

With its cloud-based platform, this solution gives users the flexibility and security they require to manage FSA or Recall data across multiple sites, departments, and people. And you can ensure faster responses to your customer. Think about how much better your communication would be if you leveraged cloud features?

Efficiently Manage FSA or Recall Records and Regulatory Reporting

Qualityze Field Safety Action and Recall Management Solution comes with powerful reporting features. It enables you to maintain compliance while keeping a summary log of events in the audit trail. It comes with pre-defined templates for gathering distribution data and other FSA or recall details. You can use them straight away or tailor them to your business and regulatory needs. Moreover, you need not worry about the storage of these records. The system automatically stores all the FSA or recall records in a centralized database. Using access rights, you can restrict the user's ability to modify or read it. The most critical benefit of this solution is the consistency and timely reporting of the product data collected during quality or post-market activities to regulatory bodies. By using the Qualityze Field Safety Action and Recall Management tool, you can easily collect post-market surveillance data and meet regulatory reporting requirements.

Integrate with Enterprise-Level Quality Systems for Improved Product Safety

The Qualityze Field Safety Action and Recall Management Solution seamlessly integrates with enterprise-level quality management systems for more effective control of FSA or recall data and product safety issues. For example, when you integrate Qualityze Field Safety Action Management and Recall with Complaints Management, you can collect insights for effective field safety actions. It can also be integrated with nonconformance and CAPA management systems to reduce risks and prevent their recurrence in the future. The solution offers next-generation integration capabilities that can reduce risks and ensure the safety of products. Get started with Qualityze today!

Capabilities	Benefits
Industry Best Practices	Manage multiple types of field safety action or recalls efficiently with industry-proven best practices.
Pre-Defined Distribution Templates	The system comes with pre-defined templates to capture distribution data of products in a consistent manner.
Centralized Database	Track all your FSA or recalls related data in a validated system with detailed audit trail for a regulatory environment.
Electronic or Digital Signature	An electronic signature for every action and decision performed on a FSCA record. 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 in later steps.
File Attachments	Multiple files of any type can be attached with the FSCA records.
Automated Dynamic Workflows	Dynamic workflow configuration allows user to standardized FSA fields to capture all the relevant details about the recalls and safety incidents.
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 about due regulatory reporting or their approvals.
Alerts & Notifications	A notification service that keeps users informed about due dates for resolving the safety issues and reporting the incidents to the local authorities.
Integration Capability	You can integrate Qualityze Field Safety and Recall Management with enterprise systems to improve product quality, safety, and compliance.
Audit Trail	This capability allows you to track all the activities related to a field safety including owner, scope, nature of the recall, and much more.