

Unexpected Events Happen.

ETQ Reliance® Quality Events application is used to track & trend or manage the investigation process of an unplanned event or deviation that impacts the quality, performance, safety, or reliability of a product or against cGMP (current Good Manufacturing Practice).

Track and Manage Event Investigation

The Quality Events app is designed to enable visibility into the impact that the event may have on an organization's business or product. The app provides a standard process for investigating an event to ensure each investigation is performed consistently and in a timely manner. Further, the organization can discover trends that might not have otherwise been obvious. Quality Events is a central component to systematically detecting and correcting issues.

With Quality Events, organizations can manage a broad set of unexpected or unplanned deviations, providing a single source of entry – one place to capture all different types of events – or add one!

Standard events include: Audit, Complaint, Deviation | Procedure, Deviation | Regulations, Deviation | Facility/services/environment, Deviation | Transport, Deviation | Audit Findings, Nonconformance, Out of Spec, Out of Trend

Who can benefit from the Lab Investigation Application?

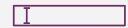
All industries needing to track & trend or investigate events, incidents, deviations.

How the quality event process works:

- An Event gets Initiated with basic information about what has happened and what immediate actions have been taken.
- Then an Initial Review is done to determine the risk and importance of the event. If it is determined to be not serious and not expected to occur again, then the user can decide to just Track the event to see if it recurs.
- If it is deemed to be more serious, then a more in-depth investigation will be necessary.
- Then an Investigation Plan is developed and Approved.
- The Investigation can look at a number of factors including the Root Cause Analysis and any Trending information to see if this is a systemic problem.
- The outcome could be follow-up actions or a CAPA. Once the disposition is known, the investigation gets Final Approval.

In addition to the standard workflows, Quality Events has optional sections to integrate with other Reliance applications, such as Audits, Document Control, and Supply Chain Management.

Key Benefits



Streamlines data entry and enhances productivity capturing all necessary information and managing any quality event.



Provides a process to capture all types of events and determine if each event needs to be investigated or just tracked.



Tracks the results of each investigation and identifies trends for root cause analysis.



Provides a determination through the analysis of the investigation to determine if a CAPA is required.



Improves quality of products with tracking and trending data to identify risk and reduce quality deficiencies



Enables users to notify management of critical issues