

Manage your Lab Investigation with consistency & ease

ETQ Reliance® Lab Investigation application is used to document the investigation process of an Out of Specification (OOS) or Out of Trend (OOT) lab test result.

Users now have the ability to investigate an OOS or OOT result to determine the cause of the result, and through the investigation process, conduct re-sampling/re-testing to confirm the test results.

Through the investigation, users document results to determine the validity of the OOS/OOT

- If valid, continue to determine the cause through full investigation, root cause and conclusion.
- If invalid, document the results, root cause, and conclusions.

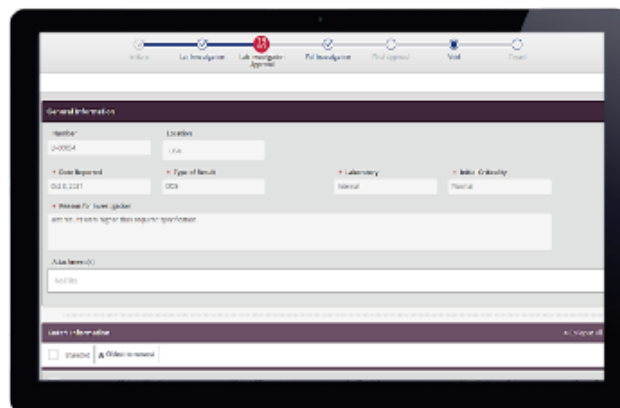
Lab Investigation can help determine risk, and the user has the ability to generate a corrective action (CAPA) or Non-Conformance material report (NCMR) after determining one is required. In many cases, Lab Investigation can eliminate the need to undertake a more costly and time-consuming CAPA.

From the Lab Investigation application, users can directly initiate the CAPA or NCMR, as the applications are connected through the ETQ Reliance platform.

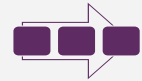
Who can benefit from the Lab Investigation Application?

Many industries will be able to take advantage of the Lab Investigation application, including Pharmaceuticals, Biotechnology, Biologics, Medical Devices, Chemical, Contract Manufacturing, General Manufacturing, and Food & Beverages. In fact, any organization that tests products and materials will benefit.

For organizations that must comply with cGMP and 21 CFR Part 210 and 211 requirements such as pharmaceutical and combination product makers, Lab Investigation enables you to capture and track your processes and results. *



Key Benefits



Provide a standard process definition that everyone follows when performing a lab investigation. This will ensure that each investigation is consistent.



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



Perform an investigation to determine if there is even a need for a CAPA. Avoiding CAPAs will save significant time and effort.



Initiate a non-conforming material report or CAPA for further action, if required.