

Course Description

This one-day training will provide participants the necessary information and classroom activities to understand how to produce thorough and complete investigations. Participants will learn about industry expectations, aspects of effective investigation programs, components, and requirements of thorough investigations as well as provide an overview of root cause analysis tools and implementing effective CAPAs. Interactive activities are performed throughout this one-day training to ensure knowledge retention and complete understanding of the concepts.

Note: Coffee, water, drinks, snacks, and lunch will be provided for on-site training.

Time	Agenda
9:00 – 9:15 AM	Welcome & Introductions
9:15 – 10:15 AM	Investigation Overview
10:15 – 10:45 AM	Regulatory Requirements for Investigations
10:45 – 11:00 AM	Break
11:00 – 12:30 PM	Conducting an Investigation
12:30 – 1:30 PM	Lunch
1:30 – 3:30 PM	Conducting an Investigation (cont.)
3:30 – 3:45 PM	Break
3:45 – 5:00 PM	Root Cause Analysis and CAPA Overview

Module	Learning Objectives
Investigation Overview	<ul style="list-style-type: none">• Review the importance of conducting thorough Investigations.• Discuss the different activities that investigations support.• Discuss effective investigation programs.
Regulatory Requirements for Investigations	<ul style="list-style-type: none">• Identify the regulations governing investigations.• Review consequences of performing inadequate investigations.• Review examples of FDA citations (483's / Warning Letters) pertaining to lack of or inadequate investigations.
Conducting an Investigation	<ul style="list-style-type: none">• Define and examine the critical parts of an investigation with interactive exercises, including but not limited to:<ul style="list-style-type: none">-Consistency when developing titles.-Aspects of a detailed description.-Documentation of immediate actions.-Performing historical reviews.-Items to review and pathways to explore during data collection.
Root Cause Analysis (RCA) Corrective / Preventative Actions (CAPA) and Effectiveness Check Overview	<ul style="list-style-type: none">• Define root cause.• Identify and review common RCA tools.• Provide guidance on when to implement a CAPA.• Review of elements that make up an effective CAPA.• Discuss Effectiveness Checks and their importance.