

Documenting Investigations

Documenting Investigations teaches proven technical writing skills needed for today's fast paced organizations. The course provides the skills, tools and techniques that are necessary to effectively document and communicate investigations.

“Our PathWise class was outstanding. The course covered when an investigation is required from a regulatory perspective, the need to understand your audience when writing, and the importance of reporting facts from the investigation process. This course was able to connect with manufacturing personnel and our non-scientific backgrounds. I would definitely do this training again at Chanel.”

— Jackie Ferro
Chanel, Inc.
Director, Validation
Compliance

LEARNING OBJECTIVES

This interactive course teaches proven technical writing techniques and tools that will meet the FDA's expectations, including:

- The purpose and components of an FDA investigation report
- The qualities of a sound investigation report
- The common patterns for organizing an investigation report
- The qualities of good technical writing
- The keys to a readable writing style
- The principles of document design

At the end of this course, participants will be able to:

- Explain FDA requirements and your organization's needs
- Write clear, concise and objective reports
- Document a clear history of events and actions
- Write reports that will meet an auditor's expectations.

AUDIENCE

Anyone who is responsible for documentation will benefit from this course. Examples include engineers, QA/QC professionals, and others responsible for performing and documenting investigations.

The learning will not only improve investigation reports, but is applicable to most communications that take place in an organization. In other words, this course will raise the quality level of most written documentation in your organization.

DELIVERY

This course is taught using a blended approach of classroom and real-life work application. It allows participants to practice those tools and concludes with a review of an organization's existing reports to apply the learning.

At course completion, participants will master how to take their investigation analysis and place all needed components into a well-crafted report.