



Conducting & Documenting cGMP Investigations with CHIM



CardinalHealth

NUJIT
A Public Research University

Overview

This 16-week course is a unique collaborative effort between Cardinal Health, Inc. and New Jersey Institute of Technology that focuses on assuring quality in the PTS business segment by providing a consistent methodology and training on a core business process - the cGMP investigation. The Cardinal Health Investigation Model (CHIM) sets a standard process for conducting cGMP investigations; and provides consistent documentation practices for use of the PTS TrackWise investigation documentation or other documentation used by Cardinal Health, PTS sites. As CHIM is taught the sites are able to collaborate on solutions and strengthen the performance driven culture of One Cardinal Health. The participants work with real life issues and learn how to use CHIM to final resolution and customer approval.

Course Summary

Length	16 weeks
Avg class time/week	1 hr
Total course hours	31 hrs
Max class size	30

Goals

- Conduct and write cGMP investigation documents to demonstrate that quality was assured (or other action was necessary).
- Employ the Cardinal Health Investigation Model (CHIM) to shorten the time and increase the accuracy of investigation reports.
- Organize the content of investigation reports to capture the investigation process.
- Ensure that investigation reports meet the needs of multiple readers across time and circumstance.
- Ensure that both precision and clarity are used in investigation reports to project a positive company image.

Format

The course is designed to include face-to-face classroom instruction and "anytime/anywhere" online learning. After a 4-hr face-to-face orientation to the course and to online learning, participants take part in training and complete assignments requiring individual and group work. The instructors review each assignment and provide detailed comments for improvement back to the participants.

Participants devote approximately 1 hour each week to viewing digital lectures from a computer and completing and submitting assignments using a commercial Learning Management System. At anytime, participants can post questions to their instructor and classmates or email the instructor regarding questions that apply directly to their writing.

Within this environment, the instructors are able to reply within 24 hours to each participant during the training course. The final two weeks of the training course consist of completing a final investigation document/writing project and submitting an overall portfolio that will enable participants to utilize skills acquired from the previous weeks' training and apply them directly to an investigation case. A briefing report on the investigation the participant works on through the course is orally presented to the instructors at the conclusion of the course.



Course Schedule

Week 1 - On-site (4-hr lecture)

Defining and Measuring in the Investigation Process; Using Brainstorming and Fishbone Analysis Techniques; cGMP Discussion Slides

Week 2 - Online

The Cardinal Health Investigation Model: A Writing Perspective

Week 3 - On-site

Current Good Manufacturing Practices and the Investigation Process; Using Flowcharting Analysis Techniques

Week 4 - Online

The Nature of Discourse Communities: Elements of Quality in Investigation Report Writing

Week 5 - On-site

Analyzing Information in the Investigation Process to Achieve Quality Assurance; Using Measurement Systems Analysis Techniques

Week 6 - Online

Audience Analysis Analytic Techniques: The Roles of Writers and Readers in Investigation Report Writing; Creating Reader-Centered Documents

Week 7 - Online

The Process of Discovery: The Role of Discovery and Drafting in Investigative Report Writing

Week 8 - On-site (4-hr lecture)

Forms of Reports: Evaluating and Revising Investigation Reports with Established Criteria; Using Failure Mode Effect Analysis Techniques

Week 9 - Online

Editing: Evaluating and Revising Investigation Reports; Using Failure Mode Effect Analysis Techniques

Week 10 - Online

Cohesion: Submitting Investigation Reports to Reflect Quality Assurance; Using Failure Mode Effect Analysis Techniques

Week 11 - On-site

Control Plans in the Investigation Process; Using Failure Mode Effect Analysis Techniques

Week 12 - Online

Preparing the Seminar Written and Oral Investigation Report: Demonstrating Proficiency with the Cardinal Health Investigation Model

Week 13 - On-site (4-hr lecture)

Assembling the Portfolio: Presenting Documents to Audiences Across Time and Circumstance

Weeks 14-15 - Online

Control Plan Development

Week 16 - On-site (4-hrs)

Seminar Conclusion: Investigation Reports-Quality in the Chain of Care