Conducting & Documenting cGMP Investigations with CHIM

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
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<tbody>
<tr>
<td>Length</td>
<td>16 weeks</td>
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<tr>
<td>Avg class time/week</td>
<td>1 hr</td>
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<tr>
<td>Total course hours</td>
<td>31 hrs</td>
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<td>Max class size</td>
<td>30</td>
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Goals
- Conduct and write cGMP investigation documents to demonstrate that quality was assured (or other action was necessary).
- Employ the Cardinal Heath 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.

6/30/05
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