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# Writing Investigation Reports

## ***Purpose***

To use the data collected in an investigation to write a report and answer management and FDA questions.

***Objectives*** At the completion of the class, students will be able to:

1. Increase investigation report suitability for FDA review.
2. Decrease the number reports returned by internal reviewers.
3. Write supported deviation statements.
4. Provide a detailed background statement to include related information, investigations, affected materials and references.
5. Document deviation investigation findings.
6. State the root cause with supporting facts.
7. Generate supported, plausible, and defensible corrective actions.
8. Develop effectiveness measures for the corrective actions.
9. Generate realistic preventive actions.
10. Develop effectiveness measures for the preventive actions.
11. Develop a follow up plan for corrective and preventive actions.
12. Write accurate executive summary statements.

## ***Prerequisite***

Students attending this session must have attended the Root Cause class first. Student's may test out of the root cause class by passing our CGMP certification exam with an 85% or higher. Students must also have a solid understanding of CGMPs.

## ***Who should attend this class?***

This class is intended for anyone who writes or reviews and approves deviation investigation reports.

## ***About the class***

1. Students use in-house investigation reports to practice the principles taught in this class.
2. The optional final exam is approximately 25 questions.
3. Each student receives a student guide containing a representation of the program's slides and graphics with space provided for note taking.
4. This class can accommodate up to 12 people.
5. Duration: 7 hours.

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## **Topics Covered**

### **Introduction**

1. Observations from the FDA
2. Regulatory requirements
3. Definitions
4. Writing guidelines
5. Common report writing traps

### **Deviation Statement**

1. Components
2. Questions for clarification
3. Expected performance versus actual practice or deviation
4. Immediate response
5. Examples
6. **Activity:** *Writing clinic*

### **Background Information**

1. Related investigations
2. Other effected materials
3. Examples
4. **Activity:** *Writing clinic*

### **Deviation Investigations**

1. Investigation findings
2. Sequence of events
3. Anticipating root cause questions from the FDA
4. Discussion of root causes eliminated
5. Discussion of most likely root causes
6. Discussion of the real root cause
7. Handling no assignable root cause
8. **Activity:** *Writing clinic*

### **Corrective Actions**

1. Path forward
2. Rationale
3. Expected outcome and completion date
4. Follow up on CA success
5. **Activity:** *Writing clinic*

### **Preventive Actions**

1. Rationale
2. Expected outcome, and completion date
3. PA Implementation
4. Follow up on CA success
5. **Activity:** *Writing clinic*

### **Background Information**

1. Rationale
2. Content
3. **Activity:** *Writing clinic*

### **Summary**

1. State the root cause
2. Summarize the important points of the investigation that support that root cause
3. State corrective action
4. State preventive action
5. **Activity:** *Writing clinic*

**This class is best taught in a computer lab. If your company does not have a computer lab, we can ship one to your site for this class usually for less than \$500 total extra charge.**

**This class is always customized to reflect the language and report structure of the site. Class us to discuss the details in more detail.**