
Qualstar: A GMP Simulation

Purpose

Employees experience real-time stresses and frustrations of working in a regulated industry and then learn to manage it while following procedures and completing proper documentation.

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

1. State the causes of documentation errors.
2. Explain the reasons for critically reading and reviewing procedures.
3. Explain the importance of reporting problems with procedures.
4. State the reasons for accurate documentation.
5. State the top five reasons for receiving 483 observations.
6. State 5 work practices to help prevent errors in following procedures.
7. State 5 work practices to help prevent documentation errors.
8. Define double-check.
9. State the consequences of procedure and documentation errors.

Prerequisite

None

Who should attend this class?

This very much hands-on course is for anyone who must follow procedures, document their work, or supervise or manage those who do.

About the class

1. This class uses a team-based simulation to dramatize how easy it is to deviate from procedure or fail to properly document work.
2. The optional final exam is approximately 15 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 25 people.
5. Duration: 4.0 Hours.

Topics Covered

Introduction

1. Agenda
2. Ground rules
3. New issues and practices in CGMPs
4. 21CFR211 – Multi-media presentation



Qualstar Simulation

1. Instructions – Part 1
2. Simulation – Part 1
3. Debrief – Plus Delta
4. Instructions – Part 2
5. Simulation – Part 2
6. Debrief – Part 2

Standard Operating Procedures

1. QA responsibility
2. Uses of procedures
3. Writing, formatting and guidelines
4. Revisions and approval
5. Review frequency

Documentation

1. Proper Documentation Practices – Multimedia presentation
2. 483 Observations relating to documentation
3. Case Study: Able Pharmaceuticals
4. Predicate rule documents
5. Other required documents

QA and Their Role in Documentation

1. Review
2. Approve
3. Get corrected
4. Reject

Summary

1. Activity: *GMP Challenge; Procedures and Documentation Modules*

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