

GMP Olympics

Purpose

This class takes CGMPs to a deeper level of understanding.

Objectives

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

1. List the hottest issues in CGMP compliance.
2. Locate items of interest in 21CFR211.
3. Explain the 21CFR211 rationale for specific 483 observations.
4. Demonstrate knowledge of common CGMP practices and details.
5. State the consequences of not following CGMPs.

Prerequisite

This class is intended for those with prior CGMP training. This class is not for new employees.

Who should attend this class?

This very much hands-on class is taught in a highly competitive and friendly environment. The course is for anyone who feels that they have little to learn in “another CGMP class”.

About the Class

1. This class uses a teams and competitive to challenge students knowledge of 21CFR211 and to seek new understandings for the CGMP rules.
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
4. Client directed presentation 20-30 minutes



Heard on the Street

1. 21 CFR 211 – Multi-media presentation
2. Activity: *Brainstorming questions about CGMP*
3. Open discussion

Inspection Detection

1. Review 483 observation note
2. Link observation to 21 CFR 211

GMP Challenge

1. Client selects 4 topics from a list of 18
2. Questions are presented

Summary

1. Activity: *Brainstorm important points to remember from the class*

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