

GMP / QSR Trainer Certification Workshop

Purpose: To develop the training skills necessary to facilitate greater knowledge of relevant regulatory requirements, and to help others apply that knowledge in the work environment.

Competencies for Certification:

1. Demonstrate ability to participate in professional discussions of basic CGMP & QSR regulations.
2. Apply CGMP/QSR knowledge through interactive activities.
3. Model support of compliance through individual inquiry and discussion.
4. Design, construct and facilitate instructional activities based on learning taxonomies and domains.
5. Use proven activity debrief strategies to emphasize important learning objectives.
6. Develop and present interesting case stories relevant to CGMP/QSR training topics.
7. Deliver energizing presentations to keep employees involved and engaged.
8. Facilitate discussions to encourage student interaction and instill greater understanding of the regulations.
9. Manage disruptive employees in the classroom environment.
10. Model proven strategies in responding to difficult questions.
11. Identify the fundamental elements of test construction and test validation.
12. Demonstrate breadth of CGMP knowledge through responses to written and verbal quiz questions.

Who Should Attend: Trainers, program designers, training supervisors, training managers, and others who conduct CGMP/QSR training in the pharmaceutical, biotech, medical device, food or dietary supplement industries.

Class Length: Five days. Monday to Friday 8AM to 5PM.

Class Size: Size is limited, so register early!

Rooms: A very small block of rooms have been reserved for us at a discounted rate. They will be available until **August 15, 2012**. After that date the hotel reserves the right to charge the standard rate.

Registration Fee Includes daily: Continental breakfast, mid-morning and afternoon break, detailed student materials on CD, selected handouts as needed, and a certificate of completion.

Where is the conference held?

Sir Francis Drake (A Kimpton Hotel)
450 Powell Street, San Francisco 94107

Room reservations are made at 800-227-5480 or 415-392-7755. Or email to reservations@sirfrancisdrake.com.

Daily Agenda

Each CGMP/QSR topic and associated activity below is linked to one or more learning categories from the cognitive, affective and psychomotor learning domains. Topics are selected based on their demonstration of each domain and are intended to address the general elements of the regulations exposing participants to skills for training success in their work environment.

Monday

- History of FDA, GMP, QSR
- Organization and Personnel
- Personnel Responsibilities
- Training
- Hygiene, Illness, & Gowning
- Management Responsibility
- Documentation
- Electronic Records
- Materials
- Purchasing Controls
- Acceptance Activities
- Quality Control
- Buildings and Facilities
- Purchasing Controls

Tuesday

- Production and Process Controls
- Equipment
- Calibration
- Design Controls
- Process Validation
- Quality Management System
- Qualstar Simulation
- Effective Presentation Flow

Wednesday

- 21 Learning Domains for Meaningful Activities
- Cognitive Domain
- Affective Domain
- Psychomotor Domain
- Designing Meaningful Activities
- Facilitation Behaviors During Classroom Activities
- Six Levels of Questioning for Discussion
- Linking Discussions to Learning Objectives
- Responding to Difficult Questions
- Debrief Strategies
- Classroom Workgroup Formation
- Story Telling for Retention

Thursday

- Effective Presentation Skills
- Student Presentations
- Goal Setting for Improvement

Friday

- Managing Disruptive Students
- Tests and Measurements
- Student Presentations

Online workshop registration: www.skillsplusinc.com
Click on Public Seminar under the Express column.

For more information, visit our web site and click on Information under the Express column

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