

GMP & QSR Trainer Certification

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 GMP & QSR regulations.
2. Apply GMP/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 GMP/QSR training topics.
7. Deliver energizing presentations that keep employees involved and engaged.
8. Facilitate discussions to encourage student interaction and instill greater understanding.
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 GMP knowledge through responses to written and verbal quiz questions.

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

Class Length: Five days. The class begins on Monday at 8AM and ends on Friday at 5PM.

Class Size: This class is limited to 15 students, for certification, so register early.

Included in Fee:

1. Continental breakfast daily.
2. Mid-morning break daily.
3. Afternoon break daily.
4. Detailed student materials on CD.
5. Selected handouts as needed.
6. Certificate of completion.

Where is the conference held?

Sir Francis Drake Hotel - Downtown San Francisco

450 Powell Street
San Francisco, CA 94102

Rooms: A very small block of rooms have been reserved for us at a discounted rate. They will be available until **the number of rooms reserved for us have been taken**. After all discounted rooms are taken, the hotel reserves the right to charge the standard rate. Room reservation information is sent with registration confirmation.

Dress: Please dress to be comfortable.

Parking: Hotel parking is \$60 daily. Shuttles or taxis are the best choice to get to the hotel.

Daily Agenda

Each GMP/QSR topic below is taught from a global GMP perspective. Each topic is linked to one or more of the learning domains; cognitive, affective and psychomotor. Topics are selected on their demonstration of each domain while addressing global regulations. Participants will expand their knowledge of GMPs and develop the teaching and facilitation skills necessary 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

Wednesday

- Effective Presentation Flow
- 21 Learning Domains for Meaningful Activities
- Cognitive Domain
- Affective Domain
- Psychomotor Domain
- Designing Meaningful Activities
- Facilitation Behaviors During Classroom Activities
- 6 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

We reserve the right to make minor agenda modifications without notice as regulatory issues surface.

About This Class:

Throughout the first two days, experience the GMP/QSR Regulations through experiential learning processes. Each topic is linked to a facilitation style and learning domain. Each activity is followed by in-depth discussion. Students learn to design and facilitate learning activities, facilitate meaningful discussions, and create a safe environment through the debrief process. Topics selected are based on the topics exemplification of one or more learning domains. This class uses the above topics to model different teaching strategies.

About Your Instructor:

Allan Dewes, President of SkillsPlus International Inc. is internationally known for delivering highly interactive and energizing training sessions. Over the past 30 years, Allan has trained thousands of employees in the pharmaceutical, biotech, medical device and dietary supplement industries with rave reviews. In this class, Allan shares his secrets to exciting training facilitation. **Register early and save!**

What students have said about the class:

"I never knew that GMP training could be so much fun" – Trainer

"The instructors really knew their stuff." – Manager

"The instructors made sure everyone learned in a safe environment." – Trainer

"This class changed my entire attitude about training, I feel more confident." – Senior Trainer

"This is the first class where I did not want to skip out early!" – Trainer

"The worst thing was that the class had to end." – Trainer

"I used to work for the FDA and I learned some things in this course." – QA Manager

Registration Form

Register on line

http://www.skillsplusinc.com/Pub_Sem.htm

Google short link: <http://goo.gl/mWV3t>

Name: _____ **Nickname, if preferred:** _____

Company: _____

Address: _____

City: _____ **State/Province:** _____ **Postal Code:** _____

Country: _____ **Email:** _____

Telephone: _____ **Fax:** _____

Please indicate any food restrictions or special access needs: _____

	Payment Received By				Payment Received After
	6/1/2012	7/1/2011	8/1/2012	10/1/2012	10/1/2012
GMP/QSR Trainer Certification	\$2800	\$2900	\$3200	\$3400	\$3600
October 22 - 26, 2012					

Cancellation Policy:

1-30 days before class, registration fee is nonrefundable, substitute participants are accepted.

31-60 days prior to class incur a 25% penalty.

More than 61 days prior to class incur a 15% penalty.

Hotel Information: Sir Francis Drake, 450 Powell Street, San Francisco 94107. Room reservations are made at 800-227-5480 or 415-392-7755. Or email to reservations@sirfrancisdrake.com. The hotel has a small block of discounted rooms at a rate of \$239 per night that will be reserved quickly, so book early and be sure to mention SkillsPlus!

Payment by credit card: Guaranteed registration requires payment in full.

Please indicate the type of card you are using: VISA/MC American Express

Name as it appears on the credit card: _____

Billing address of card, if different from above address: _____

Credit card number: _____

Expiration date on the card: _____ **Security code:** _____

Indicate the amount to be charged to your card: \$ _____. **All payments are in US Funds.**

Cardholder Signature: _____ **Date:** _____

Print name: _____