

A photograph of the Golden Gate Bridge in San Francisco, California, viewed from a low angle looking across the water. The bridge's orange-red towers and suspension cables are prominent against a clear blue sky. In the distance, the city of San Francisco and the Marin Peninsula are visible. A large ship is seen in the water below the bridge.

GMP & QSR Trainer Certification

Pharmaceutical, Biotech, Medical Device
and Dietary Supplement Industries

San Francisco
October 10 - 14, 2011

Presented by
SkillsPlus International Inc.

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 \$52 daily. Shuttles or taxis are the best choice to get to the hotel.

Daily Agenda

Each GMP/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 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
6 Levels of Discussion Questioning
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 their 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. Be sure to 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

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 7/1/2011	Payment Received By 8/1/2011	Payment Received After 9/1/2011
GMP/QSR Trainer Certification October 10 - 14, 2011	\$2750	\$3000	\$3250

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 at reservations@sirfrancisdrake.com. The hotel has a small block of discounted rooms at a rate of \$189 per night that will be reserved quickly, so book soon!

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.

Signature: _____ Date: _____

Print name: _____