

The background of the slide features a series of overlapping, colorful triangles pointing to the right. The colors include dark blue, light green, orange, and red. The text is overlaid on these shapes.

*Presented by* SkillsPlus  
International

San Francisco, CA  
October 6 - 10, 2008

**GMP Essentials for Drug Manufacturers  
&  
GMP Trainer Certification**

Advancing the  
Competitive Edge

# GMP Essentials for Drug Manufacturers

**Purpose:** To develop comprehensive regulatory knowledge and the ability to apply that knowledge to realistic work situations.

## Competency Objectives:

1. Demonstrate ability to participate in professional discussion of GMP regulations using participative in-class discussions.
2. Demonstrate breadth of knowledge through responses to written questions and in-class activities.
3. Demonstrate support of GMP compliance through individual inquiry and discussion.

**Who Should Attend:** Trainers, supervisors, managers, directors, executives, trainers, technical professionals, and others who need a solid understanding of GMPs,

**Class Length:** This class is 2 days. The class begins on Monday at 8AM and ends on Tuesday at 5PM.

**Included in Fee:** Continental breakfast each morning, afternoon break, detailed student materials, certificate of completion and lunch on Monday.

## GMP Essentials Schedule of Topics (Subject to Modification)

### Monday

#### FDA: Past, Present, and Future

1. History of the FDA
2. Regulatory Inspections
3. Legal Consequences

#### People and Procedures

1. Organization and personnel
2. Standard operating procedures
3. Investigations

#### Documentation

1. Regulations
2. Documentation rules and practices
3. Double checking
4. Required documentation

#### Electronic Records and Signatures

1. Controls
2. Documentation
3. Access controls
4. Audits
5. Performance
6. Electronic records
7. Management responsibility

#### Materials

1. Supplier qualifications
2. Specifications
3. Quarantine system
4. Sampling
5. Receipt and identification of materials
6. Packaging and labeling
7. Material Controls
8. Non-conforming materials

#### Quality Control

1. Specifications and standards
2. Sampling and testing procedures
3. Analytical results
4. Investigations
5. Certificate of analysis
6. Stability testing
7. Reserve samples

### Tuesday

#### Production and Process Controls

1. Materials and equipment
2. Sampling
3. Processing
4. Reprocessing and rework

#### Buildings and Facilities

1. Designated spaces
2. Utilities
3. Housekeeping
4. Contamination control
5. Environmental monitoring

#### Equipment

1. Design and construction
2. Filters
3. Cleaning and maintenance
4. Identification
5. Calibration

#### Validation

1. Qualification and documentation
2. Process validation & timing
3. Cleaning validation
4. Change control

#### Quality Assurance

1. Suppliers and contractors
2. Materials and products
3. Investigations
4. Documentation
5. Recall procedure

## Visit Our Website

### Classes Taught At Your Company

<http://www.skillsplusinc.com/serv01.htm>

- Basic GMP Training
- Advanced GMP Training
- GMP Simulation
- Root Cause Investigations
- Writing Investigation Reports
- Writing Procedures
- GMP Olympics

### CBT Training Modules Currently Available

<http://www.skillsplusinc.com/CBPresent.htm>

- 21 CFR 211 Review
- Organization and Personnel
- Contamination Control
- Documentation Practices
- Equipment and GMPs
- Materials
- Production and Process Controls
- Root Cause Analysis
- Buildings and Facilities

# GMP Trainer Certification

**Pre-requisite:** GMP Essentials for Drug Manufacturers

**Purpose:** To develop competency in content delivery and classroom facilitation skills to enable discussions and activities for effective training of the GMP regulations..

## Competency Objectives:

1. Design and use engaging ice-breakers and activities to maintain interest.
2. Present and develop interesting stories relevant to training topics.
3. Deliver energizing presentations that keep employees involved.
4. Construct and facilitate activities that stimulate learning.
5. Facilitate discussions to provoke student interaction and foster greater understanding
6. Manage difficult employees in the classroom environment.
7. Respond to difficult questions.
8. Identify the fundamental elements of tests and measurements.
9. Demonstrate GMP knowledge through skill practice teaching.

**Class Length:** This class is 3.0 days. The class begins on Wednesday at 8AM and ends on Friday at 3PM.

## Included in Fee:

1. Continental breakfast each morning, afternoon break, detailed student materials, certificate of completion and lunch on Monday and Friday.
2. Celebration dinner for graduates on Thursday evening.
3. SkillsPlus Trainer Excellence Award for those who have demonstrated excellent training delivery and pass the on-line exam.
4. One SkillsPlus basic GMP instructor guide (Valued up to \$1,500)

## Competencies for Certification:

1. Demonstrate verbal communication through participation in class discussions.
2. Demonstrate breadth of GMP knowledge through responses to written and verbal quiz questions.
3. Demonstrate support for compliance through personal in class inquiry.
4. Demonstrate skills in teaching GMPs through practice training sessions.
5. Demonstrate activity facilitation in class.

**Who Should Attend:** Trainers, supervisors, managers, and others who conduct GMP training. This class is also appropriate for those who need more exposure to GMPs.

## Trainer Certification Class Schedule of Topics

Subject to Modification

### Wednesday

1. Overview of certification class
2. Designing effective ice breakers and activities
3. Creating real life based stories
4. Planning and developing a presentation
5. Facilitating meaningful discussions
6. Assignments for class certification

### Thursday

1. Effective presentation skills
2. Presentation 1: GMP content with class discussion
3. Peer feedback
4. Instructor feedback
5. Thursday evening celebration

### Friday

1. Managing disruptive behavior
2. Fundamentals of tests and measurements
3. Presentation 2: GMP content with activity and disruptive behavior
4. Peer feedback
5. Instructor feedback
6. Trainer Excellence Awards

## 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 that I did not want to skip out early!" - Trainer

## Where is the conference held?

Marriott Fishermans Wharf  
1250 Columbus Avenue  
San Francisco, CA 94133

Telephone: (312) 372-7200

**Rooms:** A small block of rooms have been reserved for us at a discount rate.

They will be available while supply lasts or until September 19, 2008.

Be sure to mention SkillsPlus Inte to get the discounted room rate.

**Room Reservation Telephone Number:** 800-525-0956.

**Dress:** Please dress to be comfortable.

## About the Session Instructors:

Allan Dewes, President of SkillsPlus International and Jackie O'Neill, Senior Training Consultant.

Jackie and Allan have been teaching this course together for over six years and continue to draw great reviews.

Every year there is a waiting list to attend. So, register early and save!

Registration Form

Name: \_\_\_\_\_ Nickname if preferred: \_\_\_\_\_

Company: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State/Providence: \_\_\_\_\_ Postal Code: \_\_\_\_\_

Country: \_\_\_\_\_ Email: \_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

Please indicate any food restrictions or special access needs: \_\_\_\_\_

Please circle which workshop you plan to attend. April 2008 Session in Chicago, IL.

Class	Payment By 8/1/2008	Payment By 8/22/2008	Payment After 9/5/2008
<b>GMP Essentials - October 6 - 7, 2008</b>	\$1750	\$1950	\$2100
<b>GMP Trainer Certification October 6 - 10, 2008</b>	\$2500	\$2750	\$3000

The above Trainer Certification rate includes GMP Essentials. There is no need to add the two rates together.  
Cancellation Policy: Cancellations: 1-30 days before class, registration fee is nonrefundable, substitutes accepted. 31-60 days prior to class incur a 25% penalty. More than 61 days prior to class incur a 15% penalty. Guaranteed registration requires payment in full.

**Hotel Information:** Marriott Fishermans Wharf, 1250 Columbus Avenue, San Francisco, CA. To make room reservations call 800-525-0956. Be sure to mention the SkillsPlus conference. The hotel has a small block of discounted rooms that will be reserved quickly, so book soon!

Payment by credit card

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: \_\_\_\_\_