3 Ways To Register

- Internet: www.cfpa.com
- Fax registration form to: 732.238.9113
- Mail registration form to:
  The Center for Professional Advancement (CIPA)
  190 State Highway 18, Suite 203, East Brunswick, NJ 08816 USA

Registration Form

Course Offering # 1 605-502
Batch Records: Simplified and Clarified
30–31 May 2016 • Amsterdam, The Netherlands

Terms and Conditions

Payment: Tuition payable in US funds net of all charges. Payment is due at time of registration or upon receipt of invoice. If payment has not been received two weeks before the course, a credit card will be required to guarantee registration.

Discounts/Rates: To receive the Early Bird tuition rate, payment is required at time of registration and/or BEFORE early registration tuition expires or the regular tuition rate will apply. If choosing invoice/ wire transfer, payment must be received prior to expiration of early registration tuition or the regular tuition rate will apply. All tuition prices are a per person rate. To qualify for the Group Rate discount, registration must be for two or more enrollments registering at the same time, from the same company, for the same course. Please note: Group Rate Discount cannot be combined with any other discount. Multiple discounts not applicable.

Cancellations/Substitutions/FEES: All cancellations must be in writing and emailed to: info@cfpa.com. All cancellations are subject to a $300.00 cancellation fee. Applicants may cancel up to four (4) weeks prior to the course start date for a refund less cancellation fee. Applicants that cancel less than four (4) weeks prior to the course will be issued a credit less cancellation fee that can be used towards a future course up to one year from the date of issuance. If you do not cancel and do not attend you are still responsible for the full payment. If for any reason, CIPA decides to cancel this course, we are not responsible for airfare, hotel or other costs incurred by the registrant. Program content, schedule and instructors are subject to change without notice. Substitutions are permitted at any time, must be in writing and emailed to Customer Service at info@cfpa.com.

Confirmation Letters: Before each course begins, all registrants will receive written Final confirmation including detailed information regarding course location – V.A. EMAIL. We recommend that travel/hotel arrangements not be made until final confirmation package is received. If confirmation is not received within two weeks prior to the course please contact Customer Service at info@cfpa.com.

Course photography / video: By registering and attending a CIPA course, you agree to have your photograph and/or video taken at the course venue, and you do not have any objections to CIPA using these photos and/or videos for marketing or any other CIPA Course and/or promotional purposes. You agree to release CIPA from any kind of claims arising out of copyright or privacy violations. All questions regarding this matter should be sent to Customer Service at info@cfpa.com.

Who We Are

The Center for Professional Advancement (CIPA) is the largest accredited technical training organization in the world with a curriculum of approximately 450 short courses in 16 industries including Pharmaceutical, Biotechnology, Medical Device, Chemical, Cosmetics, Food and more.

Since our founding in 1967, we have successfully trained nearly a half million people worldwide in topics ranging from basic and introductory concepts to new advances and cutting edge technology, and current U.S. and European regulations. CIPA courses are offered in a variety of formats – Public offering, Client Site and Online – to fit you or your company’s training needs.

Accreditations/Recertifications

The Center for Professional Advancement (CIPA) has been approved as an Accredited Provider by the International Association for Continuing Education and Training (IACET), 1010 North Hunter St., Suite 130, Reston, VA 20190. In obtaining this approval, CIPA has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. CIPA is therefore authorized to offer IACET CEUs for its programs that qualify under the ANSI/IACET Standards. CEUs will be awarded for participation in CIPA’s courses at the rate of 1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners’ Assessment.

The American Society for Quality (ASQ) Recertification Opportunities

The following information was provided courtesy of ASQ, and is not meant as an endorsement of CIPA products. It serves only as an informational guide about the certifications offered by ASQ. Many CIPA courses offer training that may be helpful in obtaining required ASQ’s recertification education units. To view a list of recommended courses that may be appropriate please visit www.cfpa.com.

For more information about ASQ, contact them at: help@asq.org

Tuition and Payment Methods

Early Bird (Save $350)
(Must register and pay by 18 April 2016)
U.S. $1870 pp
Group Discount: Register 2 or more from the same company, at the same time, for this course and receive a 10% discount off each registration.

Regular Tuition
U.S. $2070 pp

Tuition payable in US funds net of all charges includes continental breakfast, luncheons, breaks and course notes.

Note: Payment is due 2 weeks prior to course or at time of registration.

Send Invoice/Bill Me
Purchase Order # If required

Check payable in U.S. funds to The Center for Professional Advancement

Bank Transfer
Pay by Bank Transfer to: Account # 200001088468 (USD)
ABA Routing No. 121000248, Swift Code WFlB6US6 at Wells Fargo, 420 Montgomery Street, San Francisco, CA, USA.

Credit Card
Visa MasterCard American Express Discover
Card #
Exp. Date
Security code

Cardholder Name
(As appears on card)
Signature
(Credit Card billing address if different than above address)

Course Topics Include:
- Relating to Quality Systems
- CAPA
- Annual Product Review
- Data Integrity
- Regulatory Perspective
- Case Studies

Courses of Interest

• Annual Product Reviews for the Pharmaceutical and Related Industries
course id# 1998

• CGMP In-Depth Analysis for Pharmaceutical Life Cycle Management
course id# 2474

• Developing and Maintaining an Effective Complaint System
course id# 1834

• Documentation Management and Control
course id# 1998

• Ensuring Data Integrity: A Multi-Disciplinary Approach
course id# 2549

• Microbiological Control and Validation
course id# 902

The Center for Professional Advancement
190 State Highway 18, Suite 203, East Brunswick, NJ 08816
Phone: 732.238.1600 • Fax: 732.238.9113
E-mail: info@cfpa.com
www.cfpa.com

William G. Marshall
President
William G. Marshall & Associates
Batch Records: Simplified and Clarified

| Course Outline | 30–31 May 2016 • Amsterdam, the Netherlands | Offering# 1605-502 |
|----------------|---------------------------------------------|
| **First Day**  |                                             |
| 08.00: Registration/Continental Breakfast |
| 08.30–16.30:   |                                             |
| First session: | • Introduction and overview of the present cGMP environment in relation to Batch Records |
|                | • What does the regulation say?            |
| Second session:| • Interpretation of the regulation         |
|                | • Several approaches to batch record content.|
| Third session: | • What MUST BE IN THE BATCH RECORD          |
|                | • Good Documentation Practices             |
| Fourth session:| • Making Changes to the Batch record format.|

**Second Day**

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<td>First session:</td>
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<td>• Process Failures and OOS, Investigations</td>
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<td>• Batch record Review.</td>
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<td>Second session:</td>
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<td>Third session:</td>
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Numerous Case studies will be presented to emphasize key points during the presentation.

A one-half hour break at approximately 10.00 and 14.30 pm and a one-hour lunch at noon are planned for each day.

Who Should Attend

This intensive 2 day course is designed for professionals in the Pharmaceutical, Biotech and other FDA regulated industries who are involved with preparing, issuing, entering data into and reviewing batch records and related reports. This includes, but is not limited to, people from:

- Regulatory
- QA
- QC
- Production

Drug and API manufacturers as well as manufacturers of excipients and clinical supplies will find the information covered essential.

Learning Objectives

Upon completion of this course, you will be able to:

- Construct a batch record that is clear, easy to audit and review
- Prepare batch records that meet regulatory requirements
- Describe how the Batch record relates to other Quality Systems, such as CAPA, Annual Review, and Data Integrity
- Present the batch record to an auditor or agency investigator

Course Description

The Batch Record is the most crucial archived document in a Pharmaceutical Company. It plays a pivotal role in monitoring processes, initiating investigations and CAPA’s, in the Annual Review, and will always be a key issue in Agency Inspections. Hopefully, there won’t be a problem with marketed product; but if and when a disaster occurs, the batch record is where the investigation begins!

Many attendees to this course will be surprised to learn that many of the items in a batch record are not required.

Simplification and clarification strategies for developing or revising batch record formats, batch record review methods, the relation of the batch record to key quality systems, and typical problems involved in batch record format and review will be covered in numerous case studies.

Attendees are invited to bring their specific issues (which are frequently shared by the other attendees) to the sessions.

Course Director

William G. Marshall is President of William G. Marshall and Associates. He has over forty years experience in the Pharmaceutical and Medical Device Manufacturing Environment. Mr. Marshall has held Director level and Chief Operating Officer positions with large multinational pharmaceutical corporations as well as start-up ventures. He has been the Director of a major reference laboratory, and has been active in clean room design and validation. In the last five years, he has acted as a third party in several consent decrees.

Mr. Marshall is currently a consultant to the worldwide drug and device industry as well as to the FDA. He lectures worldwide in GMP related issues including Clean Room Technology and Sterilization.

Course Location

This course will be held in the Amsterdam area. Specific hotel information will be sent to you in your final confirmation package which will be emailed to you approximately three (3) weeks prior to the course start date. Please note that participants must make their own hotel reservations; the cost of the hotel accommodations is not included in the course fee.

We recommend that travel/hotel arrangements not be made until final confirmation package is received.

- Located in downtown area, near shopping, dining and local attractions

Client Site

Training at your site and at your convenience. For further information, please contact Client Site Programs. Direct Dial (USA) +1/732.238.1600, ext. 4547; or fax +1/732.238.9113; or E-mail clientsite@cfpa.com.

Online Training Now Available

A convenient and cost-effective way to experience our accredited training, easily access the knowledge you need through the Internet. For a list of upcoming courses visit www.cfpa.com/online-training.

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