Registration Form

Course Offering # **1506-205**

Drug Product Stability and Shelf Life

8–10 June 2015 • Amsterdam, The Netherlands

Priority Code:
(Please use this code when registering) 520

Dr. Mr. Ms _____
Surname Given Name

Job Title _____

Company/Organization _____

Department/ Mail Code _____

Mailing Address _____

_____

Postal Code _____ City _____ Country _____

Tel _____ Fax _____

E-mail Address _____

(Required in order to send confirmation material. CfPA does not rent or sell e-mail addresses)

Note: Please complete separate form for each registrant.

Tuition and Payment Methods

Early Bird (Save $200)
(Must register and pay by 27 April 2015) U.S.$ **2250 pp**

Regular Tuition U.S.$ **2450 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.

Tuition payable in US funds **net of all charges** includes **continental breakfast, luncheon, 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 No. 2000012656408 (US$) ABA Routing No. 121000248, Swift Code WFBIUS6S at Wells Fargo, 420 Montgomery Street, San Francisco, CA, USA.
The course Offering # (above) and participant's name must be included on bank transfer.)

❑ **Credit Card** ❑ Visa ❑ MasterCard ❑ American Express ❑ Discover

Card # _____ Exp. Date _____

Cardholder Name _____
(As appears on card)

Signature _____ Security code_____
(3 or 4 digit code)

Credit Card billing address (if different than above address)

_____

_____

ID 599

3 Ways To Register

- Internet: **www.cfpa.com**
- Fax registration form to: **732.238.9113**
- Mail registration form to:

The Center for Professional Advancement (CfPA)
190 State Highway 18, Suite 203
East Brunswick, NJ 08816 USA

General Information

Payment: Tuition payable in US funds net of all charges. Payment is due 2 weeks prior to course or at time of registration. 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 $200 Discount, payment is required at time of registration and/or BEFORE early registration discount expires or the regular tuition rate will apply. If choosing invoice/check/wire transfer, payment must be received prior to expiration of early registration discount or the regular tuition rate will apply. All tuition prices are a per person rate. To qualify for the Group 10% Discount, registration must be for two or more enrollments registering at the same time, from the same company, for the same course offering.

Cancellations/Fees: ALL cancellations, must be in writing and 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 full payment. All course cancellations must be in writing and e-mailed to: **info@cfpa.com**. If for any reason, CfPA 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: Substitutions are permitted at any time and must be made in writing.

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

For those requiring visas, invitation letters will not be sent until payment is received.

Please note: **English** will be used in all lectures and course notes.

Our full terms and conditions can be found on our website at www.cfpa.com

Courses of Interest

- **Active Pharmaceutical Ingredients Production**
  course id# 840
- **Analytical Methods Validation for FDA Compliance**
  course id# 1887
- **Drug Specifications for API's and Drug Products**
  course id# 1918
- **ICH-Q7A**
  course id# 2091
- **Lyophilization Technology**
  course id# 279
- **Sterile Products: Formulation, Manufacture and Quality Assurance**
  course id# 435

Who We Are

The **Center for Professional Advancement (CfPA)** is the largest accredited technical training organization in the world with a curriculum of approximately 450 short courses in 15 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. CfPA 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 (CfPA) has been approved as an Authorized Provider by the **International Association for Continuing Education and Training (IACET),** 7918 Jones Branch Dr., Suite 300, McLean VA 22102. In obtaining this approval, **CfPA** has demonstrated that it complies with the ANSI/IACET Standards which are widely recognized as standards of good practice internationally. **CfPA** therefore authorized to offer IACET CEUs for itsprograms that qualify under the ANSI/IACET Standards. CEUs will be awarded for participation in CfPA'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 CfPA products. It serves only as an informational guide about the certifications offered by ASQ. Many CfPA 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

The Center for Professional Advancement offers many courses which have a chemical component. Such courses may earn up to **20** Certification Units toward certification by **The National Certification Commission in Chemistry and Chemical Engineering,** sponsored by **The American Institute of Chemists.**

The Center for Professional Advancement
190 State Highway18, Suite 203, East Brunswick, NJ 08816
Phone: 732.238.1600 • Fax: 732.238.9113
E-mail: info@cfpa.com
www.cfpa.com

SAVE $200-Register & Pay by 27 April

8–10 June 2015
Amsterdam, The Netherlands

Continually Updated

Drug Product Stability and Shelf Life

An Intensive Review of Technical and Regulatory Aspects

Course Topics Include:

- FDA Stability Guidelines
- ICH Stability Guidelines
- Data Analysis Workshop

Directed by:
Dr. Pardeep K. Gupta
Professor of Pharmaceutics
Philadelphia College of Pharmacy
University of The Sciences in Philadelphia (USP)

Maximize your learning! Attend this course and its companion
*See inside for details

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Who Should Attend

This course contains **in-depth** coverage of the science and practice of drug stability, shelf-life and is designed to benefit the following personnel:

- QC/QA Managers/Supervisors
- Product Stability Managers
- Manufacturing Personnel
- Research & Product Development Scientists and Managers
- Regulatory Personnel
- Pharmaceutical Consultants

Learning Objectives

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

- Define the scientific and regulatory terminology in stability
- Identity the stability protocols and data acceptable to FDA and ICH
- Design a stability program
- Analyze and interpret stability data and write stability reports

Course Description

This course focuses on the science and principles concerning stability of pharmaceutical, biotechnology and cosmetic products. Kinetic approaches to chemical stability will be covered and the advantages and limitations of accelerated stability testing will be discussed. Degradation by chemical, physical and microbiological factors will be covered. Data analysis and practical aspects of stability such as the role of packaging in stability will be included. Considerable attention will be given to analytical methodology, data analysis and data management. Current FDA Stability guidelines and ICH Guidelines on stability will be discussed.

The course includes a workshop for hands-on experience of data and statistical analysis.

Course Location

This course will be held at the **Amsterdam Marriott Hotel.** Participants must, however, make their own reservations; the cost of hotel accommodation is not included in the course fee. Hotel information will be included with your acceptance.

Amsterdam Marriott Hotel
Stadhouderskade 12
1054 ES Amsterdam, The Netherlands
Phone: +31/20/607.55.08
Fax: +31/20/607.55.12

Drug Product Stability and Shelf Life

Course Outline — **8–10 June 2015 • Amsterdam, The Netherlands | Offering# 1506-205**

First Day

08.00: Registration

Science and Fundamentals of Drug Stability

08.45–12.00: Session 1:
Review of Learning Objectives/Introduction
- Definitions, Terminology and Guidelines: FDA and ICH
- Sources of information

Solution Kinetics
- Mechanisms and pathways of degradation of drugs
- Theory of degradation kinetics

13.00–16.30: Session 2:
Design of Stability Studies
- Design of pH and photo-stability studies
- Data analysis
- Clinical, pilot, and production batches stability
- ICH zones classification and transition

Solid-state Degradation
- Models and data treatment of solid-state degradation
- Role of water in solids stability

Second Day

Data Analysis and Practical Aspects of Stability and Shelf-Life

08.45–12.00: Session 1:
Practical Outcomes of Stability Studies
- Methods of calculating shelf-life
- Shelf life determination for solution and solid formulations
- Data pooling statistical analysis for different batches

Workshop on Data Analysis
- Sample shelf-life determination
- Simulated statistical calculations
- Use of statistical packages

13.00–16.30: Session 2:
Regulatory Aspects of Drug Stability
- ICH and FDA approaches to Drug Stability
- Study design for stability in preformulation and marketed products
- Sampling requirements and methods
- Matrixing and bracketing in testing
- Sample designs of stability protocols
- Stability reporting formats

Role of Packaging in Product Stability
- Effect of packaging on product stability
- Regulatory requirements on packaging testing

Special Cases of Stability
- Peptide and Protein stability
- Regulatory perspective on biotechnology drugs
- Issues related to coated medical devices and polymer based systems
- Stability issues related to inhalation products (pMDIs and DPIs)

16.30–18.00: Session 3:
Evening Session (Discussion)
- Practical issues in stability testing

Third Day

Special Topics and Analytical Considerations in Stability Studies

08.00–11.15: Session 1:
Disperse System Degradation
- Physical degradation vs. chemical degradation
- Parameters to be considered in stability of disperse systems
- Unique issues of stability in disperse systems
- Stability design for semi-solids (parameters, specifications, data analysis)

Microbiological Degradation
- Role of preservatives in microbiological stability
- Regulatory perspective on preservatives
- Testing requirements and shelf-life expectations of preservatives
- Testing frequency, specifications and reporting

Analytical Methodology and Data Handling
- Assay methods in stability studies
- Definitions and requirements of stability indicating method
- Comparisons of various analytical methods
  – Physico-chemical methods
  – Biological methods
- Development and validation of analytical methods for drug substance and drug product
- Assay method transfer-within a company and between companies
- Results analysis, limits and specifications
- Identification and follow-up of OOS and OOT results

11.15–12.00: Session 2:
Computerization of Stability Studies and Data
- FDA requirement on computerization of data
- Examples of commercially available systems
- Online sources of information

Assessment Opportunity

12.00:
Lunch is provided

www.cfpa.com

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.**

Course Director

Dr. Pardeep K. Gupta is a Professor of Pharmaceutics in Philadelphia College of Pharmacy at the University of The Sciences in Philadelphia (USP). He received his B. Pharm. and M. Pharm. (pharmaceutical chemistry) degrees from India. He also received a M.S. degree in medicinal chemistry from USP and his Ph.D. in pharmaceutics from University of Wisconsin. His research interests include delivery of proteins and peptides and study of the interaction of drugs with biomembranes. He has published several articles and has authored several book chapters. His teaching responsibilities include courses in solubility, controlled drug delivery and drug stability at the graduate level. He has served on the editorial board of Remington: The Science and Practice of Pharmacy, as the editor of Pharmaceutical Chemistry and Pharmaceutical Testing, Analysis and Control sections of the book, and as author of two chapters.

Past Participants Have Said:

"Excellent lecture and instructor. This entire course was just "perfect" for me."
– N.L., Analytical Chemist, Molecular Insight Pharmaceuticals

"Pardeep has an extensive knowledge of the science behind stability"
– K.W., QC Analyst, Cubist Pharmaceuticals

"Great course packed with useful information."
– J.K., R&D Director, Marianna Industries.

Maximize your learning! Attend this course and its companion

***Companion Course: Dissolution Testing: Methods, Validation and Regulations**
11–12 June 2015 • Amsterdam • Course ID #2011

This 2-day, **intensive** course focuses on the science and principles concerning dissolution of pharmaceutical, bio-technology and cosmetic products. There is an in-depth discussion on the background and theory of dissolution, purpose and classification of dissolution methods and regulatory requirements for dissolution testing. Current FDA and ICH guidelines on dissolution will be discussed.