SiTec PharmaBio

DRUG PRODUCT STABILITY AND SHELF LIFE
An intensive review of Technical and Regulatory Aspects

28 - 29 September 2015

Parc Científic de Barcelona

Baldiri Reixac, 10 - 08028 Barcelona - Spain

Course Topics Include:

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

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.

Gain in-depth knowledge of the practice of pharmaceutical stability with emphasis on study design and data analysis.

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 is on the editorial board of Remington: The Science and Practice of Pharmacy, and is the editor of Pharmaceutical Chemistry and Pharmaceutical Testing, Analysis and Control sections of the book.

Course offered by CfPA THE CENTER FOR PROFESSIONAL ADVANCEMENT FOUNDED 1967

COURSE OUTLINE

FIRST DAY

8:30-9:00

Registration

9:00-17:30

Science and Fundamentals of Drug Stability

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

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

Data Analysis and Practical Aspects of Stability and Shelf-Life

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

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

SECOND DAY

9:00-17:30

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)

Discussion: Practical issues in stability testing

Special Topics and Analytical Considerations in Stability Studies

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

Computerization of Stability Studies and Data
- FDA requirement on computerization of data
- Examples of commercially available systems
- Online sources of information

TUITION AND PAYMENT

Early registration:
(received before July 17th, 2015) - Euro 1600+VAT/1440+VAT (group discount*)

Regular registration:
(received after July 17th, 2015) - Euro 1800+VAT/1620+VAT (group discount*)

(Fee includes course materials, lunches and coffee breaks)
Participants are responsible for their own hotel reservations.

*Group discount is for two or more enrollments from the same company.

Payable by bank transfer upon issuing an invoice. Payment instructions will be provided upon registration.

Registration

Name .....
Surname .....
Position .....
Organization .....
VAT .....
Address. .....
Postal Code .....
City .....
Country .....
Phone/Fax .....
Participant e-mail .....
Billing e-mail .....

PLEASE RETURN BY FAX OR E-MAIL

General information

Cancellations received after September 9, 2015 will be invoiced completely. All cancellations will be subject to euro 250 processing fee. Substitutions may be made at any time. Payment is due once the participant receives an invoice. Certificates will be issued to participants upon completion of the course.

For Information please contact us at:

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