COBBLESTONE

COURSE ID 0599

Drug Product Stability and Shelf Life

An Intensive Review of Technical and Regulatory Aspects

DIRECTED BY

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18 Hours

ACCREDITED COURSE

- FDA Stability Guidelines
- ICH Stability Guidelines
- Data Analysis Workshop
- Computerization of Stability Studies
- Analytical Considerations

about the course

Every drug product must undergo sufficient stability testing before it can be introduced to the market. While ICH has standardized and harmonized the stability testing process, there are still numerous challenges that need to be addressed to ensure that stability testing is conducted accurately. Inadequate stability testing can cause delays in product introduction, which is why all drug companies need to ensure that their programs meet acceptable standards.

This 18-hour accredited training course is designed to provide participants with a comprehensive understanding of the science and principles behind stability testing for pharmaceutical, biotechnology, and cosmetic products. The course will cover kinetic approaches to chemical stability, the advantages, and limitations of accelerated stability testing, as well as degradation caused by chemical, physical, and microbiological factors. The course will also cover data analysis, and practical aspects of stability testing, such as the role of packaging in stability. Considerable attention will be given to analytical methodology, data analysis, and data management. Participants will also receive a thorough review of current FDA Stability guidelines and ICH Guidelines on stability.

The course will also include a workshop that provides participants with hands-on experience in data and statistical analysis.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer equipped with a microphone and speakers/headset to fully participate.

who should attend

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

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

Personnel who routinely review stability data or reports would additionally benefit from this course by gaining a broader understanding of stability testing.

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 outline

Review of Learning Objectives
Science and Fundamentals of Drug Stability

- 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 approach 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)
- 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 the stability of dispersed systems
- Unique issues of stability in dispersed 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

Question and Answer Session

Assessment Opportunity

course instructor

Dr. Pardeep K. Gupta has over 30 years of experience and is a Professor of Pharmaceutics at the Philadelphia College of Pharmacy at Saint Joseph's University (SJU). He received his B. Pharm. and M. Pharm. (pharmaceutical chemistry) degrees from India. He also received an M.S. degree in medicinal chemistry from USP and his Ph.D. in pharmaceutics from the University of Wisconsin. His research interests include the delivery of proteins and peptides and the 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 the Pharmaceutical Chemistry and Pharmaceutical Testing, Analysis and Control sections of the book, and as the author of two chapters.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone'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. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 18 contact hours or 1.8 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)
Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS-established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.