COBBLESTONE

COURSE ID 2928

Stability Testing - 21 CFR 211.166 (a & b)

GMP Laboratory Control Professional Certification Program

DIRECTED BY

David E. Wiggins — Analytical/Stability Consultant

90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- FDA and ICH Guidelines
- Stability Protocols
- Stability Reports

about the course

In 2006, FDA withdrew both their approved 1987 Stability Guideline and their draft 1998 Stability Guidance and referred the industry to the ICH Stability Guidances. In the absence of detailed FDA guidelines, the industry was left to interpret the somewhat ambiguous GMPs. The fact that stability issues continue to be a major cause for regulatory action and product recalls, it is apparent that not all companies are effective in understanding the requirements.

This 90-minute accredited training course will provide a better understanding of how the pre-market stability programs can be successfully managed while minimizing the overall timeline, a key factor in the timely launch of new products. In addition, those requirements related to a compliant post-market stability program will be addressed.

This training is one part of the 10-course series required for the GMP Laboratory Control Professional Certification Program.

Attend this as a step in the certification process or as a stand-alone course for personal career advancement and training.

who should attend

This course is intended for individuals who have the responsibility for establishing the stability of drug products. This course will benefit individuals in:

• R&D	• Quality Assurance
• Quality Control	• Contract Laboratories
• Technical Operations	

learning objectives

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

- Cite the Stability Regulatory Requirements
- Enumerate the Seven GMP Stability Requirements
- Describe the Relevant Stability Guidelines
- Summarize Appropriate Stability Protocol and Report Content

course outline

Review of Learning Objectives

Module 1: Introduction, Definitions, Purpose, & Regulations

- Introduction
- Definitions & Purpose
- Regulations

Module 2: Stability Guidelines

- Historical FDA
- Current FDA
- ICH

Module 3: Stability Protocols & Reports

- Seven GMP Requirements
- Stability Protocols
- Two Types of Stability Reports

Question and Answer Session

Assessment Opportunity

course instructor

David E. Wiggins is an Analytical/Stability Consultant within the pharmaceutical industry with a focus on pre-market stability, analytical method validation and method transfer.

Mr. Wiggins was previously Sr. Associate Director of Analytical Development for Bayer Consumer Care. Prior to joining Bayer, Mr. Wiggins worked for Schering-Plough and Merck with responsibility for Method Optimization, Method Validation, Method Transfer and Stability (both pre- and post-market). These responsibilities have additionally included involvement with multiple NDA submissions, ANDA submissions and FDA general and PAI inspections.

Mr. Wiggins has over 35 years of experience in the pharmaceutical industry in both a QC and an R&D setting. During this time, he has been instrumental in establishing and updating stability and method validation policy to be consistent with the changing regulatory requirements. Mr. Wiggins has frequently lectured on stability and analytical method validation in the US, Puerto Rico, and throughout Europe. He has been active in submitting comments and validated stability-indicating analytical methods to the U.S. Pharmacopeia and has been an invited speaker to FDA, university, and industry conferences.

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 1.5 contact hours, or .2 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.