COBBLESTONE

COURSE ID 2650

OTC Stability Program for FDA Compliance

Specific Focus on OTC (Over the Counter) Monograph Products

DIRECTED BY

David E Wiggins, Analytical/Stability Consultant

6 Hours

ACCREDITED COURSE

- Managing Pre-market Stability Programs
- Seven Key GMP Aspects of an OTC Stability Program
- Proper Use of Accelerated Data to Support an Expiration
- Drafting Three Types of Stability Protocols
- Writing GMP Compliant Stability Reports
- Answers to Common Stability Questions

about the course

In 2006, the FDA withdrew both their approved 1987 Stability Guideline and their draft 1998 Stability Guidance and referred the industry to the ICH Stability Guidances. With the ICH guidance documents covering New Chemical Entities (NCEs) and their associated drug products, there was no guidance provided for OTC drugs covered by an ANDA or an OTC monograph. In 2014, the FDA issued Guidance for Stability testing requirements for all drug products covered by an ANDA, but no guidance has been provided for OTC monograph drug products.

As a result, strictly following the ICH stability guidance for NCEs is unwarranted and ignores the significant database of information that is typically available for OTC drug products. For OTC drug products covered by an OTC monograph, there is frequently years of proven experience with the drug substance as well as the drug product. It is this body of data that can often be used to justify a pre-market stability program.

This 6-hour, accredited course will provide an understanding of how the pre-market stability programs can be successfully managed while minimizing the overall timeline. Lectures will address the seven key GMP aspects of a stability program along with all of the relevant stability guidelines that cover drug product stability. Accelerated testing that allows the marketing of a new OTC drug product prior to the generation of long-term, real-time stability data and confirmation of the stability projections will also be covered.

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

who should attend

This course is intended for individuals who have the responsibility for establishing the stability of Over the Counter (OTC) drug products.

This course will benefit individuals in:

- R&D
- Technical Operations
- QA/QC
- Contract Laboratories

This course will also benefit those individuals with similar responsibilities who work in the cosmetic and personal care industries.

learning objectives

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

- Establish the stability of an OTC drug product following a fully GMP compliant program
- Describe how the stability would be established for an OTC drug product covered by an OTC Monograph
- Prepare stability protocols that incorporate all cGMP requirements and are consistent with the intended purpose of the studies
- Write stability reports that concisely present the stability data and are fully supportive of the projected expiration

course outline

Review of Learning Objectives

Module 1: Stability Background

- Introduction
- Purpose, Definitions, Outcomes
- Two Types of Stability Programs
- Regulatory Requirements
- FDA Feedback (with examples)

Module 2: Stability Guidelines

- Historical FDA Guidelines
- Current FDA Guidelines
- ICH Guidance
- CHPA Voluntary Guidance

Module 3: OTC Drug Product Types

- NDA
- ANDA
- OTC Monograph

Module 4: Drug Product Test Requirements & GMP Requirements

- Universal Tests
- Specific Tests
- Acceptance Criteria
- GMP Requirements

Module 5: Pre-Market Stability Protocols

- Key Objectives
- Three Types of Stability Studies
- Protocol Required Information

- Stability Plan
- Study Schedules
- Stability Protocol Example

Module 6: Pre-Market Stability Reports

- Content
- CTD Format
- Data Tables
- Stability Report Example

Module 7: Stability Special Topics

- Stability Chambers
- Pull Windows
- Investigations
- Standard Operating Procedures
- In Use & Bulk Hold Studies

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 6 contact hours or .6 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.