COBBLESTONE

COURSE ID 2794

Stability Operations for Drugs, Biologics and Medical Devices

Steps to a Successful Stability Function

DIRECTED BY

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12 HOUR

ACCREDITED COURSE

Course Topics Include:

- Management of Stability Stakeholders
- Life Cycle Stability Strategies
- Protocols that Produce Operational Benefits
- Sample Control Measures
- Risk Management
- Auditing the Stability Function

about the course

This 12-hour accredited course focuses on the operational aspects of the stability function as practiced by the pharmaceutical, biological and medical device industries.

Establishing and maintaining strong stability operations programs will be covered, including: SOPs, training, protocols, life cycle stability strategies, storage conditions, chamber maintenance, and monitoring, trending data and sample management.

Preparing for inspections and auditing of the stability function will also be covered. Considerable attention will be given to risk management as applied to all aspects of Stability Operations.

The impact of several stability guidance's (ICH, WHO, and FDA, among others) on Stability Operations will be discussed. The course concludes with a workshop for hands-on experience in risk management and auditing of Stability Operations programs.

who should attend

This course is designed to benefit professionals in the Pharmaceutical, Biological, and Medical Device Industries who execute Stability Operations for their company. Stakeholders who support, rely or otherwise liaise with the stability function would additionally benefit from understanding the requirements and challenges of stability operations. These include:

• Stabilitarians and Product Stability Managers	• Research & Product Development Scientists and Managers
• QC/QA Professionals	• Sample Control Specialists
• Pharmaceutical Consultants	• Manufacturing Liaisons
• Calibration and Validation Specialists	• Regulatory Affairs Personnel
• Analytical Chemists, Microbiologists	• Packaging Liaisons
• Facilities/HVAC Staff	

learning objectives

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

- Identify key components of stability SOPs
- Build purposeful stability protocols to cover every Operations phase of the Stability Life Cycle
- Identify and partner with key stakeholders in the stability function
- Operate a secure stability area with a high degree of sample control
- Maintain a reliable system of stability chambers
- Conduct risk assessment of the stability function and effective stability function audits

course outline

Review of Learning Objectives/Introduction

- Definitions and Scope of course
- An overview of Guidance's and their impact on Stability Operations
- Elements of the Stability Function
- Differences and Similarities of the Stability Function across the range of Medical Products
- The Stability Universe- Stakeholders for input and output
- Stability Training (and helpful backgrounds, pathways and precursors)
- SOPs- Self-Managed and Stakeholder imposed

Stability Chambers (User Requirements, Validation, Calibration, Operation)

- Cleaning
- Handling Excursions
- Inventory Options
- Stability Monitoring Systems
- Sample Control
- Security & Safety
- LIMS and other Stability

Software Life Cycle Stability Operations from Pre-formulation to Post Approval Changes

- Building and Using Stability Protocols Wisely
- The Stability Review Board
- Defining Study Start Dates, Acceptable windows for submissions and completions
- "Aught-O's" (Out of Specification, Out of Trend, Out of Expectation, Out of Compliance, Out of Luck with respect to Stability Operations)

Risk Management

- Using Regulatory Observations of others to avoid obtaining your own
- Identifying and Remediating Risks
- Auditing the Stability Function
- Group Exercise

Assessment Opportunity

course instructor

John O'Neill is a past chair of the Stability Working Group of the International Pharmaceutical Federation and was a member of the Product Quality Research Institute Stability Working Group for Shelf Life. Mr. O'Neill is a frequent conference speaker on stability topics. For the past 34 years he has been the Facilitator of the Pharmaceutical Stability Discussion Group, which has made him privy to just about everything that can go wrong or right with the Stability function. Past participants in Mr. O'Neill's industry programs have reported that he is knowledgeable, engaging, and a great storyteller; bringing practical information backed by real-life experiences. Mr. O'Neill currently serves as the Editor of a stability information website- StabilityHub.com.

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 12 contact hours, or 1.2 CEUs. For further information, visit www.iacet.org