COBBLESTONE

COURSE ID 2801

Auditing Stability Programs

How to Ensure a Compliant Program

DIRECTED BY

John O'Neill, Stability Information Specialist/Editor StabilityHub.com Founder and Facilitator of the Pharmaceutical Stability Discussion Group

90 MINUTE

ACCREDITED COURSE

- Typical Stability Warning Letters
- Preparation for Audits
- Stability Quality Systems
- Typical Audit Points
- Stability in the Hot Seat

about the course

A significant number of 483's and Warning Letters related to the stability function is proof that not all companies have an adequate program in place. Since regulatory requirements and guidance's provide only a general picture of expectations for stability programs, much interpretation is left up to individual companies. A better understanding of regulatory expectations and careful preparation is warranted to avoid joining those organizations receiving stability citations.

This 90-minute, accredited online training will cover all aspects of preparing for and conducting/hosting an audit of the medical product stability function.

Live interaction with the instructor allows for dynamic discussions and clarifications.

For attendance verification and to maximize participation, participants attending the live training are required to use their webcam during the course. Microphones and speakers/headset are encouraged.

who should attend

This online training is intended for professionals in the pharmaceutical, biopharmaceutical, medical devices, veterinary and cosmetic industries. It will be especially valuable to those working as:

- Stabilitarians
- QA/QC Professionals
- Quality Management
- Stability Stake Holders (Chambers, Labs, Facilities, etc.)

Personnel who manage these individuals would additionally benefit from this training by gaining a better understanding of the issues faced in ensuring a GMP-compliant stability program.

learning objectives

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

- Identify sources for Audit targets
- Execute mechanics of Risk Management and identify systems to be evaluated
- Master aspects of effective audit training
- Build an Audit Host Team
- Facilitate effective "Day of" Audit practices

course outline

Review of Learning Objectives

Module 1:

- Introduction
- Why is the Stability Audit so critical?
- Audits are an unseen strength
- Audits are a source of Regulatory Intelligence
- Typical Stability Warning Letters

Module 2:

- Preparation for Audits
- Planning and Training
- Stability Quality Systems
- Risk Management
- Typical Audit Points

Module 3:

- During and After the Audit
- Stability in the Hot Seat
- Maintaining Vigilance
- Conclusion

Question and Answer Session

Assessment Opportunity

course instructor

John O'Neill, Stability Information Specialist/Editor StabilityHub.com Founder and Facilitator of the Pharmaceutical Stability Discussion Group. John O'Neill earned his Bachelor's degree in Pharmaceutical Sciences from Columbia University and a Master's in Health Systems Management from Union University. His career of 50 years has taken him from Registered Pharmacist to-Liquids and Semi-solids Formulator at Sterling Winthrop, QC Manager at Sanofi-Aventis, Medical Device Quality Steward at Boston Scientific, Independent Consultant, Principal Stability Specialist for Biologics at Genentech, and Associate Director of Stability at both Gilead and Regeneron. He 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. For the past 36 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. Mr. O'Neill is a frequent conference speaker on stability topics and currently serves as Editor of StabilityHub.com.

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.

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.