COBBLESTONE

COURSE ID 3134

Advanced Stability Operations for Drugs, Biologics, and Medical Devices

Part 3 in a 3-part series

DIRECTED BY

John O'Neill – Editor, StabilityHub.com

4 HOUR

ACCREDITED COURSE

- Assessing Risk in Stability Operations
- OOS, OOT, OOE investigations
- Chamber Excursions
- Common Pitfalls, Observations
- Stability Audit Readiness
- Stability Stakeholders in Stability Audits

about the course

New to "stability", or a key stakeholder in the stability process, or just want to firm up your stability knowledge? This series on Stability Operations for Drugs, Biologics, and Medical Devices will give you a rock-solid base for establishing or expanding your stability operations knowledge.

This 4-hour accredited course is part 3 of a 3-part series that focuses on advanced Stability Operations. This course examines how to evaluate your program on a risk basis and fine tune the stability function to improve quality and compliance, lower and mitigate risks, increase efficiency and prepare for regulatory audits and inspections.

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. This training has been designed for professionals in the personal care and consumer products industries.

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

learning objectives

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

- Conduct a comprehensive risk assessment of the Stability function
- Develop effective metrics
- Appropriately respond to the "Out of…." situations
- Prepare for the challenges of outsourcing storage and testing
- Eliminate common pitfalls in stability function audits

course outline

Review of Learning Objectives

Looking Under the Hood

- Stability Metrics
- Stability Windows Global Harmonization
  - What to measure and against what standards
- Risk Management
- Stability Aught-Ohs:
  - OOE, OOT, OOS, OOC, OOL
  - Dilemmas and Tough Problems
- Outsourcing
- Disaster Planning
- Stability Audit Preparations

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 4 contact hours, or .4 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.

The American Society for Quality (ASQ)

The American Society for Quality (ASQ)-Recertification Opportunities

Cobblestone is committed to enhancing the ongoing professional development of Quality professionals and other stakeholders through appropriate learning activities and programs. Many Cobblestone courses offer training that may be helpful in obtaining required ASQ's recertification education units.

For more information, visit: www.asq.org