

# Intermediate Stability Operations for Drugs, Biologics, and Medical Devices

**Part 2 in a 3-part series**

DIRECTED BY

**John O'Neill – Editor, StabilityHub.com**



- Life Cycle Stability Planning
- Protocols
- Stability Stakeholder Interactions
- Stability Tests & Methods
- Stability Chambers
- Sample Control

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## 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 2 of a 3-part series that will aid those stepping into or currently employed in a hands-on role in Stability Operations. This course provides an intermediate analysis into the critical elements of a well-oiled stability function and helps you make higher contributions to the Stability Team.

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.

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## 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

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## learning objectives

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

- Build stability protocols to cover every Operations phase of the Stability Life Cycle
- Establish a highly effective Stability Review Board
- Operate a secure stability area with a high degree of sample control
- Maintain a reliable system of stability chambers
- Assess the adequacy of your statistics and trending measures

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## course outline

### **Review of Learning Objectives**

- Managing Stability Studies
- Building Phase-appropriate Stability Protocols
- Stability Review Boards
- Stability Planning, Space Calculation & Financial Budget
- Stability Lifecycle Budgeting
- Leveraging & Equivalence
- Laboratory Information Management Systems (LIMS)
- Statistics
- Stability Reports for Stakeholders, Management, and Regulatory
- Stability Chambers
- Chamber Excursions
- Sample Control

### **Assessment Opportunity**

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## 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.

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## 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](http://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](http://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](http://www.asq.org)**

