

Navigating the Stability Universe

DIRECTED BY

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ACCREDITED
COURSE

- Identifying and characterizing collaborators in the Stability Universe
- Mechanics of establishing great working relationships with Stability Stakeholders
- Optimizing interactions for compliance and flow of operations

about the course

There is a universe of individuals, departments, and contract organizations outside the direct control of the Stabilitarian which interact with the stability process in ways that can boost or hinder the success of the program. Some of these are obvious while others go virtually unrecognized, yet members of both can impact us severely and deserve our attention.

This 90-minute accredited training course will demonstrate how the Stabilitarian can optimize relationships and interactions with these “stars” in the Stability Universe to bring about the best possible outcomes for both sides of the partnership.

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 in order to fully participate.

who should attend

This course is intended for professionals in the Medical Products industry and those in Contract Research Organizations who operate in Stability, Quality Control, Analytical Chemistry and Quality Assurance departments. It will be especially beneficial for Technicians, Scientists, Associates, Specialists, Supervisors/Managers and Associate Directors, as well as other stakeholder roles associated with the Stability function.

learning objectives

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

- Recognize all partners (stakeholders) engaged in the Stability process.
- Identify the positive and negative impact that each partner has on the stability process
- Establish effective relationships with the members and management of each stability partner
- Engage the members of the Stability Group in optimizing and enriching stakeholder interaction
- Steer contributions of the partners in more effective pathways
- Make effective contributions toward the success of Stability partners
- Help your partners prepare for regulatory inspections that will involve their interaction with the stability process

course outline

Review of Learning Objectives

Module 1:

Identifying the boundaries, stars, meteors, satellites, and black holes in the Stability Universe

- Establishing the boundaries of the Stability function and its Stakeholders
- Naming the players
- How each entity impacts/is impacted by the Stability function

Module 2:

The mechanics of establishing great stability stakeholder relationships

- Start at the top of the ladder; keep the rungs informed
- Reach out with informational presentations and collaboration meetings
- Ensure continuity of communication and face to face interaction
- Engage the Stability staff as liaisons to Stability stakeholders

Module 3:

Getting the most from, and giving the best back to, “the Universe”

- Stakeholder procedures that impact Stability
- Specialized Stability requirements and training for the stakeholder
- Stakeholder news, meetings and
- communications Stabilitarians need to monitor
- Involving your stakeholder in audits and inspections preparation

Question and Answer Session

Assessment Opportunity

course instructor

John O’Neill has a degree in Pharmaceutical Sciences from Columbia University and a Masters in Health Systems Management from Union University. His experience includes Registered Pharmacist, 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 for Stability at both Gilead and Regeneron. For over 30 years, John has been the Facilitator of the Pharmaceutical Stability Discussion Group, which has made him privy to just about everything that can go right or wrong with the Stability process. As Editor of StabilityHub.com, he oversees a website to provide stability information of all types for those connected with the Stability function.

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