



Biopharma Potency Testing: Assuring Quality Throughout Product Lifecycle

Virtual | December 9-10, 2026
All times are in US Pacific



Day 1 | Wednesday, Dec. 9

Session 1: Potency as a Unique CQA & Its Impact on Inspection Readiness

- 7:00** Welcome, Logistics & Session Introduction
Anton Stetsenko, BioQual Consulting
- 7:30** Potency vs. Physicochemical Attributes: Inherent Complexity and Variability for QA
Speaker To Be Announced
- 8:00** CBER Inspections for Biological Products – cGMP Overview and Trends
Invited FDA Speaker To Be Announced
- 8:30** Ensuring Inspection Readiness in Potency Testing Laboratories
Stefan Freischem, Quality Auditor, Charles River Laboratories
- 9:00** Q&A Panel Discussion
- 9:15** Break ☕

Session 2: Validation and Reference Standards

- 9:30** Reference Standards Lifecycle: Establishment, Qualification and Replacement
Speaker To Be Determined
- 10:00** A Consultants Perspective: Lessons Learned in Critical Reagent Management
Speaker To Be Announced
- 10:30** Break ☕
- 10:40** Q&A Panel Discussion
- 11:10** Conference Day Adjourns

Planning Committee & Panelist Members

Siân Estdale, ACM Global
Ulrike Herbrand, Charles River Labs
Damian Larrington, PQP Group
Laureen Little, BEBPA
Jane Robinson, BEBPA
Maija Sorensen, MLS BioConsultants
Anton Stetsenko, BioQual Consulting

Day 2 | Thursday, Dec. 10

Session 3: Data Analysis and Integrity

- 7:00** Welcome, Logistics & Session Introduction
Anton Stetsenko, BioQual Consulting
- 7:15** Total Analytical Error (TAE): The Emerging Framework QA Needs To Know
Speaker To Be Determined
- 7:45** Practical Approaches to Outlier Management
Speaker To Be Determined
- 8:15** Presentation To Be Determined
Speaker To Be Determined
- 8:45** Q&A Panel Discussion
- 9:00** Break ☕

Session 4: Regulatory and Lifecycle

- 9:15** Potency of Biological Products: Navigating Biological Complexity and Variability with Regulatory Expectations
Rajesh Gupta, President, Biologics Quality & Regulatory Consultants, LLC
- 9:45** Presentation To Be Announced
Invited FDA Speaker To Be Announced
- 10:15** Break ☕
- 10:25** Q&A Panel Discussion
- 11:00** Conference Day Adjourns