



Virtual Conference Biotherapeutic Shelf-Life Determination

November 4-6, 2025

All times are in Pacific Time

Day 1 | Tuesday, November 4

Session Topic: Short Pre-Event Educational Day (S.P.E.E.D) Webinar

- 7:00** Session Introduction
Lauren Little, President, BEBPA
- 7:30** Scientific and Regulatory Principles for Establishing and Maintaining a Stability Program for Commercial Products
Speaker To Be Announced
- 9:00** Webinar Concludes

Slides not available for distribution are highlighted in **BLUE**

Day 2 | Wednesday, November 5

Session Topic: How to Determine the Shelf-Life of Biotherapeutic Products

- 7:00** Conference Opening Remarks, Session Intro & Audience Survey
Lauren Little, President, BEBPA
- 7:30** Opening Presentation Outlining Key Analytical Issues for Supporting Product Stability
Speaker To Be Determined
- 8:15** Break ☕
- 8:30** Case Study: Clinical Phase-Specific Stability Studies
Speaker To Be Determined
- 9:00** Case Study: Use of Predictive Data to Support Real-Time Stability
Speaker To Be Determined
- 9:30** Case Study: In-Use Stability Study Design
Speaker To Be Determined
- 10:00** Break ☕
- 10:15** Conference Highlights & Further Challenges
Speaker To Be Determined
- 10:45** Panel Discussion with Q&A
- 11:30** Conference Day 2 Adjourns

Day 3 | Thursday, November 6

Session Topic: Product-Specific Workshops/Discussion Groups

- 7:00** Session Introduction
Lauren Little, President, BEBPA
- 7:15** Workshop/Discussion Groups:
 - rDNA products
 - Biosimilars
 - Vaccines
 - New modalities (Cell-based and genetic therapies)*Speakers To Be Determined*
- 8:30** Panel Discussion with Q&A
- 9:00** Conference Concludes

Planning Committee & Panelist Members

Marla Abodeely, Sanofi
Kevin Brooks, K.R. Brooks Associates LLC
Patricia Cash, Independent Consultant
Lauren Little, BEBPA
Ken Miller, TG Therapeutics, Inc.
Nadine Ritter, Global Biotech Experts LLC