



Virtual Conference Reference Material Conference: Commercial Products

February 25-26, 2025

All times are in Pacific Time

Day 1 | Tuesday, February 25

7:00 Conference Opening Remarks,
Session Intro & Audience Survey
Lauren Little, President, BEBPA

Session Topic: Overview Of A 2-Tier System For An In-House Commercial Reference

7:30 A Regulators Perspective on Late
Stage/Commercial Reference Material
*Invited US FDA, Office of Vaccines,
CBER Speaker*

8:15 Industry Insights
Speaker To Be Announced

9:00 Break

Session Topic: Bridging Studies For An In-House Commercial Reference

9:15 Regulatory Insights Into The
Practices Related To In-House
Reference Materials And Use Of
International Reference Standards
For Potency Assays
*Jaana Vesterinen, Head of Section,
Finnish Medicines Agency Fimea*

10:00 Reference Qualification for Relative
Potency Assays: You Can't Prove Not
Different Only Not Too Different
*Nancy Sajjadi, Principal Consultant,
Sajjadi Consulting*

10:45 Break

11:00 Panel Discussion with Q&A

12:00 Conference Day 1 Adjourns

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

Day 2 | Wednesday, February 26

7:00 Session Intro & Audience Survey
Lauren Little, President, BEBPA

Session Topic: Stability Programs for Commercial Reference

7:30 Regulatory Requirements
Speaker To Be Announced

8:15 Industry Insights
Speaker To Be Announced

9:00 Break

Session Topic: Trending Programs For Commercial Reference

9:15 International Organizations Approach
Speaker To Be Announced

10:00 Industry In-House Comparability Of
Value Assignment
Speaker To Be Announced

10:45 Break

11:00 Panel Discussion with Q&A

12:00 Conference Day 1 Adjourns

This conference is our follow-up to the recent BEBPA conference about Potency Standards for Early-Stage Development held June 24-28, 2024. The number one request from speakers and attendees of this conference was that we produce a similar program for Late-stage and Commercial products. Designed to bring all the players to the table for open discussion. Presenters will represent various regulatory agencies, international standard organizations and industrial representatives.

The agenda is evolving. Watch here for updates.