



Collaborating to solve CMC challenges and support efficient development of lentiviral-mediated CAR T cell therapies

October 26, 2022, 9am – 5pm EDT at
USP Headquarters in Rockville, MD USA

Exploring the industry's most pressing challenges at the intersection of quality and innovation

Final Agenda

All times are in Eastern Daylight Time (EDT)

Event Moderator: Edward Chess, Ph.D., USP Biologics Stakeholder Forum Planning Committee, Chair

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| 8:45 a.m. – 9:15 a.m. | Onsite Registration and Information
Meeting Center Foyer |
| 9:15 a.m. – 9:30 a.m. | USP Welcome and Opening Remarks
Speaker: Maura C. Kibbey, Ph.D., Director, Biologics Marketing, Global Biologics, USP |
| 9:30 a.m. – 9:40 a.m. | Introduction and Objectives for today's Biologics Stakeholder Forum
Moderator: Edward Chess, Ph.D., USP Biologics Stakeholder Forum Planning Committee, Chair |
| 9:40 a.m. – 10:05 a.m. | USP standards to support the development of cell and gene therapy products
Speaker: Ben Clarke, Ph.D., Senior Scientist II, Global Biologics, USP |
| 10:05 a.m. – 10:30 a.m. | Regulatory Considerations for the Development of Potency Assays during CAR T Cell Development
Speaker: Andrew Timmons, Ph.D., Biologist, U.S. Food and Drug Administration (FDA) |
| 10:30 a.m. – 10:55 a.m. | Approaches to Potency Testing for Chimeric Antigen Receptor T Cells
Speaker: Shree Joshi, Senior Scientist, BioTD, Analytical Development, Janssen Pharmaceutical |
| 10:55 a.m. – 11:10 a.m. | Morning Break |
| 11:10 a.m. – 11:35 a.m. | Implementation of AQBd principles in potency assay development and overcoming challenges on the road to commercialization
Speaker: Kim Nguyen, Ph.D., Head of Product Attribute Sciences, Analytical Development, Kite Pharma |
| 11:35 a.m. – 12:00 p.m. | Q&A Panel Discussion
Moderator: Edward Chess, Ph.D.
Panelists: Ben Clarke, Andrew Timmons, and Shree Joshi |
| 12:00 p.m. – 1:00 p.m. | Lunch and networking break for in-person attendees |
| 1:00 p.m. – 4:30 p.m. | Moderated Discussion
Moderator: Kok-Seong (KS) Lim, Ph.D., Senior Director of Analytical Sciences and Quality Control, Metagenomi <ul style="list-style-type: none">• Biological activity and potency• Safety (replication-competent virus, integration, etc.) |
| 2:30 p.m. – 2:45 p.m. | Afternoon Break |
| 4:30 p.m. – 5:00 p.m. | Next steps and closing remarks
Speaker: Linda Narhi, USP Biologics Stakeholder Forum Planning Committee, Vice-Chair |