



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

### Draft 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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| 9:00 a.m. – 9:15 a.m.   | <b>USP Welcome and Opening Remarks</b><br>Speaker: Fouad Atouf, Ph.D., Vice President, Global Biologics, USP   |
| 9:15 a.m. – 9:25 a.m.   | <b>Introduction and Objectives for today's Biologics Stakeholder Forum</b><br>Speaker: Edward Chess, Ph.D., USP Biologics Stakeholder Forum Planning Committee, Chair  |
| 9:25 a.m. – 9:45 a.m.   | <b>USP standards to support the development of lentiviral-mediated CAR T cell therapies</b><br>Speaker: Ben Clarke, Ph.D., Senior Scientist II, Global Biologics, USP  |
| 9:45 a.m. – 10:10 a.m.  | <b>FDA Request has been made (TBC)</b><br>A representative from the US FDA, Center for Biologics Evaluation and Research   |
| 10:10 a.m. – 10:35 a.m. | <b>Approaches to Potency Testing for Chimeric Antigen Receptor T Cells</b><br>Speaker: Shree Joshi, Senior Scientist, BioTD, Analytical Development, Janssen Pharmaceutical  |
| 10:35 a.m. – 10:50 a.m. | <b>Morning Break</b>   |
| 10:50 a.m. – 11:15 a.m. | <b>Implementation of QbD principles in potency assay development and overcoming challenges on the road to commercialization</b><br>Speaker: Kim Nguyen, Ph.D., Head of Product Attribute Sciences, Kite Pharma   |
| 11:15 a.m. – 11:35 a.m. | <b>Q&amp;A with the Speakers and conclusion of the hybrid portion</b>  |
| 11:35 a.m. – 1:00 p.m.  | <b>Lunch and networking break for in-person attendees</b>  |
| 1:00 p.m. – 4:30 p.m.   | <b>Moderated Breakout Discussions to Consider</b><br><b>Facilitators: TBC</b> <ul style="list-style-type: none"><li>• Biological activity and potency</li><li>• Safety (replication-competent virus, integration, etc.)</li><li>• Potential other sessions</li></ul> |
| 2:30 p.m. – 2:45 p.m.   | <b>Afternoon Break</b>   |
| 4:30 p.m. – 5:00 p.m.   | <b>Next steps and closing remarks</b><br>Speaker: Linda Narhi, USP Biologics Stakeholder Forum Planning Committee, Vice-Chair  |