

Innovative Analytical Approaches to Cell and Gene Therapy

NGS and other methods

February 22, 2024
8:30a.m. - 3:00p.m. (ET)
USP Headquarters in Rockville, MD



AGENDA

08:00 a.m. - 08:30 a.m. Registration and Check-in

08:30 a.m. - 08:35 a.m. Welcome and Opening Remarks
Fouad Atouf, Senior Vice President, Global Biologics, USP

08:35 a.m. - 08:50 a.m. Introduction and Objectives for Today's Biologics Stakeholder Forum
Edward Chess, USP Biologics Stakeholder Forum Planning Committee, chair

Session 1 Innovations to overcome limitations in an evolving regulatory landscape

08:50 a.m. - 09:05 a.m. USP Standards to Support Gene Therapy
Ben Clarke, Senior Scientist II, Global Biologics, USP

09:05 a.m. - 09:30 a.m. Minimizing the impact of stability studies on gene therapy batch yield
Gaël Debaube, Head of Gene Therapeutics CMC Analytics, UCB Pharma S.A.

09:30 a.m. - 09:55 a.m. EDQM/Ph. Eur. activities in the field of NGS/HTS
Gwenael Cirefice, Scientific Officer, EDQM, European Pharmacopoeia

09:55 a.m. - 10:10 a.m. **Break**

10:10 a.m. - 10:35 a.m. FDA Perspectives on NGS in Adventitious Virus Testing
Arifa Khan, Senior Investigator, Center for Biologics Evaluation and Research, US FDA

10:35 a.m. - 11:20 a.m. Moderated Breakout Discussion
Kok-Seong (KS) Lim, USP Biologics Stakeholder Forum Planning Committee, Vice-Chair

11:20 a.m. - 12:20 p.m. Lunch and networking break for in-person attendees

Session 2 NGS: improvement, replacement, or new standard approach?

12:20 p.m. - 12:25 p.m. Introduction and Objectives for Session 2
Edward Chess, USP Biologics Stakeholder Forum Planning Committee, Chair

12:25 p.m. - 12:50 p.m. NGS transcriptome analysis in cell banking
Colette Cote, Chief Scientific and Portfolio Officer, US General Manager, Pathoquest

12:50 p.m. - 01:15 p.m. Off-Target Analysis: Identification, Verification and Compliant Testing
Aaron ZC, CTO, GeneGoCell

01:15 p.m. - 01:30 p.m. **Break**

01:30 p.m. - 01:55 p.m. Recommendations for the Validation of rAAV Identity by Next Generation Sequencing
Jarrod Dean, Associate Director, Sanofi. Genomic Medicine Unit BioAnalytics, NGS CMC

01:55 p.m. - 02:50 p.m. Moderated Breakout Discussion
Michael Jesudoss, Senior Scientist, NGS, BioMarin Pharmaceutical Inc

02:50 p.m. - 03:00 p.m. Next steps and closing remarks
Ed Chess, USP Biologics Stakeholder Forum Planning Committee, Chair

03:00 p.m. Adjourn

