

Innovative Analytical Approaches to Cell and Gene Therapy

NGS and other methods

February 22, 2024
8:30a.m. - 5:00p.m. (ET)
USP Headquarters in Rockville, MD



AGENDA

Draft

08:30 a.m. - 08:35 a.m. Welcome and Opening Remarks

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. (15min) USP Standards to Support Cell and 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 Debaeve, Head of Gene Therapeutics CMC Analytics, UCB Pharma S.A.

09:30 a.m. - 09:55 a.m. Limited sample availability, challenging lots, flow cytometry approaches (MAM)

Kim Nguyen, Director of Analytical Development, Kite Pharmaceuticals

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

10:10 a.m. - 10:35 a.m. (25min) 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. - 01:20 p.m. Lunch and networking break for in-person attendees

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

01:20 p.m. - 01:25 p.m. Introduction and Objectives for Session 2

Edward Chess, USP Biologics Stakeholder Forum Planning Committee, Chair

01:25 p.m. - 01:50 p.m. NGS transcriptome analysis in cell banking

Colette Cote, Chief Scientific and Portfolio Officer, US General Manager, Pathoquest

01:50 p.m. - 02:15 p.m. Off-target analysis: identification, thresholds, random integration site profiling

Aaron ZC, CTO, GeneGoCell

02:15 p.m. - 02:40 p.m. Validation of NGS Bioidentity Testing for rAAV

Jarrod Dean, Associate Director, Sanofi. Genomic Medicine Unit BioAnalytics, NGS CMC

02:40 p.m. - 02:55 p.m. Break

02:55 p.m. - 03:20 p.m. EDQM/Ph. Eur. activities in the field of NGS/HTS

Gwenael Cirefice, Scientific Officer, EDQM, European Pharmacopoeia

03:20 p.m. - 04:50 p.m. Moderated Breakout Discussion

Kok-Seong (KS) Lim, USP Biologics Stakeholder Forum Planning Committee, Vice-Chair

04:50 p.m. - 05:00 p.m. Next steps and closing remarks

Ed Chess, USP Biologics Stakeholder Forum Planning Committee, Chair

05:00 p.m. Adjourn



The standard of trust