

Characterization and Comparability for Complex Biological Products

Establishing Methods to Better Define Products and Demonstrate Comparability

2nd Annual Meeting

Sunday, January 23

4:00–6:00 pm: **Registration and Welcome Reception, plus Exhibit & Poster Setup**

Monday, January 24

7:00–8:00 am: **Registration and Continental Breakfast – Exhibit Area Foyer**

8:00–8:30 am: **Introduction**
Keith L. Carson – Conference Chairman

8:30–9:15 am: **Characterization of Virus Reassortants that Make up the Pentavalent Live Virus Vaccine**
Todd Ranheim – Merck & Company, Inc.

9:15–10:00 am: **Optimization and Qualification of Release Assays for a Gene Therapy Product**
Reyaz Kango, Ph.D. – VIRxSYS Corporation

10:00–10:30 am: **Break – Exhibit Area**

10:30–11:15 am: **Analytical Characterization of a Therapeutic Monoclonal Antibody: Comparing Antibody Heterogeneity Between Processes**
Brian Schmidt, Ph.D. – Protein Design Labs

11:15–12:00 noon: **A Complementary Mass Spectrometry-Based Approach to the Identification of Host Cell Protein Impurities in Therapeutic Biopharmaceutical Processes**
Greg Adams, Ph.D. – Diosynth Biotechnology

12:00–1:30 pm: **Lunch – Exhibit Area**

1:30–2:15 pm: **Oncolytic Adenovirus Characterization**
Andy Lin, Ph.D. – Cell Genesys

2:15–3:00 pm: **Analytical and Quality Control Issues Related to PEGylated Cytokines**
Merry Sherman, Ph.D. – Mountain View Pharmaceuticals, Inc.

3:00–3:30 pm: **Break – Exhibit Area**

3:30–4:15 pm: **Automated, Quantitative Analysis of Protein Glycosylation**
Johanna Griffin – Procognia, Inc.

4:15–5:00 pm: **The Pharmacokinetics and Pharmacodynamics of Biotechnologically Derived Products: Function Follows Form**
Diane R. Mould, Ph.D. – Projections Research, Inc.

6:00–7:30 pm: **Reception – Exhibit Area**

Tuesday, January 25

7:30–8:30 am: **American Breakfast – Exhibit Area**

8:30–9:15 am: **Characterization of Live, Attenuated Influenza Virus Vaccine**
Hersh Mehta – MedImmune Vaccines, Inc.

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- 9:15–10:00 am: **How to Prepare a Successful Comparability Protocol for Process Changes**
Jeanne Novak, Ph.D. – CBR International Corp.
- 10:00–10:30 am: **Break – Exhibit Area**
- 10:30–11:15 am: **Application of Real-Time, Label-Free, SPR Technology for GxP Compliant Characterization of Protein-Based Therapeutics**
Fredrik Sundberg – Biacore, Inc.
- 11:15–12:00 noon: **Assessment Methods of Post-Preservation Cellular Function: Excipient Standardization**
John Baust – Biolife
- 12:00 noon–5:00 pm: **Free Afternoon with Recommended Group Activities**
- 6:00–9:00 pm: **Conference Banquet**

Wednesday, January 26

- 7:30–8:30 am: **Continental Breakfast – Exhibit Area**
- 8:30–9:15 am: **Characterization of a Potency Assay**
Katharine Miller – Xcyte Therapies, Inc.
- 9:15–10:00 am: **Characterization of Complex Virus Preparations Used in Commercial Vaccine Products**
John Hennessey, Jr., Ph.D. – Merck & Company, Inc.
- 10:00–10:30 am: **Break – Exhibit Area**
- 10:30–11:15 am: **Structural Analysis of Biotechnology Products**
Arthur A. Chirino – Xencor
- 11:15–12:00 noon: **Comparability Case Studies for Viral and Cellular Products**
Elisabeth Lehmborg, Ph.D. – Berlex Laboratories, Inc.
- 12:00–1:30 pm: **Lunch – Exhibit Area**
- 1:30–2:15 pm: **Considerations for Characterization and Comparability of Cell and Gene Therapy Products**
Lilia Bi, Ph.D. – FDA-CBER
- 2:15–3:00 pm: **Immunological and Clinical Efficacy of A Telomerase-Activated Autologous Dendritic Cell Prostate Cancer Vaccine (TVAX)**
Sohel Talib – Geron Corporation
- 3:00–3:30 pm: **Break – Exhibit Area (Exhibit & Poster Teardown at 3:30 pm)**
- 3:30–4:15 pm: **In Situ Monitoring of CHO Cell Culture Medium Using Near-Infrared Spectroscopy**
Robert Mattes – FOSS NIRSystems, Inc.
- 4:15–5:00 pm: **Panel Discussion**

Due to circumstances beyond the control of the conference organizers, the program is subject to change.
