

Characterization and Comparability for Complex Biological Products

January 26 – 28, 2004

Sunday, January 25

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

Monday, January 26

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: **New Methods for *In Vitro* Characterization of Recombinant AAV Vector Purity and Potency**

Jurg Sommer, Ph.D. — *Avigen*

9:15–10:00 am: **Biochemical and Bioactivity Equivalence of Human Monoclonal Antibodies Derived from Hybridoma and CHO Cell Lines**

Dorit Landstein — *XTL Biopharmaceuticals Ltd.*

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

10:30–11:15 am: **Comparison of a Static and a Bioreactor-Based Process for the GMP Manufacture of Autologous Xcellerated T Cells™ for Clinical Trials**

Stewart Craig, Ph.D. — *Xcyte Therapies, Inc.*

11:15–12:00 noon: **Role of Accelerated Stability Studies in Evaluating Product Comparability Following Process Changes**

Supriya Gupta, Ph.D. — *Protein Design Labs*

12:00–1:30 pm: *“Flavors of the Del” Lunch — Exhibit Area*

1:30–2:15 pm: **Purity and Potency of Cell Therapy Products: Unique Aspects**

Scott Burger, M.D. — *Advanced Cell & Gene Therapy, LLC*

2:15–3:00 pm: **Characterization of an HIV-1 Based Lentiviral Vector Produced at Clinical-Scale**

Vladimir Slepushkin, Ph.D. — *VIRxSYS Corporation*

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

3:30–4:15 pm: **Strategies for the Characterization of Recombinant Ad5 & the Challenge Within the Assay for Complex Biological Products**

Eike Zimmermann, Ph.D. — *Berlex Laboratories, Inc.*

4:15–5:00 pm: **Building Your Product Profile: Practical Considerations for Acquiring Materials, Developing Plans, and Assembling the Toolkit**

Nancy Sajjadi — *Sajjadi Associates, Inc.*

5:00–5:45 pm: **Characterization and Comparability for Cellular and Tissue-Based Products: Perspectives of a Former FDA Reviewer**

Darin Weber, Ph.D. — *Biologics Consulting Group, LLC*

6:00–7:30 pm: *“Some Like It Hot” Reception — Exhibit Area*

Tuesday, January 27

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

8:30–9:15 am: ***In Vitro* and *In Vivo* Evaluation of Activated T Lymphocytes as Cellular Vaccines for Cancer and HIV**

Bruce Levine, Ph.D. — *University of Pennsylvania*

9:15–10:00 am: **Clinical Validation of Pathotropic Injectable Vectors for Cancer Gene Therapy**
Erlinda M. Gordon — *Epeius Biotechnologies Corporation*

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

10:30–11:15 am: **In-Process Monitoring of Selected Recombinant Proteins and Monoclonal Antibodies**

Shantani Jeyarajah, Ph.D. — *Diosynth RTP, Inc.*

11:15–12:00 noon: **Recombinant Adenovirus: Characterization Techniques for Process Development**

Gary Vellekamp, Ph.D. — *Schering-Plough Research Institute*

12:00 noon–5:00 pm: **Free Afternoon with Recommended Group Activities**

6:00–9:00 pm: **Conference Banquet On The Beach**

Wednesday, January 28

7:30–8:30 am: **Continental Breakfast — Exhibit Area**

8:30–10:00 am: **Technical Workshops I**

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

10:30–11:15 am: **Changes in Product Heterogeneity during Process Optimization**

Katie Reid, Ph.D. — *Protein Design Labs*

11:15–12:00 noon: **Characterization of the Influence of Purification Process Changes on the Purity and Potency of Recombinant Adeno-Associated Viruses**

Fraser Wright, Ph.D. — *Avigen, Inc.*

12:00–1:30 pm: **“Dim Sum” Lunch — Exhibit Area**

1:30–2:15 pm: **How to Statistically Compare Your Results to Those Published for the Adenoviral Reference Material**

Janice Callahan, Ph.D. — *Callahan Associates, Inc.*

2:15–3:00 pm: **Equivalence of Biotechnological Substances and Products: The USP Conference Workshop Perspective**

Roger Dabbah, Ph.D. — *U.S. Pharmacopeia*

3:00–3:30 pm: **Break — Exhibit Area (Exhibit Tear Down at 3:30 pm)**

3:30–5:00 pm: **Panel Discussions**

Due to circumstances beyond the control of the conference organizers, the program and speaker list are subject to change.

Participating Exhibitors Include:

- ◆ **BioProcessing Journal**
- ◆ **BioReliance Corporation**
- ◆ **Biologics Consulting Group, LLC**
- ◆ **Lark Technologies**