

# Facilities for Mammalian Cell Products

November 1-3, 2004

## Sunday, October 31

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

## Monday, November 1

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

8:00–8:30 am: **Introduction**

Keith L. Carson — *Conference Chairman*

8:30–9:15 am: **The Design and Use of a Multiproduct Facility for GMP Virus Production**

Michael Kelly — *Cell Genesys*

9:15–10:00 am: **Benchmarking Trends in Biomanufacturing Facility Design**

Jeff Odum — *CRB Consulting Engineers*

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

10:30–11:15 am: **Biopharmaceutical Manufacturing Facilities: Avoiding Common Regulatory Problems**

David Cho, Ph.D. — *FDA-CBER*

11:15–12:00 noon: **Process Equipment - From Design to Delivery**

Robert W. Reed — *Turner Construction Company*

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

1:30–2:15 pm: **Gene Therapy and Cell Processing at a Children's Hospital**

Barbara Engel, M.D. — *Children's Hospital Los Angeles*

2:15–3:00 pm: **Large Scale Mammalian Cell Bioreactor Manufacturing Case Studies**

Andrew Morris — *Paul Mueller Company*

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

3:30–4:15 pm: **Design and Operation of a cGMP Facility in an Academic Environment**

David Hsu, Ph.D. — *City of Hope National Medical Center*

4:15–5:00 pm: **Design Basis for a Multiproduct Contract Manufacturing Facility, Part II: Start-up, Commission, and Validation**

Ernest Bogner — *AppTec Laboratory Services*

5:00–5:45 pm: **Vertical Integration of cGMP Manufacturing for the Production of a Gene-Modified Cell Product**

Rueben Cohen — *VIRxSYS*

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

## Tuesday, November 2

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

8:30–9:15 am: **A State-of-the-Art, Large-Scale, Mammalian Cell Culture Facility Nearing Completion: Biogen Idec's NIMO Facility**

Johannes Roebbers, Ph.D. — *Biogen Idec MA, Inc.*

9:15–10:00 am: **Business and Practical Considerations for Building a Multiproduct Manufacturing Facility for Viral Vaccines and Therapeutics**

David Backer — *Molecular Medicine BioServices*

- 10:00–10:30 am: **Break — Exhibit Area**
- 10:30–11:15 am: **Utilizing OPC to Automate Traditional Stand-Alone Instruments Such as Glucose Monitors, Blood Gas Analyzers, Cell Counters, and Mass Spectrometers**  
Larry West — *Broadley-James*
- 11:15–12:00 noon: **Considerations and Lessons Learned from Upgrading an Existing Biopharmaceutical Manufacturing Facility to Add Larger Mammalian-Cell Bioreactors**  
Lawrence Mullen— *Laureate Pharma*
- 12:00–6:00 pm: **Facility Tour - Molecular Medicine BioServices**
- 6:00–9:00 pm: **Conference Banquet**

### Wednesday, November 3

- 7:30–8:30 am: **Breakfast — Exhibit Area**
- 8:30–9:15 am: **Effective Engineering Partnerships: Key to Success of a New Facility**  
Leslie Wood — *Lonza Biologics*; Michael Avant — *Parsons Engineering*
- 9:15–10:00 am: **Design and Development of the NIAID/Vaccine Research Center's Vaccine Pilot Plant**  
Criss Tarr, Sc.D. — *National Institutes of Health*
- 10:00–10:30 am: **Break — Exhibit Area**
- 10:30–12:00 noon: **Technical Workshops I**
- 12:00–1:30 pm: **Lunch — Exhibit Area**
- 1:30–2:15 pm: **Building, Commissioning, and Validating a New Building**  
Jesse Gillikin — *cGMP Validation, L.L.C.*
- 2:15–3:00 pm: **A Unique Way to Build a Biotech Clinical-Trial Fermentation Plant**  
Jerry Arthur — *Cook Pharmica*
- 3:00–3:30 pm: **Break — Exhibit Area (Exhibit Teardown at 3:30 pm)**
- 3:30–4:15 pm: **Perspectives from a Bioprocessing Pilot Plant**  
Victor Vinci, Ph.D — *Eli Lilly*
- 4:15–5:00 pm: **Planning and Executing Process Design for a Large-Scale Multiproduct Mammalian Cell Culture Manufacturing Facility**  
Louis Martin — *Fluor Daniel*

*Due to circumstances beyond the control of the conference organizers, the speaker list is subject to change.*

### **Participating Exhibitors Include:**

- Avid Bioservices, Inc.
- Paul Mueller Co.
- Broadley James
- PALL Life Sciences Corporation
- Consolidated Polymer Technologies
- Nova Biomedical
- Westfalia Separator, Inc.
- JRH Biosciences, Inc.
- Sartorius BBI Systems
- Cuno, Inc.
- Laureate Pharma
- Molecular Medicine BioServices
- AppTec
- Spectrum Laboratories, Inc.
- Wave BioTech LLC
- Irvine Scientific