

Williamsburg BioProcessing Foundation **Facilities for Mammalian Cell Products**

October 24–26, 2005
Philadelphia, PA

8th Annual Meeting

Sunday, October 23

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

Monday, October 24

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

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

8:30–9:15 am: **Conquering Facility Design Challenges in the Construction of Immunomedics' Cell Culture Facility**
Jeng-Dar Yang, Ph.D. — *Immunomedics*

9:15–10:00 am: **Commissioning, Validation, and Start Up of the NIAID/Vaccine Research Center Vaccine Pilot Plant**
Criss Tarr, Sc.D. — *SAIC Frederick*

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

10:30–11:15 am: **Retrofitting Non-Cleanroom Spaces to GMP Cleanrooms in an Academic Medical Center**
Lilith Reeves — *Cincinnati Children's Hospital Medical Center*

11:15–Noon: **Establishing a Multifunctional Facility for Cellular and Tissue-Based Products**
Natika Calhoun — *LifeCyte*

Noon–1:30 pm: **Lunch** — *Exhibit Area*

1:30–2:15 pm: **Optimization of Alpha-1 Antitrypsin Production Using Process Analytical Technology (PAT)**
Sanjay Joshi, Ph.D. — *Bayer Technology Services*

2:15–3:00 pm: **Disposable Bioprocessing: Economics and Manufacturing Case Study in the Use of Disposable Bioreactors for Mammalian Seed Train Development**
Tom Rohrer — *Cambrex Bio Science Baltimore*

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

3:30–4:15 pm: **Design Basis for a Multi-Product Contract Manufacturing Facility Part 3: Implementation of Disposables and Operating Costs**
Ernie Bognar — *AppTec*

4:15–5:00 pm: **Benchmarking Large-Scale Cell Culture Facilities**
Jeff Sarvis — *Fluor*

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

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Tuesday, October 25

- 7:30–8:30 am: **Continental Breakfast — *Exhibit Area***
- 8:30–9:15 am: **A Novel Approach to Environmental Characterization of a Qualified Environment**
Arun Kejariwal — *Merck Research Laboratories*
- 9:15–10:00 am: **FDA Perspectives on Manufacturing Facility Design and Operation for Processes Utilizing Mammalian Cell Culture**
John Finkbohner, Ph.D. — *CBER, FDA*
- 10:00–10:30 am: **Break — *Exhibit Area***
- 10:30–11:15 am: **cGMP Implementation in a Multi-Product Facility**
Barbara Zinck — *Cambrex*
- 11:15–Noon: **Optimization of Monoclonal Antibody Production and Purification Processes Using Simulation and Scheduling Tools**
Demetri Petrides — *Intelligen*
- Noon–6:00 pm: **Facility Tour — *AppTec***
- 6:00–9:00 pm: **Conference Banquet**

Wednesday, October 26

- 7:30–8:30 am: **Continental Breakfast — *Exhibit Area***
- 8:30–10:00 am: **Technical Workshops**
- 10:00–10:30 am: **Break — *Exhibit Area***
- 10:30–11:15 am: **Technical Workshops**
- 11:15–Noon: **Some Recent Experiences and Lessons Learned in Biopharmaceutical Plant Design and Start-Ups**
Kim Nelson, Ph.D. — *CRB Consulting Engineers*
- Noon–1:30 pm: **Lunch — *Exhibit Area***
- 1:30–2:15 pm: ***Design and Construction of a Cell Culture Facility***
Roger Lias, Ph.D. — *Cytovance Biologics*
- 2:15–3:00 pm: **A Case Study in Modular Construction of a State-of-the-Art Fill/Finish Facility**
Charlotte Ekström, M.Sc. — *Pharmadule*
- 3:00–3:30 pm: **Break — *Exhibit Area (Exhibit Teardown)***
- 3:30–4:15 pm: **Manufacturing in a Multi-Product Viral Facility: Lessons Learned After One Year**
David Backer — *Molecular Medicine BioServices*
- 4:15–5:00 pm: **Review of Disposable Technology and the Effects of its Implementation on Validation Costs**
Phil James, Ph.D. — *Biotech Design & Validation*

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