

Facilities for Mammalian Cell Products

From Design Through Operation

October 16–18, 2006

9th Annual Meeting

Sunday, October 15

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

Monday, October 16

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: **Accepting the Challenge of Being Pioneers, and the Rationale Behind Establishing a Start-Up cGMP Compliant Contract Manufacturing Business and Facility for Mammalian Cell Derived Proteins in Malaysia**
Simon Saxby — *Alpha Biologics Sdn Bhd*

9:15–10:00 am: **Design and Operation of a Large-Scale Facility**
Paul Magreta — *Genentech, Inc.*

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

10:30–11:15 am: **Florida Biologix: Facility and Operations**
Richard Snyder, Ph.D. — *University of Florida*

11:15–Noon: **Vapor Phase Hydrogen Peroxide Process—Facility Requirements for Large Scale Decontamination**
Carl Watters — *Merck & Company, Inc.*

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

1:30–2:15 pm: **Development and Qualification of Vapor Phase Hydrogen Peroxide Bio-decontamination Process for Multi-Product Pilot Facility**
Frank Leu — *Merck & Company, Inc.*

2:15–3:00 pm: **Dynamic Design of a Cell Culture Manufacturing Facility Utilizing 3D Modeling**
Peter Cramer and Daniel Lavin, Ph.D. — *Parsons Corporation*

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

3:30–4:15pm: **Cost-Effective cGMP Biopharmaceutical Manufacturing Starts with Facility Location and Design**
Roger Lias, Ph.D. — *Cytovance Biologics*

4:15–5:00pm: **cGMP Implementation in a Multi-Product Facility**
Barbara Zinck — *Cambrex Biosciences Baltimore*

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

Tuesday, October 17

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

8:30–9:15 am: **The LEX System™ – An Alternative Biopharmaceutical Manufacturing Platform**
Glen Williams — *Biolex Therapeutics*

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- 9:15–10:00 am: **Case Study: Merck's New Vaccine Manufacturing Facility (VMF) Nearing Completion in Durham, NC**
Pär Almhem — *Pharmadule, Inc.* and George Cusick — *Merck & Company, Inc.*
- 10:00–10:30 am: **Break — Exhibit Area**
- 10:30–11:15 am: **Responding to Pandemic Events: A Case Study of Flexible Manufacturing Space for Vaccine Production**
Jeff Odum — *NCBiosource*
- 11:15–Noon: **Start-Up, Validation and Running of a Contract Manufacturing Facility (CMO)**
Tom DeLuca — *AppTec Laboratory Services*
- 12:00 pm: **Board Bus for Biolex Therapeutics Tour – Boxed Lunch Provided**
- 12:30–4:30pm: **Biolex Therapeutics Tour**

Wednesday, October 18

- 7:30–8:30 am: **Continental Breakfast — Exhibit Area**
- 8:30–9:15 am: **Fieldbus, OPC & Objectivity... The Expanding Role These Technologies are Playing in Your Competitors Facility and the Advantages They are Delivering**
Larry West — *Finesse, Inc.*
- 9:15–10:00 am: **LEAN in the Pharma Business**
Dion Rasmussen — *NNE US, Inc.*
- 10:00–10:30 pm: **Break — Exhibit Area**
- 10:30–Noon: **Technical Workshops**
- 12:30–1:30 pm: **Lunch — Exhibit Area**
- 1:30–2:15 pm: **Debottlenecking of Multi-Product Biopharmaceutical Manufacturing Facilities Using Simulation and Scheduling Tools**
Demetri Petrides, Ph.D. — *Intelligen, Inc.*
- 2:15–3:00 pm: **Project Phoenix – A Qualification Case Study**
Les Huffman — *Cook Pharmica, LLC*
- 3:00–3:30 pm: **Break — Exhibit Area (Exhibit & Poster Teardown at 3:30 pm)**
- 3:30–4:15 pm: **Process Engineering Optimization for Bioreactor Operations**
Mark McElligott — *NNE US, Inc.*
- 4:15–5:00 pm: **The Evolution of Single Use Bioprocess Systems in the Mammalian Cell Culture Industries**
Ahmad Shahidi — *Lockwood Greene*

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