

# Raw Materials & Contract Services

July 12-14, 2004

## Sunday, July 11

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

## Monday, July 12

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: **Bioburden and Endotoxin Clearance on Column Chromatography Steps - A Case Study**

Paul Tamburri — *F. Hoffmann-La Roche Ltd.*

9:15–10:00 am: **(1→3)-β-D-Glucan Contamination Derived from Raw Materials and Process Equipment in Drugs and Devices**

Malcolm Finkelman, Ph.D. — *Associates of Cape Cod, Inc.*

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

10:30–11:15 am: **Developing Quality and Value with a Contract Laboratory**

Daniel Lobato — *Micro-Virology Laboratories, Inc.*

11:15–12:00 noon: **GMP Production and Development of a Retroviral Vector for Use in a Clinical Trial**

Shirley Bartido, Ph.D. — *Memorial Sloan Kettering Cancer Center*

12:00–1:30 pm: **Italian Countryside Luncheon — Exhibit Area**

1:30–2:15 pm: **Challenges in Process Development Services for Glycoprotein Production**

Rene Brecht, Ph.D. — *ProBioGen AG*

2:15–3:00 pm: **QC Involvement in a Raw Material Release Program to Support a Contract Manufacturing and Testing Organization**

Dave Streelman, Ph.D. — *AppTec Laboratory Services*

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

3:30–4:15 pm: **Qualifying Raw Materials and Suppliers During Product Development**

Paula Shadle, Ph.D. — *Shadle Consulting*

4:15–5:00 pm: **Cellular GlycoEngineering for Fully Human Glycosylation & Optimized Sialylation of Proteins**

Steffen Goletz, Ph.D. — *GLYCOTOPE GmbH*

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

## Tuesday, July 13

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

8:30–9:15 am: **Outsourcing: Where Do You Really Want to Put Your Effort?**

Maureen Costello, Ph.D. — *Seraphim Life Sciences, LLC*

9:15–10:00 am: **Cellular Therapy Contract Manufacturing in an Academic Center**

Dennis A. Gastineau, M.D. — *Mayo Clinic*

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

- 10:30–11:15 am: **Managing Technology Transfer for Cost Effective Scale Up and Manufacturing**  
Allan Watkinson, Ph.D. — *Avecia*
- 11:15–12:00 noon: **Selecting Contract Manufacturing Organizations: A Quality Perspective**  
Tina Young — *Quality, Compliance & Management, Inc.*
- 12:00–6:00 pm: **Invitrogen Facility Tour**
- 6:00–9:00 pm: **Niagara Conference Banquet**

### **Wednesday, July 14**

- 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
- 10:30–12:00 noon: **Technical Workshops II**
- 12:00–1:30 pm: **Backyard BBQ Buffet** — Exhibit Area
- 1:30–2:15 pm: **USP, Excipient Quality Standard, and PDG Harmonization**  
Catherine M. Sheehan — *United States Pharmacopeia*
- 2:15–3:00 pm: **Building Quality into Protein Hydrolysates Used in Cell Culture Media**  
Matthew Caple — *Sigma-Aldrich Fine Chemicals*
- 3:00–3:30 pm: **Buffalo Sports Break** — Exhibit Area (Exhibit Teardown at 3:30 pm)
- 3:30–4:15 pm: **Strategies for a Successful Technology Transfer of Therapeutics**  
Steven Herrick — *BioReliance Corporation*
- 4:15–5:00 pm: Panel Discussion

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

### **Participating Exhibitors Include:**

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|----------------------------------|-------------------------------------|----------------------------------|
| ◆ BioProcessing/WilBio           | ◆ SeraCare Life Sciences, Inc.      | ◆ Invitrogen / Gibco Corporation |
| ◆ Irvine Scientific              | ◆ HyClone Laboratories, Inc.        | ◆ Serologicals Corporation       |
| ◆ Diosynth RTP, Inc.             | ◆ Sigma-Aldrich Fine Chemicals      | ◆ JRH Biosciences                |
| ◆ Pall Life Sciences Corporation | ◆ Consolidated Polymer Technologies | ◆ Neogen Corporation             |
| ◆ Ajinomoto Aminoscience         | ◆ Charles River Laboratories        | ◆ TerraCell International        |
| ◆ BioReliance Corporation        | ◆ Miltenyi Biotec Inc.              |                                  |