

# Facilities for Mammalian Cell Products

From Design Through Validation

## 1st Annual Meeting

June 22-25, 1998

Hotel Complexe Desjardins

Montreal, Quebec

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### Program

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#### **Sunday, June 21**

4:00-9:00 pm: **Welcome Reception, Exhibit Set-Up**

#### **Monday, June 22**

7:00-8:00 am: ***Continental Breakfast - Meeting Room Foyer***

8:00-8:30 am: **Introduction**

Keith L. Carson - Conference Chairman

8:30-9:15 am: **Viral Safety Evaluation, Design Consideration and Validation for the Mammalian Cell**

**Product Manufacturing**

Yuan Xu, Ph.D. - *Genentech, Inc.*

9:15-10:00 am: **Facility Requirements for Manufacture of Immunotherapeutic Cell Products**

Madhusudan V. Peshwa, Ph.D. - *Dendreon Corporation*

10:00-10:30 am: ***Break - Exhibit Area***

10:30-11:15 am: **Multi-Product Facility for Contract Manufacturing: Case Study of Design, Construction, and Start Up**

John W. Imbaratto - *Covance Biotechnology Services*

11:15-12:00 noon: **Design Considerations for an Inactivated HIV Production Facility Manufacturing**

**Remune™**

Christopher P. Prior, Ph.D. - *The Immune Response Corporation*

12:00-1:30 pm: ***Lunch - Exhibit Area***

1:30-2:15 pm: **Design of a Biopharmaceutical Production Facility**

Steven Miller - *SmithKline Beecham*

2:15-3:00 pm: **From R&D to Licenced Manufacturing: The Evolution of a Production Facility**

Eric I. Tsao, Ph.D. - *MedImmune, Inc.*

3:00-3:30 pm: ***Break - Exhibit Area***

3:30-4:15 pm: **Meeting Compendial Requirements for Water Systems**

James F. Cooper, Ph.D. - *Charles River Endosafe*

4:15-5:00 pm: **Building Flexibility Into Cell Culture Facilities**

Kim L. Nelson, Ph.D. - *Clark, Richardson & Biskup*

6:00-8:00 pm: ***The Montreal Reception - Exhibit Area***

## **Tuesday, June 23**

- 7:30-8:30 am: **Continental Breakfast - Exhibit Area**  
**Design, Construction, Commissioning, and Validation of a State of the Art Multi-Purpose Animal Cell Product Facility: A Case Study**  
Steve Fuhrman - *Gist-Brocades/Bio-Intermediair, Inc.*
- 8:30-9:15 am: **Strategies for a Successful Validation Project**  
Myron F. Dittmer, Jr. - *BioMetics, Inc.*
- 9:15-10:00 am: **Break - Exhibit Area**
- 10:00-10:30 am: **Multi-Vector GMP Production Facility: Retrofit in a Clinical Environment for the Institute for Human Gene Therapy**  
Jonathan Friedan, PE & Travis H. Peyton, PE - *Ballinger Architects*
- 10:30-11:15 am: **Design of a Large-Scale Multi-Product Facility for the Manufacture of Viral Vectors**  
Wei Chen, Ph.D. - *Magenta Corporation*
- 11:15-12:00 noon: **Commissioning Mixer (Happy Hour) - Exhibit Area**

## **Wednesday, June 24**

- 7:30-8:30 am: **Continental Breakfast - Exhibit Area**
- 8:30-10:00 am: Panel Discussion
- 10:00-10:30 am: **Break - Exhibit Area**
- 10:30-11:15 am: **Operation of a Facility for Somatic Cellular Therapy Products**  
Shaun McCormack - *Genzyme Tissue Repair*
- 11:15-12:00 noon: **Balancing Containment and Regulatory Issues in the Design of Cell Culture Facilities**  
Kenneth J. Jacobson, Ph.D. - *Clark, Richardson & Biskup*
- 12:00-1:30 pm: **Lunch - Exhibit Area**
- 1:30-2:15 pm: **Start-Up and Shakedown of Genzyme's Allston Landing Facility**  
Christine Powers - *Genzyme Corporation*
- 2:15-3:00 pm: **Minimizing Risk and Uncertainty with the Design/Build Facility Delivery Method**  
William R. Brydges - *bioKinetics*
- 3:00-3:30 pm: **Break - Exhibit Area (Exhibit Tear Down at 3:30 pm)**
- 3:30-4:15 pm: **Case Study: Development of a Large Volume Liquid Manufacturing System**  
James M. Kubiak - *Life Technologies, Inc.*
- 4:15-5:00 pm: **Design and Operation Principles for Flexible Multi-Product Manufacturing**  
Andrew Sinclair - *LONZA Biologics, plc*
- 7:00-10:00 pm: **Conference Banquet - River Cruise**

## **Thursday, June 25**

- 7:30-8:30 am: **Continental Breakfast - Foyer**
- 8:30-9:15 am: **Building a New Recombinant Mammalian Cell Culture Facility for an Approved Biologic**  
John P. Ward - *Biogen, Inc.*
- 9:15-10:00 am: **Design of a Large-Scale Facility for Engineered Tissue Products**  
William R. Tolbert, Ph.D. - *W.R. Tolbert & Associates, LLC*
- 10:00-10:30 am: **Break - Foyer**
- 10:30-11:15 am: **Serum Free Media Development for Monoclonal Antibody Production in High Cell Density Perfusion Bioreactors**  
Bert Van Loon - *IDEC Pharmaceuticals Corporation*
- 11:15-12:00 noon: **Integration of Validation in the Design, Construction, and Start Up of Biotech Facilities and Operations**  
Dennis M. Kluba - *AAC Consulting Group, Inc.*