

Facilities for Mammalian Cell Products

from Design to Validation

2nd Annual Meeting

June 20-23, 1999

Hotel Wyndham Montreal

Montreal, Quebec

Program

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| <u>Sunday, June 20</u> | |
| 10:00 am - 2:00 pm: | Exhibit Set-Up/Registration |
| 2:00-2:30 pm: | Introduction Keith L. Carson - Conference Chairman |
| 2:30-3:15 pm: | Scale-Up Considerations in Facility Design Louise Duffy, Ph.D. - <i>SmithKline Beecham</i> |
| 3:15-4:00 pm: | De-Bottlenecking Analysis of Cell Culture Manufacturing Facilities Kim Nelson, Ph.D. - <i>Clark, Richardson & Biskup</i> |
| 4:00-4:45 pm: | From Development to Production: A Project Management Perspective John K. Plowman - <i>KINETICS</i> |
| 6:00-7:00 pm: | Mixer - Exhibit Area |
| <u>Monday, June 21</u> | |
| 7:30-8:30 am: | Continental Breakfast - Exhibit Area |
| 8:30-10:00 am: | Technology Workshops |
| 10:00-10:30 am: | Break - Exhibit Area |
| 10:30-11:15 am: | Some Past Pitfalls in Facility Designs Thomas R. Campbell - <i>AAC Consulting Group</i> |
| 11:15-12:00 noon: | Design of a Commercial Facility for a Viral Gene Therapy Product Pierre Bay - <i>Rhone-Poulenc Rorer Gencell</i> |
| 12:00-1:30 pm: | Lunch - Exhibit Area |
| 1:30-2:15 pm: | Design, Construction, & Qualification of a Highly Flexible cGMP Biologicals Pilot Plant R. Andrew Ramelmeier - <i>Merck & Company</i> |
| 2:15-3:00 pm: | Advances in Hydrogen Peroxide Sterilization for Rooms and Isolators Julian Wilkins - <i>TPC Microflow, Ltd.</i> |
| 3:00-3:30 pm: | Break - Exhibit Area |
| 3:30-4:15 pm: | Design & Operation of a Multi-Product Facility: Solutions for Effective Cell Culture |

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| | Product Changeover and Production Aaron Heifitz, Ph.D. - <i>BioScience Contract Production</i> |
| 4:15-5:00 pm: | Genentech's Vacaville Facility Carla Boragno - <i>Genentech, Inc.</i> |
| 6:00-8:00 pm: | <i>The Montreal Cabaret - Reception in Exhibit Area</i> |
| <u>Tuesday, June 22</u> | |
| 7:30-8:30 am: | <i>Continental Breakfast - Exhibit Area</i> |
| 8:30-9:15 am: | Expansion of Centocor's Leiden Facility Paul Treacy - <i>Centocor</i> |
| 9:15-10:00 am: | Discoloration & Its Prevention by Surface Treatment in High-Purity Water Systems Doug Newberg - <i>NL Technologies</i> |
| 10:00-10:30 am: | <i>Break - Exhibit Area</i> |
| 10:30-11:15 am: | Project Planning & Basis of Design for Mammalian Cell Culture Facilities Scott Mackler - <i>Cleanroom Consulting</i> |
| 11:15-12:00 noon: | The Immunex Process Development Facility Doug Ward - <i>Immunex Corp.</i> |
| 1:00-4:00 pm: | Plant Tour - IRB/CNRC - BRI/NRC |
| 7:00-10:00 pm: | <i>Tour & Conference Banquet - Sucrerie de la Montagne</i> |
| <u>Wednesday, June 23</u> | |
| 7:30-8:30 am: | <i>Continental Breakfast - Exhibit Area</i> |
| 8:30-9:15 am: | Transgene's Gene Vector Manufacturing Facility: Present & Future Development Stephen Brown, Ph.D. and Remi Gloeckler - <i>Transgene Corp.</i> |
| 9:15-10:00 am: | Control System Implementation for the World's Largest Multi-Product Biotech Facility Tom Cowl - <i>Moore Process Automation Solution</i> |
| 10:00-10:30 am: | <i>Break - Exhibit Area</i> |
| 10:30-12:00 noon: | Panel Discussion |
| 12:00-1:30 pm: | <i>Lunch - Exhibit Area (Exhibit Tear Down Begins at 1:30 pm)</i> |
| 1:30-2:15 pm: | Management of a Hyperimmune Antibody Process with Focus on Viral Safety and Multi Product Issues Bill Bees - <i>Cangene Corp.</i> |
| 2:15-3:00 pm: | Automating a cGMP Multi-Product Pilot Plant: A Case Study Tim Kratzer - <i>Merck & Company</i> |