

Facilities for Mammalian Cell Products

From Design Through Operation

3rd Annual Meeting

October 16-18, 2000

The Tremont Plaza Hotel

Baltimore, Maryland

Program

Sunday, October 15

4:00-6:00 pm: *Welcome Reception, Exhibit Set Up*

Monday, October 16

7:30-10:00 am: *Registration, Continental Breakfast*

10:00-10:30 am: **Introduction**
Keith Carson - *Conference Chairman*

10:30-11:15 am: **Future Capacity Planning: Design and Integration Into an Existing Operating Facility**
Cian G. Ryle - *Merck Research Laboratories*

11:15-12:00 noon: **Overview and Design Basis for Biogen's New 15,000 L Scale Cell Culture Facility**
Vince Narbut - *Biogen, Inc.*

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

1:30-2:15 pm: **Facility Design for Multi-Product Virus Manufacturing**
John Gilley - *BioReliance*

2:15-3:00 pm: **Optimizing the Operation of Cell Culture Manufacturing Facilities**
Kim Nelson, Ph.D. - *Clark, Richardson & Biskup*

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

3:30-4:15 pm: **Design and Operation of a Production Facility for Advanced Cellular Therapies**
Bruce L. Levine, Ph.D. - *University of Pennsylvania School of Medicine*

4:15-5:00 pm: **Meeting Regulatory Expectations - Some Problem Areas**
John A. Eltermann - *FDA/CBER*

6:00-7:30 pm: *E.A. Poe Reception - Exhibit Area*

Tuesday, October 17

7:30-8:30 am: *Full Breakfast - Exhibit Area*

8:30-9:15 am: **Managing Biopharmaceutical Expansions and Regulatory Approval: A Case Study**
Paul A. Treacy - *Centocor*

9:15-10:00 am: **Design and Operation of a Multi-Product Biological Manufacturing Facility for Animal Vaccines**
R. Wayne Behan - *Clark, Richardson & Biskup*

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

10:30-11:15 am: **Design and Operation of a Multi-Product Facility: Solutions for Effective Cell Culture Product Changeover and Production**

Aaron H. Heifetz, Ph.D. - *BioScience Contract Production Corporation*

Automating a cGMP Multi-Product Pilot Plant: Case Study and Lessons Learned

Tim Kratzer - *Merck & Co., Inc.*

11:15-12:00 noon:

Box Lunch and Bus Tour

12:30-1:30 pm:

Facility Tour - BioScience Contract Production Corp.

1:30-4:00 pm:

Reception - BioScience Contract Production Corp.

4:00-5:00 pm:

Wednesday, October 18

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:

Electronic Laboratory Notebooks: Are We Ready For Them?

Thomas R. Sharp, Ph.D. - *Pfizer Central Research*

11:15-12:00 noon:

Operating a Facility for the Production of Cell-Based Therapies

Alan Smith, Ph.D. - *Osiris Therapeutics*

12:00-1:30 pm:

Lunch - Exhibit Area

1:30-2:15 pm:

Updating a Plant-Wide Automation System

Philip Maderia - *Genzyme Corporation*

2:15-3:00 pm:

Containment Strategies and Isolation Technology Advances for BioProcessing

Julian Wilkins - *PharmaConsult US LLC*

3:00-3:45 pm:

Transgenic Goat Production Platform

Philip Onigman - *Genzyme Transgenics Corporation*

3:45-4:00 pm:

Break - Exhibit Area

4:00-5:00 pm:

Panel Discussion

List of Exhibitors

Corning

PALL BioPharmaceuticals

BioSpace.Com

HyClone Laboratories, Inc.

Beckman Coulter

KINETICS

Amersham Pharmacia Biotech

B.Braun Biotech International

NCSRT