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Concord, California, USA



Featuring a Tour of the Stedim Facility in Concord, California, USA

Single-Use BioProcessing Components and Systems

July 16-18, 2007

Ensuring the Quality and Usability of Single-Use Components

As more biopharmaceutical products enter clinical trials and commercial production, it is becoming ever more challenging to guarantee the supply of critical raw materials and disposable process components. The sheer volume of raw materials is testing the limits of many suppliers, while more applications move toward the use of prepared and pre-sterilized materials.

Concurrently, quality control expectations are expanding to keep pace with the availability of increasingly powerful analytical techniques. As a response to these trends, reliable vendors must be identified, evaluated, and then worked with closely to make sure they understand and are able to satisfy the volume, quality, documentation, and communication requirements of this rapidly growing industry.

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Topics:

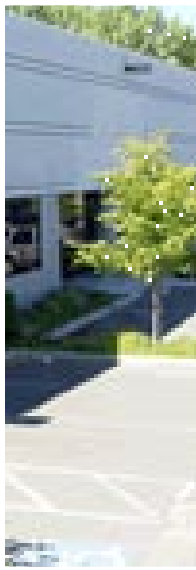
- Single-Use versus Reusable Components
- System Integration and Validation
- Vendor Certification and Audits
- Disposal Issues
- Testing Requirements
- Media and Buffers
- Chromatography Resins
- Animal-Sourced Materials
- Critical Raw Materials
- Storage and Qualification





Single-Use BioProcessing Components and Systems

Ensuring the Quality and Usability of Single-Use Components



SUNDAY, JULY 15, 2007

4:00-6:00 pm **Registration and Welcome Reception**

MONDAY, JULY 16, 2007

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

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

Keith L. Carson - Conference Chairman

8:30-9:15 am **Evaluation of Disposable Technologies for Mammalian and Microbial Applications**

Malhar Ambhaikar - Amgen, Inc.

9:15-10:00 am **Disposable Systems for Nanofiltration and Tangential Flow Filtration**

Matt Mergy - Eli Lilly & Company

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

10:30-11:15 am **The Use of Extractable/Leachable Testing for Qualification of Disposable BioProcessing Components and Systems**

Steve Doherty, Ph.D. - Toxikon Corporation

11:15-Noon **Disposable Costs, Three Examples**

David Wareheim - Centocor, Inc.

Noon-1:30 pm **Lunch and Poster Session - Exhibit Area**

1:30-2:15 pm **Innovative Disposable Bioreactors Based on Tide Principle for Membrane Protein Production**

Lewis Ho, Ph.D. - IDL Bioservices LLC

2:15-3:00 pm **Stability Considerations for Biotechnology / Biopharmaceutical Products**

Daniel Lobato - Micro-Virology Laboratories, Inc.

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

3:30-4:15 pm **An In-Depth Look at a "Fully Disposable" Monoclonal Antibody Process**

Christian Manzke - Sartorius Biotech, Inc.

4:15-5:00 pm **Adding Patent Strength to Single-Use Products - Targeted Intellectual Property Strategies for Product Defense and Market Dominance**

Dale Hunt, Ph.D. - Sonnenschein Nath & Rosenthal LLP

5:00-5:45 pm **Implementation of Single-Use Processes in Existing Facilities**

Kim Nelson, Ph.D. - CRB Consulting Engineers. Inc.

6:00-7:30 pm **Reception - Exhibit Area**

TUESDAY, JULY 17, 2007

- 7:30-8:30 am **American Breakfast - Exhibit Area**
- 8:30-9:15 am **Challenges and Strategy for Cell Culture Process Scale-Up: Disposable vs. Stainless Steel Bioreactors**
Brian Lee, Ph.D. - Amgen, Inc.
- 9:15-10:00 am **Aseptic Transfer: Zone to Zone and Isolator Applications Using a Disposable Based Technology**
Susan Tomberg - Stedim Biosystems, Inc.
- 10:00-10:30 am **Break - Exhibit Area**
- 10:30-11:15 am **Evaluating Extractables from Disposable Equipment**
Don Miller, Ph.D. - Pharmaceutical Industry Consultant
- 11:15-Noon **A Risk Assessment Methodology for the Evaluation of Leachables and Extractables**
Scott Haller - Regeneron Pharmaceuticals, Inc.
- Noon-1:30 pm **Lunch and Poster Session - Exhibit Area**
- 2:00-7:00 pm **Stedim Biosystems Facility Tour and Reception**

WEDNESDAY, JULY 18, 2007

- 7:30-8:45 am **Breakfast - Exhibit Area**
- 8:45-9:30 am **21st Century Technologies for Increasing Manufacturing Efficiency & Lowering Production Costs**
Peter Watler, Ph.D. - JM Hyde Consulting, Inc
- 9:30-10:00 am **Technical Workshops I**
- 10:00-10:30 am **Break - Exhibit Area**
- 10:30-Noon **Technical Workshops II**
- Noon-1:30 pm **Lunch and Poster Session - Exhibit Area**
- 1:30-2:15 pm **Meeting the Challenges of Alternate Sourcing Bioprocess Materials for Risk Mitigation**
Len Grant - Bristol-Myers Squibb
- 2:15-3:00 pm **Enhanced Cell Growth and Productivity by Animal-Free Recombinant Human Serum Albumin**
Steve Pettit, Ph.D. - InVitria
- 3:00-3:30 pm **Break - Exhibit Area**
- 3:30-4:15 pm **Validation of Single-Use Bioprocess Containers: Film Structure and It's Impact on Extractables**
Tom Murphy, Ph.D. - ThermoFisher Scientific
- 4:15-5:00 pm **High Density Insect Cell Culture in a 200L Disposable Bioreactor**
Geoff Hodge - Xcellerex, Inc.
co-presented by David Clements - Hawaii Biotech

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