



Presents:



April 5-6, 2012 • Rosslyn, Virginia USA

WEDNESDAY ► APRIL 4, 2012:

6:00 pm – 9:00 pm **Welcome Reception in Registration Area, and Exhibit Setup**

THURSDAY ► APRIL 5, 2012:

7:00 am – 8:00 am **Registration, Breakfast in Meeting Foyer, and Exhibit Setup**

8:00 am – 8:30 am **Meeting Introduction – Keith L. Carson** ► ISBioTech

8:30 am – 9:00 am **Jeffery Lee Craig** ► ATMI LifeSciences
Recent Advances in the Integration of Single-Use Bioprocessing Technologies

9:00 am – 9:30 am **Phillip B. Maples, PhD** ► Gradalis, Inc.
Flexible Manufacturing: FANG Autologous Cancer Vaccine — Phase I and II Trials

9:30 am – 10:00 am **Parrish M. Galliher** ► Xcellerex, Inc.
Risk Assessment for the Design of Flexible Manufacturing Facilities

10:00 am – 10:30 am **Morning Break in Exhibit Area**

10:30 am – 11:00 am **Jerold Martin** ► Pall Life Sciences
Single-Use Technology — Establishing Best Practices, Standardization Efforts, and Managing Expectations

11:00 am – 11:30 am **Nicolas Taquet** ► Gradalis, Inc.
Decontamination and Waste Disposal

11:30 am – 12:00 noon **Jeffery N. Odum and Mark F. Witcher, PhD** ► Integrated Project Services
Next Generation Biomanufacturing

12:00 noon – 12:30 pm **Heath Coats** ► Lonza Walkersville, Inc.
Validation of Flexible Facilities and Systems for the Contract Production of Cellular Products

12:30 pm – 1:30 pm **Lunch in Exhibit Area (Poster Presentations from 1:00 pm – 1:30 pm)**

1:30 pm – 2:00 pm **Andrew R. Scherer** ► SmartFit Modular, LLC
Modular Biologics Facilities with Integrated Bioprocess Manufacturing Platforms

2:00 pm – 2:30 pm **Mark Wells** ► KTEC Cleanroom Systems
Flexibility Using Modular Cleanrooms

2:30 pm – 3:00 pm **Tim Schuster** ► Foster Wheeler Biokinetics
Marc Paquin ► Cambryn Biologics
All Single-Use Plasma Fractionation Facility Saves Millions and Accelerates Timeline for Critical Surgical Adhesive

3:00 pm – 3:30 pm **Afternoon Break in Exhibit Area**

3:30 pm – 4:00 pm **Chrysta Mayhew** ► Sanofi Pasteur Ltd.
GMP Compliance in Multi-Use Facilities

4:00 pm – 4:30 pm **Kim Nelson, PhD** ► CRB Consulting Engineers, Inc.
Shire's Project Atlas: A Case Study in Flexible Facilities and Single-Use Systems

- 4:30 pm – 5:00 pm **Klaus Hermansen** ▶ NNE Pharmaplan
New Concept for Modern Design of Modular Vaccine Facilities
- 5:00 pm – 5:30 pm **R. Thomas Warf** ▶ US BARDA/Health & Human Services
Flexible Manufacturing and Its Strategic Importance in the Development of Medical Countermeasures to Biothreats
- 6:00 pm – 8:00 pm **Reception in Exhibit Area**
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FRIDAY ▶ APRIL 6, 2012:

- 7:00 am – 8:00 am **Breakfast in Exhibit Area**
- 8:00 am – 8:30 am **Spencer Parkinson** ▶ Thermo Fisher Scientific
Single-Use Coming of Age — Next Generation Systems and Advantages
- 8:30 am – 9:00 am **Paul Priebe** ▶ Sartorius Stedim Biotech
Large-Scale Media and Buffer Preparation in a Single-Use Mixer
- 9:00 am – 9:30 am **Chris N. Steffas** ▶ Rockwell Automation
System Integration and Platform Requirements for Flexible Manufacturing
- 9:30 am – 10:00 am **Eric S. Langer** ▶ BioPlan Associates, Inc.
Global Industry Analysis: Flexible Facilities Enabled by Growth in Single-Use Devices
- 10:00 am – 10:30 am **Morning Break in Exhibit Area**
- 10:30 am – 11:00 am **Nancy Waites** ▶ FDA CBER
Multiproduct Facility Considerations for Biological Products
- 11:00 am – 11:30 am **Mary Pat Moyer, PhD** ▶ INCELL Corp., LLC
From Designer Stem Cells to Vaccines with Single-Use Production Systems
- 11:30 am – 12:00 noon **Morten Munk** ▶ CMC Biologics A/S
Implementation of 2000 L SUB and Disposable Clarification System in an Existing cGMP Facility
- 12:00 noon – 1:00 pm **Lunch in Exhibit Area (Poster Presentations from 12:30 pm – 1:00 pm)**
- 1:00 pm – 1:30 pm **Christopher Seth and Bryan Jones** ▶ The Beck Group
Managing Design Build for Biopharma Facilities: Assembling and Managing a Team for Rapid Delivery and Cost Efficiency
- 1:30 pm – 2:00 pm **Barry Holtz, PhD** ▶ G-Con, LLC
They Came and We Built It
- 2:00 pm – 2:30 pm **Barbara Paldus** ▶ Finesse Solutions
Implementation of Single-Use Bioreactors to Help Meet the Flexible Requirements of Multi-Use Biopharmaceutical Operations
- 2:30 pm – 3:00 pm **Engin Ayturk, PhD** ▶ Pall Life Sciences
A Process and Economic Analytical Approach to Single-Use TFF
- 3:00 pm – 3:30 pm **Ingrid Long** ▶ GE Healthcare Bio-Sciences AB
Strategies for Facility Design and Resource Optimisation When Utilising Single-Use Technologies for Multi-Product Vaccine Manufacturing
- 3:30 pm – 4:00 pm **Final Networking Break in Exhibit Area (Exhibit teardown begins at 3:45 pm)**
- 4:00 pm **Meeting Adjourns**