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 Biokinetcs*

  *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*
**ISBioTech Flexible Facilities & Systems • April 5-6, 2012 • Rosslyn, Virginia**

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>4:30 pm – 5:00 pm</td>
<td><strong>Klaus Hermansen</strong> ► NNE Pharmaplan  &lt;br&gt;New Concept for Modern Design of Modular Vaccine Facilities</td>
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<tr>
<td>5:00 pm – 5:30 pm</td>
<td><strong>R. Thomas Warf</strong> ► US BARDA/Health &amp; Human Services  &lt;br&gt;Flexible Manufacturing and Its Strategic Importance in the Development of Medical Countermeasures to Biothreats</td>
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<td>6:00 pm – 8:00 pm</td>
<td><strong>Reception in Exhibit Area</strong></td>
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**FRIDAY ► APRIL 6, 2012:**

- **7:00 am – 8:00 am** **Breakfast in Exhibit Area**
  - **Spencer Parkinson** ► Thermo Fisher Scientific  <br>Single-Use Coming of Age — Next Generation Systems and Advantages

- **8:00 am – 8:30 am**
  - **Paul Priebe** ► Sartorius Stedim Biotech  <br>Large-Scale Media and Buffer Preparation in a Single-Use Mixer

- **8:30 am – 9:00 am**
  - **Chris N. Steffas** ► Rockwell Automation  <br>System Integration and Platform Requirements for Flexible Manufacturing

- **9:00 am – 9:30 am**

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

- **10:30 am – 11:00 am**
  - **Nancy Waites** ► FDA CBER  <br>MultiProduct Facility Considerations for Biological Products

- **11:00 am – 11:30 am**
  - **Mary Pat Moyer, PhD** ► INCELL Corp., LLC  <br>From Designer Stem Cells to Vaccines with Single-Use Production Systems

- **11:30 am – 12:00 noon**
  - **Morten Munk** ► CMC Biologics A/S  <br>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  <br>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  <br>They Came and We Built It

- **2:00 pm – 2:30 pm**
  - **Barbara Paldus** ► Finesse Solutions  <br>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  <br>A Process and Economic Analytical Approach to Single-Use TFF

- **3:00 pm – 3:30 pm**

- **3:30 pm – 4:00 pm** **Final Networking Break in Exhibit Area (Exhibit teardown begins at 3:45 pm)**

- **4:00 pm** **Meeting Adjourns**

*Due to circumstances beyond the control of meeting organizers, this program is subject to change without notice.*