

Annual Meeting

5 Days: March 11-15, 2013 • Rosslyn, Virginia USA

ANCILLARY Track: Programs At-A-Glance

WEDNESDAY • MARCH 13, 2013

6:00 pm – 9:00 pm **Welcome Reception at Meeting Venue, plus Exhibit Setup**

THURSDAY • MARCH 14, 2013

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

8:00 am – 8:30 am **Meeting Overview (Riverview Room)**

FLEXIBLE FACILITIES & SYSTEMS™
Riverview Room

CONTAMINANT CONTROL™
Cityview Room

8:30 am – 9:15 am **Speaker Presentations**

Jeffery N. Odum • Integrated Project Services (IPS)
Making the Old New Again: Implementing Single-Use Biomanufacturing Platforms Into Traditional Stainless Steel-Based Facilities

Steven R. Bauer, PhD • FDA CBER
FDA Perspectives on Cell Therapy Product Identity and Purity

9:15 am – 10:00 am **Speaker Presentations**

Lori P. Peters • FDA CBER
FDA Expectations: Multi-Product Facility Considerations for Biological Products

Yvonne A. Reid, PhD • American Type Culture Collection
International Cell Line Authentication Committee (ICLAC) Activities — Case Studies in STR Profiling

10:00 am – 10:30 am **Morning Break in Exhibit Area** / 10:30 am – 11:15 am **Speaker Presentations**

Mark J. Wells • KTEC Cleanroom Systems — *Single Pass Versus Recirculated Airflow for Biomedical Cleanroom Facilities*

David Henry • Medicago USA
Material and Process Containment in Plant-Based Vaccine Manufacturing

11:15 am – 12:00 noon **Speaker Presentations**

Eric S. Langer • BioPlan Associates, Inc. — *Standards-Setting for Single-Use Equipment in Biopharmaceutical Manufacturing: An Update on Progress, and the Impact of Standards Implementation*

Raymond Nims, PhD • RMC Pharmaceutical Solutions, Inc.
Using FBS in Your Process? Do You Feel Lucky?

12:00 noon – 12:30 pm **Technology Workshops**

Pall Life Sciences

Charles River Laboratories

12:30 pm – 1:30 pm **Lunch in Exhibit Area**

1:30 pm – 2:15 pm **Speaker Presentations**

R. Barry Holtz, PhD • G-Con, LLC
Global Systems Integration of Flexible Facilities — Data is the New Currency

Arifa S. Khan, PhD • FDA CBER — *Regulatory Expectations for Adventitious Virus Testing and Characterization of Vaccine Cell Substrates*

2:15 pm – 3:00 pm **Speaker Presentations**

Kim L. Nelson, PhD • CRB Consulting Engineers, Inc.
Risk Management in Flexible Facilities

John L. Kolman, PhD • BioReliance Corporation
Massively Parallel Sequencing for Virus Detection: Regulatory Compliance

3:00 pm – 3:30 pm **Afternoon Break in Exhibit Area** / 3:30 pm – 4:15 pm **Speaker Presentations**

Michael K. O'Brien, PhD • Pfizer, Inc.
Platform Technologies for Process Development, Technology Transfer, and Commercial Manufacturing in Any Environment

Rebecca Sheets, PhD • National Institutes of Health (NIH)
Compensal Assays - Do They Meet Today's Standards?

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

THURSDAY • MARCH 14, 2013 (continued)

**FLEXIBLE FACILITIES & SYSTEMS™
Riverview Room**

**CONTAMINANT CONTROL™
Cityview Room**

4:15 pm – 5:00 pm **Speaker Presentations**

Kevin Briggs • SAFC Carlsbad Inc. — *Design, Operation, and Expansion of a cGMP Multi-Product Viral Manufacturing Facility*

S. Steve Zhou, PhD • MicroBioTest, div. of Microbac Laboratories, Inc. — *Zero Tolerance for Contamination: Critical Issues to Consider in Establishing an Effective Facility Cleaning Program*

5:00 pm – 5:45 pm **Speaker Presentations**

Panel Discussion:
R. Barry Holtz, PhD • G-Con, LLC
Michael K. O'Brien, PhD • Pfizer, Inc.
Nancy T. Waites • FDA CBER
Parrish Galliher • Xcellerex, Inc.

6:00 pm – 8:00 pm **Reception in Exhibit Area**

FRIDAY • MARCH 15, 2013

7:30 am – 8:30 am **Breakfast in the Exhibit Area** / 8:30 am – 9:15 am **Speaker Presentations**

Nicolas Taquet • Gradalis, Inc. — *Phase II Ovarian Tumor Tissue Processing to Prepare Autologous Tumor Cell Vaccine (FANG): Manufacturing Developments for Scale-Up*

Patrick McCarthy • EMD Millipore — *Rapid Mycoplasma Detection Coupling a Novel Sample Preparation Device to Molecular Methods*

9:15 am – 10:00 am **Speaker Presentations**

Trent A. Carrier, PhD • Biologics Consulting Group, Inc. — *Strategies for Sizing Modular Facilities for Optimal Production Capacity, Manufacturing Costs, and Capital Investment*

James C. Leung, PhD • Consortium on Adventitious Agent Contamination in Biomanufacturing (CAACB), MIT — *An Academic and Industry Collaborative Initiative on Preventing Adventitious Agent Contaminations in Biomanufacturing*

10:00 am – 10:30 am **Morning Break in Exhibit Area** / 10:30 am – 11:15 am **Speaker Presentations**

Nancy T. Waites • FDA CBER — *FDA Expectations for cGMP Compliance for Different Clinical Trial Phases*

William T. Lucas, PhD • WuXi AppTec Inc. — *Applying New Technologies for the Detection of Viral Contaminants*

11:15 am – 12:00 noon **Speaker Presentations**

Mauricio Barraza • Acceleron Pharma, Inc. — *Pilot and Clinical Manufacturing Facilities*

Feny Gunawan • Genentech, Inc. — *Case Study: Identification and Development of an Assay for a Specific Host Cell Protein*

12:00 noon – 12:30 pm **Technology Workshops**

Finesse Solutions

Thermo Scientific

12:30 pm – 1:30 pm **Lunch in Exhibit Area**

1:30 pm – 2:15 pm **Speaker Presentations**

Stuart Hassard, PhD • deltaDOT Ltd. — *Label Free Intrinsic Imaging (LFII®) in Process Analytical Technology (PAT) Workflows*

Laurie J. Graham, PhD • FDA CDER — *FDA Viewpoint on Generic (Kit) Versus Process-Specific Host Cell Protein ELISA Assays*

2:15 pm – 3:00 pm **Speaker Presentations**

William G. Whitford • Thermo Fisher Scientific — *Biosimilar Manufacturing Supported by SUT*

Robert J. Duff, PhD • Lancaster Laboratories Inc. — *Detection of Host Cell Protein in a Drug Product Using Protease Digestion with LTQ-Orbitrap Mass Spectrometry*

3:00 pm – 3:30 pm **Afternoon Break in Exhibit Area (Exhibit teardown begins at 3:30 pm)**

3:30 pm – 4:15 pm **Speaker Presentations**

Christopher S. Miles • Foster Wheeler Biokinetics — *Design Solutions for Integration of Disposables into GMP Facility Design*

Nadine M. Ritter, PhD • Biologics Consulting Group, Inc. — *Host Cell Protein Analysis: Complementary Strategies, Emerging Technologies, and Critical Mistakes*

4:15 pm – 5:00 pm **Speaker Presentations**

Fabien Moncaubieg • ATMI LifeSciences — *Recent Advances in the Integration of Single-Use Bioprocessing Technologies for Cell Therapies*

5:00 pm **Meeting Adjourns**