Innovative Biopharmaceutical Manufacturing Solutions for Multi-Product Pipelines, Global Markets, On-Demand Scale-up/Scale-down and Capacity Optimization

February 24-25, 2014
The Claremont Hotel Club & Spa Berkeley, CA

Biopharmaceutical Pipelines and Facility Needs are Changing ... Are You Prepared?

- Novel Facility Design Concepts
- Clinical and Commercial Implementation
- Flexible Vaccine Facilities
- Facilities for Emerging Markets
- Single-use vs. Stainless Steel: Pros and Cons
- Lessons from the U.S. Government: BARDA and DOD

Share New Ideas in 2 Interactive Discussions

- Functionally-Closed Processing in CNC Environments: What is Holding Us Back?
- Where Do You Have to Compromise When Designing and Implementing a Flexible Facility?

www.IBCLifeSciences.com/Facilities
Register Today for a Look at State-of-the-Art Facilities, Technologies

IBC’s 2nd Annual **Flexible Facilities** conference brings together senior level executives and scientists from biopharmas, CMO’s, technology providers, engineering firms and regulatory groups to explore the changing landscape of biologics manufacturing and to share case studies of the latest flexible facility implementations, lessons learned and practical experiences.

Attend this ground-breaking event to learn about current and future state-of-the-art innovations in flexible technology, facility design and process design. You will learn about the technical, business, regulatory and economic considerations, as well as the opportunities and challenges of creating flexible production facilities for your organization.

**LEARN about Novel Facility Design Concepts**
- 100% disposable and hybrid facilities
- Retrofitting stainless steel to be more flexible
- Modular systems and plug & play designs
- Multi-product facilities, open ballrooms and closed systems

**DISCOVER How BARDA and the DOD are Developing Flexible Facilities**
- Emergent’s flexible manufacturing capabilities and facilities
- Novartis Vaccines and the Holly Springs manufacturing site
- Kalon Therapeutics and Texas A&M University’s Collaboration
- Nanotherapeutics flexible manufacturing for Medical Countermeasures

**HEAR about Practical Experiences in Single-use Implementation**
- Single-use in vaccine upstream processes
- Case study comparing a single use mAb process to a stainless steel process
- Functionally-closed systems and multi-product facilities

**PREPARE Yourself for Rapid Deployment and Emerging Market Opportunities**
- Biosimilars, flexible systems and emerging markets
- Establishing manufacturing capacity in BRIC regions
- Production strategies for pandemics and biothreats

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“This a timely meeting that addressed the benefits and challenges of flexible facilities and single use bioreactors and the necessity to prepare ourselves for the future.”
Tony D’Amore, Vice President, Bioprocess Research & Development North America, Sanofi Pasteur

“Great dialogue on how “adaptable” and flexible designs and facilities are likely to be in the future.”
Kevin Lear, Senior Process Engineer, NNE Pharmaplan

“Very worthwhile conference providing excellent information on different facility design options.”
Maik Jornitz, Vice President, G-CON LLC

“Thank you for a great conference. I thought it was fantastic.”
Andy Walker, Ph.D., Vice President, Process Development, CMC Biologics

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This event sold out in 2013 – be sure to register early to save your spot: www.IBCLifeSciences.com/Facilities
President's Welcome and Opening Remarks

The Changing Landscape of Biomanufacturing Facilities

Featured Presentations

8:20 Critical Aspects and Risks in Implementing Single Use Technologies in Flexible Facilities

9:00 Regulatory Perspectives on Flexible Facilities

9:40 Networking Refreshment Break and Exhibit/Poster Viewing

Rapid Deployment and Facilities for Emerging Markets

Featured Presentation

10:10 Flexible Facilities Democratization of Biosimilars’ Opportunity in Emerging Markets

10:50 Case Study Reinventing Biomanufacturing: Case Studies of Flexible Facilities; Multi-product Vaccine Facility – Benefits and Challenges

11:30 Case Study Facility of the Future – Single Use Facility, A Case Study from Biogen Idec

12:00 Flexible Facilities: Too Much Too Soon?

12:30 Networking Luncheon followed by Exhibit/Poster Viewing and Dessert

1:45 Development Pilot Plant Design and Considerations for Vaccine and Cell Therapy Projects

2:15 Creating Flexibility in Biomanufacturing Facilities

2:45 Flexible Supply Chain – A Complement to Flexible Facility Operations

3:15 Networking Refreshment Break and Exhibit/Poster Viewing

Flexible Facility Design Strategies and Practical Implementation Experiences

Monday, February 24, 2014

For up-to-date program information and new abstracts, visit: www.IBCLifeSciences.com/Facilities
### Flexible Facilities and Closed Systems

3:45 **Case Study** Implementing New Flexible and Single-Use Devices and Processes for Vaccine Manufacturing: Case Study on Formulation and Filling

This presentation will cover two case studies as they relate to biopharmaceutical manufacturing. The first discussion formulates a multi-component vaccine product in closed system, single-use manifolds: technical considerations for filtration, mixing, sampling and fluid transfer. The second will review experiences designing and testing novel pre-sterile, single-use filling lines. Both will cover challenges and lessons learned from planning, process design and implementation stages.

Kirsten Strahlendorf, Senior Scientist, Sanofi Pasteur, Canada

4:15 **New Data** Evaluating the Effectiveness of Liquid Sanitizing Agents to Establish Functionally-Closed Systems

Functionally-closed systems are frequently encountered when single-use systems are connected to stainless steel systems. The effectiveness of sanitization methods can impact the facility design and operation. Approaches for evaluating sanitization effectiveness are presented as well as how that data can potentially be leveraged to simplify facility design.

Scott Probst, Ph.D., Group Head, HealthCare and Biotechnology, Bayer Technology Services, Germany

### Panel Discussion

4:45 **Functionally-Closed Processing in CNC Environments: What is Holding Us Back?**

- What defines a closed system?
- How closed is a closed system process?
- Regulatory perspectives in closed systems

**Panelists:**
- Marc Pelletier, Ph.D., Director of Biotechnology, CRB Consulting Engineers
- Scott Probst, Ph.D., Group Head, HealthCare and Biotechnology, Bayer Technology Services, Germany
- Sebastien Ribault, Ph.D., Director, Bioproduction and Development, Merck Millipore, France

5:15 Close of Day One

Tuesday, February 25, 2014

7:45 Registration and Coffee

8:30 **Chairman’s Remarks**

R. Thomas Warf, Director, Manufacturing, Facilities & Engineering, BARDA, U.S. Department of Health & Human Services

### Flexible Biomanufacturing Facilities: Lessons from the U.S. Government Centers for Innovation in Advance Development and Manufacturing

8:40 **HHS Centers for Innovation in Advance Development and Manufacturing (CIADM) Facilities**

This presentation reviews the current and designed facilities of the Health and Human Services Centers for Innovation in Advance Development. The current facilities and the designs of future facilities will be discussed to show the support the CIADM contracts. The contractors are Emergent BioSolutions, Baltimore, MD, Novartis Vaccines, Holly Springs, NC and Texas A & M University System, College Station, TX, and they support flexible process development (phase I thru III) and manufacturing of final product. The HHS requirements and some potential HHS projects will be reviewed.

R. Thomas Warf, Director, Manufacturing, Facilities & Engineering, BARDA, U.S. Department of Health & Human Services

9:00 **Partnering with HHS BARDA to Establish Flexible Manufacturing Capacity to Develop Medical Countermeasures**

Discussion will include an overview of the Novartis Vaccines and the Holly Springs manufacturing site. The site is the product of a public/private partnership between HHS BARDA and Novartis Vaccines. This site is comprised of Bulk Cell Culture Influenza manufacturing, a pre-filled syringe filling facility, and a pilot plant facility. The pilot plant facility is being retrofitted to provide additional capabilities for clinical trial filling as part of an HHS contract to provide a Center of Innovation and Advanced Development and Manufacturing (CIADM) capability to develop medical countermeasures.

Chris McDonald, Site Head, Holly Springs Site, Novartis Vaccines and Diagnostics

9:30 **Emergent’s Flexible Manufacturing Facility**

In June 2012, Emergent was selected by DHHS as one of the Centers for Innovation in Advanced Development and Manufacturing (CIADM). This presentation gives an overview as to how this important public-private partnership builds on Emergent’s existing flexible manufacturing capability and further expands it for pandemic influenza surge production, as well as for advanced development of other medical countermeasures for emergencies and threats.

Vijay Yabannavar, Ph.D., Senior Vice President, Manufacturing Operations and Process & Analytical Development, Emergent BioSolutions

10:00 Networking Refreshment Break and Exhibit/Poster Viewing

10:30 **Case Study** Flexibility Defined: A Case Study on Multi-Product, Multi-Technology Vaccine Manufacturing Facilities

In partnership with BARDA and the Texas A&M University System, Kalon operates the National Center for Therapeutics Manufacturing (NCTM) which employs multi-product, single use technologies and mobile clean rooms. In addition, the partnership is breaking ground on next generation, high containment facilities for pandemic influenza response and viral-based vaccines. This case study examines the NCTM operations and the design basis for the new facilities.

Andrew Strong, President and CEO, Kalon Biotherapeutics

11:00 **Intersection of cGMP & Biocontainment Design in Biopharmaceutical Medical Countermeasure Production**

This presentation provides an overview of several projects funded by the Biomedical Advanced Research & Development Authority (BARDA) in which biocontainment and biosafety design elements had to be incorporated into pilot- and commercial-scale biopharmaceutical facilities. The projects will encompass both retrofitting and new construction (green field).

Michael P. Angelastro, Deputy Director, Manufacturing, Facilities & Engineering, BARDA, U.S. Department of Health & Human Services

11:20 **The Application of Single Use Technology for Agile, Flexible Manufacturing of Medical Countermeasures**

Nanotherapeutics, Inc. (Alachua, FL) has recently been awarded a government contract to provide the Department of Defense with an Advanced Development and Manufacturing (NANO-ADM) Center as a dedicated resource to rapidly develop and manufacture Medical Countermeasures (MCMs). The NANO-ADM Center will include facilities, equipment and expertise to manufacture biologic products to respond to the US Government’s national security needs for Medical Countermeasures, leveraging flexible manufacturing and modern platform technologies to provide warm-based vaccine and MCM capabilities for potential outbreaks of emerging infectious pathogens of currently known or unknown threats. The facility design will integrate flexible, modular (single use, disposable), adaptable and scalable processes and equipment in a facility that is compliant with cGMP and BSL-3 guidelines.

Andrew Graham, Senior Director, Operations-Manufacturing, Nanotherapeutics, Inc.
**Panel Discussion**

11:50 **Where Do You Have to Compromise When Designing and Implementing a Flexible Facility?**
- What facility design criteria are most important for your product portfolio?
- How to balance optimal facility needs with accelerated timelines and limited resources?
- What compromises should you never make when designing your facility?

*Moderator:*
R. Thomas Warf, Director, Manufacturing, Facilities & Engineering, BARDA, U.S. Department of Health & Human Services

*Panelists:*
Chris McDonald, Site Head, Holly Springs Site, Novartis Vaccines and Diagnostics
Vijay Yabannavar, Ph.D., Senior Vice President, Manufacturing Operations and Process & Analytical Development, Emergent BioSolutions
Andrew Strong, President and CEO, Kalon Biotherapeutics
Andrew Graham, Senior Director, Operations-Manufacturing, Nanotherapeutics, Inc.

12:20 Networking Luncheon followed by Exhibit/Poster Viewing and Dessert

1:25 **Chairman's Remarks**
Thorsten Peuker, Ph.D., Vice President, Integrated Solutions, Sartorius Stedim Biotech GmbH, Germany

**Implementing Single-Use and Other Technologies to Create More Flexible Facilities**

1:30 **Case Study: Single-use Mixing Systems in Large-scale Live-viral Vaccine Upstream Processes**
The rapid development and licensure of two live-attenuated viral vaccines produced in SP's Canton MA facility has been accelerated by the incorporation of single-use technology. We have successfully applied Single-use Mixing Systems (SUM) at various stages of the upstream processes for cell expansion and bioreactor harvest, all under closed-system aseptic conditions. Boundary-condition experiments for solution and suspension mixing were followed by investigations to establish cell suspension homogeneity while maintaining viability. Representative sampling, mixing homogeneity, and maintenance of cell viability results will be presented.

Daniel C. Vellom, Ph.D., Senior Director, Biotechnology Expert, Global Technology Innovation, Sanofi Pasteur Biologics, LLC

2:00 **Case Study: Increasing Control and Flexibility for Development and Manufacturing Processes**
A case study is presented comparing a single-use mAb process to an established stainless steel process. The quality of the molecule plus titer and cell growth is compared between the different technologies at different scales. Several clinical runs at 200L and 1250L scale were performed to ensure a meaningful comparison. Operator feedback on the ease of use and the necessary changes in the GMP area to introduce single-use technologies are also discussed.

Sebastien Ribault, Ph.D., Director, Bioproduction and Development, Merck Millipore, France

2:30 **Process4Success - Flexible Biomanufacturing Processes Addressing the Needs of the Future**
In order to reduce cost and shorten timelines, engineering efforts have to be reduced as much as possible. Generic process platform concepts for the overall process enable a faster execution time as well as more efficient qualification procedures. In this contribution, we focus on monoclonal antibody (mAb) processes as a major product class from the biopharmaceutical industry. A study will introduce our process platform concepts “Process4Success” integrating single-use equipment for an existing building and for a greenfield facility. In addition, innovative facility layouts using modular cleanrooms will be presented.

Thorsten Peuker, Ph.D., Vice President, Integrated Solutions, Sartorius Stedim Biotech GmbH, Germany
Fritjof Linz, Ph.D., Vice President, Global R&D, DSM Biologics

3:00 Networking Refreshment Break and Exhibit/Poster Viewing

**Featured Presentation**

3:30 **Case Study: Single Use Systems – An End User’s Perspective**
Shire, faced with the need to increase manufacturing capacity in a flexible way to meet growing demand for its commercial and clinical products, responded with construction of a state-of-the-art plant that maximized deployment of Single Use Systems (2011 ISPE Facility of the Year Honorable Mention). This talk will review the business case, the challenges associated with design and start-up, regulatory acceptance / approval, routine use of Single Use Systems, and some lessons learned along the way.

Alex Tschumakov, Director, Manufacturing, Shire

4:00 **"The Dinosaurs Reborn": Optimally Retrofitting Facilities for Flexibility**
One of the critical considerations for Biomanufacturers today, is how to make best use of their current facilities (‘dinosaurs’) in an environment that is becoming increasingly modular and single-use based. While existing facilities can be retrofitted at a fraction of the cost and downtime of building a new facility, analyzing the impact of new technologies is more difficult than for a ‘greenfields’ facility. In this talk, we examine data collected by Bio-G that show which areas have proven optimal for maximizing the flexibility of facility retrofits. We discuss a set of simple rules that can be used to understand where new technologies like disposables can be robustly applied. Several case studies will be presented.

Rick Johnston, Ph.D., Principal, BIO-G

4:30 **The Flexible Factory is Not Just a Room Full of Bags!**
Although “flexible” is defined as “capable of bending easily without breaking” it also means: “able to be easily modified to respond to altered conditions” or “able to adapt to different circumstances”. Biopharmaceutical manufacturers are riding the “wave of plastic” in an attempt to improve productivity, lower overall cost of goods and to lower the risk of their bioprocess operations. This presentation will compare facility design strategies in an attempt to understand where real manufacturing efficiencies can be gained.

Marc Pelletier, Ph.D., Director of Biotechnology, CRB Consulting Engineers

5:00 **Case Study: Implementing and Improving Disposable Systems in BioMarin's Manufacturing Environment to Meet Growing Capacity**
Abstract not available at time of print. Please visit www.IBCLifeSciences.com/Facilities for updates.

Chris M. Brodeur, Associate Director, Commercial Operations, BioMarin

5:30 Close of Conference

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**Take an Active Role in the Conference and Present a Poster**

Any registered conference attendee may register to present a poster. The deadline to submit an abstract online is January 27, 2014 to have the abstract be included in the conference materials. Full payment of conference registration and poster fees must be received by this date for the abstract to be included in the conference materials and a poster board assignment to be made (see the registration page for details on the poster fee). Posters should be PORTRAIT orientation, with maximum dimensions of 36 inches wide (3 feet) x 48 inches high (4 feet). Please note: Poster presentations may not be used as exhibit displays or for marketing purposes, and all posters are subject to approval by conference organizers. Only one poster presentation is allowed per registered attendee/author.

**For up-to-date program information and new abstracts, visit: www.IBCLifeSciences.com/Facilities**
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For more information, please contact: Sherry Johnson at sjohnson@ibcusa.com or 508-614-1451
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- Discover exciting new concepts in facility design and deployment so you can rapidly scale-up/scale-down while saving time and money
- Evaluate technical, regulatory and economic perspectives so you can make the right facility choice for your products
- Learn how to design a multi-product facility with closed systems to maximize output and reduce cross-contamination risk
- Hear practical implementation stories of single-use in facilities so you can capitalize on the opportunities and avoid the pitfalls

Register Today and Prepare your Facilities for the Future
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