Biopharmaceutical Development & Production Week At-A-Glance

Monday, March 1, 2010

Exhibit & Poster Hall Hours: 9:45 am - 6:30 pm

	Outsourcing Manufacturing of Biopharmaceuticals	Technology Transfer for Biopharmaceuticals	Process & Product Validation
8:00 am - 9:45 am	*Keynote Presentations:* **Lessons Learned and Where are We Going? – A CMO's Perspective** **John McGrath,** *Busniess Unit Head,* **Lonza Biologics** **The Critical Elements of a Successful Regulatory Filing for Outsourcing Biopharmaceutical Manufacturing** **Terry Milby, M.S.,** *Director, Regulatory CMC,* **Genentech, Inc.**		Process Monitoring – Prospective and Retrospective Approaches
9:45 am-10:30 am	*Networking Refreshment Break in Exhibit/Poster Hall*		
10:30 am - 12:00 pm	The Critical Roles of Due Diligence and Risk Management	Process of Process Transfers	Advances/Challenges in Drug Product Validation
12:00 pm - 12:30 pm	*Technology Workshop Presented by Bruker Daltonics*		
12:30 pm - 1:45 pm	*Luncheon in Exhibit/Poster Hall*		
1:45 pm - 3:00 pm	Contracts and Quality Agreements	Co-Development during Technology Transfer	Importance of Analytics in Process Validation
3:00 pm - 3:30 pm	Panel Discussion – Technical Aspects and Issues Surrounding Due Diligence		
3:30 pm- 4:00 pm	*Networking Refreshment Break in Exhibit/Poster Hall*		
4:00 pm - 5:00 pm	*Featured Presentations:* **Upstream Process Development Using a QbD Approach – Results from the CMC Biotech Working Group Case Study** **Victor A. Vinci, Ph.D.,** *Director, Bioprocess Operations, Bioproduct R&D,* **Eli Lilly and Company** **Downstream Process Development Using a QbD Approach – Results from the CMC Biotech Working Group Case Study** **Amit Banerjee, Ph.D.,** *Research Fellow, Global Biologics,* **Pfizer Inc.**		
5:00 pm - 6:30 pm	*Networking Cocktail Reception in Exhibit/Poster Hall*		

Tuesday, March 2, 2010

Exhibit & Poster Hall Hours: 9:45 am - 3:30 pm

8:00 am - 9:45 am	*Keynote Presentations:* **Global Regulatory Strategies for Validation and Transfer of Biotech Processes and Products** **Robert L. Garnick, Ph.D.,** *President & CEO,* **Lone Mountain Biotechnology and Medical Devices, Inc.** **Manufacturing Synagis: Life Cycle Management of a Life Saving Antibody** **Jeffrey Baker, Ph.D.,** *Senior Director, Manufacturing Sciences,* **MedImmune** *Featured Presentation:* **Humira History – The Impact of Global Technology Transfers and Validation – Challenges and Lessons Learned** **George Avgerinos, Ph.D.,** *Senior Director, Global Pharmaceutical Operations,* **Abbott Bioresearch Center**		
9:45 am - 10:15 am	*Networking Refreshment Break in Exhibit/Poster Hall*		
10:15 am - 11:45 am	Overcoming the Challenges of Outsourcing Antibody Drug Conjugates	Lessons Learned/Case Studies	Overcoming Facility and Logistical Challenges for Process Validation
11:45 am - 12:15 pm	*Technology Workshop Presented by Aegis*		
12:15 pm - 1:15 pm	*Luncheon in Exhibit/Poster Hall*		
1:15 pm - 3:00 pm	Ensuring Success and Quality of External Transfers – Sender and Recipient Perspectives		Upstream and Downstream Approaches to Process Validation
3:00 pm - 3:30 pm	*Networking Break in Exhibit/Poster Hall*		
3:30 pm - 5:00 pm	Transfer of Analytical Methods		Upstream and Downstream Approaches to Process Validation *(continued)* & Viral Validation Approaches

Wednesday, March 3, 2010

Exhibit & Poster Hall Hours: 9:45 am - 7:00 pm

	Antibody Development & Production	Recombinant Protein & Complex Biologic	Strategic Discussion Groups
8:00 am - 9:45 am	Cell Culture – What Comes Next after Titer Increase?	Applications of Systems Biology in Cell Culture	
9:45 am - 10:30 am	*Networking Refreshment Break in Exhibit/Poster Hall*		
10:30 am - 12:00 am	Cell Culture – What Comes Next after Titer Increase? *(continued)*	Overcoming Challenges of Cell-Culture Based Production	New Technologies for Antibody Purification *Sponsored by Sartorius Stedim North America*
12:00 am - 12:30 pm	*Technology Workshops Presented by Applied Biosystems and Bio-Rad Laboratories*		
12:30 pm - 1:45 pm	*Luncheon in Exhibit/Poster Hall*		
1:45 pm - 3:30 pm	Impact of Quality by Design / Design of Experiments on Process Development	Engineering Protein Expression Systems for Hard to Express Proteins – What are the Barriers?	2:00 Enabling Technologies - What are the Tools that will Take us to the Next Level?
3:30 pm - 4:00 pm	*Networking Refreshment Break in Exhibit/Poster Hall*		
4:00 pm - 5:00 pm	*Featured Presentations:* **Upstream Process Development Using a QbD Approach – Results from the CMC Biotech Working Group Case Study** **Victor A. Vinci, Ph.D.,** *Director, Bioprocess Operations, Bioproduct R&D,* **Eli Lilly and Company** **Downstream Process Development Using a QbD Approach – Results from the CMC Biotech Working Group Case Study** **Amit Banerjee, Ph.D.,** *Research Fellow, Global Biologics,* **Pfizer Inc.**		
5:00 pm - 7:00 pm	*Presentation and Cocktail Reception Sponsored by Pall Life Sciences in Exhibit/Poster Hall*		

Thursday, March 4, 2010

Exhibit & Poster Hall Hours: 9:45 am - 3:30 pm

7:15 am - 7:45 pm	*Technology Workshop Presented by Gyros*		
8:00 am - 9:45 am	*Keynote Presentations:* **Life Sciences Navigating the Sea Change** **G. Steven Burrill,** *Chief Executive Officer,* **Burrill & Company** **Industrialization of mAb Production: Implications, Challenges and Opportunities** **Dana C. Andersen, Ph.D.,** *Senior Director, Process R&D Oceanside, Operations & Engineering,* **Genentech, Inc.**		
9:45 am - 10:30 am	*Networking Refreshment Break in Exhibit/Poster Hall*		
10:30 am - 11:30 am	Approaches to Optimizing Manufacturability and Quality during Cell Line Development	10:30 am - 12:00 pm Upstream Challenges of Developing and Producing Specific Proteins	**Using BioSMB™ or Other ulti Column Approaches to Enable Facility Fit for High Titer Processes and to Decrease Clinical Manufacturing Scale and Costs** *Sponsored by Tarpon*
11:30 am - 12:00 pm	*Technology Workshops Presented by Bruker Daltonics and DSM Biologics*		
12:00 pm - 1:15 pm	*Luncheon in Exhibit/Poster Hall*		
1:15 pm - 3:00 pm	Capacity Issues and Facility Optimization	Current and Future Challenges in Downstream Processing for Specific Classes of Proteins	2:00 Outsourcing of Upstream Bioprocess Development *Sponsored by Thermo Scientific*
3:00 pm - 3:30 pm	*Networking Refreshment Break in Exhibit/Poster Hall*		
3:30 pm - 5:30 pm	Antibody Drug Conjugate Development & Production		

Friday, March 5, 2010

8:00 am - 10:15 am	Streamlining Development and Ensuring Robustness of Your Downstream Process	Alternative Scaffold Proteins	9:15 Can the Biopharma Industry Make Better Progress Working Together as a Community Rather than Individual Companies? What are the Hurdles?
10:15 am - 10:45 am	*Networking Refreshment Break*		
10:45 am - 11:45 am	Featured Presentations	Impact of Disruptive Technologies on Development of Protein Therapeutics	
11:45 am - 12:15 pm	*Technology Workshops Presented by GE Healthcare and WuXi Apptec*		
12:15 pm - 1:15 pm	*Luncheon and Presentation Sponsored by Pall Life Sciences (Space is limited)*		
1:15 pm - 3:00 pm	Demonstrating Comparability from Early Development through Approval		
3:00 pm - 3:30 pm	*Networking Refreshment Break*		
3:30 pm - 5:00 pm	Demonstrating Comparability from Early Development through Approval *(continued)* & Expanding the Scope of Process Monitoring and Control		

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