

Tuesday, May 1, 2012					
9:00am - 9:15am	Welcome and Introduction				
9:15am - 10:15am	Keynote: What the New Bio/Pharma Business Model Means for CMOs and CROs				
	Regulatory QA/QC	Product Development	Facility & Process Design	Manufacturing & Packaging	Supply Chain
10:30am - 11:30am	Case Study: Regulatory Consequences from Poor Microbiological Manufacturing and Laboratory GMPs	Panel Discussion: Best Practices and Regulatory Expectations in Continuous Processing	Case Study: You Need a Small Clean Room For.... So Where Do I Start?	Case Study: Implementing Single-Use Technologies in a GMP Facility	Guidance for Industry Process Validation: General Principles and Practices - A CMO's Approach
11:45am - 12:30pm	Technical Workshop: Fette Compacting America, Inc; Glatt Air Techniques; Pall Life Sciences				
12:30am - 1:30pm	Lunch				
1:30pm - 2:30pm	Keynote: Control, Capability, and Capacity: Elements Assuring a Reliable Drug Supply				
2:45pm - 3:45pm	Seven Things You Should Do Before Facing an Inspection	Technical Challenges in the Development of Biosimilars	Case Study: Optimizing Execution with Modular Construction	Single-Use Technology Enabling Biosimilar Manufacturing	Is Your CMO Committed to Your Success?
4:00pm - 5:00pm	Case Study: An Enterprise-Wide Approach to Global Change Management	Making Risk Assessment Part of Technology Transfer	Case Study: Greener Manufacturing with Reduce, Reuse, Recycle & Reclaim of Water	Case Study: Use of Pre-Sterilized Single-Use Disposable Fluid Paths in Sterile Manufacturing	Case Study: Pharmaceutical Distribution Outsourcing
Wednesday, May 2, 2012					
	Regulatory QA/QC	Product Development	Facility & Process Design	Manufacturing & Packaging	Supply Chain
9:00am - 10:00am	Export Control on Processing Equipment	Case Study: Designing Critical Cleaning Processes to Mitigate Microbial Risk in Multi-Product Facilities	Case Study: Meeting Sustainability Challenges with the Revamping of Your Wastewater Plant	Case Study: Aspects of a Sustainable Maintenance for a Lifecycle Cleaning Validation Program	Deploying Lean Six Sigma in Global Manufacturing Networks
10:15am - 11:15am	Keynote: Creating Innovative Cold Chain Solutions for your Pharmaceutical and Biopharmaceutical Products				
11:30am - 12:15pm	Technical Workshop: GE Healthcare; STERIS; Thermo Fisher Scientific				
12:15pm - 1:15pm	Lunch				
1:30pm - 2:30pm	Streamlining Risk Management Evaluations for New Manufacturing Processes	Case Study: Product and Process Understanding in Supporting Post-approval Change	Case Study: Asset Optimization & Flexible Multi-Product Facility Concepts: Abstract	Case Study: Translating the New Process Validation Paradigm to Cleaning Process	Supply Chain Security
2:45pm - 3:45pm	Manufacturing Execution Systems (MES) for BioPharm Manufacturers	Online Analytics as a PAT Tool to Enable QbD in Upstream Cell Culture	Case Study: Logistics Modeling and Architectural Layouts	Case Study: Introduction to the New ISPE Guide: Science and Risk Based Approach for the Delivery of Systems	A Knowledge-Based Approach to Supply Chain Pharmaceutical Temperature Control Management
4:00pm - 5:00pm	Proven Processes and Metrics to Optimize Operational Excellence: Co-Presentation	Bioburden Control for Sterile Filtration for Injectable Biotechnological and Pharmaceutical Drug Product Manufacturing	Implementing Commissioning and Qualification in Line with the FDA's Recent Process Validation Guidance	Case Study: Path to Reduce Operational Expenses and Improve Operational Efficiency	Regulatory Strategies and Considerations for Successful Site Transfers
5:00pm	Conference Ends				