

Monday, February 27

Exhibit Hall Hours: 10:00 am - 6:30 pm

	Process & Product Validation	Technology Transfer	Outsourcing	Raw Materials	Viral Safety
Morning	Progression of Process Validation & Recent Trends	Managing Risks in Technology Transfer	Compliance Audit & Quality Oversight	Strategies for Raw Material Variability Testing, Characterization & Control	Strategies & Solutions for Developing a Viral Safety Action Plan Regulatory Perspective
	Linking QbD, Design Space and New FDA Guidance	Facility Flexibility and Readiness in Technology Transfer	Co-Development with CMOs for Enhanced Technology or Innovation	Case Studies & Experiences in Upstream Process Development	Establishing Effective Viral Barriers
Afternoon	Interpreting and Implementing the New FDA PV Guidance	Case Studies on Overcoming Challenges in Tech Transfer	Modeling/Simulation Tools for Plant Optimization	Case Studies in Downstream Process Development & Manufacturing	Nanofiltration & Pre-Filtration
	Keynote Session			Strategies for Single Use & Disposable "Raw Materials"	Panel Discussion

Tuesday, February 28

Exhibit Hall Hours: 10:00 am - 4:00 pm

	Process & Product Validation	Technology Transfer	Outsourcing	Raw Materials	Viral Safety
Morning	Process Knowledge and Lifecycle Management in Enabling Continuous Verification	Ensuring Partnership Success During Technology Transfer		Mitigating Risk of Raw Material Contamination by Adventitious Agents	
	Trouble-shooting Challenges in Process Validation	Strategies for External Manufacturing and Measuring its KPI		Panel Discussion	
Afternoon	Trouble-Shooting Challenges in Process Validation	Supply Chain Risk Management		Raw Materials Management: Mitigation Initiatives and Control Strategies	Strategies & Technologies to Prevent Contaminations in Upstream & Downstream Development
	Case Studies and Strategies for Manufacturing Facility Control, Protection and Remediation	Evaluation and Quality Management of Supplier-Derived Raw Materials			Case Studies & Strategies for Manufacturing Facility Control, Protection & Remediation

Wednesday, February 29

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

	Antibody Development	Analytical Technologies	Recombinant Proteins	Biobetters & Biosimilars
Morning	Next Wave of Process Development – Improvements through Innovation, Integration and Optimization	Analytics of the Future - Development and Implementation of Novel Technologies and Tools	From Development to Manufacturing of Biobetters, Biosimilars and Novel Biologics	
	Implementation of Novel, Cost Effective Approaches to Capitalize on High Titer Processes	DUSP Introduces General Chapter <129> Quality Attributes of Therapeutic Monoclonal Antibodies	Scale Up and Transfer of Complex Biologics - Successful Approaches and Alternatives	Beyond Half-Life Extension
Afternoon	Improving the Interface Between Upstream and Downstream Processing	Higher Order Structure and Biophysical Techniques	Novel Approaches and Technologies to Overcome the Challenges of Downstream Processing	Extending Half-Life and Reducing Dosing Frequency
	Keynote Session			

Thursday, March 1

Exhibit Hall Hours: 9:45 am - 4:15 pm

	Antibody Development I	Antibody Development II	Analytical Technologies	Recombinant Proteins	Biobetters & Biosimilars
Morning	Impact of Antibody Engineering on Development and Production	Advances and Alternatives to Improve Harvest and Capture	Analytical Approaches to Developing Novel and Enhanced Molecules		Creating Biobetters with Enhanced Efficacy
	Advances in Cell Line Selection, Development and Engineering		Interfacing Analytics with Process Development and Formulations	Disruptive Technologies Causing Paradigm Shifts in Upstream and Downstream Processing to Improve Speed and Reduce Cost	Improving Delivery through Enhanced Formulations/Reducing Immunogenicity
	Overcoming Challenges of Developing and Delivering High Concentration Formulations				
Afternoon	Improving Product Quality in Process Development		Identifying and Controlling Critical Quality Attributes	Advances in Half-Life Extension	Value Proposition of Biobetters vs. Biosimilars
	Keynote Session				

Friday, March 2

	Antibody Development	Recombinant Proteins	Analytical Technologies	Biobetters & Biosimilars
Morning	New Approaches & Strategies for Characterization and Comparability			
	Development and Production of Novel Antibody Formats and Drug Conjugates		Development of High Powered Mass Spec Tools	Quality Testing and Assay Development of Biobetters & Biosimilars
Afternoon	Development and Production of Next Generation and Novel Molecules		Advances in High-Throughput Analytics, Data Analysis and Electronic Data Handling	Development of Biobetters/Biosimilars in China
			Process-Related Impurity Analysis	