Analytical Considerations When Developing ADCs, Bispecifics and Other Biotherapeutics

A Scientific Technology Summit

AUGUST 14-15, 2018

Waters Corporation 5720 Stoneridge Drive, Suite 200 Pleasanton, CA 94588

PRELIMINARY AGENDA - Day 1 - Tuesday, August 14th

44.00			
11:00 am	Arrival/Registration		
11:30 am	Complimentary Lunch		
12:00 pm	Welcome to Waters Luis Vaca, Waters		
12:10 pm	Summit Introductions Ananya Dubey Kelsoe, Waters		
1:00 pm	Overview of CMC Challenges, Regulations and Strategies for Biologics- From Today to MAM Jeffrey Staecker, BioPhia Consulting		
1:35 pm	The AQCUITY [®] Arc Bio System - A biocompatible UHPLC platform for your daily bioseparations challenges <i>Brooke Koshel, Waters</i>		
2:05 pm	Application of a Novel Phenyl RPLC Column for Heightened Characterization of Hydrophobic Monoclonal Antibodies and Antibody Drug Conjugates Jacquelynn Smith, Pfizer		
2:40 pm	Break		
3:00 pm	Early Stage LC-MS Based Workflow for N-Glycan Analysis and PTM Identification for Bispecific IgGs Gary Li, Aptevo Therapeutics		
3:35 pm	Biophysical Characterization of Antibody Conjugates and Related Species Shawn Owen, University of Utah		
	Stability and Contamination Studies of Antibodies using Isothermal Calorimetry Colette Quinn, TA Instruments		
4:05 pm	Beyond Aggregates: Light Scattering Tools for Studying Protein Binding and Stability Sophia Kenrick, Wyatt Technology		
4:35 pm	Technical Round Table Session #1: Regulatory Requirements and Analytical Challenges for Development of Biologics <i>Co-led by Jeff Staecker, BioPhia and Ann Gray, Waters</i>		
5:15 pm	Travel to Hotel/Restaurant		
5:30 pm	Poster Viewing and Cocktails at Restaurant		
6:15 pm	Dinner at Hap's Original Restaurant, 122 West Neal Street, Pleasanton Waters		
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PRELIMINARY AGENDA - Day 2 - Wednesday, August 15th



WORKKING LAB SESSIONS

8:30 am	Day 2 Welcome Ananya Dubey Kelsoe, Waters		
8:35 am	High Throughput Application of High Resolution LC-MS for Upstream and Downstream Biotherapeutics Process Development Daniella Cohen, Systimmune		
9:10 am	Deploying a Fit for Purpose LCMS Platform in Biopharmaceutical Regulated Development & QC <i>Min Du, Waters</i>		
9:45 am	Session 1:		
	Group A:	Multi-Attribute Monitoring Workflows in UNIFI® Scientific Information System Nilini Ranbaduge, Waters	
	Group B:	Application of High Resolution MS: Native Protein Analysis Maria Basanta Sanchez, Waters	
	Group C:	Routine Monitoring of Peptides using I-Class and ACQUITY [®] QDa [®] System Emily Sible, Waters	
10:20 am	Coffee Break		
10:30 am	Session 2:		
	Group A:	Routine Monitoring of Peptides using I-Class and ACQUITY [®] QDa [®] System Emily Sible, Waters	
	Group B:	Multi-Attribute Monitoring Workflows in UNIFI® Scientific Information System Nilini Ranbaduge, Waters	
	Group C:	Application of High Resolution MS: Native Protein Analysis Maria Basanta Sanchez, Waters	
11:05 am	Session 3:		
	Group A:	Application of High Resolution MS: Native Protein Analysis Maria Basanta Sanchez, Waters	
	Group B:	Routine Monitoring of Peptides using I-Class and ACQUITY [®] QDa [®] System Emily Sible, Waters	
	Group C:	Multi-Attribute Monitoring Workflows in UNIFI® Scientific Information System Nilini Ranbaduge, Waters	
12:10 pm	Lunch		
1:00 pm	Employment of Denaturing UPLC-MS and Native-MS to Expand Membrane Protein Characterization in a Biopharmaceutical Setting Jennifer Lippens, Amgen Inc.		
1:40 pm	Application of HDX-MS in Antibody Discovery Deepa Balasubramaniam, Eli Lilly and Company		
2:15 pm	Technical Round Table Session # 2: Heterogenous and Evolving Role of Mass Spectometry for Biotherapeutics Development and Quality Control Co-Led by Richard Seipert, Genentech and John Gebler, Waters		
3:00 pm	Meeting Conclu	ision & Departures	
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