1st Meeting on Advancing Analytics for Biotechnology Products

November 6-8, 2017
NIST Headquarters, Gaithersburg

An IABS and FDA Conference, co-sponsored by

This meeting is to bring together regulators, and scientists, or those interested in analytics from academia and industry to help resolve existing challenges in ensuring the quality of biotechnology medicinal products and to bring high quality medicines to patients. Guidance on how to use current and novel analytics for a variety of activities required during biotechnology product development such as method development, improvement and replacement, product comparability and process development and execution will be provided by the speakers and panel members. In addition, the complexity of the types of data and the volume being analysed is ever increasing and how best to manage such data will be discussed. The meeting will bring the right experts together to discuss the issues and through roundtables attempt to reach conclusions that will be valuable globally to public health.

Scientific / Organizing Committee

Antony Mire-Suis	AstraZeneca; Chair, IABS Biotherapeutics Scientific Committee
Michael Tarlov	National Institute of Standards and Technology (NIST)
Rohini Deshpande	Amgen
Emanuela Lacana	CDER FDA
Ingrid Markovic	CBER FDA
John Schiel	National Institute of Standards and Technology (NIST)
Dieter Schmalzing	Genentech
Patrick Swann	Biogen
Gary Takle	Merck and Co

AGENDA

Day 1 – Monday, November 6, 2017

7:30am **Registration & Welcome Coffee**

8:00am Introduction to the meeting and IABS
Tony Mire-Sluis, Chair – IABS Human Therapeutics Committee

Session 1 – Novel analytics for monitoring and controlling product quality

Chairperson: John Schiel, NIST

8:15am Multi attribute methods and raman for continuous assessment
Rajeev Ram, Massachusetts Institute of Technology, Cambridge, Massachusetts

8:45am Addressing the challenge of higher-order structure assessment of therapeutic monoclonal antibodies (mAbs) with NMR'
John Marino, National Institute of Standards and Technology (NIST), Gaithersburg, Maryland

9:15am Application of PAT tools (MAM, Raman, rapid sterility)
Valerie Tsang, Biogen, Raleigh-Durham, North Carolina

9:45am **Coffee Break**

10:15am Technologies for rapid micro testing and rapid PCR applications for adventitious agent testing
Ivar Kljavin, Genentech, a member of the Roche Group, San Francisco, California

10.45am Field flow fractionation for analysis of biotechnology samples
Robert Reed, Postnova

11:15am Roundtable discussion

12:00 noon **Lunch**

Session 2 - Novel Analytics for novel modalities

Chairperson: Kristen Nickens, CDER / FDA

1:00pm Process robustness in the manufacturing of new modalities: breakthrough technologies in cell and viral therapies
Eytan Abraham, Lonza

1:30pm mRNA vaccine analytics
Prakash Koodathingal, GlaxoSmithKline

2:00pm Analytical strategies for CART-cell therapies
Tam Soden, **Kite**

2:30pm **Coffee Break**

3:00pm Characterization of antibody drug conjugates
Oscar Salas-Solano, Seattle Genetics, Bothell, Washington

3:30pm Analytical characterization strategies for bispecific antibodies
Jingjie Mo, Janssen R&D (Johnson and Johnson), Philadelphia, Pennsylvania

4pm Roundtable discussion

5:00pm **End of Day 1**

Day 2 – Tuesday, November 7, 2017

Session 3 – Progress in bioassays and immunogenicity assays

Chairperson: Steve Bowen, CDER, FDA

8:15am Prediction of immunogenicity - where are we?
Annie de Groot, EpiVax, Providence, Rhode Island

8:45am Immunogenicity of aggregates – a current view
TBD, FDA

9:15am Critical questions for immunogenicity assay technology
Gopi Shankar, Janssen Research & Development, LLC (Johnson & Johnson), Philadelphia, Pennsylvania

9:45am **Coffee Break**

10:15am What does Quality by Design mean for bioassays?
Ken Miller, AstraZeneca, Gaithersburg, Maryland

10.45am Advancing laboratory efficiency through automation
Len Blackwell, Biogen, Raleigh-Durham, North Carolina

11:15am Roundtable discussion

12:00 noon **Lunch**

Session 4 – Employing complex technology and future perspectives on QC

1:00pm NMR of monoclonal antibodies
Yves Aubin, Health Canada

1:30pm Top-Down mass spectrometry of monoclonal antibodies - an inter-laboratory study
Joseph Loo, UCLA and the Consortium for Top-Down Proteomics

2:00pm Rethinking scientific data – applying the allotrope framework as an innovative solution advancing our capabilities to collaborate around shared scientific objectives
Janet Cheetham, Allotrope Foundation

2:30pm **Coffee Break**

3:00pm Optimizing QC now and in the future
Vinny Browning, Amgen, Thousand Oaks, California

3:30pm Considerations for moving new technology into a QC environment
Anthony Mire-Sluis, AstraZeneca, Gaithersburg, Maryland

4.00pm Roundtable discussion

5.00pm **End of Day 2**

Day 3 – Wednesday, November 8, 2017

Session 5– Progress in setting specifications

Chairperson: Ingrid Markovic, CBER, FDA

8:15am Cellular therapies: novel approaches to the problem of control
Jack Price, National Institute for Biological Standards and Control (NIBSC)

8:45am Specification and stability testing optimization
Barry Cherney, Amgen, Washington, D.C.

9:15am Specification setting using a QbD strategy to justify ranges
John Stults, Genentech, a Member of the Roche Group, San Francisco, California

9:45am **Coffee Break**

10:15am Roundtable discussion

Session 6 - Next-generation analytical tools

Chairperson: Rohini Deshpande, Amgen

11:00am Novel NGS, Next Generation Sequencing approach for clonality testing and biosafety
TBD

11.30am Biological 2D-IR spectroscopy
Christopher Middleton, PhaseTech Spectroscopy, Wisconsin

12:00 noon Lunch

1:00pm Individual particle electron tomography (Cryo-EM)
Sriram Subramanian, NIH, Bethesda, Maryland

1:30pm Advanced scattering approaches
Yun Liu, University of Delaware, Newark, Delaware

2:00pm Regulatory perspectives on the adoption of novel analytical technologies
Jeff Baker, FDA

2:30pm **Coffee Break**

3:00pm Roundtable discussion

3:45pm **End of Meeting**