Best of Biotherapeutics Analytical Summit VIRTUAL

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Empowering Innovation with the Right Tools & Techniques

ONE DAY EVENT | ALL TIMES EASTERN DAYLIGHT (UTC-4:00)

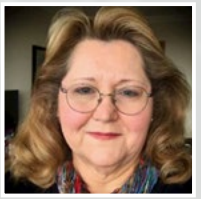
SEPTEMBER 29, 2020

2020 SUMMIT PRESENTERS

PRACTICAL APPROACHES | ENGAGING CASE STUDIES | CUTTING-EDGE TECHNIQUES

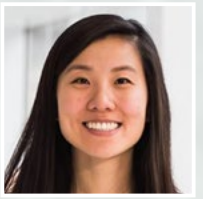
Laurence Fayadat-Dilman, PhD
Merck Research Lab

John P. Marino, PhD
NIST



Nadine M. Ritter, PhD
Global Biotech Experts LLC

Satish K. Singh, PhD
Moderna Therapeutics, Inc.



Jennifer Hu, PhD
Bristol-Myers Squibb

Monica Sadek
Genentech, Inc.

Cavan Kalonia, PhD
AstraZeneca Biologics

Yi Pu, PhD
Biogen

Slobodanka (Dina) Manceva, PhD
NIH/NIAID/VRC/VPP
Merck Research Lab

Brian Gfeller
Seattle Genetics, Inc.

Krishna Mallela, PhD
University of Colorado

Matt Traylor, PhD
Mosaic Biosciences, Inc.

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Best of
Biotherapeutics Analytical Summit VIRTUAL

SEPTEMBER 29, 2020

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Energize your research at this **one-day virtual program** of inspiring presentations and focused panels connecting people to science

As we face the unprecedented task of fighting this pandemic, we at CHI strongly believe that our community's collective expertise will lead to our success in overcoming it.

We're entering a new era of discovery and finding new ways to connect scientists to innovation. Join your peers at this one-day virtual summit, where leaders in biotherapeutics discovery share insights and experiences, and help turn the gears of innovation to speed development.

CHI is proud to be a leader in developing the pathways that spark research innovations, and in connecting the people who drive them, by presenting real-time research and technologies, novel discoveries and best practices from industry front runners and biotherapeutics leaders.

Don't miss this unique virtual biotherapeutics event.

September 29, 2020 | Accessible From Anywhere

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Best of Biotherapeutics Analytical Summit VIRTUAL

Empowering Innovation with the Right Tools & Techniques

SEPTEMBER 29, 2020

ONE DAY EVENT
ALL TIMES EASTERN DAYLIGHT (UTC-4:00)

This new 1-day Virtual Summit is the first in our series of "Best of" Biotherapeutics Analytical Summit, which will present key trends, compelling case studies, practical strategies and cutting-edge approaches that you've come to expect from our in-person event. Bringing together 4 of the hottest themes, the Summit will highlight developability strategies for candidate selection, impact of excipients and oxidative degradants, NMR for higher-order structure analysis, MAM for QC, characterization of AAV capsid proteins, and other critical topics of interest. Live Chat/Q&A Panels will enable attendees to engage with speakers throughout the sessions, and provide real-time answers to your questions.

We hope you'll join us as we embark on a new way of connecting people to science.

TUESDAY, SEPTEMBER 29

SESSION I: DEVELOPABILITY & DATA INTEGRITY

10:00 am Chairperson's Opening Remarks
Nadine M. Ritter, PhD, President & Analytical Advisor, Global Biotech Experts LLC

10:05 Predicting Antibody Developability Profiles through Early Stage Discovery Screening
Laurence Fayadat-Dilman, PhD, Senior Director, Protein Sciences, Merck Research Labs

10:25 Candidate Selection from a Pool of Engineered Protease Constructs Using Fit-for-Purpose Analytical Methods
Matthew Traylor, PhD, Principal Scientist, Mosaic Biosciences, Inc.
A preclinical candidate was selected from a diverse pool of engineered protease constructs expressed in mammalian and bacterial hosts. Selection from this diverse pool required generic analytical methods and candidate ranking based on developability/QbD principles with an emphasis on production levels and intrinsic stability. Analytical methods were further developed as the program progressed with a fit-for-purpose approach based on performance monitoring and streamlined method verification.

10:45 Current and Emerging Expectations for R&D CMC Data Integrity
Nadine M. Ritter, PhD, President & Analytical Advisor, Global Biotech Experts LLC
- What kind of data integrity operational elements are appropriate for R&D vs. GxP labs?
- How can it be confirmed that everyone in the lab understands the rationale and justification of quality practices for R&D CMC labs?
- How can a regulatory affairs reviewer assure all of the R&D data included in a product dossier are in fact authentic, complete, accurate, etc.?

11:05 Sponsored Presentation *(Opportunity Available)*

11:15 Live Chat / Q&A Session: Early Analytical Characterization - Harnessing Technologies to Speed Developability and Candidate Selection
Moderator: Nadine M. Ritter, PhD, President & Analytical Advisor, Global Biotech Experts LLC
Panelists:
Sarah Auclair, PhD, Scientist, Developability & Preformulation Sciences, Sanofi
Laurence Fayadat-Dilman, PhD, Senior Director, Protein Sciences, Merck Research Labs
Matthew Traylor, PhD, Principal Scientist, Mosaic Biosciences, Inc.

11:30 Refresh Break

SESSION II: IMPURITIES & DEGRADANTS

11:40 Chairperson's Opening Remarks
Satish K. Singh, PhD, Head, Sterile Product Technology, Moderna Therapeutics, Inc.

11:45 The Impact of Excipients and Oxidative Degradation on Protein Product Stability
Satish K. Singh, PhD, Head, Sterile Product Technology, Moderna Therapeutics, Inc.
Excipients in drug products fulfill a range of functions. In parenteral protein biotherapeutics, excipients provide physical and chemical stability, while contributing to osmolality. Excipients can however display complex behavior and under certain circumstances, may even destabilize the active protein molecule. Additionally, excipients may not be pharmacologically inert. Excipients must therefore be selected with care, and their control considered during development of the control strategy for the product.

12:05 pm Protein Adsorption and Degradation at Surfaces
Cavan Kalonia, PhD, Scientist II, Formulation, AstraZeneca Biologics
Physical degradation and aggregation of proteins at interfaces (e.g., solid-liquid, liquid-liquid, and air-liquid) can negatively impact the manufacturability, shelf-life stability, and administration of protein therapeutics. In this work, we have collaborated with the National Institute of Standards and Technology and University of Manchester to implement and develop state of the art metrology and modeling tools to investigate protein interfacial degradation at pharmaceutically relevant surfaces.

12:25 Characterization of HEK 293 Host Cell DNA in Cell Therapy
Jennifer Hu, PhD, Bioanalytical Scientist, Cell Therapy Development & Operations, Bristol-Myers Squibb
Manufacturing of CAR T cell products relies on viral vectors for transgene delivery. During vector production, washing and nuclease treatment steps aid in the clearance of residuals, but there is a potential for DNA impurities to exist in the vector

product and be transferred into the CAR T drug product. Residual DNA is a critical quality attribute. A risk-based analytical strategy for characterizing DNA impurities will be presented.

12:45 Sponsored Presentation *(Opportunity Available)*

12:55 Live Chat / Q&A Session: Strategies & Techniques to Improve Characterization of Particles & Impurities

Moderator: Satish K. Singh, PhD, Head, Sterile Product Technology, Moderna Therapeutics, Inc.

Panelists:

Niomi R. Peckham, MSc, Science & Standards Liaison, Global Biologics, US Pharmacopeia

Shu Min Zhang, Associate Fellow & Investigator, BPD Analytical Sciences & Biopharm R&D, GlaxoSmithKline

Cavan Kalonia, PhD, Scientist II, Formulation, AstraZeneca Biologics

Jennifer Hu, PhD, Bioanalytical Scientist, Cell Therapy Development & Operations, Bristol-Myers Squibb

1:10 Lunch Break

SESSION III: CUTTING-EDGE TECHNOLOGIES & APPLICATIONS

1:50 Chairperson's Opening Remarks

Krishna M.G. Mallela, PhD, Associate Professor, Pharmaceutical Sciences, University of Colorado Anschutz Medical Campus

1:55 Higher Order Structure Assessment of Biotherapeutics Using NMR

John P. Marino, PhD, Group Leader, Biomolecular Structure & Function Group, NIST

Development of high-resolution techniques for defining the higher order structure (HOS) of biotherapeutics has emerged as a priority in the pharmaceutical industry. This talk will describe applications of nuclear magnetic resonance (NMR) for HOS assessment, with a focus on mAbs. It will cover the extent to which NMR can detect and assign HOS differences and provide examples of chemometric methods for automated spectral analysis.

2:15 Qualification of MAM for QC

Monica Sadek, Technical Development Research Associate, Protein Analytical Chemistry, Genentech, Inc.

Multi-attribute method (MAM) is a peptide mapping-based method that provides targeted monitoring of product quality attributes and non-targeted new peak detection. MAM has been implemented in the pharmaceutical industry for process development and is advancing into the quality control (QC) environment in alignment with quality by design principles. This talk describes the qualification of MAM as a potential platform method for QC at Genentech.

2:35 2D NMR Methods for Analytical Characterization of Protein Drug Substances and Drug Products

Krishna M.G. Mallela, PhD, Associate Professor, Pharmaceutical Sciences, University of Colorado Anschutz Medical Campus

Nuclear magnetic resonance (NMR) spectroscopy provides site-specific atomic-level information about protein drugs, and hence can detect any changes in local protein structure and dynamics that are often not detectable by global probes, such as circular dichroism and fluorescence. We will present recent case studies in which we used 2D NMR techniques to probe antibody-polysorbate interactions and the effect of chemical modifications on therapeutic proteins.

2:55 Presentation to be Announced

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3:25 Live Chat / Q&A Session: New Trends and Data Science Approaches in Analytical Development of Vaccines & Biotherapeutics

Moderator: Krishna M.G. Mallela, PhD, Associate Professor, Pharmaceutical Sciences, University of Colorado Anschutz Medical Campus

Panelists:

John P. Marino, PhD, Group Leader, Biomolecular Structure & Function Group, NIST

Monica Sadek, Technical Development Research Associate, Protein Analytical Chemistry, Genentech, Inc.

3:40 Refresh Break

SESSION IV: CHARACTERIZING NOVEL & COMPLEX MODALITIES

3:50 Chairperson's Opening Remarks

Slobodanka (Dina) Manceva, PhD, Senior Scientist, Formulation and Stabilization Sciences, NIH/NIAID/VRC/VPP

3:55 Identification and Characterization of Adeno-Associated Virus (AAV) Capsid Proteins by Mass Spectrometry

Yi Pu, PhD, Scientist II, Analytical Development, Biogen

The development of mass spectrometric (MS) methods for characterization of AAV capsid proteins allows for the complete structural elucidation of constituent viral capsids in gene therapy development. Conventional peptide map and intact protein analysis, as well as a recently developed ZipChip capillary electrophoresis-MS method will be discussed for various AAV capsid analyses, including serotype identification, confirmation of mutation and characterization of post-translational modifications.

4:15 Broadening the Expectations: Characterization and Stability Indicating Assay Identification for Conjugate Vaccines

Slobodanka (Dina) Manceva, PhD, Senior Scientist, Formulation and Stabilization Sciences, NIH/NIAID/VRC/VPP

Methods for characterization and stability assessment of therapeutic monoclonal antibodies (mAbs) are well established. Same applies to protein subunit vaccine candidates. However, when working with conjugated products, this does not hold true. Here we present the challenges, findings, and at the end the bordering of expectations, in evaluation and identification of assays suitable for characterization, formulation and stability assessment of a conjugated vaccine candidate.

4:35 Implementation of MS Peptide Map for ADC Characterization: A Perspective from a High-Throughput Service Lab

Brian Gfeller, Senior Research Associate, Seattle Genetics, Inc.

Streamlining ADC process development activities is key for enabling fast-to-clinic timelines. Increasingly, we find the need to implement mass spectrometry to characterize our ADCs during preclinical development activities. In this talk, we will focus on workflows that we have implemented to alleviate two methodological pain-points; data analysis and sample preparation, to ensure we support process development.

4:55 Sponsored Presentation *(Opportunity Available)*

5:05 Live Chat / Q&A Session: Analytical Characterization at the Different Phases of Product Development - Challenges and Tips to Fast-Tracking

Moderator: Slobodanka (Dina) Manceva, PhD, Senior Scientist, Formulation and Stabilization Sciences, NIH/NIAID/VRC/VPP

Panelists:

Yi Pu, PhD, Scientist II, Analytical Development, Biogen

Brian Gfeller, Senior Research Associate, Seattle Genetics, Inc.

5:20 Close of Summit

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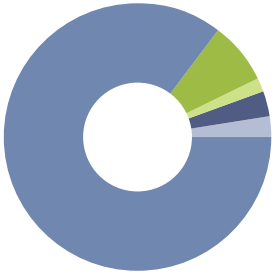

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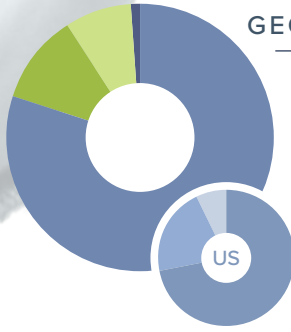

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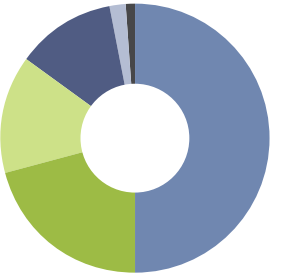

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