11th Annual Biotherapeutics Analytical Summit

Empowering Innovation with the Right Tools & Techniques

JUNE 1-5, 2020 | ALEXANDRIA, VA
WESTIN ALEXANDRIA HOTEL

Register by March 13 & Save up to $500

Keynote & Featured Speakers

Alain Beck, PhD
Senior Director, Biologics CMC & Developability, Center for Immunology, Pierre Fabre

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

Nadine M. Ritter, PhD
President & Analytical Advisor, Global Biotech Experts LLC

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

Emily Shacter, PhD
Consultant, ThinkFDA LLC

CONFERENCES

Early Analytical Development of Biotherapeutics

Characterizing Novel Modalities

Impurities & Degradants

Advances in Characterization, Comparability & Analytical Similarity

TRAINING SEMINARS

• Practical Strategies for Analytical Method Lifecycle Management for Biological Products
• Regulatory Requirements across the Product Development Lifecycle

SHORT COURSES

• Particles in Biotherapeutics: Characterization & Impact
• Advanced Analytical Technologies for Developability and Early Formulation Assessments
• Critical Quality Attributes and Testing Strategy for Biotherapeutics Development
• Gene Therapy Products: Phase-Appropriate Analytical Development Strategies

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Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve your booth today!

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2019 ATTENDEE DEMOGRAPHICS

COMPANY TYPE
- Biotech & Pharma 86%
- Academic & Government 7%
- Healthcare 2%
- Commercial 3%
- Services 2%

DELEGATE TITLE
- Scientist/Technologist 50%
- Executive/Director 21%
- Manager 14%
- Sales & Marketing 12%
- Professor 2%
- Assistant 1%

GEOGRAPHIC LOCATION
- United States 80%
- Europe 11%
- Asia 8%
- Rest of World 1%
- East Coast 72%
- West Coast 21%
- Midwest 7%
SC1: Particles in Biotherapeutics: Characterization & Impact

Instructors:
Dean C. Ripple, PhD, Group Leader, Bioprocess Measurements Group, NIST
Srivalli Telikepalli, PhD, Research Chemist, Biomolecular Measurement Division, NIST

Introduction:
This short course will give an introduction to current issues surrounding particle formation & characterization in biotherapeutics. Regulatory expectations provide the context of why particle loads are characterized and controlled. The basics of why and how proteins can aggregate will be presented along with a discussion of other particle types. An overview of the recent technology to accurately characterize various classes of aggregates and particles will be discussed. Studies from the current literature will be used to highlight various key points throughout the course.

Topics covered include:
1. Introduction to Protein Aggregates & Other Particles
   • Overview of particles in biotherapeutics: protein aggregates & other types
   • Current regulatory expectations
   • Rationale for characterization & control
   • Recent experiences & case studies
2. Causes & Mechanisms behind Aggregation/Particle Formation
   • Causes of protein aggregation
   • Mechanisms behind formation of aggregates
   • Sources of other types of particles
   • Methods to minimize aggregation & particle formation
   • Case studies
3. Technologies & Tools for Measuring & Characterizing Aggregates & Particles
   • Visible particles (manual and automated inspection)
   • Sub-visible particles (microflow imaging, light obscuration, etc.)
   • Sub-micrometer aggregates (size exclusion SEC, AUC, FFF, etc.)
   • Approaches to standardize particle counts
   • Comparisons between technologies regarding limits of detection
4. Strategies for Particle Control & Characterization
5. Discussion with Q&A

SC2: Advanced Analytical Technologies for Developability and Early Formulation Assessments

Instructor:
Danny K. Chou, PhD, Founder & CEO & President, Formulation Development & Protein Characterization, Compassion BioSolutions LLC

Introduction:
For biopharmaceuticals, drug design, lead selection and formulation/ manufacturing process development constitute significant areas of risk because of their decisive influence on product quality, biological activity and safety, as well as cost of goods. The purpose of this short course is to introduce how a range of advanced analytical technologies, along with the concept of Quality by Design (QbD) may be incorporated at the interface of drug discovery and development in order to both select drug candidates with the best inherent stability and deliver the most suitable formulation for these molecules. Part of the course will be focused on the practical tools (both conceptual tools and analytical tools) one can use to achieve this objective.

Topics covered include:
• What are developability and formulability and how they relate to the principles of Quality by Design?
• How to assess formulability of a new therapeutic protein drug candidate: Define the suitability of a given drug candidate to be formulated for a desired route of administration or delivery method.
• What are some off-the-shelf tools that are available (statistical, time-saving approaches, and analytical tools that can help us assess molecules on attributes include, among others, solubility, aggregation, viscosity or product stability.
• A real case study of how one implements some of the tools mentioned above to evaluate new therapeutic protein drug candidates.

Who Should Attend?
Scientists, Project leaders, or Heads of departments for drug discovery, formulation, R&D, analytical development, process development, technical and pharmaceutical development.

SC3: Critical Quality Attributes and Testing Strategy for Biotherapeutics Development

Instructor:
Christine P. Chan, PhD, Director, Global Manufacturing Science & Technology, Sanofi

Introduction:
Biotherapeutics are challenging to develop due to the complexity of the molecular structure as well as the manufacturing process. Identification of product critical quality attributes (CQAs) is an important component in the development of a robust control strategy using the Quality-by-Design approach. In this short course, we will discuss the key concepts of CQA risk ranking based on potential impact on safety and efficacy, defining control strategies, the common analytical characterization technologies used, and the considerations for development of an integrated testing strategy.

Topics covered include:
• CQA criticality assessment: leveraging prior knowledge and gathering product structure-function relationship (SAR) information;
• Acceptable ranges through development stages
• Analytical characterization strategy and test methods selection: commonly used assays and emerging tools
• Conducting forced degradation studies; product stability profile
• Linkage of process to product quality: defining control strategies, comparability studies
• Towards a streamlined testing strategy: evolving the test panel and specifications through the product lifecycle
• Practical examples and discussions

SC4: Gene Therapy Products: Phase-Appropriate Analytical Development Strategies

Instructors:
Francis Poulin, PhD, Scientific Director, Analytical Development, Sanofi
Claire Davies, PhD, Associate Vice President, Bioanalytics, Sanofi

Introduction:
This short course introduces concepts that can be used to facilitate analytical development for gene therapy products. The instructors will review regulatory guidance and present phase-appropriate analytical development and control strategies. Several challenges unique to this modality will also be discussed. The course combines instruction and an interactive workshop on platform method development.

Topics covered include:
• Overview of Manufacturing for Gene Therapy Products
• Analytical Development Strategies
• Phase appropriate Control strategy
• Comparability and Stability
• Regulatory guidance and unique challenges for gene therapy
• Interactive workshop on platform method development

Who Should Attend:
Research Associates, CMC and analytical project leads, regulatory affairs specialists and managers, process and analytical development scientists.
Instructor: Nadine M. Ritter, PhD, President & Analytical Advisor, Global Biotech Experts LLC

Practical Strategies for Analytical Method Lifecycle Management for Biological Products

Introduction/Objective of the Seminar:
Current GMP requirements for test method validation are quite clear: Methods used for GMP product testing must be validated to demonstrate they can produce accurate and reliable results. But FDA and EU guidances are less clear about method ‘validation’ during product development. On one hand, they indicate method validation is an evolving process, but on the other they state that method validation data should be available upon request at Phase 2 and Phase 3. These guidances also indicate that test methods only need to be qualified for Phase 1 (except safety methods, which do require validation prior to Phase 1). Methods used only for product or process characterization, comparability or similarity also need to be qualified to demonstrate they are scientifically sound. Some of these methods will start out in non-GMP labs, then transfer to GMP labs; others will only ever be used in non-GMP labs. But during development, even data generated in non-GMP studies are critical for making process and product decisions, and are reported in product dossiers as supportive information. Although there is guidance on lab data integrity in GMP labs, there are no current guidance documents on data integrity in non-GMP labs.

The Seminar will cover:
• Overview of ICH, FDA and EU guidance documents associated with method validation and data integrity for in-house and contract testing labs
• Outline of types of test methods typically used with biotech/biosimilar products for characterization, comparability, similarity, release and stability testing
• Illustration of typical method lifecycle events for test methods (optimization, qualification, validation, method changes, method transfer, method replacement)
• Differences in study designs between qualification, validation, verification, tech transfer and bridging for biotech/biosimilar products
• Overview of data integrity expectations for GMP analytical testing labs
• Risks to data from non-GMP R&D labs at each phase of development and for key CMC analytical studies
• Illustration of best practices for lab quality and data integrity for non-GMP R&D labs

Target audience:
• Analysts from R&D (non-GMP) and QC (GMP) laboratories
• Process development scientists conducting process design, QbD, PPQ and CPV studies
• QA reviewers of analytical data from key CMC process and product studies
• RA managers of CMC analytical and stability dossier sections and updates
• CMC project managers for pre- and post-approval activities
• Personnel involved with in-house testing and/or contract testing facilities

Nadine Ritter obtained her master and doctoral degrees in cell and molecular biology at Rice University (Houston, TX). She entered the biopharm industry as a protein chemist in analytical R&D at Abbott Laboratories where she performed development, validation, transfer and troubleshooting of test methods for the analytical QC lab, and contributed to compliance remediation efforts for QC inspection observations. She later joined BioReliance as the Director of the Analytical Services. There, she led a team of CMC scientists in the design and conduct of method qualification, validation, and transfer, product characterization and comparability studies, and QC release and stability testing. In 2003, she was one of six industry and two FDA founders of the CaSSS CMC Strategy Forum, which has led to the publication of major industry/regulatory white papers on CMC topics. In 2014, Nadine formed Global Biotech Experts. LLC., and is a renowned speaker and instructor at many conferences.
The Seminar will cover:
- The evolution of drug compliance in the US
- FDA structure and function
- The product development timeline from IND to commercialization
- Special considerations for newer treatment modalities
- Good laboratory practice
- Good manufacturing practice
- Compliance across the product development lifecycle
- The CMC section of the initial IND
- Meetings with FDA during drug development
- The BLA, NDA and beyond

Christina Vessely, PhD, RAC, has over 18 years of experience in analytical and formulation development within the biotechnology industry. Her experience ranges from early stage research and development for small and start-up firms through late stage development and commercialization for mid-sized and large pharmaceutical companies. She has been involved in priority review and fast track programs, she has participated in pre-approval inspections (PAI) and PAI enabling activities such as design and execution of validation studies and evaluation of GMP systems, as well as authoring and editing of analytical sections for multiple filings in both the U.S. and in the EU (IND/IMPD, BLA/MAA).
Early Analytical Development of Biotherapeutics
Accelerating Candidate Selection and Lead Optimization

MONDAY, JUNE 1

7:30 am Registration and Morning Coffee
8:30 Welcome by Conference Organizer
8:35 Chairperson’s Remarks
Krishnan Sampathkumar, PhD, Senior Director, Analytical and Drug Product Sciences, Development, MacroGenics, Inc.

Joint Opening Plenary Session

8:40 KEYNOTE PRESENTATION: Cutting-Edge, Multi-Dimensional Chromatographic, Electrophoretic, and Mass Spectrometry Methods for Biologics
Alain Beck, PhD, Senior Director, Biologics CMC & Developability, Center of Immunology, Pierre Fabre
State-of-the-art techniques, such as LC, high-resolution native, and ion mobility mass spectrometry (IM-MS), multi-dimensional (2-4D) LC (RP, HIC, HILIC, CEX, SEC), and capillary electrophoresis hyphenated to MS will be discussed, as well as additional MS fragmentation techniques (CIU, UVPD, TDS). Multiple-level and orthogonal workflows case studies for mAbs, biosimilars, ADCs, BsAbs, and Fc-fusions will be presented.

9:10 KEYNOTE PRESENTATION: The Impact of Excipients and Oxidative Degradation on Product Stability
Satish K. Singh, PhD, Head, Sterile Product Technology, Moderna Therapeutics, Inc.
Excipients in drug products fulfill a range of functions. In 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 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.

9:40 KEYNOTE PRESENTATION: 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.?
• What should be done if errors or omissions are discovered in key R&D CMC study reports?

10:10 PANEL DISCUSSION: Challenges in Ensuring Data Integrity in R&D and GxP Labs: Emerging Regulatory Policies and Best Laboratory Practices
Moderator: Nadine M. Ritter, PhD, President & Analytical Advisor, Global Biotech Experts LLC
• Which CMC data are at risk?
• How to ensure the R&D data are authentic, complete and accurate
• What operational control mechanisms should be in place?
• What have been good vs. bad experiences with R&D data integrity?

10:40 Networking Coffee Break

Analytical Strategies for Early Stage Development

11:10 Chairperson’s Remarks
Matthew Traylor, PhD, Principal Scientist, Mosaic Biosciences, Inc.

11:15 Analytical Method Development and Characterization Strategies for Early-Stage Novel Antibody-Based Molecules
Krishnan Sampathkumar, PhD, Senior Director, Analytical & Drug Product Sciences, MacroGenics, Inc.
Monoclonal antibodies and novel bispecific DART® molecules are being developed for a variety of indications including immune-oncology. Stage-appropriate and risk-based analytical control strategy needs to be developed to ensure product quality as molecules progress from early to late stages of development. This presentation will discuss analytical method development and high-throughput characterization approaches during early stages of development using the above molecules as case studies.

11:45 KEYNOTE PRESENTATION: Early Cell Culture Development of Biotherapeutics
Rachel Chen, PhD, Scientist II, Analytical Development, Biogen
Accelerating early development of biotherapeutics to enable a fast timeline to first-in-human trials has been of interest across the industry. This presentation discusses the analytical strategies and opportunities to accelerate program development timelines while maintaining product quality, safety, and efficacy. These include establishing efficient characterization plans via prior knowledge, utilizing high-throughput assays and automation, and developing platform and molecule-specific methods to meet product quality requirements.

12:15 pm Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

12:45 Session Break

Developability Assessment and Candidate Selection Strategies

1:30 Chairperson’s Remarks

1:35 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.

2:05 High-Throughput Developability Platform to Screen Therapeutic Candidates for Biophysical and Biochemical (PTM) Liabilities
Amish Karanjit, Scientist, Denali Therapeutics Inc
Biotherapeutic developability assessment (DA) represent a new industry trend. At Denali, we apply a series of state-of-the-art analytical and biophysical technologies to carry out these molecular assessments as early as possible in the preclinical stage of development to select the candidate with the most stable profile. Here we present a case study where we use these techniques to characterize the biophysical stability of therapeutic proteins.

2:35 Sponsored Presentation (Opportunity Available)

3:05 Networking Refreshment Break and Breakout Discussions
4:30 Integrated Analytical Strategies in Developability Assessment for Complex Modalities
Guodong Chen, PhD, Research Fellow, Pharmaceutical Candidate Optimization, Research & Development, Bristol-Myers Squibb Company
Since the introduction of the first recombinant DNA-derived insulin, the biopharmaceuticals market has shown steady growth. Given significant challenges in the treatment of many life-threatening diseases, biopharmaceuticals are becoming increasingly complex. Integrated analytical strategies are required to address potential issues in developability assessment for such complex molecules. This presentation will discuss recent developments in leveraging protein analytics for elucidating key aspects of molecular developability.

5:00 Analytical Challenges with Complex Modalities in Developability Assessments
Sarah Auclair, PhD, Scientist, Developability & Preformulation Sciences, Sanofi
Determining the development risk of an IgG1 mAb therapeutic is relatively straightforward. However, multi-specific antibodies, Fc-fusion, Fab, or other novel modalities can present many analytical challenges. As more complex modalities enter the biologics drug development landscape, developability assessments must remain flexible to address the challenges that they exhibit. This talk will highlight several case studies where biophysical characterization has been instrumental in determining risk.

5:30 Close of Day One and Dinner Short Course Registration

6:00 Dinner Short Courses

SC1: Particles in Biotherapeutics: Characterization & Impact
SC2: Advanced Analytical Technologies for Developability & Formulation Assessments

TUESDAY, JUNE 2

8:00 am Morning Coffee

Early Stage Formulation Development

8:30 Chairperson’s Remarks
Lisa A. Kueltzo, PhD, Director, Formulation & Stability, Vaccine Production Program Lab, NIH NIAID

8:35 Parallelism and Risk in Early Formulation Development: Strategies and Case Studies
Lisa A. Kueltzo, PhD, Director, Formulation & Stability, Vaccine Production Program Lab, NIH NIAID
“First-in-human” biologic programs often rely upon rapid development of GMP suitable process, analytics and formulation, to reach Phase I trials as quickly as possible. Complex programs, (co-formulated therapeutics, multi-valent vaccines) can require parallel development of multiple components. This talk discusses potential risks of parallelism in early stage development, specifically formulation, analytical and stability challenges that arise and strategies to overcome them.

9:05 Evaluation and Implementation of Automated Buffer Exchange for Early-Stage Formulation Development
Huan Kang, PhD, Development Scientist I, Alexion Pharmaceuticals
Buffer exchange is a critical step during formulation development. However, the process is labor-intensive and time-consuming, requiring multiple cycles of manual buffer refills and mixing. An automated buffer exchange workflow in a 96 well format is implemented using Big Tuna and evaluated using a model protein. Implementation of automation enables early-stage high-throughput formulation screening in a timely manner.

9:35 Sponsored Presentation (Opportunity Available)

10:05 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Early Implementation of QbD in Biopharmaceutical Development, and Practical Approaches to Biopharmaceutical Candidate Selection and Formulation Development
Danny K. Chou, PhD, Founder & CEO & President, Formulation Development & Protein Characterization, Compassion BioSolutions LLC
Early developability assessment of biopharmaceutical drug candidates, using rational methodologies and computational methods, can assist in reducing stability risks during development in a cost-effective way. In this presentation, the author will discuss one potential algorithm to illustrate how developability strategies can be introduced in practical terms during early protein drug development in order to mitigate risks, and ultimately increase the robustness of the biopharmaceutical.

11:15 Challenges and Mitigation in Early-Stage Formulation Development of Biologics
Yongmei Wu, Principal Scientist, Drug Product Science & Technology, Bristol-Myers Squibb Co.
The presentation will focus on major challenges in formulation development, analytical method development and stability assessment of biologics drug candidates in early phase clinical trials. Mitigation strategies used to stabilize the biologics will be discussed. Close collaboration of formulation scientists and analytical scientists are essential to ensure quality and successful product development within aggressive timelines. Case studies will be included in the presentation.

11:45 Early Prediction of Particle Formation in Protein Formulation during Long-Term Storage
Ying Wang, Assistant Professor, Chemistry, University of North Carolina Wilmington
In biologics formulation development, particle formation in protein solutions is often monitored over 2-3 years. Early assessment of the risk of particle formation is difficult because some protein particles form in a stable formulation solution only after months of storage. Here, I will present an analytical method to evaluate the risk of particle formation in monoclonal antibody solutions with a lag-time during long-term storage.

12:15 pm Close of Early Analytical Development of Biotherapeutics

“I found it to be a very interesting, well run and attended meeting. I most enjoyed the case studies, but I also liked the poster sessions and being able to talk with the other speakers one on one. I also met some old colleagues that I hadn’t seen in many years.”

Associate Director, ImmunGen
MONDAY, JUNE 1

7:30 am Registration and Morning Coffee

8:30 Welcome by Conference Organizer

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Krishnan Sampathkumar, PhD, Senior Director, Analytical and Drug Product Sciences, Development, Macrogenics

Joint Opening Plenary Session

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Alain Beck, PhD, Senior Director, Biologics CMC & Developability, Center of Immunology, Pierre Fabre

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Nadine M. Ritter, PhD, President & Analytical Advisor, Global Biotech Experts LLC

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Which CMC data are at risk?

How to ensure the R&D data are authentic, complete and accurate

What operational control mechanisms should be in place?

What have been good vs. bad experiences with R&D data integrity?

10:40 Networking Coffee Break

Characterizing Product-Related Impurities

11:10 Chairperson's Remarks
Bernice Yeung, PhD, Director, Protein Analytical Chemistry, Analytical Development, Biogen

11:15 Impurities and Potential Impact on Generating Immunogenicity Response to a Biotherapeutic
Boris Gorovits, PhD, Senior Director, Pharmacokinetics, Pharmacodynamics & Metabolism, Pfizer Inc.

All biotherapeutics have the potential to induce an unwanted immunogenicity response with significantly varying clinical sequelae. Potential consequences of anti-drug antibody induction include loss of exposure, associated loss of efficacy as well as immediate or latent hypersensitivity reactions and other safety related concerns. The degree of immune response may significantly contribute to the success or failure of the product. Related risk factors are often described as intrinsic (drug substance specific) and extrinsic (associated with patient status, treatment and other product characteristics). Intrinsic factors include protein aggregates, co-purified contaminants and impurities, variety of post-translational adducts. The origin and immunogenicity induction impact potential of various impurities and contaminants will be discussed.

11:45 In vitro Immunogenicity Risk Assessment of Aggregates & Impurities in Protein Formulations
Michael D. Swanson, PhD, Senior Scientist, Biologics & Vaccines Bioanalytics, Merck & Co., Inc.

Protein aggregates and other impurities found in drug products have the potential to stimulate immune responses. Aggregation of proteins can result in increased innate and adaptive phase responses. Contaminating host cell proteins (HCP) can also be immunogenic and could potentially impact drug efficacy and safety. Here, in silico and in vitro tools for immunogenicity risk assessment of aggregates and impurities will be discussed.

12:15 pm Luncheon Presentation (Sponsorship Opportunity Available)
or Enjoy Lunch on Your Own

12:40 Session Break

Characterizing Product-Related Impurities (CONT.)

1:30 Chairperson's Remarks
Bernice Yeung, PhD, Director, Protein Analytical Chemistry, Analytical Development, Biogen

1:35 Identification, Characterization and Criticality Assessment of Product-Related Quality Attributes
Romina Hofele, PhD, Scientist II, AstraZeneca

Assessing criticality of product-related impurities is a key step in characterizing quality attributes. We studied the formation and characterization of quality attributes in mAbs using analytical techniques. We studied the kinetics of isomerization of two CDR sites and investigated oxidation rates of amino acid residues in conserved regions across mAbs with various Fc formats. Implications to molecule understanding and criticality assessment will be discussed.
Residual HCPs can impact product quality. To date, the standard method for HCP detection is ELISA, which is usually not able to identify and quantify single HCPs. Therefore, orthogonal methods where individual HCPs can be analyzed are evolving. So far, the most popular orthogonal method is LCMS. Here, we present workflows to support identification and quantification of HCPs impacting product stability and their aggregation propensity.

9:05 Characterization of HEK 293 Host Cell DNA in Cell Therapy Jennifer Hu, PhD, Scientist, Analytical Development, Juno Therapeutics 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.

9:35 Sponsored Presentation (Opportunity Available)

10:05 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Developing Next-Generation Sequencing Approaches to Quantify Residual DNA and Characterize AAV Vector Genomes Magalie Penaud-Budloo, PhD, Research Scientist, INSERM UMR1089, University of Nantes

With the success of clinical trials using AAV vectors, the regulatory bodies have increased the level of requirements regarding their quality control. Related to the risk assessment of oncogenicity, immunogenicity, and reduction of vector potency, NGS-based methods, such as the SSV-Seq, offer greater power to identify and quantify residual DNA, as well as detect undesired variations and truncation events in the therapeutic AAV genome.

11:15 A Novel Method for Removing PEI from Biopharmaceutical Samples: Improving Assay Sensitivity of Residual DNA qPCR Shu Min Zhang, Associate Fellow & Investigator, BPD Analytical Sciences & Biopharm R&D, GlaxoSmithKline Polystyreneimine is a flocculent that’s widely used in monoclonal antibody downstream purification. PEI is an in-process residual that is carried through the drug purification process and strongly inhibits residual DNA qPCR. Removing PEI while retaining DNA, by the use of sodium dodecyl sulfate, Heparin, and/or Sarkosyl, can overcome the interference of PEI and allow a more accurate quantitation of residual DNA.

Protein Interactions and Degradation at Interfaces

11:45 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 interferfacial degradation at pharmacologically relevant surfaces.

12:15 pm Close of Impurities & Degradants
Characterizing Novel Modalities
From Proteins & Antibodies to Cell & Gene Therapies

TUESDAY, JUNE 2

1:00 pm Registration

Characterization of Gene- and Cell-Therapy Products

1:40 Chairperson's Remarks
Sunny Zhou, PhD, Professor, Chemistry & Chemical Biology, Northeastern University

1:50 Development of Novel Analytics for Gene Therapy Recombinant Adeno-Associated Virus
Zhu Z. Pirot, PhD, Director, Analytical Method Development, Sangamo Therapeutics
This presentation will discuss analytical method development strategies and methods to address critical attributes of rAAV, including quantification of empty and full particles and vector biological activity. Using HPLC, we have achieved separation of full and empty capsids, which allows accurate quantification. Potency matrix assays utilizing engineered cell line for gene therapy product characterization and release will also be discussed.

2:20 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.

2:50 Evaluation of the Multi-Attribute Method for AAV in Gene Therapy Applications
Halyna Narepekha, Senior Associate Scientist, Global Biologics, Pfizer Inc.

3:20 Sponsored Presentation (Opportunity Available)

3:50 Refreshment Break with Exhibit Hall with Poster Viewing

4:30 AAV Empty/Full Determination by Anion Exchange Chromatography
Chunlei Wang, PhD, Senior Scientist, AstraZeneca Pharmaceuticals, Inc.
Adeno-associated virus (AAV) vectors are clinically proven gene delivery vehicles attracting an increasing amount of attention. Non-genome-containing empty AAV capsids are by-products during AAV production that have been reported to potentially impact AAV product safety and efficacy. We use AAV serotype 6.2 (AAV6.2) as an example to show the development of a QC-friendly AEX assay for the determination of empty and full capsid percentages.

5:00 New Methods and Approaches for the Analysis of New Therapeutic Modalities
Sunny Zhou, PhD, Professor, Chemistry & Chemical Biology, Northeastern University
Due to their intrinsic structural complexity and complicated manufacture processes, viral capsids or particles (e.g., adeno-associated virus, AAV) are markedly heterogenous than well-established modalities (e.g., monoclonal antibodies, mAbs). As such, novel analytical and characterization approaches are needed. In this talk, both new methods and findings (e.g., post-translational modifications, PTMs) will be presented. Furthermore, I will also discuss analytical artefacts, which are common yet underappreciated, thereby often leading to erroneous interpretation and counterproductive approaches.

5:30 Analytical Development and Characterization of Deep IL-15 Nanogel
Tao Ye, PhD, Senior Scientist, CMC Analytical Development, Torque Therapeutics
Deep IL-15 is Torque’s nanogel formulation of IL-15. When tethered to T cell drug products, Deep IL-15 creates sustained and controlled activation of T cells in the tumor microenvironment and minimizes systemic exposure. As a bioactive nanogel, Deep IL-15 presents interesting analytical challenges. A panel of assays have been developed for process control, release, and characterization. The analytical development and extended characterization strategies will be discussed.

6:00 Welcome Reception in the Exhibit Hall with Poster Viewing
Close of Day

WEDNESDAY, JUNE 3

8:00 am Registration and Morning Coffee

8:30 Chairperson's Remarks
Sunny Zhou, PhD, Professor, Chemistry & Chemical Biology, Northeastern University

Characterization of Vaccines

8:35 Phase-Appropriate Analytical Control Strategies for the Early Clinical Development for Recombinant Protein-Based Vaccines
Vaneet K. Sharma, PhD, Manager, Analytical Development, International AIDS Vaccine Initiative (IAVI)
This presentation will outline phase appropriate CMC analytical control strategies for protein-based vaccines intended for successful regulatory submissions. Analytical approaches for the assay development, assay qualification, and characterizing the critical quality attributes (CQAs) relevant to Phase I/II programs will be discussed. A case study will be presented to demonstrate the application of the regulatory accepted phase appropriate analytical strategies to support HIV vaccine development.

9:05 Broadening the Expectations: Characterization and Stability Indicating Assay Identification for Conjugate Vaccines
Slobodanka (Dina) Manceva, Formulataion 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.

9:35 New QC Identity Testing for Acellular Pertussis Combination Vaccines Using LC-MS
Hong Zhang, PhD, Scientist, Analytical Sciences, Sanofi Pasteur
A liquid chromatography-mass spectrometry method (LC-MS) was developed, validated, and implemented in quality control (QC) for the identity testing of acellular pertussis combination vaccines. A single LC-MS method is able to replace several antibody-based identity tests to enhance quality, increase efficiency, and reduce cost and cycle time.

10:05 Sponsored Presentation (Opportunity Available)
10:35 Coffee Break in the Exhibit Hall with Poster Viewing

**Formulation and Delivery of Novel Therapeutics**

11:15 **Formulation and Delivery Challenges for Adeno-Associated Virus (AAV) Gene Therapy Products**

*Jared S. Bee, PhD, Associate Director, Formulation & Drug Product Development, REGENXBIO, Inc.*

The clinical development of adeno-associated virus (AAV) for gene therapy is an emerging field. AAV vectors can deliver genes to cells to address genetic defects or to enable cells in the body to produce therapeutic proteins that are intended to impact disease. This talk will describe formulation and drug product presentation considerations and challenges for AAV gene therapy candidates.

11:45 **Adapting Formulation Development Strategies to Address New Modalities**

*Christina Vessely, PhD, Senior Consultant, CMC Analytics & Formulation Development, Biologics Consulting Group, Inc.*

Strategies for development of formulations for therapeutic proteins and monoclonal antibodies have become reasonably well established over the last 20+ years. However, the emergence of new treatment modalities begs the question of how much of those strategies are still relevant. This presentation takes a look at the complexities brought on by conjugation of antibodies to small molecules, as well as specific concerns related to bispecifics and gene therapy candidates from the formulation perspective. New formulation development plans must take into account not only established principles, but also prior knowledge surrounding the biophysical and biochemical differences for novel molecules.

12:15 pm Luncheon Presentation I to be Announced

12:45 Session Break

**Characterization of Bispecifics, ADCs and mAbs**

1:30 **Chairperson's Remarks**

*Zhu Z. Pirot, PhD, Director, Analytical Method Development, Sangamo Therapeutics*

1:35 **Site-Specific Antibody-Drug Conjugate Heterogeneity Characterization and Heterogeneity Root Cause Analysis**

*Mingyan Cao, PhD, Senior Scientist, AstraZeneca*

We designed time-course studies to understand the root cause of heterogeneity generated during the ADC conjugation process. We found half ADC and unconjugated antibody were generated during oxidation as a result of alternative disulfide bond arrangements. The elevated level of size variants, especially HHL and LC resulted from the quenching step. Underconjugated and overconjugated species arose from the equilibrium established during the conjugation reaction.

2:05 **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.

2:35 Breakout Discussions

3:45 **Refreshment Break in the Exhibit Hall with Poster Viewing**

4:25 **Characterization of a Novel Bispecific Antibody with Improved Conformational and Chemical Stability**

*Prakash Manikwar, PhD, Scientist II, Dosage Form Design & Development, AstraZeneca*

4:55 **USP Standards for Assessment of Size Heterogeneity in Monoclonal Antibodies**

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

Size heterogeneity is a CQA of monoclonal antibodies monitored through the product lifecycle, from assessments of developability, through preclinical, and ultimately commercialization. USP is developing several mAb standards which can be utilized in analytical assays to support method development, validation, transfer, training, and method performance monitoring. This talk focuses on characterization of size heterogeneity of these standards using various analytical techniques including SEC and CE-SDS.

5:25 Close of Characterizing Novel Modalities

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“The event was definitely useful for me and I enjoyed it very much. It gave me what I was looking for. (I especially enjoy) the opportunity to network and listen to presentations of so many different people from different companies and get insights into their approaches. Especially the talks touching on the new FDA guidelines and the statistical evaluation.”

Scientist, Analytical Sciences & Operations, Teva
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.

8:00 am Registration and Morning Coffee

8:30 Chairperson's Opening Remarks

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

8:35 KEYNOTE PRESENTATION: 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.

9:40 Sponsored Presentation (Opportunity Available)

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

10:50 Bridging Product Quality Attributes and HOS of mAbs Using NMR

Arun Alphonse Ignatius, PhD, Principal Scientist & Group Leader, Pharmaceutical R&D, Pfizer Inc.

Based on QbD principles, prior knowledge of the critical quality attributes and its potential impact on the safety and efficacy are strongly desired for mAb-based product development. Backbone and methyl group based 2D NMR fingerprinting provides for a robust technology to monitor HOS changes at an amino acid level during various stages of product development. Multiple attributes of mAbs can be monitored using a single NMR spectra acquired under non-denaturing solution conditions. In addition to the stress-induced impact on the global HOS, localized HOS changes spanning few residues that may be involved in functionally relevant protein-protein interactions can be monitored using NMR. A case study on the applications of NMR as a heightened characterization tool for bridging structure-function will be discussed.

11:20 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.

11:50 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

12:20 pm Session Break

Machine Learning and Automation Approaches

1:10 Chairperson's Remarks

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

1:15 Laboratory Automation Supporting Process Development for Protein and Gene Therapy Modalities

Peter Bryngelson, PhD, Senior Scientist, Analytical Development, Biogen

Cell line and cell culture development require a great deal of data to make good decisions. Manual analytical workflows are resource intensive and inefficient. Our approach at Biogen is to provide lab and data workflows that are highly automated. Here we will discuss two cases where automated analytical approaches support protein and gene therapy modalities.

1:45 Bringing Data Science to Vaccine Development: First Principles

Eliehu C. Ihms, PhD, Senior Scientist, Vaccine Production Program Lab, NIH NIAID

Data science is now an inescapable buzzword in biotech, but what does it mean in the biotherapeutic development context, and how can its tools be adopted productively? This talk will describe the foundations of a robust data science platform applied to early stage development, how it can be integrated across functional units, and its potential benefits to developmental and operational efficiency.

2:15 Machine Learning Enables Accurate Prediction of Asparagine Deamidation Probability and Rate

Jared Delmar, PhD, Scientist I, Biopharmaceutical Development, AstraZeneca

Deamidation is a major pathway of protein degradation that has been shown to negatively affect both in vitro stability and in vivo biological function of diverse classes of proteins. Using a large LC-MS/MS dataset of monoclonal antibody peptides, we trained machine learning models to predict antibody variable region deamidation with nearly 5% increased accuracy and 0.2 MCC over the best currently available models.

2:45 The Future of Laboratory Automation: Elevating the Science via a Novel Pipetting Algorithm, 3D Printing Technology, and a Next-Generation Advanced Control Machine

Idris Mustafa, Lead Automation Scientist, BioMolecular Resources, Genentech, Inc.

Three functional advances aim to manage the evolution of drug discovery in our organization: in-house advanced robotics programming, part design/architecturing and the liquid-handling robot of the future. Our patent-pending TipSort technology has exploited mathematical optimization for robot/process efficiency, 3D printing in the lab has dispersed a variety of containers/adapters, serving the automation, and the Vantage robot has expanded our technological capabilities.

3:15 Refreshment Break in the Exhibit Hall. Last Chance for Poster Viewing

Attributes Characterization and Comparison

3:45 Two-Dimensional Liquid Chromatography (2D-LC) for the Characterization of Biotherapeutics: Case Studies

Zhi Chen, PhD, Senior Research Investigator II, Bristol Myers Squibb Co.

2D-LC is a viable tool to support online and real-time characterization of biotherapeutics. In this presentation, a few case studies will be discussed including charge and size variant characterization of a monoclonal antibody (mAb) and aggregate characterization of combination products.
4:15 Analysis of Glycosylation in Monoclonal Antibodies
Harleen Kaur, PhD, Senior Research Scientist I, Analytical Sciences, Aurobindo Pharma Ltd. (Aurobindo Biologics)
Monoclonal antibodies are a rapidly growing class of therapeutic molecules in biopharmaceuticals. Understanding the impact of glycosylation and close monitoring is critical for monoclonal antibodies’ development as a therapeutic molecule. This presentation will highlight the influence of different glycan variants on the drug’s behavior inside the body and draw attention to commonly employed analytical techniques to determine and quantify glycan composition, structure, and glycosylation site.

4:45 Statistical Comparison of Attributes of Pharmaceutical Products
Franz Innerbichler, Senior Fellow, Statistical Process & Technology Development, Novartis
Statistical comparison of quality attributes is important in many areas of pharmaceutical development, e.g., comparability, scale-down model qualification, method transfer. Besides the well known equivalence test and similar Bayesian comparisons, new approaches will be presented viewing the problem from a different, but basic angle: Are the minimum and maximum of both groups comparable? What about the results between minimum and maximum?

5:15 Close of Day and Dinner Short Course Registration

6:00 Dinner Short Courses
SC3: Critical Quality Attributes and Testing Strategy for Biotherapeutics Development
SC4: Gene Therapy Products: Phase-Appropriate Analytical Development Strategies

FRIDAY, JUNE 5

8:00 am Breakout Discussions with Continental Breakfast
Evaluation and Approval for Biosimilars and Protein Drug Products

9:15 Chairperson’s Remarks
Renuka Sivendran, PhD, Director, Analytical Development, Five Prime Therapeutics, Inc.

9:20 KEYNOTE PRESENTATION: Importance of Structure-Function Studies for Evaluation and Approval of Biosimilars and Other Protein Products
Emily B Shacter, PhD, Consultant, ThinkFDA LLC.

9:50 QbD Quality Study for Evaluation of Analytical Similarity and Process Comparability of Biosimilar mAbs
Michael H. Xie, PhD, Vice President, Analytics; Head, Bioassay and Analytical Development, Shanghai Henlius Biotech, Inc.
QbD quality study and determination of CQAs of biosimilar mAbs were performed following a developed platform at Henlius, which was applied in analytical similarity and process comparability studies of biosimilar mAbs. The major results of analytical similarity and process comparability on the 1st China biosimilar mAb Hanlikang® (Henlius rituximab biosimilar HLX01 to MabThera) and trastuzumab biosimilar HLX02 to Herceptin will be presented and discussed.

10:20 Networking Coffee Break

CQA Assessment for Characterization and Comparability

10:50 Evaluating Process Changes on Gene Therapy Vectors Using Analytical Comparability & Characterization
Russell Goetze, PhD, Scientist I, bluebird bio
As autologous gene therapy programs reach late clinical and commercial stages, the vector manufacturing process must scale to meet increasing demand. Process improvements and changes needed for scale-up require thorough evaluation of analytical comparability to ensure that vector meets or exceeds quality standards once changes are implemented. We will discuss an industry perspective on the strategy for testing analytical comparability and review some examples.

11:20 Risk-Based Assessment of CQAs for Bispecific Molecules
Dana I. Filoti, PhD, Senior Scientist II, Research and Early Developability Group Leader, NBE Analytical R&D, AbbVie Bioreserach Center

11:50 Utilizing Traditional CQA Assessment for Comparability Studies of New/Novel Molecules
Renuka Sivendran, PhD, Director, Analytical Development, Five Prime Therapeutics, Inc.
The control strategy for biologic products requires identifying the CQAs that impact efficacy and safety of the product. Traditionally, CQA assessment for comparability required the knowledge of process history, control strategy and clinical experience. To successfully demonstrate comparability for new/novel modalities, the risk assessment should evaluate the type/extent of process change and its impact to CQAs that affect efficacy and safety of the product.

12:20 pm Close of Summit
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