FINAL AGENDA

FINAL WEEKS TO REGISTER

Cambridge Healthtech Institute's 9th Annual

Biotherapeutics Analytical Summit

Empowering Innovation with the Right Tools and Techniques

March 12-16, 2018 | Sheraton Inner Harbor Hotel | Baltimore, MD

MARCH 12-13
Method Development Qualification & Validation

MARCH 12-13
Characterizing Aggregates & Impurities

MARCH 13-14
Advances in Characterization Methods & Approaches

MARCH 15-16
Comparability & Biosimilarity

TRAINING SEMINARS

TS1: Core Principles and Best Practices for Biotech Analytical Test Methods across the Product Lifecycle

TS2: Regulatory Requirements across the Product Development Lifecycle

SHORT COURSES

- Particles in Biotherapeutics: Characterization & Impact
- The Multi-Attribute Method (MAM) for Improving Product and Process Development
- Critical Quality Attributes and Testing Strategy for Biotherapeutics Development

FEATURED SPEAKERS

Ramesh Potla, PhD
Product Quality Team Leader, CDER, FDA

Stephan O. Krause, PhD
Director, QA Technology, AstraZeneca

Mark T. Fisher, PhD
Professor, Biochemistry and Molecular Biology, University of Kansas Medical Center

Baolin Zhang, PhD
Senior Investigator, Review Team Leader, OBP, CDER, FDA

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

Bernice Yeung, PhD
Global Head of Characterization, Analytical Development, Shire

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Cambridge HEALTHTECH Institute

SC Dinner Short Courses*

*Dinner included. Separate registration required. Please see Registration page for details.

MONDAY, MARCH 12, 6:00 – 8:30 PM

SC1: Particles in Biotherapeutics: Characterization & Impact

Instructors:

Dean Ripple, PhD, Supervisory Physicist, Bioprocess Measurements Group, National Institute of Standards and Technology

Srivalli Telikepalli, PhD, Research Chemist, Biomolecular Measurement, National Institute of Standards and Technology

Maryam Mazaheri, MS, PMP, CMC Project Manager, Pipeline Management, MedImmune

This short course will give an introduction to current issues surrounding particle formation and 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.

SC2: The Multi-Attribute Method (MAM) for Improving Product and Process Development

Instructor: Richard Rogers, PhD, Scientist 4, Just Biotherapeutics

During biotherapeutic development, it is necessary to monitor properties of the therapeutic molecule and formulation that have been identified as critical quality attributes (CQAs) for product safety and efficacy. In particular, the industry is seeking to monitor post-translational modifications (PTMs), glycosylation profiles, and excipients with both UV and mass data by implementing multi-analyte or so-called Multi Attribute Methods (MAMs). The course offers hands-on training on how to apply the Multi-Attribute Method (MAM) to mass spectrometry data. We will be performing attribute analytics (quantifying product quality attributes) and new peak detection (purity test) on mass spec data. During the course, we will discuss the uses of the MAM in process development and in a QC lab.

WEDNESDAY, MARCH 14, 6:00 – 8:30 PM

SC3: Critical Quality Attributes and Testing Strategy for Biotherapeutics Development

Instructor: Christine Chan, PhD, Principal Scientist /Technical Lead, Global Manufacturing Sciences & Technology, Sanofi

Biotherapeutics are challenging to develop due to 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.

~~SC4: New Analytical Approaches & Strategies for Biosimilarity~~

~~*Instructors:*~~

~~*Hans-Martin Mueller, PhD, Director, BioProcess Development, Biologics and Vaccines, MSD*~~

~~*David Wylie, PhD, Principal Scientist, Sterile Process and Analytical Development, Merck Research Labs*~~

~~Providing convincing analytical similarity studies is a key success factor for the filing of biosimilars. For proper planning of novel or biosimilar development programs, it is important to understand the development costs, timelines and the authoring of CMC regulatory sections. The analytical characterization of comparability and similarity studies will form the cornerstone for each successful marketing authorization application of these products. This short course will focus on analytical development and its challenges, technical hurdles, BLA authoring, timelines and costs. Participants will be introduced to state-of-the-art analytical similarity strategies, which anticipate occurrences of non-identity between biosimilar and originator, leading to a smooth and efficient IND/BLA application and approval.~~

Conference-at-a-Glance

	March 12-13 (Mon-Tue)	March 13-14 (Tue-Wed)	March 15-16 (Thu-Fri)
Conferences	Method Development Qualification & Validation Characterizing Aggregates & Impurities	Advances in Characterization Methods & Approaches	Comparability & Biosimilarity
TS Training Seminars		TS1: Core Principles and Best Practices for Biotech Analytical Test Methods across the Product Lifecycle	TS2: Regulatory Requirements across the Product Development Lifecycle
	Monday, March 12: 6:00-8:30pm	Wednesday, March 14: 6:00-8:30pm	
SC Short Courses	SC1: Particles in Biotherapeutics: Characterization & Impact SC2: The Multi-Attribute Method (MAM) for Improving Product and Process Development	SC3: Critical Quality Attributes and Testing Strategy for Biotherapeutics Development ~~SC4: New Analytical Approaches & Strategies for Biosimilarity~~	

*Separate registration is required for short courses.

TUESDAY, MARCH 13, 2:00 - 6:00 PM – WEDNESDAY, MARCH 14, 8:30 AM - 5:30 PM

Training Seminar 1

Core Principles and Best Practices for Biotech Analytical Test Methods across the Product Lifecycle

Instructor: Nadine Ritter, PhD, President & Senior Analytical Advisor, Global Biotech Experts, LLC

Introduction/Objective of the Course:

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 the 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 II and Phase III. These guidances also indicate that test methods only need to be qualified for Phase I (except safety methods, which do require validation prior to Phase I). 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

About the Instructor:

Nadine Ritter obtained her master and doctoral degrees in cell and molecular biology at Rice University (Houston, TX) on evolutionary mechanisms for subcellular translocation of mitochondrial proteins. She was engaged in basic academic research in the field of extracellular matrix proteins and the process of bone mineralization at the University of Texas Health Science Center in Houston for over 10 years. She entered the biopharm industry as a protein chemist in analytical R&D at Abbott Laboratories (Abbott Park, IL). There, she performed development, validation, transfer and troubleshooting of test methods for the analytical QC lab, generated protein characterization data for diagnostic product submissions, responded to FDA comments, contributed to compliance remediation efforts for QC inspection observations, and led the ISO9000 certification of the R&D analytical lab.

THURSDAY, MARCH 15, 8:30 AM - 5:00 PM – FRIDAY, MARCH 16, 8:30 AM - 12:00 PM

Training Seminar 2

Regulatory Requirements across the Product Development Lifecycle

Instructor: Christina Vessely, PhD, Senior Consultant, Biologics Consulting Group

Introduction/Objective of the Seminar:

The successful development of a pharmaceutical product requires not only good science, but also compliance with FDA regulatory expectations. This course will include a comprehensive review of the Chemistry, Manufacturing and Controls (CMC) section of regulatory filings, with a focus on phase appropriate requirements. The level of detail that must be included in the filing will be discussed as well as systems and controls that must be in place in the manufacturing setting. Topics such as process development, analytical development, Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) will be discussed in the context of the stage of drug development. Regulatory strategies for navigating the path to approval will also be discussed. This course is intended to provide participants from all facets of the pharmaceutical and biotech industry with a broad understanding of regulatory requirements across the product development lifecycle.

The Seminar Will Cover:

- The Evolution of Drug Compliance in the US
- FDA Structure and Function
- The Product Development Timeline from IND to Commercialization
- 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

About the Instructor:

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 the authoring and editing of analytical sections for multiple filings in both the U.S. and in the EU (IND/IMPD, BLA/MAA).

Training SEMINARS
By Cambridge Healthtech Institute

Each CHI Training Seminar offers 1.5 Days of instruction with start and stop times for each day shown above and on the Event-at-a-Glance published in the onsite Program & Event Guide. Training Seminars will include morning and afternoon refreshment breaks, as applicable, and lunch will be provided to all registered attendees on the full day of the class.

Each person registered specifically for the training seminar will be provided with a hard copy handbook for the seminar in which they are registered. A limited number of additional handbooks will be available for other delegates who wish to attend the seminar, but after these have been distributed no additional books will be available.

Though CHI encourages track hopping between conference programs, we ask that Training Seminars not be disturbed once they have begun. In the interest of maintaining the highest quality learning environment for Training Seminar attendees, and because Seminars are conducted differently than conference programming, we ask that attendees commit to attending the entire program, and NOT engaging in track hopping, as to not disturb the hands-on style instruction being offered to the other participants.

Second Annual

Method Development, Qualification & Validation

Developing Fit-for-Purpose Methods throughout the Product Lifecycle

MONDAY, MARCH 12, 2018

7:30 am Registration & Morning Coffee

8:30 Chairperson's Opening Remarks
Mark T. Fisher, PhD, Professor, Biochemistry and Molecular Biology, University of Kansas Medical Center

JOINT PLENARY SESSION

8:40 REGULATORY ADDRESS: Regulatory Perspectives on Analytical Method Validation and Transfer for Biopharmaceutical Products
Ramesh Potla, PhD, Product Quality Team Leader, CDER, FDA
A risk-based approach should be used to determine the totality of evidence needed to demonstrate a successful method transfer. This presentation will focus on our current expectations about the validation and any subsequent site transfer of validated analytical methods for biotechnology products. Case studies will be presented with the goal of sharing lessons learned during the regulatory review of non-compendial analytical method validation and transfer for licensed therapeutic proteins.

9:20 MAM Method Development and Qualification
Richard Rogers, PhD, Scientist 4, Just Biotherapeutics
We have developed and implemented a mass spectrometry based multi-attribute method (MAM) that monitors known CQAs but also can identify new CQAs on the biotherapeutics. This method has been successfully used in the process development lab. Our goal is to leverage the MAM for release of biotherapeutics from the quality lab. Method qualification and specification limits for the MAM will be discussed in this presentation.

9:50 The Next Frontier in Subvisible Particle Analysis: New Tools and Potential Opportunities
Danny K. Chou, PharmD, PhD, President, Compassion Biosolution, LLC
In the past decade, we have witnessed the arrival of a large number of analytical technologies that are useful for characterizing sub-visible particles in protein therapeutics. Even with the diverse tools that are available today, there are still important gaps that have not been filled but yet have a significant role in our ability to fully analyze particles for either product characterization or development purpose. The goal of this presentation is to highlight some of these gaps and share the potential opportunities that may be captured by new tools that are on the horizon.

10:20 Networking Coffee Break

STRATEGIES FOR LATE-STAGE DEVELOPMENT

FEATURED PRESENTATION

10:50 Analytical Method Replacement Strategies and Case Studies for Late-Stage Development and Approved Products
Stephan O. Krause, PhD, Director, QA Technology, Clinical/Commercial Biologics Operations, AstraZeneca

11:20 Developing and Qualifying a Flow Cytometry Assay for Release Testing
Sindhuja Rao, PhD, Senior Scientist, Biotherapeutics & Pharmaceutical Sciences, Analytical R&D, Pfizer, Inc.
A cellular drug product requires accurate quantification of the level of expression of pertinent cell surface proteins on a per-cell basis. This can be accomplished by flow cytometry, but qualifying a cytometry-based release test is challenging due to the inherent variability of acquisition and the subjective analysis of the data, as well as software and hardware capabilities. Working through these components led to key learnings for future cellular identity assays.

11:50 Development and Implementation of High-Throughput Assays to Support Process Development
Greg Cantin, PhD, Scientist III, Manufacturing Sciences, Five Prime Therapeutics, Inc.
The development and implementation of high(er)-throughput methods to support process development will be discussed. The two main goals for these activities are: 1) increasing the speed of sample throughput, and 2) achieving acceptable method performance. Examples of activities that resulted in significant increases in sample throughput will be presented. Additionally, method performance outcomes will be presented for multiple higher-throughput methods that have been implemented.

12:20 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:50 Session Break

1:40 Chairperson's Remarks
Greg Cantin, PhD, Scientist III, Manufacturing Sciences, Five Prime Therapeutics, Inc.

STRATEGIES FOR COMPLEX MOLECULES AND EARLY-PHASE PROGRAMS

1:45 ADC Method Development and Validation Strategies
Michelle Palmer, PhD, Director, Bioanalytical Science, ImmunoGen, Inc.

2:15 Analytical Strategies for the Regulatory Filing of Early-Phase Biotherapeutics
Kevin Zen, PhD, Senior Director, Analytical and Formulation Development, AnaptysBio Inc.

2:45 Sponsored Presentation *(Opportunity Available)*

3:15 Networking Refreshment Break

3:45 Method Development and Qualification of Next-Generation Antibody-Based Therapeutics
Jared Bee, PhD, Senior Scientist, Analytical Sciences, Macrogenics
DART(R) molecules are bispecific antibody-based proteins developed for a variety of indications including immuno-oncology, and are designed to simultaneously bind to two targets. These versatile molecules have the potential for improved efficacy and safety profile through enhanced selectivity and recruitment of specialized effector cells. This presentation will discuss method development and qualification approaches using this novel class of molecules and other antibody molecules as case studies.

4:15 Platform Approach for Method Development and Qualification for Early-Phase Programs
Matt Valcorba, Principal Research Associate, Bioanalytics, Sanofi

4:45 Roundtable Breakout Session

• How Do You Determine the Appropriate Levels of Process-Related Impurities for Early Development Stages (Non-Pivotal, Phase I-II Studies)?

Moderator: Greg Cantin, PhD, Scientist III, Manufacturing Sciences, Five Prime Therapeutics

- Information used in setting appropriate levels (acceptance criteria) for contaminants
- Are statistical methods needed to set expected range or acceptance criteria in Phase I-II?
- When is testing not needed for release?
- Overall risk assessment for the decision process

• Application of Design of Experiment (DOE) in Analytical Method Development

Moderator: Dengyun "Daisy" Sun, PhD, Senior Scientist, Biologics Analytical Sciences, Merck & Co.

- Design of Experiment (DOE) versus One Factor at a Time (OFAT)
- How to interpret DOE result
- Challenges in DOE and how to overcome (case studies)
- Regulatory expectation

5:45 Close of Day/Short Course Registration

6:00 Dinner Short Courses*

SC1: Particles in Biotherapeutics: Characterization & Impact

SC2: The Multi-Attribute Method (MAM) for Improving Product and Process Development

**Separate registration applies. Please see page 2 for details.*

TUESDAY, MARCH 13, 2018

8:00 am Morning Coffee

8:30 Chairperson's Opening Remarks

Danny K. Chou, PharmD, PhD, President, Compassion Biosolution, LLC

NOVEL ASSAY DEVELOPMENT

8:40 Development and Qualification of an Activity Assay Using a Physiologically Relevant Substrate

Kannappan Veeraragavan, PhD, Head, Method Development Separation Science, Analytical Development, Shire

Mucopolysaccharidosis II (Hunter syndrome) is an X-linked lysosomal storage disease cause by lack of a specific enzyme called iduronate-2-sulfatase (I2S). The *in vitro* activity of I2S is measured by using a physiologically relevant substrate (PRS). An assay was developed and qualified to measure the specific activity of I2S which is being manufactured by recombinant technology.

9:10 Development and Qualification of a Novel Cell-Based Assay for Therapeutic mAb against Viral Infection

Dengyun Sun, PhD, Senior Scientist, Biologics Analytical Sciences, Merck & Co.

We have explored several cell-based assay platforms in support of therapeutic mAb development against viral infection. The advantages and disadvantages of the methods were compared to meet different project needs. In this study, we chose a luciferase based method and further optimized the assay using Design of Experiment (DOE). The new assay is under qualification in terms of accuracy, linearity, intermediate precision, specification and robustness.

9:40 Developing Cell-Based Functional Assays to Modulate Nature Killer Cells (NK cells) for Cancer Immunotherapy

Zhengmao Ye, PhD, Scientist, Biochemical and Cellular Pharmacology, Genentech, Inc.

In searching for novel biotherapeutics for cancer immunotherapy, we targeted a soluble protein that regulates human NK cell function. In this talk, I will present several novel cell-based functional assays for screening and advancing the lead candidates.

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10:10 Presentation to be Announced

10:40 Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:20 The Impact of Excess Antigen and Non-Linearity of Dilution on Host Cell Protein Immunoassay Development and Qualification

Matthew Roberts, PhD, Manager, Analytical Development, Cell & Gene Therapy, GlaxoSmithKline

Proper immunoassay design is essential to the reliable measurement of host cell protein (HCP) content throughout the manufacturing process used to produce biotherapeutics from cells. Validated platform methods offer distinct advantages toward development of product-specific residual HCP assays; however, excess HCP antigen can pose issues to the design space of such methods, particularly in the form of non-linearity of dilution. Strategies on how to overcome this effect will be highlighted.

11:50 How to Utilize Design of Experiment (DoE) Principles for Developing Robust Analytical Methods for QC Environments

Jeremy Springall, PhD, Scientist I, Analytical Sciences, MedImmune

Developing robust analytical methods that will be routinely used in QC environments can prove to be very challenging when using a one factor at a time approach. In this presentation, I will communicate how we can use DoE approaches and a large design space to develop analytical methods and assess their robustness.

12:20 pm Close of Method Development, Qualification & Validation

Inaugural

Characterizing Aggregates & Impurities

Prediction, Detection and Characterization of Aggregates and Particulates

MONDAY, MARCH 12, 2018

7:30 am Registration and Morning Coffee

8:30 Chairperson's Opening Remarks
Mark T. Fisher, PhD, Professor, Biochemistry and Molecular Biology, University of Kansas Medical Center

JOINT PLENARY SESSION

8:40 REGULATORY ADDRESS: Regulatory Perspectives on Analytical Method Validation and Transfer for Biopharmaceutical Products
Ramesh Potla, PhD, Product Quality Team Leader, CDER, FDA
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Danny K. Chou, PharmD, PhD, President, Compassion Biosolution, LLC
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10:20 Networking Coffee Break

AGGREGATION IN NON-mAbs

10:50 New Developments in the Characterization of Fibril Aggregates in Peptide Therapeutics: From Aggregation Kinetics to Single Nanoparticle Detection Methods
Jingtao Zhang, PhD, Principal Scientist, Pharmaceutical Sciences, Merck & Co.
The formation of irreversible aggregates such as fibrils, has proven to be a key challenge in developing synthetic peptide therapeutics. In this presentation, we will discuss the investigation on the aggregation kinetics of a fibril-prone peptide, the projection of physical stability shelf-life, and the development of highly sensitive characterization methods for fibrils. In particular, the application of highly sensitive submicron detection tools such as Archimedes and flow cytometry instrument to investigate the fibril behavior in lag-phase will be discussed.

11:20 CE Methods on Quantification of Adeno-Associated Virus (AAV) Capsid Purity
Wei-Chiang Chen, PhD, Scientist I, Analytical Development, Biogen
Recombinant adeno-associated virus (AAV) was demonstrated as a promising platform in human gene therapy. AAV capsids are comprised of three viral proteins, VP1, VP2, and VP3, and their theoretical ratio is 1:1:10. Capillary electrophoresis (CE) SDS has been widely used to analyze fragments or impurities in biologics. In this study, we demonstrate successful development of AAV capsid purity assay on multiple CE platforms which are commonly used in industry. The results from different CE platforms are compared and summarized in this presentation.

11:50 Characterization of Aggregates and Impurities of Proteins Used in Diagnostic Blood Screening Assays
Jeffrey Fishpaugh, PhD, Senior Principal Research Scientist, Analytical Chemistry R&D, Abbott
Biologics used in clinical diagnostics blood screening assays occupy a unique design space. These assays and their components (biologics/proteins) fall under the purview of the FDA's CBER section, the same section that inspects and reviews biotherapeutic products. Our current biologics release testing uses classic 20th century techniques. Recent characterization work identified and quantified impurities in our blood screening biologics. Follow-up activities include analysis employing more modern methods that are used to characterize biotherapeutics and biosimilars.

12:20 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:50 Session Break

1:40 Chairperson's Remarks
Linda Yi, PhD, Senior Scientist, Analytical Development, Biogen

AGGREGATION IN EARLY STAGE DISCOVERY

FEATURED PRESENTATION

1:45 Using Nature's Toolbox to Capture and Detect Preaggregate Transient States
Mark T. Fisher, PhD, Professor, Biochemistry and Molecular Biology, University of Kansas Medical Center
We've developed numerous automated GroEL chaperonin-based biolayer interferometry platforms to 1) detect preaggregate states of multiple biotherapeutic samples and 2) assess ligand or solution based stabilities at ambient or physiologically relevant temperatures. The target protein states that are captured by GroEL-biosensors can be released into ul volumes where visualization of structures potential preaggregate proteins is easily accomplished using negative stain electron tomography and can be identified using Mass spectroscopy.

2:15 Functional, Biophysical and Structural Characterization of Engineered Antibody Variants and Quantitative Correlation between Self-Association and Particle Size in Early Stage Discovery
Sam Wu, PhD, Principal Scientist, Janssen Biotherapeutics, Janssen R&D, LLC
An early-stage developability workflow was designed to set stage gate for molecules progressing to late-stage development. Application of solubility and stability analysis in antibody selection will be presented in this study. Stability analysis of engineered antibody variants was evaluated using Intrinsic Fluorescence Conformational Stability™ and Colloidal stability (Tagg). B22/kD parameters for monoclonal antibodies (mAbs) in solution were determined and validated by Small-Angle-X ray-scattering (SAXS). Quantitative correlation between Tagg and particle size for mAbs was observed in this study.

2:45 Sponsored Presentation *(Opportunity Available)*

3:15 Networking Refreshment Break

PREDICTION OF PROTEIN SOLUBILITY

3:45 Prediction of Protein Solubility for Biologics Development: From Basics to Practice

Ying Wang, PhD, Assistant Professor, Chemistry, University of North Carolina at Wilmington

One challenge in biologics development is that proteins may lose their solubility and form aggregates, crystals, viscous liquids, or gels. The protein solubility problems are frequently encountered throughout biologics development: from early developability evaluation and formulation to manufacture and purification DOE. I will talk about the universal mechanism underlying various protein solubility issues. Then, I will show how to predict short-term and long-term solubility problems with a simple quick experiment.

4:15 Monitoring Oxidative Damage in Therapeutic Proteins by Spectroscopic Methods

Sambit Kar, PhD, Principal Scientist & Head, Biophysics Center of Excellence, Molecular & Analytical Development, Bristol-Myers Squibb Co.

This presentation will discuss oxidative stress on therapeutiic proteins and share strategies for monitoring degradation pathways and identifying degradation products.

4:45 Roundtable Breakout Session

• Rapid Evaluation of Therapeutic Protein Preaggregate States Using Microscale Biolayer Interferometry Methodologies

Moderator: Mark T. Fisher, PhD, Biochemistry and Molecular Biology, University of Kansas Medical Center

- Detection of preaggregate states with GroEL Biosensors
- Release and evaluation of captured proteins using Electron microscopy and Mass spectroscopy
- Stability assessments using Denaturant pulse Biolayer interferometry
- Future Expansion of these methods

• CQA Assessment, Control Strategies and Specification Setting

Moderator: Sambit Kar, PhD, Principal Scientist & Head, Biophysics Center of Excellence, Molecular & Analytical Development, Bristol-Myers Squibb Co.

5:45 Close of Day/Short Course Registration

6:00 Dinner Short Courses*

SC1: Particles in Biotherapeutics: Characterization & Impact

SC2: The Multi-Attribute Method (MAM) for Improving Product and Process Development

**Separate registration applies. Please see page 2 for details.*

TUESDAY, MARCH 13, 2018

8:00 am Morning Coffee

8:30 Chairperson's Opening Remarks

Sambit Kar, PhD, Principal Scientist & Head, Biophysics Center of Excellence, Molecular & Analytical Development, Bristol-Myers Squibb Co.

DETECTION, CHARACTERIZATION AND MONITORING OF SVPs AND HCPs

8:40 Factors Influencing Biotherapeutic Monoclonal Antibody Aggregation

Linda Yi, PhD, Senior Scientist, Analytical Development, Biogen

Aggregation has been identified as one of the major degradation pathways that may affect safety, quality and efficacy of therapeutic mAbs. Aggregates present in mAb products can be complex, varying by size, type and origin, with underline mechanisms not always being well-understood. This presentation will provide an overview of the factors that may influence biotherapeutic mAb aggregation. A case study will follow on impact of a chemical modification catalyzed by metals on aggregation of a few mAbs.

9:10 Characterization of Subvisible Particles: Old Challenges and Newest Improvements

Anacelia Rios Quiroz, PhD, Scientist, Group Leader Particle Lab, Pharma Technical Development Europe-Analytics Biochemistry (PTDE-A), F. Hoffmann-La Roche Ltd.

The talk will give an overview on commercially available counting methodologies for detection of subvisible particles (SbVP). This species, ubiquitously present in protein formulations, had been in focus due to immunogenicity and quality attributes of biotechnological products. Thus, the analytical toolbox to characterize them undergoes constant renewals and innovations. Their applicability towards the assessment of a meaningful array for particle counting characterization will be discussed including examples of their use in the frame of immunogenicity studies.

9:40 Challenges in Characterization of Subvisible Particles in High Concentration Protein Formulations

Miguel Saggu, PhD, Scientist, Late Stage Pharmaceutical Development, Genentech, Inc.

Regulatory agencies require manufacturers of protein therapeutics to control subvisible particles in drug products to ensure the safety and efficacy of the drug as well as to demonstrate process consistency. This talk will cover case studies of challenges in particle characterization of high concentration mAb samples.

10:10 Best Practices and Strategies for Host Cell Protein ELISAs

Sponsored by CYGNUS TECHNOLOGIES

Alla Zilberman, Technical Marketing Manager, Cygnus Technologies

Regulatory agencies around the world expect sponsors to have a good understanding of the HCP profile of their Drug Product. Knowing that low HCP results are due to HCP content and not due to an insensitive HCP ELISA is key. Talk will highlight current best practices and strategies to effectively demonstrate that an HCP ELISA is fit for purpose, and focus on Antibody Affinity Extraction (AAE) as a superior method for demonstrating HCP antibody coverage and reactivity to HCPs that persist through the purification process.

10:40 Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:20 Characterization of Process-Related Impurities for Next-Generation Antibody-Based Therapeutics

Jennifer Kessler, MSc, Development Associate III, Macrogenics, Inc.

Monoclonal antibodies and bispecific DART(R) molecules are being developed for a variety of indications including immuno-oncology. A risk-based approach for analytical characterization of process related impurities is required to ensure product quality of pipeline molecules during development. This presentation will discuss characterization of process-related impurities using this novel class of molecules and other antibody molecules as case studies.

11:50 New Standards for Protein Particulates

Dean Ripple, PhD, Leader, Bioprocess Measurements Group, National Institute of Standards and Technology

12:20 pm Close of Characterizing Aggregates & Impurities

Third Annual

Advances in Characterization Methods & Approaches

Harnessing Technologies to Speed Innovation

TUESDAY, MARCH 13, 2018

12:30 pm Registration

1:45 Chairperson's Opening Remarks
Zahra Shahrokh, PhD, Chief Development Officer, STC Biologics, Inc.

KEYNOTE PRESENTATION

1:50 Potency Assays for Biopharmaceuticals: Design, Validation and Beyond
Baolin Zhang, PhD, Senior Investigator, Review Team Leader, Office of Biotechnology Products, CDER, FDA
Potency tests are required throughout all stages of biopharmaceutical development programs, where they are performed as part of characterization, lot release, and stability testing. Assay acceptability depends on product type, mechanism of action, associated risk, stage of development, and availability of other quality data. This presentation provides regulatory expectations on potency assays and discusses several case studies highlighting some of the relevant issues commonly seen in the regulatory submissions.

BEYOND mAbs - CHARACTERIZING COMPLEX DRUGS

2:20 Informing the Criticality of Quality Attributes with Targeted Product Characterization: A Case Study
Jonathan van Dyck, Scientist, Analytical Biochemistry, Seattle Genetics
Defining and understanding the critical quality attributes (CQAs) of a therapeutic protein and their relevance to safety and efficacy is an important and necessary part of product characterization. ICH Q8(R2) defines CQAs as "A physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range or distribution to ensure the desired product quality". As products move through clinical development, CQAs should be identified and well understood, however this can be challenging given the structural and functional complexity of therapeutic proteins and the number of quality attributes that need to be evaluated. Initial CQA assessments can be informed by platform knowledge, literature, and risk ranking and filtering approaches. This knowledge can be supplemented with focused product specific experiments demonstrating the impact of a specific attribute on structure and function. Here we present a case study where oxidation and no-glycosylated heavy chain (NGHC) species were enriched via targeted degradation studies to understand impact to structure and function and inform the CQA risk assessment.

2:50 CQA Determination and Control Strategy Development for Besponsa
Jim (Jianming) Mo, PhD, Research Fellow, Analytical R&D, Pfizer, Inc.

3:20 Automated Data Processing and Analysis for Quality Monitoring of Biotherapeutics by Multi-Attribute Method (MAM)
Sponsored by Genedata
Aude Tartiere, Scientific Account Manager, Expressionist, Genedata
MS-based methodologies offer the benefit of measuring many different quality attributes on a given biotherapeutic with a single test. The multi-attribute method (MAM) can potentially reduce development and manufacturing costs and at the same time increase product quality. Here, we present an implementation of MAM using a single software platform for the data processing, analysis, and management of MS data.

3:50 Refreshment Break in the Exhibit Hall with Poster Viewing

4:30 Achievements, Disappointments and Lessons Learned from Characterization of Nanotechnology-Formulated Complex Drugs
Marina Dobrovolskaia, PhD, MBA, Senior Principal Scientist, Head of Immunology Section, NCL, Frederick National Laboratory for Cancer Research, NCI
There is an increasing evidence that nanotechnology can improve outcomes of vaccines and immunotherapies. However, translation of these formulations to clinic is accompanied with many challenges. This presentation will discuss achievements, disappointments and lessons learned from characterization of nanotechnology-formulated complex drugs. Case studies focusing on various types of nanocarriers and APIs will be presented to demonstrate structure activity relationships, *in vitro-in vivo* correlation, efficacy and toxicity.

5:00 Characterization of Dolaflexin-Based ADCs
David Lee, PhD, Director, Analytical Chemistry, Mersana Therapeutics
The use of Dolaflexin, a polymer-drug platform, enables the generation of ADCs with drug-to-antibody ratios between 12-15 while maintaining acceptable pharmacokinetics and drug-like properties. This talk will describe selected innovative analytical approaches used to characterize these antibody-polymer-drug systems.

5:30 Analytical Challenges to Characterization of Self-Amplifying RNA Delivered by a Non-Viral Cationic Nanoemulsion
Mandy Xie, Senior Manager, Product Analytics, Analytical R&D, GSK
The self-amplifying mRNA (SAM) is a platform under early development in GSK vaccines to provide rapid response for pandemic situations. SAM contains a self-amplifying and a gene-of-interest portion, and is assembled via an *in vitro* transcription process. The novel design of the SAM construct substantially increases the potency with limited dosage requirement. However, the inherent large size of SAM also poses great analytical challenges. We will present the current state of RNA analytical tools, challenges and potential solutions.

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

7:00 Close of Day

WEDNESDAY, MARCH 14, 2018

8:00 am Morning Coffee

8:30 Chairperson's Opening Remarks
David Lee, PhD, Director, Analytical Chemistry, Mersana Therapeutics

CHARACTERIZATION FOR CANDIDATE SELECTION AND CLINICAL SAMPLE COMPARISON

8:40 Analytical Strategies for Therapeutic Proteins
Aaron Beach, PhD, Scientist, Protein Analytics and Formulation, Integrated Biologics Profiling, Novartis Institute of Biomedical Research
The Integrated Biologics Profiling group at Novartis uses custom analytical methods for developability assessments of wide ranging therapeutic protein modalities transitioning from research to development. A broad variety of diverse biologics entities are evaluated by employing cutting edge analytical strategies such as automated LC method development using DoE, multiple cutting-edge liquid chromatography, and bottom-up and top-down LC-MS/MS.

9:10 *In vitro* Bioassays to Accelerate Immuno-Oncology Candidate Selection
Sofie Pattijn, CTO, ImmunXperts SA
This talk will cover the usage of *in vitro* assays to support immuno-oncology drug development. Early functional screening and unwanted immunogenicity assessment can accelerate drug development and lower attrition rate. A series of assays using primary cells will be discussed and the limitations, challenges and opportunities will be highlighted.

CHARACTERIZING POST-TRANSLATIONAL MODIFICATIONS

9:40 Highly Glycosylated Therapeutic Proteins: Novel Methods for Sample Generation, Structural and Functional Characterization
Alexander Buettner, PhD, Scientist, Analytical Development and Quality Control, Pharma Technical Development Europe, Roche Diagnostics GmbH
Glycoprotein function is strongly influenced by composition of glycan

moieties. Glycan variety in combination with presence of multiple glycosylation sites can result in thousands of different proteoforms. We have been developing sample generation techniques as well as structural and functional analysis methods to examine structure function relationships in this complex situation. The talk focuses on *in vitro* glycoengineering, chromatographic separation of glycoforms and binding analysis (SPR).

10:10 Meet the Challenge of Discovering Unknowns: Functional Proteomics and Protein Modifications in Biotherapeutics

Zhaohui Sunny Zhou, PhD, Professor, Department of Chemistry and Chemical Biology, Faculty Fellow, Barnett Institute of Chemical and Biological Analysis, Northeastern University

Scientific research, to a significant degree, is about discovering unknowns. However, without *a priori* knowledge of the enzyme-substrate pairs or the chemical nature and site of protein modification, it is extremely challenging to deploy proper analytical methods and search algorithms. To this end, my laboratory (a.k.a. SunnyLand) has devised chemo-enzymatic approaches that complement both instrumental and traditional methods, as illustrated by the cases that will be presented at the conference.

10:40 Coffee Break in the Exhibit Hall with Poster Viewing

HIGHER ORDER STRUCTURE ANALYSIS

11:20 Monoclonal Antibody Higher Order Structure Analysis Using High Throughput Protein Conformational Array

Yuanli Song, PhD, Scientist II, Late Stage Biologics Development, Bristol-Myers Squibb

Protein conformational array (PCA) is a novel method for determining higher order structure of mAbs. We applied PCA to analyze structural changes along bioprocessing steps. We deciphered mechanistic insights on structural information acquired using PCA. We also correlated PCA results to protein stability results from other traditional methods such as size exclusion chromatography and protein thermal shift assay. PCA has potential applications in biologics discovery, and product and process development.

11:50 Hydroxyl Radical Footprinting-Mass Spectrometry (HRF-MS): Expanding the Toolbox for Biotherapeutic Higher Order Structure Characterization

Aaron T. Wecksler, PhD, Technical Development Scientist, Protein Analytical Chemistry, Genentech

We are developing HRF-MS technology which utilizes a high power laser to photo-lyse hydrogen peroxide into hydroxyl radicals, initiating the sub-microsecond surface oxidation of solvent exposed amino acid residues. This technology is orthogonal to HDX but has advantages that include: (1) ultra-fast labeling time scales, (2) irreversible protein modification and (3) information on the structural positioning of the protein side-chain residues. In this presentation, we show multiple case studies demonstrating the utility of this emerging technology for the structural characterization of therapeutic mAbs.

12:20 pm Sponsored Presentation *(Opportunity Available)*

12:50 Luncheon Presentation to be Announced

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Greg Adams, PhD, Senior Director, Global Analytical Strategy & Development, Analytical and Formulation Development, FUJIFILM Diosynth Biotechnologies

1:20 Dessert Break in the Exhibit Hall with Poster Viewing

1:55 Chairperson's Remarks

Sofie Pattijn, CTO, ImmunXperts SA

ADVANCED ANALYTICS, MAM AND INTEGRATIVE APPROACHES TO BIOTHERAPEUTICS DEVELOPMENTS

2:00 Integrating Protein Chemistry, Formulation and Biology for Effective Development of Biotherapeutics

Zahra Shahrokh, PhD, Chief Development Officer, STC Biologics, Inc.

2:30 Harnessing the Power of Automation to Support High-Throughput Analytics for Critical Characterization Platforms: MAM, Developability and Clone Selection

Stephen D'Eri, MSc, Scientist, Sanofi

Rapid technological growth in analytical instrumentation and data processing has enabled researchers to develop powerful new methods for use in the biopharmaceutical industry. Unfortunately, sample preparation methods have progressed at a much slower rate, leading to a bottleneck in high throughput analytics. By incorporating automation into our sample preparation methods, we address the bottleneck issue while supporting harmonization of workflows across multiple sites.

3:00 Sponsored Presentation *(Opportunity Available)*

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:10 Talk Title to be Announced

Christina Vessely, PhD, Senior Consultant, CMC, Analytical and Formulation Development, Biologics Consulting

4:40 Quantitative Analysis of Free Circulating Light Chains Using a Novel Time-Resolved Deconvolution Approach for Reliable Comparison of a Clinical Sample Cohort on the Tribrid Orbitrap Fusion Lumos

Yishai Levin, PhD, Head, de Botton Institute for Protein Profiling, The Nancy and Stephen Grand Israel National Center for Personalized Medicine, Weizmann Institute of Science

Serum immunoglobulin free light chains (FLC) are secreted into circulation as a by-product of immunoglobulin production. Recent reports show that detection of high levels of FLC can be used to diagnose and monitor light chain amyloidosis (AL), a rare and fatal disease. Evidence shows that these FLCs dimerize in patient sera. We present a quantitative analysis on a large clinical sample cohort from patients and controls using a time-resolved deconvolution approach for unbiased and precise comparison that could eventually be used as a risk indicator of AL.

5:10 Why Is Platform Approach to Formulation Development Obsolete? How to Leverage Advanced Analytical Technologies to Develop Better Formulations Faster While Reducing Resource Requirements?

Danny K. Chou, PharmD, PhD, President, Compassion BioSolution, LLC

One of the major dilemmas biopharmaceutical formulation scientists face today is whether to invest resources to develop formulations for molecules in the early stages of development or utilize a platform formulation. In this presentation, we discuss an alternative approach that can effectively identify a good formulation design space that is tailored to a specific molecule without significant time and resource demand. The strategy utilizes multivariate study design (response surface DoE) and high throughput analytical methods to develop biopharmaceutical products in accordance with the principles of QbD.

5:40 Close of Advances in Characterization Methods & Approaches/ Short Course Registration

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6:00 Dinner Short Courses*

SC3: Critical Quality Attributes and Testing Strategy for Biotherapeutics Development

~~**SC4:** New Analytical Approaches & Strategies for Biosimilarity~~

**Separate registration applies. Please see page 2 for details.*

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Fourth Annual

Comparability & Biosimilarity

Ensuring Regulatory Compliance and Demonstrating Analytical Control

THURSDAY, MARCH 15, 2018

7:30 am Registration and Morning Coffee

8:30 Chairperson's Opening Remarks

John Marino, PhD, Leader, Biomolecular Structure & Function Group, National Institute of Standards and Technology

KEYNOTE PRESENTATIONS

8:40 Application and Data Evaluation of HDX-MS Results in the Analytical Comparability Studies of Complex Non-mAb Biotherapeutics

Bernice Yeung, PhD, Global Head of Characterization, Analytical Development, Shire

High data content is obtained in HDX-MS analysis, especially for highly glycosylated and other complex biotherapeutics. The approach and benefit of using similarity scores will be demonstrated which are used to establish appropriate acceptance criteria in an analytical comparability study. The resulting comparability acceptance criteria are quantitative and objective, and alleviate the issues of relying on qualitative comparison of butterfly plots or other arbitrary cut-off limits.

9:15 Data Integrity and Lab Quality Practices for Non-GMP and GMP CMC Studies

Nadine Ritter, PhD, President and Senior Analytical Advisor, Global Biotech Experts, LLC

Numerous CMC process and product development studies are necessary for the development, approval and commercial support of biotech/biosimilar products. This talk will highlight the key non-GMP vs. GMP data sets generated during the product lifecycle, present the data integrity elements currently expected for GMP laboratories, and illustrate a set of best practices for non-GMP R&D labs to consider as a means of assuring the reliability and integrity of the data they generate.

9:50 Coffee Break in the Exhibit Hall with Poster Viewing

COMPARABILITY FOR COMPLEX MOLECULES

10:20 Similarity & Comparability Considerations for Therapeutic Peptides

David Wylie, PhD, Principal Scientist, Sterile Process and Analytical Development, Merck Research Labs

10:50 Strategies for Comparability Assessments of Early Phase Gene Therapy Products

Eric Pastor, PhD, Principal Scientist, Analytical Development, Sanofi

11:20 Risk-Based Comparability for Complex Molecules during Expedited Development: Leveraging Enhanced Technology and Regulatory Mechanisms

John Armando, MSc, Senior Associate II, Regulatory Affairs CMC, Biogen

There are many challenges faced during expedited biopharmaceutical development. Advancements in technology, program needs, and product knowledge inevitably result in the need for comparability assessments. The use of enhanced technologies and risk-based approaches can build robustness in one's comparability assessments and improve both product and process knowledge. As comparability assessments become increasingly important for evaluating changes during expedited development or in planning for post-approval changes, risk-based approaches and increased agency and industry collaboration are essential enablers for success.

11:50 Sponsored Presentation *(Opportunity Available)*

12:20 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:50 Dessert Break in the Exhibit Hall with Last Chance for Poster Viewing

1:35 Chairperson's Remarks

Elsie DiBella, PhD, Senior Director, CMC Development, Pharmaceutical Sciences, Momenta Pharmaceuticals

RISK-BASED APPROACHES AND ADVANCED ANALYTICS FOR COMPARABILITY ASSESSMENTS

1:40 Risk-Based Approaches to Demonstrate Comparability during Clinical Development

Matt Kalo, PhD, Associate Director, Protein Analytical Chemistry, Genentech

During clinical development, it is expected and perhaps even beneficial that product quality will be altered by manufacturing changes. Process modifications before commencement of pivotal clinical studies have reduced development and regulatory risks than modifications during or after pivotal clinical trial initiation. The assessed impacts of changes are based on the potential for detectable patient-impacting differences. Unlike post-approval changes, a clinical development team's favorable assessment will be confirmed by clinical studies that are closely monitored.

2:10 Approaches to Comparability following a CMC Change

Vedangi Sample, PhD, Scientist, CMC Regulatory Sciences, Regeneron Pharmaceuticals

2:40 Multivariate Analysis of 2D NMR for Assessment of Biopharmaceutical Structure

John Marino, PhD, Leader, Biomolecular Structure & Function Group, National Institute of Standards and Technology

The application of two-dimensional nuclear magnetic resonance (2D-NMR) methods for the acquisition of 1H-13C spectral 'fingerprints' for the standard monoclonal antibody (NISTmAb) and glycan remodeled NISTmAb at natural isotopic abundance will be described. Using this sample set, principle component analysis (PCA) applied directly to the spectral data matrices will be shown to discriminate highly similar species, with low limits of detection, which could not be distinguished by visual inspection or simple intensity based statistical approaches.

3:10 Roundtable Breakout Session with Refreshment Break

• Current Practice and Expectation on Demonstrating Higher Order Structures

Moderator: Bernice Yeung, PhD, Global Head of Characterization, Analytical Development, Shire Pharmaceuticals

- What are the most useful and informative techniques for HOS determination during process development?
- What are the most useful and informative techniques for HOS determination for demonstrating product understanding (e.g., structure-function studies)?
- What techniques are less useful and why are we still using them?
- What is the recent experience for the above in regulatory submissions?

• Forced Degradation Studies: Trends & Challenges

Moderator: Christine Chan, PhD, Principal Scientist /Technical Lead, Global Manufacturing Sciences & Technology, Sanofi

- Study conditions and choice of assays
- Managing resources and data: phase-appropriate considerations
- FD studies in comparability assessment: how many lots, profile and rate comparisons
- Relevance to process excursions, accelerated stability, real-time stability

• Usage and Application of *in vitro* Assays during Drug Development

Moderator: Sofie Pattijn, CTO, ImmunXperts

- Challenges and opportunities
- Standardization
- How to translate results

DEVELOPING BIOSIMILARS

4:10 Developing Third Wave Biosimilars

Florian Wolschin, PhD, Director, Protein Analytics, Formycon

Third wave biosimilars are versions of biologic reference product drugs that come off patent after 2020. The talk will center on some of the opportunities and challenges that come with the development of such products.

4:40 Differentiating Biosimilar Products from Originator Using a Novel Platform Pharmaceutical Technology

Jun Liu, PhD, Executive Director, Operation, Coherus Biosciences

A novel pharmaceutical technology and manufacturing process were developed to improve product safety, quality and stability. This technology can be applied to differentiate biosimilar products from originator. A few case study examples will be presented to demonstrate its potential benefits to a broad class of pharmaceutical products.

5:10 Close of Day

FRIDAY, MARCH 16, 2018

8:00 am Morning Coffee

8:30 Chairperson's Opening Remarks

Bernice Yeung, PhD, Global Head of Characterization, Analytical Development, Shire

DEMONSTRATING ANALYTICAL SIMILARITY

8:40 Fingerprint-Like Similarity: Making the Connection between Product Characteristics and Clinical Outcomes

Elsie DiBella, PhD, Senior Director, CMC Development, Pharmaceutical Sciences, Momenta Pharmaceuticals

Starting with a detailed understanding of the product, clinical indications and safety profile of the reference product and/or other similar products, attributes (physicochemical and functional) that are either known or likely to impact clinical outcomes can be determined. The assessment of fingerprint-like similarity can then be based on both (1) the full physicochemical and functional comparison of the product to the reference product and (2) the detailed analysis using sensitive assays, that allow for linkage between key product attributes and clinical outcomes.

9:10 Challenges for Demonstrating Biosimilarity and Data Quality for Sponsors of Biosimilars for the US Market

Stephan O. Krause, PhD, Director, QA Technology, Clinical/Commercial Operations, MedImmune/AstraZeneca

9:40 The Use of Structural Biology to Demonstrate Finger-Print Like Similarity

Edward R. Zartler, PhD, Senior Group Leader, Biophysics, Analytical R&D, Pfizer

10:10 Networking Coffee Break

10:40 Assessment of Critical Quality Attributes vs. Demonstration of Bio-Similarity

Renata Varga, PhD, Manager R&D, Analytical Sciences and Operations, Teva Pharmaceuticals

Critical quality attribute assessment is a crucial step in antibody development either if it's innovative or biosimilar. But when we are developing a biosimilar product, we tend to mix up CQA assessment with biosimilarity; however, these two should be clearly distinguished, but still kept in relation. The presentation will focus on special aspects of CQA assessment for biosimilar mAbs.

11:10 Statistical Considerations for Analytical Biosimilarity Assessments

Shu-Yi Su, PhD, Scientist, Physical Chemistry Characterization, Technical Development Biosimilars, Novartis

The analytical similarity assessment of critical quality attributes (CQAs) is an important step to demonstrate the biosimilarity of a proposed biosimilar to the reference product. This talk will present recent work aimed at exploring statistical approaches for assessing analytical biosimilarity.

11:40 Challenges in Assessing the Structural Component of Biosimilarity

Steve Berkowitz, PhD, Independent Consultant

A key component in assessing the biosimilarity of a biosimilar to its reference product is the adequate demonstration of its structural similarity to the structure of the reference product. The process for achieving this involves extensive analytical physicochemical testing. In this talk, the underlining challenges in making these measurements will be reviewed. In so doing, particular emphasis will be focused on the biophysical part of this process.

12:10 pm Close of Conference

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