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Final Agenda

CAMBRIDGE HEALTHTECH INSTITUTE'S FIFTH ANNUAL

BIOTHERAPEUTICS ANALYTICAL SUMMIT

MARCH 24-28, 2014 | HYATT REGENCY BALTIMORE | BALTIMORE, MARYLAND

Following year over year success, CHI presents the Fifth Annual Biotherapeutics Analytical Summit. This event features 175+ industry, regulatory and biosimilar professionals gaining insight into PTMs, analytical characterization, and comparability and developability for innovators and biosimilars. Features case studies, interactive breakout discussions, posters, networking opportunities and more!

PROGRAMS

MARCH 24-25
POST TRANSLATIONAL MODIFICATIONS

MARCH 25-26
ANALYTICAL CHARACTERIZATION OF BIOTHERAPEUTICS

MARCH 27-28
COMPARABILITY AND DEVELOPABILITY

SHORT COURSES

Impurities: Measurement, Characterization and Impact

Glycobiology of Antibodies

The Science and Regulation of Process Changes for Biologics

Strategy for Entering the Biosimilars Market

KEYNOTE PRESENTATIONS

Shantha T. Raju, Ph.D., Scientific Director, Biologics Research, Centocor, Inc.

Alain Beck, Ph.D., Senior Director, Antibody Physico-Chemistry, Centre d'Immunologie Pierre Fabre; Associate Editor, mAbs

John Stults, Ph.D., Director, Protein Analytical Chemistry, Genentech, Inc.

FEATURED PRESENTATIONS

Strategies to Control Reproducibility of Glycosylation in Biomanufacturing
Michael Butler, Ph.D., Professor, Microbiology, University of Manitoba

Particle Characterization and Product Release Limits: Established and Evolving Techniques
Joey Kotarek, Ph.D., ORISE Fellow, CDER/FDA

Regulatory Perspectives on Comparability Studies for Biotechnology Products
Lixin Xu, M.D., Ph.D., Product Quality Reviewer, Monoclonal Antibodies, Office of Biotechnology Products, CDER/FDA

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CONFERENCE AT A GLANCE

	MONDAY MARCH 24	TUESDAY MARCH 25	WEDNESDAY MARCH 26	THURSDAY MARCH 27	FRIDAY MARCH 28
AM	POST TRANSLATIONAL MODIFICATIONS			COMPARABILITY AND DEVELOPABILITY	
PM		ANALYTICAL CHARACTERIZATION OF BIOTHERAPEUTICS			SC4: BIOSIMILARS
EVENING	RECEPTION	SC1: IMPURITIES SC2: GLYCOBIOLOGY	RECEPTION	SC3: COMPARABILITY	

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SHORT COURSES*

**Separate Registration Required*

Dinner SC1: Impurities: Measurement, Characterization and Impact

Tuesday, March 25 (5:45 – 8:45 pm)

Instructors:
Björn Boll, Ph.D., Pharma Technical Development Europe, F. Hoffmann-La Roche Ltd.
Matthew Seefeld, Ph.D., CSO, Barofold, Inc.

This interactive short course will examine the nature of process- and product-related impurities that can be present in biotechnology products, and their clinical impact. It will provide an overview of current regulatory expectations and advice on how to assess impurities to satisfy regulatory requirements and to ensure safety and efficacy with your product.

- Introduction to SVPs, aggregates and impurities
- Current regulatory expectations
- Mechanisms behind formation of soluble aggregates and SVPs
- Potential biological impacts
- Overview of aggregates
- Causes of aggregation
- Characterization
- Current concerns in the context of immunogenicity with examples
- Elimination of aggregates through protein refolding and high pressure dissociation
- Technologies and tools for identification and characterization
- Size exclusion SEC, AUC, FFF, etc.
- Microflow imaging and newer technologies
- Comparisons between technologies regarding limits of detection
- Which approaches can be regarded as FDA compliant
- Recent experiences and case studies of critical process- and product-related impurities
- Discussion with Q&A

Dinner SC2: Glycobiology of Antibodies

Instructor:
Shantha T. Raju, Ph.D., Scientific Director, Biologics Research, Centocor, Inc.

The workshop will cover:

- Introduction to protein glycosylation
- Fc glycan heterogeneity
- Methods to analyze Fc glycans
- Glycoengineering methods
- Role of Fc glycans on antibody effector functions
- Impact of Fc glycans on antibody stability

Dinner SC3: The Science and Regulation of Process Changes for Biologics (Comparability)

Thursday, March 27 (5:30 – 8:30 pm)

Instructors:
Christopher J. Holloway, Ph.D., Group Director, Regulatory Affairs & CSO, ERA Consulting Group
Kazumi Kobayashi, Ph.D., Director, Bioprocess Development, Biogen Idec, Inc.
Marjorie Shapiro, Ph.D., Chief, Laboratory of Molecular and Developmental Immunology, Division of Monoclonal Antibodies, FDA/CDER

Manufacturing changes can impact on quality attributes of biologics, and may affect efficacy and/or safety of the product. For that reason, a thorough comparability exercise is required, to assess the impact of the change and whether CMC data alone will suffice to support the change. This interactive short course will consider comparability exercises during development, as well as post-approval, addressing regulatory and technical requirements. This should provide the attendee with the knowledge on how to prepare a comparability package for discussion with regulatory agencies, towards acceptance of the proposed change to the process/product. Attendees will be contacted before the event and asked about topics on which they would like to focus.

- Ways that manufacturing changes can impact on quality attributes
- Features of a thorough comparability exercise
- Critical evaluation of quality data
- The comparability exercise during development
- Post-approval comparability, ICH Q5E, Comparability Protocols (US) and Change Management Protocols (EU)
- Regulatory requirements in the EU and US: guidelines, their interpretation and application
- Discussion with Q&A

SC4: Strategy for Entering the Biosimilars Market

Friday, March 28 (1:30 – 4:30 pm)

Instructors:
Alain Beck, Ph.D., Senior Director, Antibody Physico-Chemistry, Centre d'Immunologie Pierre Fabre; Associate Editor, mAbs
Christopher J. Holloway, Ph.D., Group Director, Regulatory Affairs & CSO, ERA Consulting Group
Zahra Shahrokh, Ph.D., CSO, STC Biologics
Kathleen M. Williams, Ph.D., J.D., Partner, Sunstein Kann Murphy & Timbers LLP

A short course led by experts in the field to help the industry take advantage of opportunities for biosimilar production. It offers advice on collecting a robust characterization data package for the authorities, clarifies current regulatory pathways, and provides strategies for dealing with the remaining uncertainties. It also examines the complex legal issues and advises on how to work out freedom to operate and how to clear the path for development. This short course will arm investigators with the information required for entering this exciting and potentially highly rewarding field.

- Extensive use of mass spectrometry for the characterization of originator and biosimilar mAbs and Fc-fusion proteins
- Revisions to EU guidelines and their impact on biosimilar product development
- Product development implications of the recent FDA guidances on biosimilars
- Intellectual property strategies for biosimilars
- Discussion with Q&A

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- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes

MONDAY, MARCH 24

7:30 am Registration and Morning Coffee

PTM PROFILING AND STRUCTURE FUNCTION RELATIONSHIP

8:30 Chairperson's Opening Remarks

Hubert Kettenberger, Ph.D., Principal Scientist, Protein Analytics, Large Molecule Research, Pharma Research and Early Development (pRED), Roche Diagnostics

» KEYNOTE PRESENTATION

8:35 Correlating the Role of PTMs with Structure-Functions for Therapeutic Antibodies

Shantha T. Raju, Ph.D., Scientific Director, Biologics Research, Centocor, Inc.

Post-translational modifications (PTMs) of antibody therapeutics affect their functions and stability. Understanding the structure and functions of PTMs is necessary to successfully develop and market antibody therapeutics. Linking structure to function is critical to understand the mechanism of action (MOA), potential mechanism of toxicity (MOT), and critical quality attributes (CQAs). These correlations will be helpful for setting intelligent specifications. This presentation will illustrate the structural analyses of PTMs in relation to functional analyses, MOA and MOT.

9:05 Rapid Profiling of N-Linked Glycans from Antibody Therapeutics Using Chip Nano LC-MS

Niclas Tan, Ph.D., Scientist II, Analytical Development – Biologics, Takeda Pharmaceuticals International Co.

Rapid characterization of glycan post-translational modifications of monoclonal antibodies is of utmost importance due to their impact on efficacy, half-life, and mechanism of action. We present the results from the optimization of an integrated LC-MS chip for rapid online cleavage, purification, separation, identification and quantitation of label-free N-linked glycans based on accurate mass. The N-linked glycan characterization results from different production cell lines are presented to examine similarities and differences.

9:35 Accurate Determination of PTMs and Micro-Variants by Stable Isotope Labeling and LC-MS Analysis

Hongcheng Liu, Ph.D., Development Scientist III, Protein Characterization, Alexion Pharmaceuticals, Inc.

Heterogeneity is a common feature of recombinant monoclonal antibodies due to various chemical modifications. The nature and amounts of modifications are generally characterized by liquid chromatography and mass spectrometry analysis of peptides produced from protease digestion. However, the same modifications can also occur during sample preparation, which will result in overestimation of the levels of modifications. Several methods using the combination of stable isotope labeling and LC-MS to accurately determine the levels of modifications, including deamidation, oxidation and free sulfhydryl, will be discussed.

10:05 Sponsored Presentation *(Opportunity available, please contact Jon Stroup, jstroup@healthtech.com)*

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

CHARGE ISOFORMS, DEAMIDATION AND OXIDATION

11:00 Case Study on Analysis of Heterogeneity from Charge Isoforms

Patricia W. Cash, Ph.D., Senior Director, Analytical Biotechnology, MedImmune, Inc.

Identification and characterization of charge isoform heterogeneity is important to biopharmaceutical product development. Charge heterogeneity generally arises from product-related variants such as C-terminal heterogeneity, glycation, or asparagine deamidation. Since these variants are often active, setting specifications based on a range of heterogeneity can be difficult. Deciding on acceptable levels of heterogeneity and the importance of prior knowledge will be discussed.

11:30 Case Studies on Aspartic Acid Isomerization and Oxidation

Dirk Chelius, Ph.D., Fellow, Biologics Research & Development, Novartis Pharma

In this case study we show the development of a reversed-phase HPLC method for the quantification of isomerization in a monoclonal antibody. We used different techniques for the identification of the isomerization site, like enzymatic digestions and advance technology like ETD mass spectrometry. The amino acids most susceptible to oxidation were identified and the mass spectrometry data was used for the routine quantification of the oxidation levels during formulation development studies.

12:00 pm New Insights into Deamidation in Antibodies

Yung-Hsiang Kao, Ph.D., Principal Scientist and Senior Group Leader, Late Stage Pharmaceutical Development, Genentech, Inc.

Deamidation of asparagine is a major degradation pathway for proteins. We have used different methods, including a domain ion exchange chromatography method and several different biophysical techniques, to evaluate the effects of deamidation in antibodies and the dependence of demaidation rate on buffer type, pH and temperature. We also used a mutagenesis approach to model the deamidation and to evaluate the impact of deamidation on antibody functions. A summary of our findings will be presented.

12:30 Luncheon Presentation *(Opportunity available, please contact Jon Stroup, jstroup@healthtech.com)* **or Lunch on Your Own**

PTMS AND DEVELOPABILITY ASSESSMENT

2:00 Chairperson's Opening Remarks

Jeffrey W. Hudgens, Ph.D., Research Chemist, Institute for Bioscience and Biotechnology Research, Biomolecular Measurement Division, National Institute of Standards and Technology

2:05 Early Stage Characterization for Developability Assessment of Biologics

Hongling Han, Ph.D., Senior Scientist, Integrated Biologics Profiling, Novartis, Inc.

Developability of biologics candidates should be assessed in the early stage of development to minimize the risk of technical hurdles. The concept of developability assessment presented here includes molecular profiling for biochemical (e.g., sensitivity to clipping, deamidation, aspartate isomerization and oxidation) & biophysical (e.g., high molecular weight species, viscosity and melting temperature) properties and pre-formulation assessment for evaluation of short-term stability profiles.

2:35 Identification of Antibodies Free from Chemical Degradation Sites: Prediction versus Reality

Hubert Kettenberger, Ph.D., Principal Scientist, Protein Analytics, Large Molecule Research, Pharma Research and Early Development (pRED), Roche Diagnostics

Besides function, chemical stability is an important selection criterion in the discovery of therapeutic proteins. Degradation "hotspots", i.e. amino acids which degrade particularly quickly during manufacturing, storage or *in vivo*, should be avoided whenever possible. By combining mass spectrometry, structural biology and machine learning, we developed a reliable *in silico* approach to predict Aspartate and Asparagine degradation hotspots in the variable regions of monoclonal antibodies.

3:05 Sponsored Presentation *(Opportunity available, please contact Jon Stroup, jstroup@healthtech.com)*

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Structural Characterization, Quality Attribute Risk Assessment and Control of Atypical Modifications in Therapeutic Monoclonal Antibody Product Development Following the Quality by Design Principle

Zhirui (Jerry) Lian, Ph.D., Senior Research Scientist and Group Leader, Bioproducts Research and Development, Eli Lilly and Company

Two atypical post-translational modifications in a therapeutic mAb in development were identified and thoroughly characterized using mass spectrometry and biophysical techniques. Their impacts on biological activities of the molecule including antigen binding and potency were assessed. The critical quality attribute (CQA) risks were assessed based on the data. Some aspects of the control strategy will also be discussed.

4:30 FEATURED PRESENTATION: Strategies to Control Reproducibility of Glycosylation in Biomanufacturing

Michael Butler, Ph.D., Professor, Microbiology, University of Manitoba

The glycan profile of the final product of a bioprocess can depend upon the producer cell line, the growth media, the culture conditions as well as the protein structure. The presentation will review bioprocess parameters that can be controlled in order to minimize batch to batch variation of Mab glycosylation. Strategies will also be discussed to produce Mabs with pre-defined glycan structures.

5:00- 6:00 Breakout Discussions

Table 1: Analysis of Heterogeneity of Charge Isoforms
Moderator: Hongcheng Liu, Ph.D, Development Scientist III, Protein Characterization, Alexion Pharmaceuticals, Inc.

Table 2: Glycosylation as a Strategy to Improve Antibody-Based Therapeutics
Moderator: David Spencer, BSc, Scientist II, Analytical Biochemistry, MedImmune, Inc.

Table 3: Practical Application of Glycosylation Characterization
Moderator: Dietmar Reusch, Director, Pharma Development Analytics, Pharma Biotech Production and Development Characterization, Roche Diagnostics GmbH

Table 4: Challenges of Controlling Reproducibility of Glycosylation in the Manufacturing Process
Moderator: Michael Butler, Ph.D., Professor, Microbiology, University of Manitoba

Table 5: Application of New Technologies for Analysis of PTMs
Moderator: Bing Gong, Ph.D., Associate Principal Scientist, GlycoFi, Biologics Discovery

Table 6: Characterization of Native and Scrambled Disulfide Bonds
Moderator: Yung-Hsiang Kao, Ph.D., Principal Scientist and Senior Group Leader, Late Stage Pharmaceutical Development, Genentech, Inc.

Table 7: Evaluation of Impact of PTMs on Product Properties and Development of Control Strategies
Moderator: Zhirui (Jerry) Lian, Ph.D., Senior Research Scientist and Group Leader, Bioproducts Research and Development, Eli Lilly and Company

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

7:00 End of Day One of Post Translational Modifications

TUESDAY, MARCH 25

GLYCOANALYSIS

8:30 am Chairperson's Opening Remarks

Dirk Chelius, Ph.D., Fellow, Biologics Research & Development, Novartis Pharma

8:35 Glycosylation Characterization of Glycoengineered Pichia-Derived Biotherapeutics

Bing Gong, Ph.D., Associate Principal Scientist, GlycoFi, Biologics Discovery

Glycosylation is a major biochemical attribute of therapeutic proteins and plays essential roles in modulating their biochemical and biological properties. Glycoengineered *Pichia pastoris* capable of assembling human-like glycans has emerged as an alternative production platform and been successfully used to express several therapeutic proteins. We will present detailed glycosylation analyses of such glycoproteins using modern analytical techniques.

9:05 Practical Application of Glycosylation Characterization and Control of Glycopatterns

Dietmar Reusch, Director, Pharma Development Analytics, Pharma Biotech Production and Development Characterization, Roche Diagnostics GmbH

Several methods for glycoanalysis of antibodies are presented. This includes chromatographic, electrophoretic and mass spectrometry-based methods. A focus will be on high-throughput techniques. A study where we compared the results for a therapeutic antibody obtained with different methods will be shown. The influence of glycosylation on function of antibodies will be included.

9:35 Satisfying the Increasing Regulatory Expectations for Glycosylation Characterization for mAbs, ADCs and BiSpecifics

Qinwei Zhou, Ph.D., Vice President, BioAnalytical Sciences, ImClone Systems, a wholly-owned subsidiary of Eli Lilly and Company

Glycosylation is one of the key post-translational modifications for mAbs, and is the most sensitive attribute to the cell culture process variations. With the rapid development of oligosaccharide characterization techniques in recent years, and the understanding of the importance of glycosylation to the CQAs and process consistency, the regulatory expectations and requirements for the glycosylation testing are increasing substantially. This presentation will share our strategy.

10:05 Sponsored Presentation *(Opportunity available, please contact Jon Stroup, jstroup@healthtech.com)*

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

GLYCOSYLATION AND DEGLYCOSYLATION

11:00 O-Xylosylation in a Recombinant Protein is Directed at a Common Motif on Glycine-Serine Linkers

David Spencer, B.Sc., Scientist II, Analytical Biochemistry, MedImmune, Inc.

Glycine-serine linkers are commonly used in recombinant proteins to connect domains. We report the post-translational O-glycosylation of a glycine-serine linker in a novel fusion protein. The O-glycan moiety has a xylose-based core substituted with hexose and sulfated hexauronic acid residues. The modification could be attributed to the inherent xylosyltransferase motif present in glycine-serine linkers. The levels of modification in different expression systems were evaluated and an alternative linker that eliminated the O-glycosylation was introduced.

11:30 Effects of Deglycosylation on Human alpha1-Acid Glycoprotein-Ligand Interactions: A Hydrogen/Deuterium Exchange Mass Spectrometry Study

Jeffrey W. Hudgens, Ph.D., Research Chemist, Institute for Bioscience and Biotechnology Research, Biomolecular Measurement Division, National Institute of Standards and Technology

Hydrogen/Deuterium Exchange Mass Spectrometry (HDX-MS) is recognized as a powerful technique that measures the dynamical structure of glycoproteins. The method has no known upper mass limit, and it can provide information of protein dynamics that are difficult to achieve by other analytical strategies such as NMR and X-ray crystallography. In our study, we utilized the advantages of this technique to reveal, for the first time, the effects of glycan structure on the conformational dynamics of Human alpha1-Acid Glycoprotein (AGP) and AGP-ligand binding at high resolution.

12:00 pm End of Post Translational Modifications

12:00 Registration

ADVANCES WITH ANALYTICAL TECHNOLOGIES

2:00 Chairperson's Opening Remarks

Qin Zou, Ph.D., Senior Principal Scientist, Analytical Research & Development, Pfizer, Inc.

» KEYNOTE PRESENTATION

2:05 State of the Art Mass Spectrometry Methods for Antibodies, Biosimilars, Bispecifics and ADC Characterization

Alain Beck, Ph.D., Senior Director, Antibody Physico-Chemistry, Centre d'Immunologie Pierre Fabre; Associate Editor, mAbs

The early use in the R&D process of Mass Spectrometry (MS) methods helps to optimize the structure and the function of next-generation mAbs (OptimAbs), as well as more sophisticated derivatives such as bispecific antibodies and antibody-drug conjugates (OptimADCs). These MS techniques are also very helpful for comparability studies and for biosimilarity evaluation. Case studies on deep structural characterization of antibodies and derivatives based on emerging methods such as middle-up/down, native and Ion-Mobility MS will be showcased and discussed.

2:35 TEM as an Analytical Characterization Tool for Biotherapeutics and other Protein Macromolecules

Bridget Carragher, Ph.D., Integrative Structural and Computational Biology, Scripps Research Institute

Transmission electron microscopy (TEM) is an emerging analytical tool for the characterization of proteins, protein complexes and submicron protein aggregates. Single particle EM (SPEM), can be used to reveal the architecture and dynamics of individual antibodies and antibody complexes, so as to understand their degree of conformational heterogeneity, and determine the binding sites between antibodies and antigens. The methods will be described and several case studies will be presented.

3:05 The Hunt for the Missing S: Detection, Control and Impact on Product Properties of Thioether Bonds in Fabs

John O'Hara, Ph.D., Director, Characterization & Method Development, Analytical Sciences, Biologicals, UCB

During a large scale GMP manufacturing campaign for a late stage development candidate a non-reducible species was detected on non-reducing SDS-PAGE. The characterization of this species resulted in the identification of a thioether bond. This presentation will review the characterization of the thioether bond as well as studies on the effect of process conditions on the levels of thioether. Finally, the impact of thioether bonds on the product quality and activity was assessed using a range of analytical techniques.

3:35 Improved Understanding of Association Between Protein Colloidal and Conformation Stability with Combined DLS/Raman

Sponsored by Malvern

E. Neil Lewis, CTO, Malvern Instruments Limited

A novel technique for protein therapeutics characterization, specifically the combination of dynamic light scattering (DLS) and Raman spectroscopy in a single platform. This system simultaneously characterizes protein secondary and tertiary structure, as well as hydrodynamic size, even at high concentrations (> 50 mg/mL), enabling the link between colloidal and conformational stability to more fully understood. The new insights and observations gained by applying DLS/Raman to actual bio-pharmaceutical formulations will be shown.

4:05 Refreshment Break in the Exhibit Hall with Poster Viewing

ANALYSIS OF VARIANTS

4:30 Effective and Meaningful System Suitability Control for Sequence Variant Analysis

Melissa Alvarez, MS, Senior Research Associate, Protein Analytical Chemistry, Genentech, Inc., a member of the Roche group

Sequence variants in recombinant protein therapeutics are product-related variants arising from unintended amino acid substitutions. Peptide mapping LC-MS/MS is currently the method of choice for confirming sequence fidelity in protein products. To ensure the highest detection sensitivity and consistency during sequence variant analysis, a system suitability test was developed. The control sample and its use were designed to reflect the desired detection capability and to verify assay performance.

5:00 Analysis of Variants in PEGylated Proteins and their Non-Pegylated Precursors

Jeffrey D. Meyer, Ph.D., Director, BioProcess Development, ZymoGenetics (a Bristol-Myers Squibb Company)

PEGylated proteins pose unique analytical challenges. For the non-PEGylated form of a protein, efficient HPLC analyses can be developed to resolve charge and hydrophobic/hydrophilic variants. In contrast, the decrease in resolution upon PEGylation may necessitate analysis of the non-PEGyalted intermediates or the use of peptide maps. Further, PEGylation can lead to generation of new variants such as multiply PEGylated forms, dimeric forms arising from bifunctional dimeric PEG, and positional isomers.

5:30 End of Day One of Analytical Characterization

5:45 – 8:45 Dinner Short Courses*

SC1: Impurities: Measurement, Characterization and Impact

SC2: Glycobiology of Antibodies

* Separate registration required, see page 3 for details

WEDNESDAY, MARCH 26

CHARACTERIZATION OF CONJUGATES

8:30 am Chairperson's Remarks

Alain Beck, Ph.D., Senior Director, Antibody Physico-Chemistry, Centre d'Immunologie Pierre Fabre; Associate Editor, mAbs

8:35 Structural Characterization of Protein Conjugates by Molecular Spectroscopy

Qin Zou, Ph.D., Senior Principal Scientist, Analytical Research & Development, Pfizer, Inc.

Bioconjugates are becoming increasingly important in biotherapeutics development. Many of these molecules rely on the structural integrity of the carrier proteins for their biological activities. The conjugation process and the presence of the payload may potentially alter the higher order structure of the carrier proteins and then negatively impact the product potency. Structural elucidation of the carrier molecule in conjugates is complicated and orthogonal characterization methods are frequently needed due to the different optical properties, molecular sizes and types of payload molecules. Case studies will be presented to introduce the various spectroscopic methods in characterizing bioconjugate molecules.

9:05 Gaining Insight into Antibody-Drug Conjugates through Analytics

Samadhi Vitharana, Ph.D., Senior Scientist, Core Sciences and Technologies, Takeda California, Inc.

Monoclonal Antibodies (mAbs) linked to cytotoxic payloads known as antibody-drug conjugates (ADC) represent an emerging technology in clinical oncology. ADCs utilize the specificity of a mAb to deliver a cytotoxic drug to targeted tumor cells. Chemistry of the linker, cytotoxic drug and sites of attachment often result in complex and heterogeneous drug product preparations. How analytics can shed light in evaluating different architectures of ADCs will be discussed.

9:35 Characterization Methods for Lysine Conjugated Maytansinoid ADCs

Michael Fleming, M.S., Scientist III, Analytical and Pharmaceutical Sciences, ImmunoGen, Inc.

ADCs are heterogeneous products due to the nature of the conjugation chemistries involved. Analytical methodologies must elucidate this heterogeneity and be able to demonstrate the extent to which this heterogeneity is consistent from lot to lot. The presentation will cover characterization methods that can demonstrate conjugation consistency for several maytansinoid ADCs with different cytotoxic agent and linker combinations. Analytical methods for higher order structure assessment will also be discussed.

10:05 Comprehensive Study of O-Linked Glycans of Erythropeitin by LC-MALDI-TOF MS

Sponsored by BRUKER

Jason S. Wood, Ph.D., Biopharmaceuticals Market Manager, Bruker Daltonics

Erythropeitin (EPO) is a glycoprotein with hormone activity that controls the production of red blood cells. Therapeutically, it is utilized to treat chemotherapeutically-induced aenemia but recently has been found as a doping agent in endurance sports. We report here a comprehensive LC-MALDI-TOF and MALDI-TOF/TOF analysis, including the use of dedicated software tools, of the O-linked glycopeptides of EPO allowing for different EPO samples of different origins to be easily distinguished.

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

IMPURITIES/SUB-VISIBLE PARTICLES, AGGREGATES AND HOST CELL PROTEINS

11:00 Pushing the Frontiers for the Characterization of Sub-Visible Particles

Björn Boll, Ph.D., Pharma Technical Development Europe, F. Hoffmann-La Roche Ltd.

Rising expectations from the health authorities with regard to measurement and characterization of sub-visible particles necessitate the evaluation and use of a large array of analytical methods. In recent years a number of new particle techniques have emerged. Although these emerging methods offer some advantages, they also present new challenges. This presentation will compare these emerging techniques and discuss their advantages, shortcomings and potential means of overcoming them.

11:30 Practical Considerations for Detection and Characterization of Sub-Micron Particles in Protein Solutions

Flaviu F. Gruia, Ph.D., Scientist, Analytical Biotechnology, MedImmune, Inc.

Nanoparticle Tracking Analysis (NTA) applicability for biopharmaceutical development was evaluated by testing the method's performance with particle standards and protein solutions. To benchmark its performance, NTA was compared against two more established analytical techniques, DLS and aF4-MALS, which can also probe the sub-micron size range. The comparative results of the evaluation will be presented as case studies and will identify specific advantages and limitations of the individual methods.

12:00 pm Characterization and Quantitation of Host Cell Proteins in Biopharmaceuticals Using LC-MS

Li Zang, Senior Scientist, Analytical Development, Biogen Idec, Inc.

Host cell proteins (HCPs) can pose potential safety risks to patients and affect the efficacy of biopharmaceuticals. Traditionally, HCPs are monitored using the ELISA method, which may be biased due to incomplete coverage from the antibody reagent. LC-MS methods in combination with various protein or peptide fractionation methods are explored to identify the HCPs present in a biopharmaceutical product. Quantitation of HCPs was achieved using LC-MS analysis with heavy isotope labeled peptides as internal standards.

12:30 Luncheon Presentation

Sponsored by BIO-RAD

Speaker to be Announced

FDA PERSPECTIVES ON PARTICLE CHARACTERIZATION

2:00 Chairperson's Remarks

John O'Hara, Ph.D., Director, Characterization & Method Development, Analytical Sciences, Biologicals, UCB

2:05 FEATURED PRESENTATION: Particle Characterization and Product Release Limits: Established and Evolving Techniques

Joey Kotarek, Ph.D., ORISE Fellow, CBER/FDA

Characterizing a biotherapeutic's aggregate profile requires an array of techniques to evaluate sizes and compositional ranges that aggregates could occupy. Compilation of this aggregate information for different classes of products may provide relevant risk data and could be used to suggest product specific testing. Here we discuss the integration of new aggregate characterization techniques and present a case study illustrating the potential for establishing product specifications.

LINKING STRUCTURE WITH FUNCTION

2:35 FEATURED PRESENTATION: Regulatory Perspectives on Functional Assays to Support Product Characterization

Baolin Zhang, Ph.D., Senior Investigator & Product Quality Reviewer, Therapeutic Proteins, Biotechnology Products, CDER/FDA

Potency assays are a critical component of biologic drug discovery and development. These assays are performed to assure product quality, consistency, and stability during all phases of clinical study. This presentation will discuss a regulatory perspective on method selection, design, and validation, as well as case studies highlighting the relevant issues that are commonly seen in the regulatory submissions.

3:05 Mass Spectrometry and Software for Structural Characterization of Biotherapeutics

Sponsored by Genedata

Juergen Schaefer, Ph.D., Mass Spectrometry Lab Head, Analytical Sciences, LGCR, Sanofi

Deep characterization of biotherapeutics is essential during drug development. Mass Spectrometry is key, offering tools to determine structure on a molecular level and to deliver quantitative values. MS based qualitative and quantitative comparisons are essential for development decisions of peptide, insulin and antibody drugs. Examples out of the MS toolbox and the importance of application specific software will be shown.

3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Analytical Elements of a Comprehensive Control Strategy

David Cirelli, M.S., Principal Scientist, Analytical Research & Development, Pfizer, Inc.

4:30 Development of Functional Assays to Support Product Characterization

Max Tejada, Ph.D., Senior Scientist, Biological Technologies, Genentech, Inc.

5:00 Linking Functional Characterization with MOA, *in vivo* Activities and Potential Clinical Outcomes

Patrick Liu, M.D., Ph.D., Global Head, Bioanalytical Sciences and Technologies, Teva Pharmaceutical Industries, Ltd.

5:30 – 6:30 Breakout Discussions

Table 1: Practical Application of New Mass Spectrometry Technology for Analytical Characterization
Moderator: Alain Beck, Ph.D., Senior Director, Antibody Physico-Chemistry, Centre d'Immunologie Pierre Fabre; Associate Editor, mAbs

Table 2: Characterization of Bi-Specifics to Reveal Antigen-Binding, Product Dynamics and Behavior
Moderator: Bridget Carragher, Ph.D., Integrative Structural and Computational Biology, Scripps Research Institute

Table 3: Technologies for Characterizing Protein Conjugates
Moderator: Qin Zou, Ph.D., Senior Principal Scientist, Analytical Research & Development, Pfizer, Inc.

Table 4: Characterization and Impact of Aggregation, Sub-Visible Particles and Host Cell Proteins
Moderator: Li Zang, Senior Scientist, Analytical Development, Biogen Idec, Inc.

Table 5: Bioassays to Link Structure with Function
Moderator: David Cirelli, MS, Principal Scientist, Analytical Research & Development, Pfizer, Inc.

6:30 Reception in the Exhibit Hall with Poster Viewing

7:30 Close of Analytical Characterization

THURSDAY, MARCH 27

8:00 am Registration and Morning Coffee

COMPARABILITY CASE STUDIES

8:30 Chairperson's Opening Remarks
Jeffrey K. Glenn, Ph.D., Associate Director, Analytical Development, Janssen R&D

» KEYNOTE PRESENTATION

8:35 The Commercial Product Lifecycle: Comparability Approaches and Control System Updates
John Stults, Ph.D., Director, Protein Analytical Chemistry, Genentech, Inc.
The product lifecycle of a biotherapeutic may span decades. During this period, a number of changes are expected which require comparability assessments, including process upgrades and manufacturing site transfers. Updates to the control system are also an important component of lifecycle management. Each of these exercises requires a well-defined strategy, and provides analytical challenges and opportunities. This presentation will describe approaches for the demonstration of comparability and for updating control systems, with case studies to highlight the analytical challenges and their solutions.

9:05 Stage-Appropriate, Risk-Based Comparability for Drug Substance Manufacturing Process Changes
Kazumi Kobayashi, Ph.D., Director, Bioprocess Development, Biogen Idec, Inc.

9:35 Case Study for a Monoclonal Antibody Due to Cell Line and Process Changes
Shanthini Jeyarajah, Ph.D., Associate Director, Biologics Analytical, AVEO Oncology
Changes to the manufacturing process including cell-line, process scale and site were made to increase the production of a monoclonal antibody during clinical development. A comprehensive comparability study consisting of analytical and non-clinical components has been performed to support the implementation of these changes. The analytical comparability study design, product attributes before and after process change and demonstration of comparability through release testing, extended structural and functional characterization and assessment of stability will be discussed in this presentation.

10:05 Sponsored Presentation
Speaker to be announced
Sponsored by SGS

10:20 Sponsored Presentation *(Opportunity available, please contact Jon Stroup, jstroup@healthtech.com)*

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

CHARACTERIZATION FOR COMPARABILITY

11:00 Comparability Assessment of Antibody Higher-Order Structure after Process Changes
Tom Lerch, Ph.D., Senior Scientist, Analytical Research & Development, Pfizer, Inc.
During the development of an antibody biotherapeutic, manufacturing process changes can affect protein structure, and consequently, drug function, efficacy and stability. As a result, comparability assessments are designed and implemented to evaluate product attributes before and after process changes. Established biophysical methods are lacking in quantitative evaluation of higher order structure (HOS) comparability. Strategies for evaluating HOS comparability in biotherapeutics and applying statistical analysis for biophysical comparability will be discussed.

11:30 Higher-Order Structure Characterization for Comparability Studies
Kelly Arthur, Ph.D., Senior Associate Scientist, Analytical Sciences, Amgen, Inc.

12:00 pm Antibody Characterization Using a Time-Resolved FRET FcRn Binding Assay
Jeffrey K. Glenn, Ph.D., Associate Director, Analytical Development, Janssen R&D
FcRn receptor binding provides an estimate of *in vivo* half-life, a tool for evaluating structure-function relationships, and determining lot-to-lot comparability. Due to the low-affinity interaction between antibodies and the FcRn receptor, a robust, easy-to-use format has been difficult to achieve. This presentation will describe an FcRn binding assay using the time-resolved fluorescence resonance energy transfer (TR-FRET) format. Results from different antibodies, examples of interference, and data demonstrating the stability-indicating nature of this method will be provided along with comparison to other FcRn binding formats.

12:30 Luncheon Presentation *(Opportunity available, please contact Jon Stroup, jstroup@healthtech.com)* **or Lunch on Your Own**

LIMITS OF ACCEPTABLE VARIATION

1:30 Chairperson's Opening Remarks
Kenneth R. Miller, Ph.D., Senior Scientist, Analytical Biotechnology, Regulatory Sciences & Strategy, MedImmune, Inc.

1:35 Compendial Tests and Quality Attributes for Biotherapeutics – Special Challenges for Glycosylated Molecules
Tina S. Morris, Ph.D., Vice President, Biologics & Biotechnology, United States Pharmacopeial Convention
Glycosylation is a non-template driven, highly process dependent post-translational modification, and presents special challenges in the manufacturing, analytical development and quality control of biotherapeutics. In the context of comparability exercises, both within the space of a single manufacturer and in assessing product quality across manufacturers, defining performance criteria for appropriate analytical approaches as well as setting acceptance criteria are key decisions – how good is good enough? This presentation explores how compendial standards can serve as benchmarks for best analytical practices in general and specifically for key quality attributes of well-characterized biotherapeutics.

2:05 Acceptable Changes in Quality Attributes of Antibodies and Assimilated Biopharmaceuticals
Robert Mayer, Ph.D., Scientist, Analytical Characterization, Sandoz GmbH
Variation in quality attributes comprising identity, strength and purity that are acceptable in the product life cycle has been debated extensively. This talk presents a study focussing on variation in marketed biologics. By analyzing the quality profiles of Rituxan®/Mabthera® (rituximab) and Enbrel® (etanercept) sourced from the market between 2007 and 2010, this presentation provides examples of acceptable variations for products that have remained on the market with unchanged product labels.

2:35 Sponsored Presentation *(Opportunity available, please contact Jon Stroup, jstroup@healthtech.com)*

3:05 Refreshment Break in the Exhibit Hall with Poster Viewing

REGULATORY PERSPECTIVES ON CHARACTERIZATION AND COMPARABILITY

3:30 FEATURED PRESENTATION: Regulatory Perspectives on Comparability Studies for Biotechnology Products
Lixin Xu, M.D., Ph.D., Product Quality Reviewer, Division of Monoclonal Antibodies, Office of Biotechnology Products, CDER/FDA

In the lifecycle of a biotechnology product, manufacturing changes to the drug substance or to the drug product are unavoidable. It is the responsibility of the manufacturer to demonstrate sufficient and appropriate comparability between pre-change and post-change products. Regulatory considerations from product quality perspective for the comparability process (package), for demonstrating analytical comparability and for comparability across the product manufacturing lifecycle will be discussed.

4:00 – 5:00 Breakout Discussions

Table 1: Comparability Challenges for Glycosylated Therapeutics
Moderator: Tina S. Morris, Ph.D., Vice President, Biologics & Biotechnology, United States Pharmacopeial Convention

Table 2: Critical Quality Attributes and Critical Process Parameters
Moderator: Kenneth R. Miller, Ph.D., Senior Scientist, Analytical Biotechnology, Regulatory Sciences & Strategy, MedImmune, Inc.

Table 3: Analytical Studies Required to Support Process Change, such as Scale Up, Change of Manufacturing Site, Formulation Change etc.
Moderator: John Stults, Ph.D., Director, Protein Analytical Chemistry, Genentech, Inc.

Table 4: Putting Together a Clinical Comparability Protocol
Moderator: Kazumi Kobayashi, Ph.D., Director, Bioprocess Development, Biogen Idec, Inc.

5:00 End of Day One of Comparability & Developability

5:30 – 8:30 pm Dinner Short Course*
SC3: The Science and Regulation of Process Changes for Biologics
* Separate registration required, see page 3 for details

FRIDAY, MARCH 28

PROCESS DEVELOPMENT AND ANALYTICS

8:00 am Chairperson's Opening Remarks
John Stults, Ph.D., Director, Protein Analytical Chemistry, Genentech, Inc.

8:05 Testing Strategy as a Holistic Approach: Risk-Based Optimization for In-Process, Release and Stability Testing
Alla Polozova, Ph.D., Principal Scientist, Global Analytical Sciences, Amgen, Inc.
Analytical testing is one of the key elements of control strategy for manufacturing and release of protein therapeutics. In a holistic approach, in-process, release and stability tests for drug substance and drug product can be viewed as a testing continuum. Such an integrated approach, combined with QbD-based risk assessments, supports elimination of non-value added redundancies and optimization of the entire testing strategy without compromising product quality.

8:35 Molecule Assessment: Averting Problems in Development
Amy Hilderbrand, Ph.D., Scientist, Protein Analytical Chemistry, Genentech, Inc.
To assess the manufacturability of biological molecules coming from late stage research, a cross-functional team was established to characterize and evaluate possible issues that would hinder the development of these molecules into drug products. The evaluation includes stability assessment of specific motifs within the molecule under stressed conditions. This talk will focus on the analytical techniques used for early molecular assessment.

9:05 The Application of Quality by Design to Analytical Method Development
Kenneth R. Miller, Ph.D., Senior Scientist, Analytical Biotechnology, Regulatory Sciences & Strategy, MedImmune, Inc.
Quality by Design (QbD) has been applied to the manufacturing of pharmaceuticals to ensure satisfactory process performance and product quality. This presentation will describe how the same principle can be applied to analytical methods to ensure that analytical test methods have satisfactory performance to make development and quality decisions. Specific mention will be given to strategies for establishing an Analytical Target Profile and a Design Space for methods.

9:35 The Interface between Process Development and Analytics
Zahra Shahrokh, Ph.D., Chief Development Officer, STC Biologics
The resolution, sensitivity, speed, and breadth of the analytical methods used in early process development impact the need for later changes that in turn affect time and cost to market. Biosimilar development is the poster child of the early need for QBD, but the level of industry know-how, budget, and competition shapes how each organization approaches process development. In this presentation, case examples of the reason for and impact of improved or new analytical tools used in later stages of development will be described.

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

BIOSIMILARS

10:30 Extrapolation of Indications for Biosimilars
Christopher J. Holloway, Ph.D., Group Director, Regulatory Affairs & CSO, ERA Consulting Group
Biosimilars, approved in past years in Europe, have generally been granted "extrapolation of indications" corresponding to the label of the reference product, although not all of these indications were evaluated in comparative clinical trials. In this presentation, case studies, in particular infliximab, and rituximab, will be considered in the light of current EMA and FDA guidance, together with approaches to clinical trial indications that are most likely to reap rewards in the context of "extrapolation of indications."

11:00 Update and Perspectives on CMC Requirements for Development of Biosimilar Products in the US: When is Your Biosimilar not a Biosimilar?
Emily Shacter, Ph.D., Consultant, ThinkFDA
As the US FDA progresses in the implementation of the US pathway for development and licensure of biosimilar protein products, sponsors still have many questions regarding the analytical, non-clinical, and clinical studies required to license their biosimilar products in the US. In this talk, we will discuss how the analytical similarity assessments are employed to answer some of the most common questions, such as: What does 'highly similar' really mean? How similar is similar enough? Which attributes 'matter' and which do not? How is this demonstrated? And, most importantly, what information and data does the FDA need to determine the residual uncertainty that there may be clinically-meaningful differences in the clinical performance of the biosimilar compared to the US-licensed reference product?

11:30 Case Studies for mAbs and Glycosylated Products on Impact of Manufacturing Change on Product Quality
Laxmi Adhikary, Ph.D., Principal Scientific Manager, Research & Development, Biocon Ltd.
It is important to focus on a comparability protocol for both process parameters and product quality which delineates a well-documented plan with pre-set defined acceptance criteria for assessment of process changes which can have an impact on product quality. In this presentation comparability protocols and data presentation will be shared which will focus on change of cell line, scale and process during the product development (prior to approval). The discussion will also conclude on comparability requirements for biosimilar product development.

12:00 pm End of Comparability & Developability

1:30 – 4:30 Afternoon Short Course*
SC4: Strategy for Entering the Biosimilars Market*
* Separate registration required, see page 3 for details

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250 First Avenue, Suite 300
Needham, MA 02494
www.healthtech.com
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