SIXTH ANNUAL
Biotherapeutics Analytical SUMMIT
MARCH 9-13, 2015
Hyatt Regency Baltimore
Baltimore, Maryland

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CAMBRIDGE HEALTHTECH INSTITUTE'S SIXTH ANNUAL

Biotherapeutics Analytical SUMMIT

MARCH 9-13, 2015 | HYATT REGENCY BALTIMORE | BALTIMORE, MARYLAND

KEYNOTE PRESENTATIONS

High-Throughput Methods to Measure Multiple Mechanisms of Action of Therapeutic Antibodies
T. Shantha Raju, Ph.D., Scientific Director, Biologics Research, Janssen Research & Development, LLC

USP Perspective on Analysis of Variants
Fouad Atouf, Ph.D., Director, Biologics and Biotechnology, U.S. Pharmacopeia

New Approaches to Characterization of Biopharmaceutical Products
Igor A. Kaltashov, Ph.D., Professor, Chemistry, University of Massachusetts, Amherst

Perspectives on FDA Expectations for Phase Specific Product Characterization
Emily Shacter, Ph.D., Consultant ThinkFDA LLC

An FDA Perspective on Risk-Based and Phase Appropriate Comparability
Marjorie Shapiro, Ph.D., Chief, Laboratory of Molecular and Developmental Immunology, Division of Monoclonal Antibodies, CDER, FDA

PROGRAMS

Part One: Analytical Methodology and PTMs
MARCH 9-10

Part Two: Characterization & Compliance
MARCH 10-11

Part Three: Comparability for Biologics
MARCH 12-13

+ SHORT COURSES

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CONFERENCE AT A GLANCE

**Separate Registration Required for Short Courses.*

	MONDAY MARCH 9	TUESDAY MARCH 10	WEDNESDAY MARCH 11	THURSDAY MARCH 12	FRIDAY MARCH 13
AM	PART ONE: ANALYTICAL METHODOLOGY AND PTMS			PART THREE: COMPARABILITY FOR BIOLOGICS	
PM		PART TWO: CHARACTERIZATION AND COMPLIANCE			
EVENING	RECEPTION	SC2: SVPS, AGGREGATES AND IMPURITIES* SC3: GLYCOLOGY OF ANTIBODIES*	RECEPTION	SC4: ASSESSING BIOPHARMACEUTICAL COMPARABILITY* SC5:COMPARABILITY AND BIOSIMILARITY*	

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SHORT COURSES*

**Separate Registration Required*

Dinner will be served during the short courses

Tuesday, March 10 | 6:00 – 9:00 pm

SC2: Sub-Visible Particles, Aggregates and Impurities: Measurement, Characterization and Impact

Instructors:

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

Dean Ripple, Ph.D., Group Leader, Bioprocess Measurement Group, National Institute of Standards and Technology

Srivalli Telikepalli, Ph.D., Research Chemist, Biomolecular Measurement Division, National Institute of Standards and Technology

Agenda outline:

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 and other methods

- ***Technologies and Tools for Identification and Characterization***
- Aggregates (Size exclusion SEC, AUC, FFF, etc.)
- Sub-visible (Microflow imaging, light obscuration, etc.)
- Comparisons between technologies regarding limits of detection
- Open Discussion on which approaches can be regarded as FDA compliant

Recent Experiences and Case Studies Discussion with Q&A

SC3: Glycobiology of Antibodies

Instructor:

T. Shantha Raju, Ph.D., Scientific Director, Biologics Research, Janssen Research & Development, LLC

Agenda outline:

- 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
- Discussion with Q&A

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SHORT COURSES*

*Separate Registration Required

Dinner will be served during the short courses

Thursday, March 12 | 6:00 – 9:00 pm

SC4: Assessing Biopharmaceutical Comparability via Biophysical Characterization

Instructor:

Steven A. Berkowitz, Ph.D., Consultant

In this short course, we will focus our attention on discussions concerning the integral role that biophysical characterization plays in supporting comparability studies in developing biopharmaceuticals. Much of the activities centered in this area are concerned with the task of building and utilizing a biopharmaceutical's biophysical fingerprint. This fingerprint is a key element in assessing the higher-order structure (HOS) information on a biopharmaceutical, which is then employed as the master comparator for detecting differences in the biopharmaceutical during its development. Since no one biophysical tool can adequately provide this complete fingerprint, a battery of biophysical tools will be required.

Agenda outline:

- Setting the stage as to what the needs and goals are in conducting biophysical characterization
- Building the biophysical fingerprint
- Part I: Low resolution biophysical characterization tools
- Part II: Assessing biophysical properties
- Part III: The challenges of high-resolution biophysical characterization tools
- The H/DX-MS &NMR story
- Discussing the unique problems and challenges in biophysically characterizing biopharmaceuticals at high concentration

SC5: Comparability and Biosimilarity: Principles and Case Studies

Instructors:

Christopher Holloway, Ph.D., Group Director, Regulatory Affairs & CSO, ERA Consulting Group

Marjorie Shapiro, Ph.D., Chief, Laboratory of Molecular and Developmental Immunology, Division of Monoclonal Antibodies/OBP/OPS, CDER, FDA

The focus of this short course is on CMC issues around comparability and (bio) similarity, on the one hand covering expectations for an analytical comparability exercise accompanying process changes during development as well as post-marketing changes of a biologic and, on the other hand, addressing the analytical and functional tests used to establish (bio)similarity between a biosimilar product and the reference product. The course will offer both the US FDA and the EU perspectives and experiences on these subjects. The impact of the implementation of a design space and continual process verification on post-marketing comparability will also be discussed. Apart from the principles of comparability and (bio)similarity, practical advice on frequently asked questions, such as "how many batches?" will be discussed in detail, in the context of the attributes of the respective analytical methods, their variability, and the consistency of the datasets. Where possible, case studies will be presented, to highlight the potential pitfalls that have been encountered with comparability and (bio)similarity exercises. The particular problems arising from process changes during development of a biosimilar product will be discussed, as this adds the complication of a comparability exercise alongside the demonstration of (bio)similarity.

Topics will include:

- Principles and practice of a comparability exercise according to ICH Q5E
- Case studies in comparability accompanying process changes, during development and post-approval, what is required when?
- Comparability protocols (US) and change management protocols (EU)
- Comparability versus (bio)similarity exercises, definitions
- Demonstrating (bio)similarity between a biosimilar and reference product at various stages of development
- Experiences to date with biosimilar products, successes and failures
- The complication of process changes during clinical development of a biosimilar product

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Analytical Methodology and PTMs

Advances with Analytical Methods, Applications for Variants and Post-Translational Modifications

MONDAY, MARCH 9

7:30 am Registration and Morning Coffee

ADVANCES WITH ANALYTICAL METHODS

8:30 Chairperson's Opening Remarks
Taylor Zhang, Ph.D., Senior Scientist and Group Leader, Protein Analytical Chemistry, Genentech, Inc.

» 8:35 KEYNOTE PRESENTATION: High-Throughput Methods to Measure Multiple Mechanisms of Action of Therapeutic Antibodies
T. Shantha Raju, Ph.D., Scientific Director, Biologics Research, Janssen Research & Development, LLC

9:05 Analytical Characterization for Biologics Candidate Selection and Optimization: Where Are We Now and Where Do We Go from Here?
Guodong Chen, Ph.D. Senior Principal Scientist, Bioanalytical and Discovery Analytical Sciences, Research and Development, Bristol-Myers Squibb Company
Biologics candidate selection and optimization is an important aspect of biologics discovery and development. This presentation highlights analytical strategies and methodologies in the selection and optimization of candidates, as illustrated in case studies.

9:35 Characterization of Higher Order Structure of Biotherapeutics
Maurizio Muroni, Ph.D., Scientist II, Development, Medimmune, UK
This presentation will cover a study of the oligomerization state of non-platform biotherapeutics by light scattering techniques and MALDI-TOF mass spectrometry, and the use of circular dichroism and mass spectrometry for investigation of secondary and tertiary structures.

Sponsored by Genedata

10:05 End-To-End Software Solution for Mass Spectrometry Based Biopharmaceutical Characterization
Joe Shambaugh, Head, Expressionist, Mass Spectrometry, US, Genedata Inc.

Biopharmaceutical R&D organizations employ mass spectrometry as the method of choice for the indepth characterization of therapeutic candidates. However, it remains challenging to optimize data processing, analysis, and reporting across multiple instrument platforms and laboratories within an organization. Here we discuss how the Genedata Expressionist for Mass Spectrometry enterprise software solution enables complete automation and standardization of the end-to-end characterization process from discovery and development to production and quality control.

10:35 Networking Coffee Break

POST-TRANSLATIONAL MODIFICATIONS

11:00 Novel Methods to Speed Up PTM Profiling to Support Early Developability Risk Assessment of Biologics Candidates
Christian Graf, Ph.D., Principal Scientist, BPRD Integrated Biologics Profiling, Novartis Pharma
Characterization of critical post translational modifications is important for developability risk assessment of biotherapeutic drug candidates. However it usually involves labor-and time-consuming preparation of stressed samples, and also physicochemical analytics requiring large amounts of purified material. This talk presents new approaches and case studies using middle-down UPLC-MS and MS/MS methods combined with automated acquisition and data processing software, allowing rapid PTM profiling in much higher throughput with low concentrated antibody samples.

11:30 Tools to Examine the Driving Forces behind Chemical Degradation Hot Spots to Help with Candidate Selection
Hubert Kettenberger, Ph.D., Principal Scientist, Innovation Center, Penzberg, Large Molecule Research, Roche
Chemical degradation events such as asparagine deamidation or aspartate isomerization can be limiting factors for the stability of therapeutic proteins. Only a small subset of such residues actually degrades quickly, indicating that particular structural features define a degradation "hotspot". Combining mass spectrometry, 3D structural modeling and machine learning, we developed an in-silico tool that reliably predicts hotspots and helps to select stable lead candidates.

12:00 pm Detection and Characterization of Reversible Self-Association of Therapeutic Monoclonal Antibodies
Sophia Levitskaya, Ph.D., Scientist, Analytical Biotechnology, Medimmune
This presentation discusses the nature of reversible self-association (RSA), and how we know if a protein self-associates. A case study of IgG2 (MAB A) will be presented. Factors affecting RSA, analytical methods used for RSA detection and characterization, and means of controlling self-association will all be discussed.

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

POST-TRANSLATIONAL MODIFICATIONS *Continued*

1:55 Chairperson's Opening Remarks
Christian Graf, Ph.D., Principal Scientist, BPRD Integrated Biologics Profiling, Novartis Pharma

2:00 Case Study on Detection of Abnormal PTMs, Low Level Mutations, Sequence Variants, and Amino Acid Substitutions
Dingyi Wen, Ph.D., Principal Scientist, Analytical Biochemistry, Biologics Drug Discovery, Biogen Idec, Inc.
Biologicals, a class of drugs of growing importance, require careful characterization because of their large size and complexity. This talk will describe the mass spectrometry-based characterization strategy currently used in our laboratory to detect and quantify low levels of sequence variants, PTMs

and other modifications in biological drug candidates. Specific cases, such as those involving amino acid substitution and O-Xylosylation, will be discussed, as well as cell culture conditions that affect PTMs and sequence variation.

2:30 Antibody Fc Deamidation: The Well-Known and Less Well-Known

Taylor Zhang, Ph.D., Senior Scientist and Group Leader, Protein Analytical Chemistry, Genentech, Inc.

Deamidation is one of the most common degradation pathways and frequently occurs at "hot spots" with NG, NS or NT sequences. Here we will present the use of a chymotryptic peptide mapping method to identify and characterize a not-"hot spot" deamidated form of an IgG1 which was observed as an acidic peak. The formation of this unique deamidation and other well-known deamidation sites will be discussed.

3:00 - 4:00 Breakout Discussions

Table 1: Practical Application of Glycosylation Characterization

Moderators: T. Shantha Raju, Ph.D., Scientific Director, Biologics Research, Janssen Research & Development, LLC, and Kenneth Moore, MSc, Associate Scientist II, Novel Molecules Group, Analytical Biotechnology Division, MedImmune, Inc.

- How much glycosylation characterization is required?
- When do we evaluate the impact of glycosylation on structure and function?
- How do we control glycan microheterogeneity?
- How close are we to 'dialling-in' a glycan profile?

Table 2: Analysis of Heterogeneity of Charge Isoforms

Moderator: Taylor Zhang, Ph.D., Senior Scientist and Group Leader, Protein Analytical Chemistry, Genentech, Inc.

- Technologies for characterizing and quantifying charged isoforms
- Measures to ensure you identify all the species
- How you decide on acceptable levels of heterogeneity
- Setting specifications based on a range of heterogeneity
- Importance of prior knowledge of the product

Table 3: Analytical Characterization for Candidate Selection and Optimization

Moderator: Christian Graf, Ph.D., Principal Scientist, BPRD Integrated Biologics Profiling, Novartis Pharma

- How to best quantify fragmentation, deamidation, isomerization, glycation, glycosylation, conjugates?
- Ranking criteria for critical PTMs and the selection of different candidates
- Prediction, optimization and re-engineering of molecule liabilities
- New technologies for characterization of structural integrity and modifications

Table 4: Challenges of Structure and Sequence Analysis

Moderator: Richard Beardsley, Ph.D., Scientist, Protein Analytical Chemistry, Genentech, Inc.

- Advances being made in analytical technology that allow the discovery of new variants
- Variants observed
- Identifying and avoiding pitfalls arising from sequence variants over the course of product development
- Differences that can be tolerated / what matters and what doesn't
- Comparing sequences with products from different expression systems
- Consequences of sequence variants from a regulatory perspective
- Means of examining the impact of new variants on safety and efficacy
- Risk assessment of results in terms of immunogenicity, potency and stability

4:00 Networking Refreshment Break

4:30 Discovery and Characterization of a Novel Free Drug Species in Antibody-Drug Conjugates

Richard Beardsley, Ph.D., Technical Development Scientist, Protein Analytical Chemistry, Genentech, Inc.

This presentation will focus on the factors leading to the formation of a novel free drug species that can be found in antibody-drug conjugate materials. The impurity is a dimerized form of the drug species used to conjugate the antibody, and can appear at low levels depending, in-part, on the presence of inter-chain trisulfides in the antibody prior to the conjugation reaction.

PROTEIN AND SEQUENCE VARIANTS

5:00 Analysis of Protein Variants from Serum to Support CQA Assessment during Early Development

Fabian Higel, Ph.D., Scientist, PK Profiling, Analytical Characterization, Sandoz Biopharmaceuticals

MAbs and Fc fusion proteins are highly complex protein mixtures containing multiple different modifications that might impact the pharmacokinetics, efficacy or safety. The identification and evaluation of these critical quality attributes is important and should be implemented during early development. Case studies investigating the effect of e.g. N-glycosylation or disulfide variants on the pharmacokinetics of mAbs and Fc fusion proteins are shown, demonstrating their feasibility and usefulness in early development.

5:30 Sequence Variant Analysis of Antibody Biotherapeutics with Ultrahigh-Resolution Mass Spectrometry

Heather DeGruttola, MS, Scientist, Mass Spectrometry and Biophysical Characterization, Pfizer, Inc.

Sequence variants (SV) are protein isoforms containing unintended amino acid substitutions typically due to either DNA mutations or mis-incorporations from either transcription or translation errors. Our clone screening strategy involves a multi-tiered approach using orthogonal mass spectrometric and genomic methods applied to SV detection. Several case studies will be presented that demonstrate comprehensive detection, identification and quantitation of sequence variants arising from both mutations and mis-incorporations.

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

7:15 Close of Day

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SIXTH ANNUAL

Analytical Methodology and PTMs

PART ONE | MARCH 9-10

Advances with Analytical Methods, Applications for Variants and Post-Translational Modifications

TUESDAY, MARCH 10

8:00 am Morning Coffee

PROTEIN AND SEQUENCE VARIANTS/ CHARACTERIZATION OF GLYCOSYLATION AND GLYCAN PROFILING

8:30 Chairperson's Opening Remarks

T. Shantha Raju, Ph.D., Scientific Director, Biologics Research, Janssen Research & Development, LLC

» 8:35 KEYNOTE PRESENTATION: USP Perspective on Analysis of Variants

Fouad Atouf, Ph.D., Director, Biologics and Biotechnology, U.S. Pharmacopeia

Test specifications for recombinant proteins variants are an important component of public standards and are very often included in pharmacopeial monographs. This presentation will discuss approaches used to include these requirements into monographs and how these requirements evolve throughout the lifecycle of a public standard, as well as the type of reference standards used to support this type of tests.

9:05 High-Throughput Methodology in Characterization of Glycoproteins

Huijuan Li, Ph.D., Director, Sterile Product and Analytical Development, Bioprocess Development, Merck & Co., Inc.

The production of recombinant therapeutic glycoproteins has been an active area of research and drug development over the last 20 years. Multiple high-throughput methods for protein characterization with rapid cycle times will be discussed.

9:35 Application of Lectin-Based Microarray in Direct Glycan Profiling of Therapeutic Proteins

Lei Zhang, Ph.D., ORISE Fellow, Office of Biotechnology Products, CDER/FDA

Glycan moieties of therapeutic glycoproteins are a critical product attribute that directly affect protein folding, bioactivity, pharmacokinetics, and immunogenicity. Therefore, glycan variants must be adequately analyzed and controlled to ensure product quality and manufacturing consistency. This presentation describes our FDA research aimed at assessing the suitability of lectin-based microarray platforms for the quantitation of glycan variants in therapeutic proteins and monoclonal antibodies.

10:05 Making PTM and Sequence Variant Analysis Easy and Reliable

Sponsored by PROTEIN METRICS

Chris Becker, Ph.D., President & CEO, Protein Metrics Inc

Mass spectrometry is relied on within biopharma throughout the development pipeline. Learn about novel, risk-reducing, scalable software tools from Protein Metrics for rapid peptide mapping, similarity studies, and sensitive analysis and reporting of variants and post-translational modifications.

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

11:05 Glycoprofiling of a Highly Complex Glycoprotein

Kenneth Moore, MSc, Associate Scientist II, Novel Molecules Group, Analytical Biotechnology Division, MedImmune, Inc.

Glycosylation is a major source of heterogeneity in recombinant proteins and requires thorough characterization. The N-linked glycan structures of a highly complex glycoprotein were characterized using Hydrophilic Interaction Liquid Chromatography (HILIC) and Matrix-assisted laser desorption/ionization Time-of-flight (MALDI-TOF) spectrometry. The glycan sequence of the protein was determined using these techniques in combination with monosaccharide-specific exoglycosidases. This approach revealed the presence of a complex, heterogeneous glycoprofile with several distinct oligosaccharide populations, including some atypical glycan structures.

11:35 Case Study on Experiences with Glycosylation Analysis for Non-mAb Protein Therapeutics

Sherry Castle, Senior Analytical Development Specialist, R&D, Shire, Inc.

Existing N-linked glycan analysis platforms are not sufficient for several classes of complex glycoprotein therapeutics. Potential quality attributes may be overlooked when performing established glycan assays that were developed using mAbs. Unique technical challenges include the presence of highly charged glycan moieties, such as sialic acid, phosphate and sulfate; multi-antennarity; and complex microheterogenity. Adoption of emerging technologies provides continuous improvement to the analytical lifecycle, but these technologies must function within the framework of past reportable values. Here we share a glycan analysis modification of an established glycan methodology to test for unique properties of complex glycosylation.

12:05 pm Close of Part One - Stay on for Part Two: Characterization & Compliance

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TUESDAY, MARCH 10

12:30 pm Registration

CHARACTERIZATION OF SPECIFIC PRODUCTS

1:30 Chairperson's Opening Remarks

Ned Mozier, Ph.D., Senior Director, Analytical R&D, Biotherapeutics Pharmaceutical Sciences, Pfizer, Inc.

» 1:35 KEYNOTE PRESENTATION: New Approaches to Characterization of Biopharmaceutical Products

Igor A. Kaltashov, Ph.D., Professor, Chemistry, University of Massachusetts, Amherst

Quantitation of biotherapeutics in biological matrices remains a challenging problem in PK studies. One additional complication that is encountered frequently is the close similarity of the biopharmaceutical product and abundant endogenous proteins (e.g., transferrin- or albumin-based drug conjugates). We will discuss the application of traditional isotope labeling techniques (e.g., based on O18 labeling) and new approaches developed in our lab that utilize metal tagging protein therapeutics and their detection, quantitation and imaging based on inductively-coupled plasma mass spectrometry (ICP MS).

2:05 Overcoming Analytical Challenges in Characterization of Heterogeneities of Antibody-Drug Conjugates

April Xu, Senior Principle Scientist, BioTx – Analytical R&D, Pfizer, Inc.

An antibody drug conjugate exhibits additional heterogeneity compared to the corresponding monoclonal antibody. In this presentation, a case study will be presented on how heterogeneity in an antibody-drug conjugate is characterized. In particular, the application of improved analytical techniques using capillary electrophoresis and protein mass spectrometry are applied to characterize the heterogeneities due to drug load distribution.

2:35 Exploring the Structure and Flexibility of Dual Variable Domain Immunoglobulins Alone and with Bound Antigens

Czeslaw Radziejewski, Ph.D., Associate Director, Analytical Development, Process Sciences, AbbVie, Inc.

Dual-variable domain immunoglobulins (DVD-Ig) are engineered bispecific tetravalent molecules that are currently under development for multiple disease targets at AbbVie. We have applied electron microscopy to investigate DVD-Ig molecule and its complexes with antigens. This is the first time that the overall structure and flexibility of DVD-Ig molecules alone and accompanied by its antigens have been successfully interrogated by single particle electron microscopy.

3:05 Development of Mass Spectrometry-Based Approaches to Study the Dimerization of Therapeutic Monoclonal Antibodies

Shunhai Wang, Ph.D., Scientist, Analytical Chemistry, Regeneron Pharmaceuticals, Inc.

Sponsored by BRUKER

3:35 Epitope Mapping Enabled with Fast Photochemical Oxidation of Proteins Approach

Yuan Cao, Ph.D., Protein Analytics, Adimab, LLC

Characterization of the antibody/antigen interaction (epitope mapping) provides the fundamental understanding for rational design of therapeutic mAbs. Fast Photochemical Oxidation of Proteins (FPOP) has recently been developed in academic labs as an alternative method for HDX MS method. Here, we designed an adapted FPOP approach coupled with affinity precipitation and LC-MS/MS. As a result, we profiled the conformational epitope of target of interest #1 and #2 against commercialized mAbs and mAb leads from Adimab workflow.

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

CHARACTERIZATION AND CONTROL OF SUB-VISIBLE PARTICLES AND AGGREGATES

4:45 Assessing Aggregation of Therapeutic Proteins in Human Plasma

Shen Luo, Ph.D., Senior Staff Fellow, Division of Therapeutic Proteins, Office of Biotechnology Products, CDER/FDA

The formation of aggregates in therapeutic proteins could adversely impact product safety and efficacy. Therefore, the levels of aggregate must be adequately controlled throughout the formulation and clinical administration procedures. We are interested in understanding product aggregation under conditions mimicking clinical settings, which involve the active pharmaceutical ingredient, formulation excipients, diluent, and plasma components. This presentation describes our findings about the pathways leading to protein product aggregation in human plasma.

5:15 Reversible Self-Association and Stability in a Monoclonal Antibody

Julie Wei, Ph.D., Scientist II, Protein Pharmaceutical Development, Biogen Idec, Inc.

This work is a biophysical characterization study of a monoclonal antibody that displays reversible self-association and poor stability. A possible connection between the protein's self-association with poor stability has been investigated by a suite of biophysical methods including AUC, FTIR, thermal and chemical denaturation, and HDX-MS, as well as molecular modeling. A structural basis for the reversible self-association and poor stability is proposed.

5:45 Close of Day / Short Course Registration

6:00 – 9:00 Dinner Short Courses*

Dinner SC 2: Sub-Visible Particles, Aggregates and Impurities: Measurement, Characterization and Impact

Dinner SC 3: Glycobiology of Antibodies

(*Separate registration required; see page 3 for details)

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WEDNESDAY, MARCH 11

7:30 am Morning Coffee

REGULATORY PERSPECTIVES AND PHASE SPECIFIC REQUIREMENTS

8:00 Chairperson's Remarks
Martin Vanderlaan, Ph.D., Director, Analytical Operations, Genentech, Inc.

» 8:05 KEYNOTE PRESENTATION: Perspectives on FDA Expectations for Phase Specific Product Characterization
Emily Shacter, Ph.D., Consultant ThinkFDA LLC
When do you have to do what in order to meet FDA expectations for the development and approval of protein products for clinical and commercial use? This talk is aimed at helping you understand regulatory expectations on many of the questions that arise during product development, including the extent of analytical characterization studies, method validation, bioactivity, CQA assessment, and process control required at each stage of development.

8:35 Integration of Product Comparability into Process Development Strategies to Ensure Regulatory Approval
Alain Bernard, Ph.D., Vice President, Technical Operations GPS, UCB Pharma
We will demonstrate how appropriately and safely implemented process changes have effectively improved product quality and how some changes can contribute significantly to major progress in process and product understanding with positive impacts for the patients. We will exemplify how an extensive array of analytical tools, including some low-throughput but highly indicative quality tests can be used to increase chances of success with the comparability exercise.

9:05 Case Study on Early and Late Stage Characterization of an HSA Fusion Protein to Align with Clinical Phases
Ping Feng, MSc, Director, Analytical Sciences, Biological CMC, Teva Pharmaceuticals, Inc.
The focus of early stage characterization is evaluation of product biological activity and overall purity profile, including assessment of primary degradation pathways, and PTMs to support initiation of early clinical studies (I&II) and setting-up a baseline for future comparability. Late stage characterization includes a full understanding of the purity/impurity profile, and compatibility and product stability to support drug licensure. A case study will be presented on variant characterization of an HSA fusion protein.

9:35 Breakout Discussions

Table 1: Practical Application of New Mass Spectrometry Technology
Moderator: Igor A. Kaltashov, Ph.D., Professor, Chemistry, University of Massachusetts, Amherst
- Range of mass spec approaches for analytical characterization
- Potential applications of mass spec: sequence errors, glycoforms,etc.
- Application of mass spec for ADCs and bispecific antibody characterization
- Applications for comparability and routine structural assessments

Table 2: Aggregation: Factors that Give Rise to Aggregation and Means of Characterizing Aggregates
Moderator: Shunhai Wang, Ph.D., Scientist, Analytical Chemistry, Regeneron Pharmaceuticals, Inc.
- Aggregate heterogeneity and challenges for analytical characterization
- Discussion on contributory factors to aggregation
- Strategies for aggregate characterization
- Additional challenges with aggregates

Table 3: Appropriate Use of Functional Assays to Support Product Characterization
Moderator: Tamer Eris, Principal Scientist, Attributes Sciences, Amgen, Inc.
- Product dependent effector function characterization strategies
- Understanding product quality attribute impact on effector function activity
- Tools, technologies and assay formats, e.g. challenges with CDC, ADCC, binding assays, potency assays, surrogate assays

Table 4: Building an In-House Reference Standard System
Moderator: Baolin Zhang, Ph.D., Senior Investigator, Division of Therapeutic Proteins, Office of Biotechnology Products, CDER/FDA
- Interpretations of the primary reference standard and the working reference standard
- Discussion of when to do what (BLA stage, before process validation and/or after tech transfer)
- Forward planning required to ensure there is enough reference material at every stage
- Analytical testing that needs to be standardized
- Comparing current reference standards with previous ones
- Challenges with bioassays regarding reference standards

Table 5: Detection and Characterization of Process-Related Impurities
Maura Kibbey, Ph.D., Senior Scientist Liaison, Biologics and Biotechnology, USPharmacopeia
- Importance of ensuring that most HCPs are detected and appropriate methods for doing this
- Besides residual HCP and DNA, what are the other process-related impurities that are hot topics?
- Comments on USP activities related to residual HCP and DNA detection

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

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PRODUCT-RELATED IMPURITIES

11:05 High Throughput Microfluidic Immunoassay Technology Supporting Bioprocess Development and its Application for Titer, Residual HCP, and Protein A Quantification

Jun Heo, Ph.D., Analytical Scientist, Bioprocess Technology and Expression (BTE), Merck Co., Inc.

In this talk, high throughput technologies in bioprocess development are introduced with focus on analytical tools that support cell line and purification development. The automated microfluidic immunoassay technology enabled five times faster titer assay for screening of IgG products with no hook effect. Its application for more complex assays such as residual host cell protein and residual protein A makes it excellent tool for rapid process development.

11:35 Case Study of Development of Host Cell Protein Specific ELISAs to Monitor Process Development

Chris Fong, Senior Supervisor, Analytical Operations, Genentech, Inc.

Specific chaperones can be over-expressed in host cells to increase product titer. Chaperone specific ELISAs may be necessary if the chaperones are not detected in the platform HCP ELISA. Chaperone clearance can be monitored by chaperone specific ELISA methods. Strategies for integrating Process Validation clearance data with GMP lot release testing will be discussed.

12:05 pm Residual Host Cell Protein Measurement in Biopharmaceuticals: Chapter Development, Anti-HCP Characterization, and Method Validation

Maura Kibbey, Ph.D., Senior Scientist Liaison, Biologics and Biotechnology, USPharmacopeia, and

Ned Mozier, Ph.D., Senior Director, Analytical R&D, Biotherapeutics Pharmaceutical Sciences, Pfizer, Inc.

To be presented by key participants in the USP draft monograph on HCPs that has now been finalized. The presentation will examine the key points and controversial issues with explanations of nuances and compromises that needed to be made. It will also examine and advise on critical issues in HCP analysis.

12:35 Luncheon Presentation: Comprehensive Identification and Quantification of Host Cell Proteins by Mass Spectrometry

Sponsored by CAPRION

Daniel Chelsky, Ph.D., CSO, Caprion Proteomics

New advances in mass spectrometry allow for the direct identification and quantification of low levels of host cell proteins that copurify with biologics. Proteins in the low ppm range can be detected without antibodies or gel separation after manufacture in CHO, *E. coli* or yeast. Quantitative assays with labeled reference standards for each protein can then be rapidly constructed and used to monitor process improvements and consistency.

REFERENCE STANDARDS

2:00 Chairperson's Remarks

Baolin Zhang, Ph.D., Senior Investigator, Division of Therapeutic Proteins, Office of Biotechnology Products, CDER/FDA

2:05 Regulative Perspectives on the Use of Reference Standards in the Development of Therapeutic Proteins

Baolin Zhang, Ph.D., Senior Investigator, Division of Therapeutic Proteins, Office of Biotechnology Products, CDER/FDA

Many therapeutic proteins are new molecular entities lacking relevant international or national reference standards, which require the development of in-house reference standards from representative(s) of the actual product lots. When adequately qualified, reference standards ensure the assay performance and validity of testing results regarding product quality and manufacturing consistency. This presentation will focus on regulatory expectations on the use and qualification of in-house reference standards for novel therapeutic protein products.

2:35 The NIST mAb: A Reference Material to Supplement Biopharmaceutical Characterization and Compliance

John E. Schiel, Ph.D., Research Chemist, Biomolecular Measurement Division, National Institute for Science and Technology

This presentation will discuss the establishment of an IgG1k Reference Material expected to more firmly underpin regulatory decisions and facilitate the development of originator and follow-on biologics. The RM is intended for a variety of uses including, but not necessarily limited to: system suitability tests, establishing method or instrument performance and variability, comparing changing analytical methods, assisting in method qualification, etc.

3:05 Strategy for Building an In-House Reference Standard System for Early Development through to Commercialization

Michael Huang, Ph.D., Scientist, Analytical Technology, MedImmune, Inc.3:35 Refreshment Break in the Exhibit Hall with Poster Viewing

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IMPURITIES REVISITED

4:05 Hamster Phospholipase B-Like 2 (PLBL2), a host cell protein impurity in CHO-derived therapeutic monoclonal antibodies
Martin Vanderlaan, Ph.D., Director, Analytical Operations, Genentech, Inc.
Discovery and development of analytical methods for PLBL2 will be discussed. This HCP impurity has been identified in multiple therapeutic Mabs from multiple sources and is a potential platform impurity.

CHARACTERIZATION STRATEGY TO SUPPORT CRITICAL QUALITY ATTRIBUTES

4:35 Case Study on Control and Monitoring of Critical Quality Attributes during Process and Product Development
Tamer Eris, Principal Scientist, Attributes Sciences, Amgen, Inc.
Development of biotherapeutic molecules requires in-depth knowledge of the product quality attributes critical for the safety and efficacy of the drug candidate. Consequently, appropriate understanding and assessment of these critical attributes is necessary to develop robust manufacturing processes that deliver consistent product quality and yield. Strategies for control and monitoring of biologically relevant attributes for a monoclonal antibody process will be presented and discussed.

5:05 Networking Reception in the Exhibit Hall with Poster Viewing

6:05 Close of Part Two - Stay on for Part Three: Comparability for Biologics

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THURSDAY, MARCH 12

7:30 am Registration and Morning Coffee

REGULATORY PERSPECTIVES ON COMPARABILITY ASSESSMENTS

8:30 Chairperson's Opening Remarks
Methal Albarghouthi, Ph.D., Senior Scientist, Regulatory Sciences & Strategy, MedImmune, Inc.

» 8:35 KEYNOTE PRESENTATION: An FDA Perspective on Risk-Based and Phase Appropriate Comparability
Marjorie Shapiro, Ph.D., Chief, Laboratory of Molecular and Developmental Immunology, Division of Monoclonal Antibodies, CDER, FDA
It can be challenging to distinguish the expectations for post-marketing comparability studies from those during development. As clinical development progresses from Phase 1 through Phase 3, regulatory expectations increase; however, there may be limited numbers of pre- and post-change lots. This talk will provide case studies from different stages of the product development lifecycle and discuss FDA expectations for development of novel and biosimilar therapeutic products.

9:05 An Industry Regulatory Affairs Perspective on Managing Complex Changes
Allison Wolf, Senior Research Scientist, Regulatory Affairs CMC Biotechnology, Eli Lilly and Company
Manufacturing changes are often unavoidable during clinical development and commercialization. Implementing complex changes including multiple changes at the same time creates risk that needs to be managed. This presentation will include several examples involving complex changes and will highlight the approach taken to demonstrate comparability and to effectively communicate these changes to regulators.

RISK ASSESSMENT AFTER MANUFACTURING CHANGES

9:35 Risk-Based Comparability Assessment of Post-Manufacturing Process Change during Early Clinical Development Stage of a Monoclonal Antibody: General Considerations and Case Study
Veronique Bailly, Ph.D., Bioprocess Development CMC Team Leader, Biogen Idec
Comparability assessments at early stage of clinical development usually face limited manufacturing history and high uncertainty on the potential impact of attributes such as aggregates, acidic species and N-glycans on efficacy and safety. We will present a case study describing the comparability assessment after changes in the manufacturing process of a monoclonal antibody between phase 2a and phase 2b, as well as after a change in a raw material impurity.

10:05 Primary and Higher Order Structural Characterization Strategies for Biosimilarity Assessment
Sponsored by SGS
Fiona Greer, Ph.D., Global Director, Biopharma Services Development, Life Science Services, SGS
Biosimilar development requires comprehensive physicochemical characterization at many stages. Initially, intensive characterization of multiple originator batches determines variability of the target quality attributes for the biosimilar. Subsequently, side-by side comparison is carried out with the originator to demonstrate "Biosimilarity". Strategies for comparability will be discussed particularly for antibodies where their size and complexity requires orthogonal approaches.

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

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

11:05 Risk-Based Comparability Strategy for Clinical Development of Therapeutic Proteins
Methal Albarghouthi, Ph.D., Senior Scientist, Analytical Biotechnology, MedImmune, Inc.
Manufacturing process changes during the course of development for therapeutic proteins should be evaluated for the potential impact to safety and efficacy. A risk-based comparability strategy for pre- and post-change material can be designed based on the extent of the manufacturing process changes, knowledge of product quality attributes, and phase of clinical development. Considerations for managing variation in quality attributes levels in clinical trial material to represent long term manufacturing variability will be discussed.

11:35 Comparability Approaches during Clinical Development and Post-Approval
Matthew Kalo, Ph.D., Senior Group Leader, Protein Analytical Chemistry, Genentech, Inc.
Comparability assessments ensure drug product after manufacturing changes is not adversely impacted due to the change. Two key questions arise during the risk assessment of the change. Is the drug product generated by the changed process or at a new facility highly similar or different? If the material is different, what are the potential impacts to patients? Case studies and strategies from clinical development and after approval will be provided.

12:05 pm Sponsored Presentation *(Opportunity available, please contact Jon Stroup, jstroup@healthtech.com)*

12:35 Luncheon Presentation *(Sponsorship Opportunity Available, please contact Jon Stroup, jstroup@healthtech.com)*
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ANALYTICAL TOOLS AND APPROACHES FOR COMPARABILITY STUDIES

1:40 Chairperson's Remarks
Elizabeth Higgins, Ph.D., Founder & CEO, GlycoSolutions Corporation

1:45 New Analytical Approaches to Probe the Interrelationships between Protein Higher-Order Structure and Pharmaceutical Stability as Applied to Comparability Assessments
David B. Volkin, Ph.D., Takeru and Aya Higuchi Distinguished Professor;Director, Macromolecule and Vaccine Stabilization Center, Department of Pharmaceutical Chemistry, University of Kansas
This presentation will examine new analytical approaches to assess protein physical stability profiles and their applicability for comparability assessments. Illustrative case studies will include (1) high-throughput biophysical analysis examining the conformational stability of different IgG1-Fc glycoforms, and (2) H/D exchange mass spectrometry to correlate local flexibility and IgG1-mAb physical stability in presence of different salts and excipients.

2:15 Application of Spectral Similarity Analysis for Product Comparability Exercise
Thomas Lerch, Ph.D., Senior Scientist, Analytical R&D, Pfizer, Inc.
Biophysical tools, including circular dichroism spectroscopy, have often been used to provide qualitative assessment of the similarity in higher order structure for biological molecules through visual inspection of the characteristic spectral overlay. It is desirable to include quantitative analysis for more rigorous comparison and easier presentation of results. This presentation will focus on application of spectral similarity analysis in evaluating the similarity of spectra for lot-to-lot comparison and for sample stability analysis.

2:45 Quantitative Analysis of Site-Specific Glycosylation of Recombinant Therapeutic Glycoprotein as A Tool to Support Drug Development
Joanne Cotton, Staff Scientist I, Genzyme Corp.

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

3:45 Demonstrating Glycosylation Comparability – Assay Selection
Elizabeth Higgins, Ph.D., Founder & CEO, GlycoSolutions Corporation
One of the challenges in analyzing the glycosylation of a biotherapeutic is deciding on how many and which assays are necessary. For release testing, oligosaccharide profiling by HPLC is often sufficient to demonstrate lot-to-lot consistency. However, sometimes it is important to add additional assays for characterization and comparability testing, such as tests for specific monosaccharides, for certain carbohydrate epitopes or for O-glycosylation. A strategy will be presented for selecting the optimal mix of assays.

4:15 Breakout Discussions

4:45 Breakout Discussions

Table 1: Biologics Higher Order Structure Analysis Technologies
Moderator: Xing Wang, Ph.D., President, R&D, Array Bridge, Inc.
- What are the technologies out there for Biologics Higher Order Structure Analysis?
- Is there a gap between required HOS characterization and what the technologies can offer?
- Can we define an HOS impurity profile?
- How to link HOS impurity to immunogenicity and other properties of Biologics?

Table 2: Considerations for Pre-Approval and Post-Approval Comparability for Biosimilars
Moderator: Jennifer Liu, Ph.D., Director, Analytical Sciences, Biosimilars Process Development, Amgen Inc.
- What are the challenges in managing comparability and similarity after process changes during biosimilar development
- Are there unique issues for managing comparability post-approval for biosimilar products
- Should comparability be considered a stand-alone exercise for approved biosimilars

Table 3: Analytical Strategies For Comparability
Moderator: Thomas Lerch, Ph.D., Senior Scientist, Analytical R&D, Pfizer, Inc.
- What are the key strategic differences between comparability and biosimilarity exercises?
- What is the the right assay for a given process change?
- What are the similarity criteria for non-quantitative assays?

5:15 Close of Day and Short Course Registration

6:00 – 9:00 Dinner Short Courses*
SC4: Assessing Biopharmaceutical Comparability via Biophysical Characterization
SC5: Comparability and Biosimilarity: Principles and Case Studies
(*Separate registration required; see page 3 for details)

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FRIDAY, MARCH 13

8:00 am Morning Coffee

ANALYTICAL TOOLS AND APPROACHES FOR COMPARABILITY STUDIES (CONT'D)

8:30 Chairperson's Opening Remarks
Emily Shacter, Ph.D., Consultant, ThinkFDA, LLC.

8:35 Presentation to be Announced

9:05 LC-MS/MS for Glycan Analysis
Jianjun Li, Ph.D., Director, Institute of Biological Sciences, National Research Council, Canada
Protein N-glycosylation modulates the physical, chemical and biological properties of proteins. Alteration of the glycan structures can take on several forms including different monosaccharide compositions, changes in connectivity (sequence), and most interestingly, changes in the types of linkages between monosaccharides. In this presentation, I will discuss LC-MRM based strategy for quantification of N-glycans, which enables sensitive and consistent identification and quantification of diverse glycans across multiple samples.

9:35 Higher Order Structure Analysis for Novel and Biosimilar mAb Conformational Comparability
Xing Wang, Ph.D., President, R&D, Array Bridge, Inc.
Using antibody arrays, we've developed a novel technology that provides a sensitive, systematic and high-throughput approach for mAb Higher Order Structure comparability analysis, generating valuable information for cell line selection, process development and formulation development. Examples will be presented to demonstrate the application of the antibody array in biosimilar as well as novel mAb development and its complementary value to the bioassays and other analytical technologies.

10:05 Networking Coffee Break

ESTABLISHING BIOSIMILARITY

10:30 Current Regulatory and Scientific Issues with Biosimilars in the US
Emily Shacter, Ph.D., Consultant, ThinkFDA, LLC.
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 FDA's latest guidance and perspectives on how biosimilarity can be demonstrated and how it will be evaluated by the FDA reviewers, with emphasis on the fundamental role of the analytical similarity studies.

11:00 How Similar Does a Biosimilar Have to Be?
Christopher Holloway, Ph.D., Group Director, Regulatory Affairs & CSO, ERA Consulting Group
- Biosimilars do not need to be "identical" but they should be as "similar" as possible – what does this mean?
- For parameters that differ from the reference product, what has to be done to support the biosimilarity claim?
- What are the "deal breakers" in the biosimilar paradigm?
- What can we learn from past experience in failure of purported biosimilar products?

11:30 Demonstrating Biosimilarity from the Aspects of Functional Characterization
Patrick Liu, M.D., Ph.D., Senior Director and Global Head, Bioassays and Technology, Teva Pharmaceuticals
Functional assays are essential for biosimilar development, and characterization of molecular functionality is one of the most critical elements to demonstrating biosimilarity. This presentation will cover:
- Product critical quality attributes (CQA) and target product profile (TPP)
- Functional assays and product characterization
- Similarity range establishment
- Issues and challenges on functional similarity demonstration

12:00 pm Establishing Biosimilarity and Comparability with Process and Manufacturing Changes
Jennifer Liu, Ph.D., Director, Analytical Sciences, Biosimilars Process Development, Amgen, Inc.
During the development life-cycle of biological products, refinement of the manufacturing processes and changes in the production facilities are inevitable in order to support registration and commercialization. Managing comparability while establishing biosimilarity can be a challenge. Appropriate analytical strategies based on the type of changes introduced and stages of product development should be applied to ensure safety and efficacy of the biosimilar product during development and post approval.

12:30 Close of Part Three

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~~(SC1) Host Cell Protein Measurements: Thoughts of the USP Expert Panel and Best Practices~~	(SC4) Assessing Biopharmaceutical Comparability via Biophysical Characterization
(SC2) Sub-Visible Particles, Aggregates and Impurities: Measurement, Characterization and Impact	(SC5) Comparability and Biosimilarity: Principles and Case Studies
(SC3) Glycobiology of Antibodies	

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