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Cambridge Healthtech Institute's Sixth Annual

Immunogenicity and Bioassay Summit 2014

November 17 - 19, 2014
Hyatt Regency Bethesda
Bethesda, MD

Technologies and Strategies for Safe and Efficacious Products in the Clinic

Attend the Number 1 Immunogenicity and Bioassay Event Bringing Together Industry, Academia and Regulatory Authorities

November 17 - 18

Immunogenicity Assessment & Clinical Relevance

November 18 - 19

Immunogenicity Prediction & Mitigation

Optimizing Bioassays for Biologics

+ 4 Short Courses

Keynote Speakers

Steven J. Swanson, Ph.D.
Executive Director, Medical Sciences, Clinical Immunology, Amgen, Inc.

Amy Rosenberg, Ph.D.
Director, Therapeutic Proteins, FDA/CDER

Baolin Zhang, Ph.D.
Senior Investigator, Therapeutic Proteins, Biotechnology Products, FDA

Jaya Goyal, Ph.D.,
Director, Translational Sciences, Biogen Idec

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What's NEW for 2014?

- Eight FDA presenters this year
- More on immunogenicity challenges in clinical development: pre-existing reactivity, target interference, Fc-Fc interactions, drug interference, impact of higher order complexes, characterization of ADAs, assay validation and cut points
- Focus on specific products: interferon beta, enzyme replacement therapy, Knob-and-Hole therapeutics, ADCs, Factor VIII, immunotoxins, hemophilia products, Adnectins
- Choice of 14+ new interactive breakouts for in-depth discussion
- More focus on the impact of sub-visible particles, aggregates and impurities
- New angle on impact of route of administration
- Increased coverage and case studies on feedback from health authorities
- Presentations on working with molecules with multiple mechanisms such as ADCs, bispecifics, and fragments

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- Reception style
- Plated dinner with specific conversation focus

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For sponsorship and exhibit information, please contact:
Carolyn Benton
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Short Courses*

SUNDAY, NOVEMBER 16

1:30 – 4:30 pm SC1: Basics of Immunogenicity Testing

Instructors:

Jim McNally, Ph.D., Senior Principal Scientist, Pharmacokinetics, Dynamics and Metabolism, Pfizer, Inc.

This interactive session will enable attendees to work out a basic immunogenicity preclinical and clinical testing strategy for various molecules including bi-functional and other novel scaffolds. Areas of difficulty will be discussed with specific case studies. Attendees are encouraged to contribute with their own experiences and to bring questions for discussion or submit to the meeting organizers in advance.

The following topics will be covered:

- Basic issues regarding screening, confirmatory and titer assays
- Assay methodologies and various technologies
- Current approaches to data analysis and cutpoints
- Preclinical and clinical considerations
- Common problems

5:30 – 8:30 pm Dinner SC2: Challenges of Immunogenicity Assessment

Instructors:

Jim McNally, Ph.D., Senior Principal Scientist, Pharmacokinetics, Dynamics and Metabolism, Pfizer, Inc.

This interactive session of intermediate level will focus on the potential challenges of immunogenicity testing in preclinical and clinical development and present case studies demonstrating how they can be handled. Attendees are encouraged to contribute with their own experiences and to bring questions for discussion or submit to the meeting organizers in advance.

The following topics will be covered:

- Challenges and approaches to resolve commonly encountered issues
- Multi-domain binding proteins
- Pre-existing ADAs
- Emerging trends in the development of neutralizing antibody assays
- Cross-reactivity to endogenous proteins
- Clinical implications of ADAs

TUESDAY, NOVEMBER 18

6:30 – 9:30 pm Dinner SC3: Immunogenicity Risk Assessment and Regulatory Strategy

Instructors:

Laurie Graham, Ph.D., Product Quality Reviewer, Division of Monoclonal Antibodies FDA/CDER

Bridget Heelan, MB, Ph.D., Vice President, Consulting, Parexel (ex-MHRA)

Priorities for the regulator: Hierarchy of concerns; Data requirements; Common gaps

Integrated approach: Risk identification; Aligning identified risks with CMC; Bioanalytical, non-clinical and clinical strategy; Ongoing risk management

Difficulties in comparative immunogenicity assessment: One versus two assay format for comparing biosimilars to innovators

Interactive case study: Illustration of preparation of an effective response to a regulatory scenario pertaining to immunogenicity-related risks for an investigational therapeutic protein

Questions and Answers

The following topics will be covered:

- Benefits of timely discussion with the regulators
- Neutralizing antibody assays (NAbs): When are they necessary?
- The case for binding assays versus cell-based assays for NAbs
- Novel products and biosimilars: What challenges are the regulatory authorities seeing and anticipating?
- Pitfalls to avoid

6:30 – 9:30 pm Dinner SC4: Strategic Bioassay Design and Analysis

Instructor:

Liming Shi, MS, MA, Senior Research Scientist, Bioassay Development, Eli Lilly and Company

This course will focus on the fundamentals of statistics and simple methodology that are routinely applied in the bioassay laboratory. Covered topics will include a review of statistical concepts and calculations, study design, assessing bioassay measurement quality and comparative studies.

The following topics will be covered:

- Uniqueness of bioassay, especially cell-based potency assay
- Considerations in bioassay development and validation
- Bioassay measurements and calculations
- Quality control of bioassay performance
- Comparative studies for bioassay development and transfer

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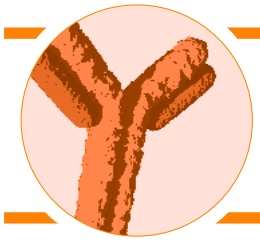

Cambridge Healthtech Institute's Sixth Annual *November 17 - 18, 2014*

Immunogenicity Assessment & Clinical Relevance

Assay Strategy and Risk Assessment for Safe and Efficacious Biotherapeutics

MONDAY, NOVEMBER 17

7:30 am Registration and Morning Coffee

8:30 Chairperson's Opening Remarks

Steven J. Swanson, Ph.D., Executive Director, Medical Sciences, Clinical Immunology, Amgen, Inc.

CHALLENGES WITH IMMUNOGENICITY ASSESSMENT

8:35 Cut Points and Confirmatory Assays: A Case Study of Pre-Existing Reactivity, ADCs and Statistics

Jim McNally, Ph.D., Senior Principal Scientist, Pharmacokinetics, Dynamics and Metabolism, Pfizer, Inc.

Determination of cutpoints for screening and confirmatory assays is a straightforward process for normal, drug-naïve individuals with no baseline reactivity for the drug. However, with increasing frequency, pre-existing reactivity is observed in anti-drug antibody assays and these individuals complicate the process of setting the cutpoint. A case study will be presented where a large percentage of normal individuals exhibited pre-existing reactivity and describes the methods to determine an appropriate cutpoint.

9:05 Overcoming Challenges with Target Interference in ADA Assays: A Case Study in Multimeric Targets

Reza Mozaffari, Investigator, Clinical Immunology, GlaxoSmithKline

Multimeric targets present in clinical samples can cause interference in bridging assay formats used for anti-drug antibody (ADA) detection. This interference may potentially generate a false positive result which could impact the immunogenicity assessment of the compound. I will present our experiences and the different approaches we have used to minimize interference of this nature.

9:35 Minimizing Interference from Fc-Fc Interactions in Bridging Immunogenicity Assays for IgG4 Monoclonal Antibody Therapeutics

Michael Partridge, Ph.D., Staff Scientist, Bioanalytical Sciences, Regeneron Pharmaceuticals, Inc.

Human IgG4 antibodies are known to interact with other IgG4s via their Fc. In bridging immunogenicity assays, IgG4 Fc-Fc contacts generate increasing signal over time for the negative control, reducing assay sensitivity and complicating confirmation cut point determination. Increasing background signal over time is especially problematic for automated analysis, as reagents are prepared in advance and used over several hours during a run. This presentation will discuss these interactions and the impact they have on immunogenicity assays for IgG4 drugs.

10:05 Overcoming the Challenges of Immunogenicity and Cell Based Neutralizing Antibody Assays for Biosimilar Drug Development

Sponsored by BioAgilytix

Kathryn Lindley, M.S., Director, Bioanalytical Operations, BioAgilytix Labs

Successful development of biosimilar drugs requires demonstration of biosimilarity to the originator drug. Immunogenicity assays require extensive method development and validation to support preclinical and clinical comparative studies, and overcoming the challenges of developing cell based assays to detect neutralizing antibodies is critical for success. The challenges of development and validation of qualitative immunogenicity (ADA) screening assays, and neutralization (Nab) assays for biosimilar drug development will be presented.

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

NEUTRALIZING ANTIBODY ASSAYS AND MANAGING DRUG INTERFERENCE

11:15 Drug Interference and Other Challenges with the Development of Neutralizing Antibody Assays

Renuka C. Pillutla, Ph.D., Director, Bioanalytical Sciences – Biologics, Bristol Myers Squibb

11:45 Improving Drug Tolerance in a Clinical Neutralizing Antibody Assay by Solid-Phase Extraction with Acid Dissociation

Gisela Peraus, Ph.D., Lab Head, Pharmacology, Novartis Biologics

Neutralizing antibody assays are inherently prone to interference from circulating drug in-vivo. This is a particular concern with therapeutic monoclonal antibodies due to long half-lives. To improve drug tolerance for the determination of human neutralizing antibodies in a competitive ligand-binding assay, Solid-Phase Extraction with Acid Dissociation (SPEAD) was implemented, which significantly increased the amount of tolerated drug in the assay

12:15 pm Immunogenicity of Topical Drug Products

Sponsored by charles river

Mirela Ionescu, Principal Scientist, Immunology, Charles River Montreal

Immunogenicity testing is a critical step in the development of biotherapeutics. Although topical dermatological products are typically lower in immunogenic potential, in some instances they do have the potential to induce an immunologic response. During this presentation, a case study where an anti-cancer antibody was administered topically in mini-pigs and humans will be discussed. A dose-dependent immunogenic effect was observed in both the preclinical and clinical studies, further confounding the need for early phase immunogenicity assessment of topical drug products and the clinical relevance of performing such assessments.

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12:45 ImmunoCAP ADA Bridging Assay – A New ADA Assay with High Inter-Laboratory Precision Based on a IVD Platform

Sponsored by ThermoFisher SCIENTIFIC

Camilla Eriksson, Senior Scientist, New Technology Development, Thermo Fisher Scientific

Anti-drug antibodies (ADAs) to therapeutic proteins could interfere with efficacy of treatment, and need to be monitored during clinical development. A case study will be presented where an automated and high performance specific ImmunoCAP ADA Bridging assay was used to detect ADAs to infliximab in a global multicenter study. Characterization of the assay demonstrates high sensitivity, drug tolerance and inter-laboratory precision, which enable robust transfer between laboratories and the use in multicenter studies.

1:45 Session Break

IMMUNOGENICITY STRATEGY AND ASSAY METHODOLOGY FOR SPECIFIC PRODUCTS

2:15 Chairperson's Remarks

Jim McNally, Ph.D., Senior Principal Scientist, Pharmacokinetics, Dynamics and Metabolism, Pfizer, Inc.

2:20 Development and Characterization of a Non-Cell-Based Assay to Assess the Presence of Neutralizing Antibodies to Interferon-Beta in Clinical Samples

Isabelle Cludts, Ph.D., Biotherapeutics, National Institute for Biological Standards and Control (MHRA, UK)

Different cell-based assay formats are available for detection of neutralizing anti-IFN-β antibodies. To overcome the limitations of these assays, a non-cell-based assay has been developed, utilizing an ECL detection platform. Neutralizing antibody titers in clinical samples from multiple sclerosis patients treated with IFN-β were determined and compared with those obtained using cell-based assays. The non-cell-based assay is less sensitive, however a good correlation between the two approaches was observed.

2:50 Immunogenicity Assessment Strategies and Assay Development for Enzyme Replacement Therapies

Stephen DeWall, Ph.D., Investigator, Clinical Immunology, GlaxoSmithKline

Enzyme replacement therapies (ERTs) have been successfully used to treat a number of rare, inherited diseases that are caused by deficiencies in specific metabolic enzymes. Although ERTs are typically highly immunogenic, they remain one of the most effective treatments for these disorders. Anti-ERT antibodies can potentially affect the safety and/or efficacy of these therapies, so monitoring patients for an immune response is vitally important. This presentation will cover immunogenicity testing strategies and assay development for ERTs.

3:20 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Re-Assessment of Immunogenicity Risk Based on Clinical Data: Case Study of a Humanized IgG1 Monoclonal Therapeutic with a Knob-and-Hole Structure

Mauricio Maia, Ph.D., Bioanalytical Sciences, Genentech, Inc.

Initial clinical immunogenicity evaluation plans are often based upon an immunogenicity risk assessment that includes a myriad of molecule and patient factors, but prior to attaining clinical experience. Clinical data can and should modify this assessment. This presentation will describe a case study of a structurally novel biotherapeutic whose risk-based assessment was changed following analysis of clinical immunogenicity data derived from early-stage trials.

4:30 Problem Solving Roundtable Discussions

Regulatory Expectations Regarding Immunogenicity Assessment

Laurie Graham, Ph.D., Product Quality Reviewer, Division of Monoclonal Antibodies FDA/CDER

Steven J. Swanson, Ph.D., Executive Director, Medical Sciences, Clinical Immunology, Amgen, Inc.

Drug Interference and Other Challenges with the Development of Neutralizing Antibody Assays

Renuka C. Pillutla, Ph.D., Director, Bioanalytical Sciences – Biologics, Bristol Myers Squibb

Dealing with Pre-Existing Positive ADA Activity in Study Patients

Moderator: Jim McNally, Ph.D., Senior Principal Scientist, Biotherapeutics Research, Pfizer, Inc.

Critical Issues in ADA Assay Validation

Moderator: Harry Yang, Ph.D., Senior Director, Translational Sciences, MedImmune, LLC

Concerns Regarding Immunogenicity of Multi-Domain Proteins

Moderator: Laura Salazar-Fontana, Ph.D., Former CDER/FDA

Focus on Immunogenicity of Biosimilars and Non-Innovator Biologicals

Moderator: Bridget Heelan, MB, Ph.D., Vice President, Consulting, Parexel, (ex-MHRA)

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 End of Day One of Immunogenicity Assessment & Clinical Relevance

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TUESDAY, NOVEMBER 18

8:30 am Chairperson's Remarks
Stephen DeWall, Ph.D., Investigator, Clinical Immunology, GlaxoSmithKline

REGULATORY PERSPECTIVES AND RISK ASSESSMENT

8:35 The Impact of Quality Attributes on Immunogenicity
Susan Kirshner, Ph.D., Associate Chief, Laboratory of Immunology, Therapeutic Proteins, Biotechnology, CDER/FDA

9:05 The Problems in Assessing and Comparing Immunogenicity of Biosimilars with the Reference Product
Bridget Heelan, M.B., Ph.D., Vice President, Consulting, Parexel, (ex-MHRA)
As biosimilars are not 100% identical to the originator this raises safety and regulatory concerns about relative immunogenicity. Comparing the results of ADA detection rates in the innovator and the biosimilar relies on an appropriate testing strategy. The advantages and limitations of comparing the results derived from a single assay or two separate assay formats will be presented.

» KEYNOTE PRESENTATION

9:35 Strategy for Immunogenicity Risk Assessment
Steven J. Swanson, Ph.D., Executive Director, Medical Sciences, Clinical Immunology, Amgen, Inc.
Immunogenicity assessment continues to be an important component of the development of therapeutic proteins. Establishing an appropriate "risk-based approach" to testing for immunogenicity involves evaluating several factors including: whether the protein therapeutic will be used in a chronic or an acute dosing regimen; if there is an endogenous counterpart for the protein therapeutic, what the likely consequences of a neutralizing immune response would be, and what the predicted immunogenicity of the therapeutic would be. Understanding these factors will greatly assist in developing an appropriate strategy to follow in assessing immunogenicity during clinical trials.

10:05 Detection of Anti Drug Antibodies to a Therapeutic Using a Photonic Ring Immunoassay
Sponsored by Genalyte
Martin Gleeson, Ph.D., CSO, Genalyte, Inc
Recent data demonstrates the exceptional growth in biologic therapeutics across all phases of development. Often, patients taking infused or injected therapeutics can develop antibodies against the drug (ADAs). These ADAs can cause a decrease in efficacy, increased clearance rate, or adverse events. Genalyte has developed an assay capable of detecting and isotyping ADAs with sensitivity and drug tolerance levels exceeding regulatory guidelines. The assay demonstrated concordance with orthogonal technologies while yielding multiplex isotyping profiles, including IgG4.

10:20 Sponsored Presentation *(Opportunity Available)*

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

CLINICAL INVESTIGATIONS

11:30 Statistical Considerations in Design of Multi-Tiered Methods to Detect and Confirm the Presence of ADAs in Clinical Studies
Harry Yang, Ph.D., Senior Director, Translational Sciences, MedImmune, LLC
Biopharmaceuticals have an inherent propensity to elicit immunogenic responses. Key to successful evaluation of immunogenicity is to have well developed and validated assays. This talk will focus on statistical strategies related to ADA assay validation, sample size determination, and cut point estimation in the presence of outliers and skewed distributions. In addition, we will explore ways to combine information from screening and confirmatory assays, so as to derive the optimal cut point.

12:00 pm Impact of Higher Order Complexes on Biomarker Target Quantitation
Surendran Rajendran, Ph.D., Senior Research Investigator II, Bioanalytical Sciences, Biologics, Bristol-Myers Squibb
During bioanalysis, quantitating the target, a biomarker, the drug interfered by an undesired higher order complex formation through multivalent interactions with target and assay reagents. This complex formation follows bell shaped concentration dependence with drug concentration which seems to explain the observed non-linear inverse relationship between immunogenicity and drug exposure. Its formation was confirmed *in vitro* by light scattering technologies.

12:30 End of Immunogenicity Assessment & Clinical Relevance

"Nice meeting; good mix of assays, technologies and experimental science."

Anu C., Senior Scientist, Biomarin

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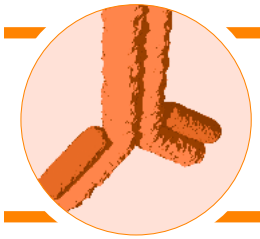

Cambridge Healthtech Institute's Sixth Annual

November 18 - 19, 2014

Immunogenicity Prediction & Mitigation

Risk Factors, Predictive Tools, Deimmunization and Tolerance Induction

TUESDAY, NOVEMBER 18

1:00 pm Conference Registration

2:00 Chairperson's Opening Remarks

Vibha Jawa, Ph.D., Principal Scientist, Clinical Immunology, Amgen, Inc.

SUB-VISIBLE PARTICLES, AGGREGATES, IMPURITIES AND IMMUNOGENICITY

2:05 Innate Immune Response Modulating Impurities and Immunogenicity Risk: What Should We Be Looking for?

Daniela Verthelyi, Ph.D., Chief, Immunology Lab, Therapeutic Proteins, FDA/CDER

A critical factor associated with product immunogenicity is the presence of innate immune response modifying impurities (IIRMIs) that can stimulate the immune response directly. This talk will discuss the need to assess common impurities that activate immune cells *in vivo* and describe new *in vitro* systems that can be used to assess them.

2:35 Assessment of the Immunogenic Potential of Antibody Aggregates in Transgenic Mice

Juliana Bessa, Ph.D., Scientist, Immunopathology, F. Hoffmann-La Roche

Transgenic (tg) mice expressing a mini-repertoire of human IgG1 antibodies (Ab) have been used for the assessment of immunogenicity of therapeutic Abs. The tg mice were found to be tolerant to a large range of human IgG1 Abs. Immunization with IgG1 aggregates generated by three different stress conditions demonstrated that extensive modifications within the primary amino acid structure (neoepitopes) were required to break immune tolerance whereas multimerization may have an enhancer factor on the immune response triggered by the neoepitopes. Taken together, this IgG tg mouse model appears suited to identify potentially immunogenic modifications in Ab preparations.

3:05 Detection and Characterization of Reversible Self-Association and Aggregation of Therapeutic Monoclonal Antibodies

Sophia Levitskaya, Ph.D., Scientist, Analytical Biotechnology, MedImmune LLC

Protein self-association is a form of solution intermolecular interaction which is important to consider during the successful development of protein therapeutics. Protein reversible self-association behavior is difficult to evaluate because the conditions of an assay can influence the observed size distribution. Our case study describes an unusual temperature sensitive reversible self-association (RSA) of an IgG2-subclass mAb, analytical methods tailored to characterize RSA, and measures to minimize RSA in drug product.

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3:35 Influence of Aggregates on *in vitro* T Cell Responses

Gary Bembridge, Ph.D., Director, Scientific Affairs , Immunology, Business Development, Antitope Limited

Protein aggregates can trigger innate responses leading to distinct antigen presenting cell phenotypes which enhance T cell activation, a significant risk factor in the development of anti-drug antibodies (ADAs). This presentation will describe methods to measure the effects of aggregates on drug immunogenicity.

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

ENHANCED IMMUNOLOGICAL PERFORMANCE WITH REDUCED IMMUNOGENICTY / IMMUNOGENICITY RISK PREDICTION

4:30 Computational and Experimental Mapping of Deimmunized Biotherapeutic Design Space

Karl E. Griswold, Ph.D., Associate Professor, Thayer School of Engineering, Dartmouth

We describe novel protein design algorithms that simultaneously optimize biologics for reduced immunogenic potential and high-level molecular function. Using combinatorial optimization methods, we are able to rapidly design an entire suite of "Pareto optimal" variants whose predicted immunogenicities and activities are not simultaneously dominated by any other single design. We have redesigned two different therapeutic enzyme candidates, and here we discuss *in vitro* and *in vivo* demonstration of their enhanced molecular and immunological performance.

5:00 Prediction of Clinical Immunogenicity of Adnectins: Guiding Lead Optimization

Daron Forman, Ph.D., Principal Scientist, Immunogenicity Prediction, Bristol-Myers Squibb

Protein biologics are making up an ever increasing proportion of the total drug market. Unlike their chemical counterparts, proteins are large enough to induce an anti-drug antibody (ADA) response. Here, we will discuss our strategy to predict ADA generation, and a few examples for minimizing the immunogenic potential of therapeutic proteins in the discovery stage.

5:30 Panel Discussion: Development and Application of Humanized Mice for Immunogenicity Predictive Studies

Moderator: Jack Ragheb, Ph.D., Principal Investigator, Therapeutic Proteins, FDA/CDER

- How predictive are these models: To what extent does the HLA restriction of a single humanized mouse clone impact on the interpretation of the results?
- What information can these mice provide regarding B cell responses: the classes of antibody being produced and the levels of antibody?
- Time, investment and skill in getting mouse models up and running
- How to work out the appropriate dose
- Applications and recent progress with biotherapeutics: e.g. recombinant cytokines, gene therapy, etc.
- How might known differences in the human and mouse adaptive and innate immune systems impact the results?

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6:00 End of Day One of Immunogenicity Prediction & Mitigation

6:00 Dinner Short Course Registration

6:30 – 9:30 Dinner Short Courses*

SC3: Immunogenicity Risk Assessment and Regulatory Strategy

SC4: Strategic Bioassay Design and Analysis

**Separate Registration Required. See page 3 for course details.*

WEDNESDAY, NOVEMBER 19

PREDICTION AND SUPPRESSION

8:00 am Chairperson's Remarks

Jack Ragheb, Ph.D., Principal Investigator, Therapeutic Proteins, FDA/CDER

8:05 Forecasting Clinical Immunogenicity from Human *ex vivo/in vitro* Assays

Tim Hickling, Ph.D., Associate Research Fellow, Pharmacokinetics, Dynamics and Metabolism, Pfizer, Inc.

Although prediction of the incidence of anti-drug antibodies (ADAs) to therapeutic proteins is not yet possible, combining knowledge of the immunogenicity risk factors for a therapeutic protein enables assessment of overall risk. A mathematical model has been developed to integrate immunogenicity risk parameters and assay outputs to enable forecasting of ADA incidence and magnitude, and the impact of ADAs on PKPD. Examples of therapeutic proteins will be discussed.

8:35 Investigations in Immune Suppression for Monoclonal Antibody Therapeutics

Vibha Jawa, Ph.D., Principal Scientist, Clinical Immunology, Amgen, Inc.

Therapeutic proteins (TP) are often immunogenic and can induce formation of anti-drug antibodies (ADA) when administered to preclinical animal models. The ADA formation may neutralize the pharmacologic activity of the TP and hence impact the exposure and efficacy by modulating its pharmacokinetics (PK) properties and clearance via immune complexes. The objective of this study is to assess the impact of immune suppression on the ADA formation and consequent impact on PK profiles of a biotherapeutic mAb. This talk will evaluate immune suppressive regimens targeting the T and B cells that can help reduce this unwanted immune response to a biotherapeutic mAb in a preclinical setting.

9:05 Preclinical Immunogenicity Risk Assessment for Optimal Lead Selection

Sponsored by Lonza

Noel Smith, Ph.D., Senior Group Leader, Lonza Biologics, Lonza Applied Protein Services, Lonza

The ability to assess the "developability" of a therapeutic candidate in early preclinical and clinical phases of development can be a very powerful tool to enhance the chance of success. This presentation will focus on how immunogenicity risk assessment can be incorporated into a wider developability platform, exploiting a wide range of *in silico* and *in vitro* tools to predict immunogenic responses and the overall developability profile of lead candidates.

9:35 Problem Solving Roundtable Discussions

Risk Factors that Contribute to Immunogenicity

Moderator: Vibha Jawa, Ph.D., Principal Scientist, Clinical Immunology, Amgen, Inc.

Sub-Visible Particles, Aggregates and Immunogenicity

Moderator: Jack Ragheb, Ph.D., Principal Investigator, Therapeutic Proteins, FDA/CDER

Methods for Examining Impurities that May Impact the Immune Response

Moderators: Daniela Verthelyi, Ph.D., Chief, Laboratory of Immunology, Therapeutic Proteins, FDA/CDER
Lydia Haile, Ph.D., Postdoctoral Fellow, Laboratory of Immunology, Therapeutic Proteins, FDA/CDER

Current Tools and Approaches for Immunogenicity Risk Prediction

Moderator: Tim Hickling, Ph.D., Associate Research Fellow, Pharmacokinetics, Dynamics and Metabolism, Pfizer, Inc.

Progress towards Inducing Immunological Tolerance to Factor VIII and Other Biotherapeutics

Moderator: David C. Wraith, Ph.D., Professor, Experimental Pathology, University of Bristol, & CSO, Apitope International NV

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

IMPACT OF ROUTE OF ADMINISTRATION

11:15 The Effect of Route of Administration on the Immunogenicity to Recombinant Murine Growth Hormone Particles

Merry Christie, Scientist, Pharmaceutical Sciences, University of Colorado

Mice were injected with recombinant murine growth hormone (rmGH) via the subcutaneous, intraperitoneal, or intravenous (i.v.) routes. In addition to soluble, monomeric rmGH, the samples contained either nanoparticles of rmGH or both nano- and microparticles of rmGH. We found that multiple mechanisms contributed to the immune response, with the most pronounced response when i.v. administration was used. No dependence of the immune response on particle size and distribution was observed.

11:45 Reverse Vaccination via the S.C. Route to Mitigate Immunogenicity

Sathy Balu-Iyer, Ph.D., Professor, Pharmaceutical Sciences, SUNY-University at Buffalo

Administration of therapeutic proteins via the subcutaneous (s.c.) route is challenging regarding unwanted immune responses. This talk will focus on mechanistic details into factors driving immunogenicity of proteins given via the s.c. route. Based on this mechanistic insight, a novel Reverse Vaccination strategy to mitigate immunogenicity was applied. The talk will discuss the induction of immunological hypo-responsiveness using this strategy.

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12:15 pm Tools and Technologies for Comprehensive Immunogenicity Risk Management

Emilee Knowlton, Sales Specialist, Immunology, ProImmune Inc.

Low immunogenicity is a key product attribute of successful biotherapeutics. This talk provides an overview of the technologies available for immunogenicity risk management including antigen presentation assays, DC-T cell assays to measure responses to formulated biologics, HLA-peptide Binding Assays, and naïve T cell Proliferation Assays to quantify responses to individual epitopes. The potential risk of a cytokine storm first infusion reaction can also be determined using whole-blood cytokine release assays.

12:45 Networking Lunch in the Exhibit Hall with Poster Viewing

(Sponsorship Opportunity Available)

TOLERANCE MECHANISMS

1:45 Chairperson's Remarks

Tim Hickling, Ph.D., Associate Research Fellow, Pharmacokinetics, Dynamics and Metabolism, Pfizer, Inc.

» KEYNOTE PRESENTATION

1:50 Immune Tolerance Induction for Therapeutic Proteins: The FDA Perspective

Amy Rosenberg, Ph.D., Director, Therapeutic Proteins, FDA/CDER

Immune responses to therapeutic proteins can prove devastating when they abrogate the efficacy of life saving therapeutic proteins or cause anaphylaxis. Immune tolerance induction (ITI) protocols have been developed to either prevent or reverse such destructive immune responses in the setting of enzyme replacement therapy (ERT) for Pompe Disease, a rare lysosomal storage disease (LSD). The safety of these regimens supports their use for ERT in the setting of other LSDs in patients predicted to respond to ERT with a robust antibody response, and, potentially, for highly effective, yet not necessarily life-saving therapeutics such as monoclonal antibodies (mAbs) for autoimmune disease.

2:20 Generation of Antigen-Processing Independent Epitopes (APITOPES) for Induction of Tolerance to Factor VIII and Other Protein Antigens

David C. Wraith, Ph.D., Professor, Experimental Pathology, University of Bristol, & CSO, Apitope International NV

Suppression of immune responses to therapeutic proteins or hypersensitivity diseases currently requires the use of non-specific, immunosuppressive agents. Improved treatment can be achieved through the adoption of natural, immunoregulatory mechanisms. Scientists at Apitope have revealed how to design the peptide epitopes associated with these conditions and administer them in order to reinstate an immunological balance. This presentation will demonstrate that apitopes are a safe and improved approach to antigen-specific immunotherapy.

2:50 Networking Refreshment Break

3:15 Tolerogenic Nanoparticles for the Prevention of Anti-Drug Antibodies

Kei Kishimoto, Ph.D., CSO, Selecta Biosciences

Anti-drug antibodies (ADAs) can adversely affect the safety and efficacy of biologic drugs. We will describe the development of Synthetic Vaccine Particles (SVPs) for the induction of antigen-specific tolerance to prevent ADAs, using coagulation Factor VIII for the treatment of haemophilia A and adalimumab for the treatment of arthritis as examples.

3:45 A Recombinant Immunotoxin for Cancer Treatment with Low Immunogenicity by Identification and Silencing of Human T Cell Epitopes

Ronit Mazor, Ph.D., Post Doctoral Fellow, Laboratory of Molecular Biology, National Cancer Institute, NIH

Recombinant immunotoxins have produced complete remissions in leukemia patients where many doses can be given, but are less active in patients with solid tumors because their immune system makes anti-drug antibodies which inactive the immunotoxin. To suppress the immune response we have identified and largely silenced the T cell epitopes responsible for the immune response. A redesigned immunotoxin with T cell epitope mutations is highly cytotoxic to cell lines and to cells isolated from cancer patients and produces complete remissions in mice with human cancer xenografts. The approach described can be applied to de-immunize other therapeutically useful foreign proteins.

4:15 Tregitope - A Natural Immune System Off-Switch for Antigen-Specific Tolerance Induction

Annie S. de Groot, Ph.D., Research Professor & Director, Immunology and Informatics, University of Rhode Island

Tregitopes are regulatory T cell (Treg) epitopes found in IgG that expand and activate natural Tregs and can be coupled to biologic proteins for antigen-specific tolerance-induction. They are currently being integrated into products such as blood factors, enzyme replacement proteins and pharmaceutical toxins. The speaker will present recent Tregitope research validating antigen-specific tolerance induction and discuss their role in the treatment of immune-mediated diseases and the development of better biologics.

4:45 End of Immunogenicity Prediction & Mitigation

"It was a pleasure being at the conference: very high quality!"

Melody S., Senior Expert, Immunogenicity and Bioanalysis, TNO, a Netherlands Applied Research Center

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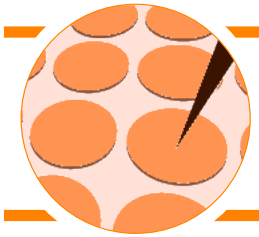

Cambridge Healthtech Institute's Second Annual

Optimizing Bioassays for Biologics

Strategies for Assay Selection, Validation, Transfer, and Maintenance

November 18 - 19, 2014

TUESDAY, NOVEMBER 18

1:00 pm Conference Registration

2:00 Chairperson's Opening Remarks
David Lansky, Ph.D., President, Statistics, Precision Bioassay, Inc.

SELECTING THE RIGHT BIOASSAY

2:05 Development of MOA Reflective Cell-Based Potency Assays for Biologic Products Involved in T Cell Co-Signaling Pathways
Shihua Lin, Ph.D., Analytical Biotechnology Development, MedImmune LLC
Potency assays play a key role at all stages of product lifecycle from early development to finished products. Due to increasing diversity and complexity of product formats as well as clinical targets, developing and optimizing MOA (mechanism of action) reflective cell-based potency assay could be challenge. This presentation will highlight general considerations and our approaches used to develop validatable cell-based potency assays for biologic products involving in T-cell co-signaling pathways.

2:35 Selecting the Best Bioassay Format to Assess mAb Stability
Natko Nuber, Ph.D., Biologics R&D, Novartis
An ideal bioassay should mimic the MoA and be able to detect changes in the integrity of the drug. A case study of two related mAbs, specific for the same epitope of a membrane target, is presented. Temperature stressed and post-translationally modified samples were tested in four different bioassays; the different bioassays generated divergent results, suggesting that caution is needed when selecting the most appropriate bioassay format for membrane-bound targets.

3:05 Improving Heparin Bioassays by Following USP <1032>
David Lansky, Ph.D., President, Statistics, Precision Bioassay, Inc.
The recently revised USP monograph on the Heparin bioassay includes specific design recommendations, several options for replication strategies, and offers users the choice of slope ratio or parallel line analyses. The recommended design imposes a split-unit design (USP <1032>). Recognizing that the assay design is a split-unit leads to useful insights about ways to improve the assay design and analysis. The split-unit design used has very low power for similarity testing in a slope ratio analysis, but good power for similarity testing in a parallel line analysis. Hence, for the Heparin bioassay (and related assays), the slope ratio analysis is a poor choice. The impact of these choices will be illustrated with data.

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3:35 Non-Wash Immunoassays and Label-Free Assay Platforms for Development of Immunogenicity Assays for Known Biosimilars
Lindsay Nelson, Ph.D., Application Scientist, PerkinElmer
We will show how Alpha Technology and label-free technology can be used as an alternative to ELISA or electro-chemiluminescence in immunogenicity and anti-drug-antibody assays. We will combine the use of antibodies to known biosimilars with PerkinElmer's assay technologies to demonstrate several ways to improve your current methods for measuring immunogenicity.

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

STRATEGIES FOR MOLECULES WITH MULTIPLE MECHANISMS

4:30 Bioassays for Antibody Maytansinoid Conjugates (AMCs) Having Multiple Activities
Gillian Payne, Senior Director, Bioanalytical Science, ImmunoGen, Inc.
All AMCs have potent maytansinoid-directed anti-tumor activity. Some AMCs also have additional antibody-directed anti-tumor activity. A control strategy for such AMCs will be presented.

5:00 Development of a Simultaneous Binding Assay to Determine Potency of a Bispecific Zybody
Palanisamy Kanakaraj, Ph.D., Associate Director, Pharmacology, Zyngenia, Inc.
Zybodies are mutli-specific antibodies generated by fusion of specific peptides to scaffold antibodies. We have developed a simultaneous binding assay to determine potency of a bi-specific zybody. The ability of the assay to measure the changes in potency of bi-specific zybody against each target molecule was determined. Comparability studies with ligand binding and cell based functional assays will be discussed.

» 5:30 KEYNOTE PRESENTATION

Characterization of Response of Multiple Domain Biotherapeutics
Jaya Goyal, Ph.D., Director, Translational Sciences, Biogen Idec
Many biotherapeutics currently in development have complex mechanisms of action and contain more than one domain, each with a specific role or function. As it is beneficial to align industry standards for evaluating immunogenicity of MDBs, this presentation highlights pertinent immunogenicity risk factors and describes steps involved in the design of a testing strategy to detect and characterize binding (non-neutralizing and neutralizing, NAb) ADAs.

6:00 End of Day One of Optimizing Bioassays for Biologics

6:00 Dinner Short Course Registration

6:30 – 9:30 Dinner Short Courses*
SC3: Immunogenicity Risk Assessment and Regulatory Strategy
SC4: Strategic Bioassay Design and Analysis
**Separate Registration Required. See page 3 for course details.*

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WEDNESDAY, NOVEMBER 19

COMPARABILITY AND CHARACTERIZATION CASE STUDIES

8:00 am Chairperson's Remarks

8:05 Presentation to be Announced

8:35 Comparability Studies for Bioassays: Technical and Regulatory Challenges for Commercial Products

Jan Bohuslav, Ph.D., Scientist, Global Biologics Quality Control, Method Management and Technology (MMTech), Genentech, Inc., A Member of the Roche Group

For commercial products, both technical and regulatory requirements need to be considered when replacing or updating the licensed potency methods. A well-designed comparability assessment with meaningful acceptance criteria, which is dependent on the capability of the method, and should be evaluated case by case, is key to technical success and regulatory acceptance.

9:05 Case Study: Product Characterization, PK and Immunogenicity Assays for the Development of Biosimilar Trastuzumab

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John Kamerud, Ph.D., Scientific Director, Eurofins Pharma Bioanalytical Services

In assessing the comparability of proposed biosimilar compounds to the innovator counterparts, regulatory agencies have stressed the "totality-of-evidence" approach, which relies on both structural and functional characterization, as well as data from animal and clinical studies. We present as a case study a package of assay methods developed for one such biosimalar, trastuzumab, which will include characterization of target binding, Fc receptor binding and ADCC activity as well as PK and immunogenicity assays to be used in clinical studies. Challenges encountered and approaches taken in the development of these methodologies will be discussed.

9:35 Problem Solving Roundtable Discussions

Strategies for Bioassays with Multiple Mechanisms
Moderator: Gillian Payne, Senior Director, Bioanalytical Science, ImmunoGen, Inc.

Selecting the Right Bioassay
Moderator: Natko Nuber, Ph.D., Biologics R&D, Novartis

Maintaining Assay Consistency
Moderator: LaKenya Williams, Ph.D., Senior Research Investigator I, Bioanalytical Sciences - Biologics, Bristol-Myers Squibb

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

MAINTAINING ASSAY CONSISTENCY

11:15 Preventing False Data Reporting: A Cell-Based Neutralizing Antibody Assay Case Study

LaKenya Williams, Ph.D., Senior Research Investigator I, Bioanalytical Sciences - Biologics, Bristol-Myers Squibb

Cell-based neutralizing antibody assays are inherently variable. Inadequate assay controls, including baseline samples and performance monitoring, can make cell-based assays particularly vulnerable to false data reporting. The FDA recognizes the difficulty in determining the degree of inhibition that is accurately indicative of neutralizing antibodies in a clinical sample. The recommendation is that the determination should be statistically based and derived using naive patient samples. This presentation will discuss various statistical approaches utilized for establishing Nab assay cut point and how we have managed inter-patient variability to ensure high data integrity during clinical trials.

11:45 Evaluation of Assay Consistency Over the Life Cycle of a Product

Janet Lathey, Ph.D., Consultant, Product and Assay Development and Evaluation

During product development and evaluation, critical assays undergo modifications. Assay results from preliminary studies often need to be bridged to those of pivotal studies. A testing and statistical approach to evaluate the consistency of assay results before and after assay modifications will be presented.

12:15 pm Sponsored Presentations *(Opportunities Available)*

12:45 Networking Lunch in the Exhibit Hall with Poster Viewing
(Sponsorship Opportunity Available)

NEW ASSAY TECHNOLOGIES AND FORMATS

1:45 Chairperson's Remarks

Janet Lathey, Ph.D., Consultant, Product and Assay Development and Evaluation

1:50 Bioassay Automation in the QC Setting

Julie TerWee, Ph.D., Quality Control, Analytical Sciences, Amgen, Inc.

2:20 High-Throughput Antibody Selection and Screening Methods for Improved Downstream Developability

William Roach, Ph.D., Scientist, Antibody Engineering and Platform Transfer Manager, Adimab, LLC

Antibody developability issues, such as aggregation and low solubility, can be reduced by employing specificity reagents during antibody discovery. These discovery approaches as well as high throughput methods for tracking antibody self or cross-interaction will be discussed.

2:50 Networking Refreshment Break

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REGULATORY EXPECTATIONS

» 3:15 KEYNOTE PRESENTATION

The Science and Regulation of Potency Assays for Assessing the Quality of Biopharmaceuticals

Baolin Zhang, Ph.D., Senior Investigator, Therapeutic Proteins, Biotechnology Products, FDA

Assay adequacy is assessed by taking account of multiple factors including, but not limited to, product type, history, mechanism(s) of action (MoA), associated risk, phases of development, and quality data from physicochemical and biochemical testing. This presentation provides an overview of regulatory expectations regarding potency assays and discusses several case studies that highlight some of the relevant issues commonly seen in the regulatory submissions.

3:45 Compendial Potency Assays and Associated Biological Reference Materials – Challenges in Assay Transition and Unit Maintenance

Maura C. Kibbey, Ph.D., Senior Scientific Liaison, Biologics & Biotechnology, U.S. Pharmacopeia

With increasing frequency, especially for legacy biologics, animal assays are being replaced by *in vitro* assays of different formats. This transition is not always straightforward, as analysts may struggle to establish equivalence between assays that measure different attributes or sets of attributes. This presentation will focus on USP's current efforts to include modern *in vitro* assays in the USP-NF to replace animal-based tests for well-characterized biologics.

4:15 End of Optimizing Bioassays for Biologics

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Discounted Room Rate: $189 s/d
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	Commercial	Academic, Government, Hospital-affiliated
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Mon - Tue am, November 17-18	Tue pm - Wed, November 18-19
C1 Immunogenicity Assessment & Clinical Relevance	C2 Immunogenicity Prediction & Mitigation
	C3 Optimizing Bioassays for Biologics

SHORT COURSES

One short course	$699	$399
Two short courses	$999	$699
Three short courses	$1299	$899

Pre-Conference Short Courses	Dinner Short Courses
Sunday, November 16	Tuesday, November 18, 6:30-9:30 pm
1:30-4:30 pm SC1 Basics of Immunogenicity Testing	SC3 Immunogenicity Risk Assessment & Regulatory Strategy
5:30-8:30 pm (Dinner Course) SC2 Challenges of Immunogenicity Assessment	SC4 Strategic Bioassay Design and Analysis

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Poster Submission - Discount ($50 Off): Poster abstracts are due by October 10, 2014. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com. *CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

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Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

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