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NOVEMBER 12-13, 2013
Hyatt Regency on Capitol Hill | Washington, DC

INAUGURAL

Optimizing Bioassays for Biologics

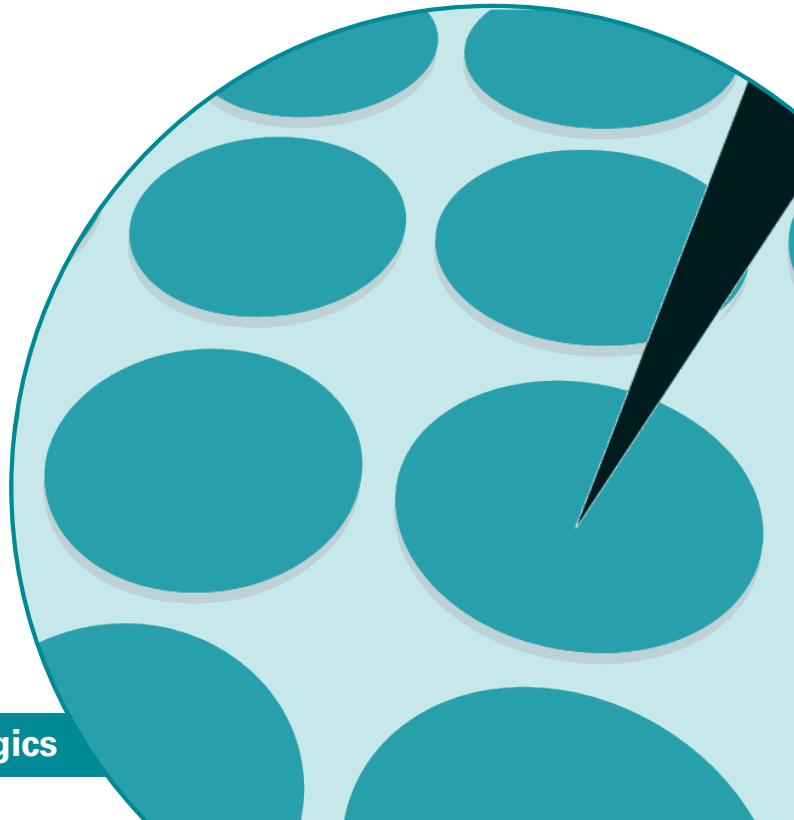
Techniques and Solutions for Biotherapeutics Development

KEYNOTE SPEAKER

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

>>> TOP REASONS TO ATTEND

- Learn how to incorporate new technologies and formats for increased success
- Discover how to automate your bioassays to reduce variability
- Hear straightforward solutions to bioassay bridging and transfer
- Explore the pros and cons of cell-based vs. non cell-based assays
- Brainstorm with bioassay experts throughout the industry
- Network with over 300 high level bioassay, immunogenicity, and PK/PD professionals



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Immunogenicity Summit 2013
November 11-13, 2013
Hyatt Regency on Capitol Hill
Washington, DC

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CONFERENCE SHORT COURSES*

SUNDAY, NOVEMBER 10

1:30 - 4:30 pm SC1: Basics of Immunogenicity Testing for Innovators and Biosimilars

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

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

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 for Innovators and Biosimilars

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

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

This interactive session of intermediate 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
- Regulatory guidance and guidelines

5:30 - 8:30 pm Dinner SC3: PK/PD Bioanalysis for Novel Biotherapeutics

Sponsored by GYROS

Lee Abberley, Ph.D., Team Leader, DMPK, GlaxoSmithKline, US

Lindsay E. King, Ph.D., Senior Principal Scientist, Pfizer Inc

Novel constructs, such as anti-drug conjugates (ADCs) and bispecific antibodies, now exist as promising candidates in biotherapeutic pipelines. With aggressive timelines and contraction in the biopharma labor force, assay development can pose challenges beyond typical assays for pharmacokinetics and pharmacodynamics. Several bioanalytical techniques can be employed to measure these novel constructs. This short course will cover assay technologies to measure ADCs and bispecific antibody therapeutics for pharmacokinetics and pharmacodynamics presented by various biopharma scientists.

** Separate Registration Required*

TUESDAY, NOVEMBER 12 | 6:30 – 9:00 PM

Dinner SC4: Immunogenicity Risk Assessment and Regulatory Strategy

Instructors: Laurie Graham, Product Quality Reviewer, Division of Monoclonal Antibodies FDA/CDER

Susan Kirshner, Ph.D., Associate Chief, Laboratory of Immunology, Therapeutic Proteins, Biotechnology, CDER/FDA

Robin Thorpe, Ph.D., FRCPath, Head, Biotherapeutics Group, National Institute for Biological Standards and Control

The following topics will be covered:

- Priorities for the regulator: Hierarchy of concerns; data requirements; common gaps
- Integrated approach: Risk identification; aligning identified risks with CMC, bioanalytical, nonclinical and clinical strategy; ongoing risk management
- 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

Topics to be discussed include:

- 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

Dinner SC5: Developing Potency Assays to Ensure Successful Biologics

Instructor: Timothy Schofield, Senior Fellow, MedImmune

This interactive short course will enable attendees to develop methods and strategies for developing and validating bioassays that support the identification and development of their biotherapeutics products. It will include coverage of assays to test both activity and potency, including cell-based and biochemical based systems.

TUESDAY, NOVEMBER 12

2:00 pm Chairperson's Opening Remarks

Optimizing Bioassays: Challenges and Solutions

» KEYNOTE PRESENTATION

2:05 New Technologies and Approaches to Bioassays

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

Cell-based potency assays can be the most challenging of analytical assays to develop. They are expected to reflect the mechanism of action (MOA) of the therapeutic but must also be suitable for use in a QC environment. Different antibody formats, an increasing diversity of clinical indications with complex MOAs, and reduced timelines due to increased competition, make assay development more challenging. Various approaches and strategies will be presented to address some of these challenges, including the incorporation of new technologies and formats, as well as the use of surrogate measures of bioactivity.

2:35 Optimization of Ligand Binding Assay by Design of Experiment

Surendran Rajendran, Ph.D., Senior Research Investigator, BAS - Biologics, Bristol-Myers Squibb

Biotherapeutics research uses predominantly Ligand Binding Assay to quantitate biomarker, biologic drug and its immunogenicity at preclinical and clinical stages to establish the PK/PD relationship and thus to accelerate drug development. Making ligand binding assay by Design of Experiment (DoE) methodology has many advantages over traditional one factor at a time method. An easy to do DoE protocol for ligand binding assay is described that optimizes the three main assay performance parameters sensitivity, dynamic range and the background simultaneously.

3:05 Development and Optimization of a Potency Assay for a 7 Component Peptide Drug

Barbara Hebeis, Ph.D., Principal Scientist, CMC Bioassay and Genomics, NDA Analytics

For drugs consisting of multiple active components, potency has to be demonstrated for all components individually.This talk focuses on the development of a bioassay for a multi peptide drug. The format selected for this example, based on the drug's mode of action, was the enumeration of drug activated T cells from primary murine splenocyte cultures isolated from animalsimmunised with individualpeptide components of the drug. Based on results demonstrating a moderate T cell response of *ex vivo* cultured and periodically re-stimulated rodent splenocytes we have developed a method suitable for routine, cGMP compliant potency testing using ELISpot for the detection of IL-2 released from activated T cells.

Reference Standards and Regulatory Expectations

3:35 Reference Standards for Potency Assays – Future Directions

Jane Robinson, Ph.D., Principal Scientist, Biotherapeutics, National Institute for Biological Standards and Control, UK

With increasing numbers of biopharmaceuticals in development, including next-generation (modified or artificial) molecules and biosimilars, meeting future requirements for publicly available reference standards for potency assays will be challenging. Parent molecules and innovator products may prove unsuitable as standards for corresponding next generation or biosimilar products, with relative potency determination proving either impossible or method-specific and resulting in a requirement for product-specific standards.

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

4:30 A Regulatory Perspective on Bioassays for Evaluation of the Quality of Protein Drug Products

Baolin Zhang, Ph.D., Senior Investigator, Division of Therapeutic Proteins, Office of Biotechnology Products, Food and Drug Administration

For all protein products, drug-specific potency assays are required to assess product quality because the complex protein structures cannot be inferred from physical-chemical characterizations alone. A suitable measure of potency is essential to assure the consistency of the product dose, the consistency of the manufacturing process, and the comparability of product lots. This talk presents the principles in the design of bioassays, regulatory perspectives, and case studies for bioassays used in the evaluation of protein products.

Assay Transition and Transfer

5:00 Compendial Potency Assays and Associated Biological Reference Materials – Challenges in Assay Transition and Unit Maintenance

Tina S. Morris, Ph.D., Vice President, Biologics & Biotechnology, United States Pharmacopeial Convention, Global Science & Standards Division

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.

5:30 A Statistical Approach to Bioassay Bridging and Transfer

Xianzhi Zhou, Ph.D., Senior Scientist, MedImmune

How does one bridge between bioassays? Assays frequently need to be replaced, whether it be a result of unsupported instrumentation or improved methodology. This talk will present a case study demonstrating how MedImmune approaches bioassay bridging and transfer using statistical guidance.

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

WEDNESDAY, NOVEMBER 13

Managing Variability

8:30 am Chairperson's Remarks

8:35 Regulatory-Compliant Validation of a Standardized ADCC Potency Assay

Alexis Rossignol, Ph.D., R&D Project Manager, Clean Cells SAS

Antibody-dependant cellular cytotoxicity (ADCC) is one of the major mechanisms of action of therapeutic monoclonal antibodies (mAbs), with a growing number of "ADCC-optimized" mAbs. Health Agencies require the use of biologically-relevant potency assays to characterize new mAbs and to release batches. But current ADCC assays are hampered by reproducibility and standardization issues, especially when they involve freshly isolated primary human cells (PBMC, NK…) as effector cells. In this context, Clean Cells and its partner INSERM UMR892 have developed an ADCC assay based on standardized CD16-expressing effector T cells. This presentation will show its outstanding performances in terms of accuracy, linearity, repeatability, reproducibility and sensitivity to mAb modifications (fucosylation…). These results were obtained in a validation study designed to meet EMA requirements and support the use of this robust assay for lot release.

9:05 Evaluation of Processes for Reducing and Monitoring Assay Variability for Bioassays

Janet L. Lathey, Ph.D., Director, Immunology and Assay Development, BioDefense Division, Emergent BioSolutions

Within the life cycle of a product several developmental phases of a bioassay usually occur. A major challenge with potency testing is the establishment of consistency of results by reducing and maintaining assay variability. Some essential processes to reduce and evaluate variability are 1) identification of assay components responsible for major assay variation; 2) identification and qualification of critical reagents; 3) bridging of reference sera to a "standard"; and 4) documented analyst training program.

Bioassay Automation Technology

9:35 Bioluminescent NFAT-RE-luciferase Reporter Bioassay: A Novel Technology to Reduce Assay Variability in ADCC

M.N. Dixit, Assistant General Manager & Head, Bioanalytical Laboratory, Clinigene International

Bioassays play a vital role in evaluating biological functions of protein biotherapeutics. Classic Antibody Dependent Cell Mediated Cytotoxicity (ADCC) assays involving Natural Killer cells are utilized for potency evaluation of therapeutic antibodies. However, high variability makes such assays less dependable for evaluating the targeted function of biologic drug products. The new bioluminescent NFAT-RE-luciferase reporter bioassay is ideal for evaluating Fc effector functionality of therapeutic antibodies in ADCC.

10:05 Sponsored Presentation *(Opportunity Available)*

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

11:15 Assay Development, Automation and De-Convolution of Multiplexed High Throughput Live-Cell Screens

Brad Greenfield, Scientist, Theraclone Sciences

Utilizing a live whole cell approach to Theraclones antibody screening platform, we are able to interrogate entire extra-cellular proteomes in a target-agnostic manner, and multiplex via pooled cell types to increase throughput and identify conserved epitopes/targets across multiple cell types. Assay design, automation, confirmation and de-convolution of multiplexed screening data will be presented.

11:45 From Spleen to Screen

Cecile Geuijen, Ph.D., Director, Oncology, Merus BV

Merus has developed and validated a powerful discovery engine for the discovery of potent and fully human bispecific antibodies targeting cancer: Biclonics™. Direct sequencing of antibody variableregions from the spleen of immunized MeMo® mice and subsequent co-expression of these antigen specific variable regions into bispecific moleculesusing automated multi-well systemsenables the rapid screening of thousands of unique Biclonics™ in *in vitro* functional assays. Lead candidates areidentified based on potent growth inhibition oftumor cells.

12:15 Problem Solving Roundtable Discussions

Table 1: Standardizing ADCC Potency Assays

Moderator: Alexis Rossignol, Ph.D., R&D Project Manager, Clean Cells SAS

Table 2: Meeting USP Standards for Bioassays

Moderator: Tina S. Morris, Ph.D., Vice President, Biologics & Biotechnology, United States Pharmacopeial Convention, Global Science & Standards Division

Table 3: Assay Automation to Decrease Variability

Moderator: Brad Greenfield, Scientist, Theraclone Sciences

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

Considerations for Biosimilars

2:00 Chairperson's Remarks

2:05 Special Considerations for Developing Cell-Based Immunogenicity Neutralizing Anti-Drug Antibody (NAb) Assays to Support Clinical Comparability Studies for Biosimilars

Xiao-Yan Cai, Ph.D., Director, Biologics Bioanalytical Development, Merck Research Laboratories

Immunogenicity assays are critical to support comparability studies to ensure safety and efficacy of a biosimilar in comparison with its originator biologic therapeutic drug per regulatory guidance. Demonstrating "equivalency" of the non-quantitative cell-based NAb assay to detect NAbs against both biosimilar and originator compounds presents unique challenges. Special considerations must be taken into account during assay development of these NAb assays.

2:35 Functional Assays for Biosimilars: An Industry Perspective

Patrick Liu, M.D., Ph.D., Senior Director and Global Head of Bioassays, Teva Pharmaceuticals, Inc.

Functional characterization of a biosimilar to its reference product is essential to biosimilar therapeutic development. With an appropriate assay strategy and clear understanding of regulatory expectations, development and implementation of validated biological assays can generate a successful regulatory submission package, and therefore, significantly contribute to the quality and success of the program, and as well as save the overall development time and cost.

3:05 Refreshment Break

Cell-Based vs. Non Cell-Based Assays

3:30 Comparison of Cell-Based and Non Cell-Based Assay Platforms for the Detection of Anti-Drug Neutralizing Antibodies

Jenny Hu, ATO Clinical Immunology, Medical Science, Amgen, Inc.

Different assay platforms have been used for the detection of neutralizing antibodies. Evaluations of these platforms were mostly focused on assay development and characterization; limited data were generated using clinical samples. In this study, non cell-based assays were developed and assessed for their ability to detect neutralizing antibodies as compared to its complementary cell-based assays. Case studies comprised of several therapeutic molecules and comparison of results from clinical samples will be discussed.

4:00 Characterization Using a Surrogate Non Cell-Based Ligand Binding Assay

Shawn Fernando, Senior Researcher, Morphotek, Inc. (tentative)

By comparing a cell-based bioassay to a ligand binding assay, this presentation will assess the feasibility of developing a neutralizing assay for a late phase clinical trial. In the end, the ligand binding assay was chosen. The case study and rationale behind the decision will be explained.

4:30 Close of Optimizing Bioassays for Biologics

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Techniques and Solutions for Biotherapeutics Development

NOVEMBER 12-13, 2013

Hyatt Regency on Capitol Hill
Washington, DC

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Monday, November 11 - Tuesday, November 12	Tuesday, November 12 - Wednesday, November 13
(T1) Immunogenicity Assessment & Strategies	(T3) Immunogenicity Risk Assessment & Mitigation
(T2) PK/PD of Novel Constructs	(T4) Optimizing Bioassays for Biologics

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SC1: Basics of Immunogenicity Testing
Dinner SC2: Challenges of Immunogenicity Assessment
Dinner SC3: PK/PD Bioanalysis for Novel Biotherapeutics
Dinner SC4: Immunogenicity Risk Assessment and Regulatory Strategy
Dinner SC5: Developing Potency Assays to Ensure Successful Biologics

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