12th Annual

Immunogenicity & Bioassay Summit

VIRTUAL

Technologies and Strategies for Safe and Efficacious Products in the Clinic

October 6-9, 2020

Keynote & Featured Speakers:

Daniela Verthelyi, MD, PhD
Chief, Laboratory of Immunology, CDER, FDA

Boris Gorovits, PhD
Senior Director, BioMedicine Design, Pfizer, Inc.

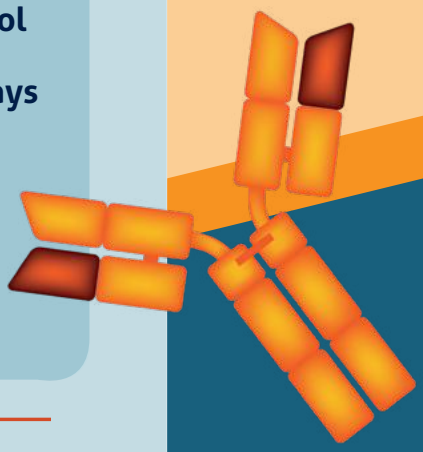
Alessandro Sette, PhD
Professor & Central Head, Vaccine Discovery & Infectious Disease, La Jolla Institute for Allergy & Immunology

Sumona Sarkar, PhD
Biomedical Engineer, Biosystems and Biomaterials Division, Biomaterials Group, National Institute of Standards and Technology

Soumi Gupta, PhD
Director, Translational Sciences, BioMarin Pharmaceutical

Conferences:

- Immunogenicity Assessment & Clinical Relevance
- Immunogenicity Prediction & Control
- Optimizing Bioassays for Biologics
- Symposium: Immunology for Biotherapeutics



[5 FDA Speakers for 2020!]

Plus!
5 Short Courses, exhibits, posters, and more.

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Bringing Together Industry, Academia & Regulatory Authorities in a VIRTUAL Format

For the first time ever, CHI is excited to bring to you its Immunogenicity & Bioassay Summit from the comfort of your own home or office! Now in its 12th year, the Immunogenicity & Bioassay Summit will examine the challenges currently facing the industry. Hear from industry leaders, academics and the FDA who will share NEW case studies, NEW perspectives and NEW approaches. This year we present 3 Conference Programs, a Symposium, and 5 Short Courses. Through our virtual platform, you have the option to move between presentations taking place at the same time. Plus, delegates can enable a live chat feature, view a virtual exhibit & poster hall, attend happy hours, breakout discussions and more. **This virtual event is available "Live" & On-Demand and will take place on Eastern Daylight Time.**

Conference At-a-Glance

Tuesday | October 6

- Symposium 1: Immunology for Biotherapeutics
- **Tues AM SC1:** Mechanism of Action and Risk-Based Approach for Developing Neutralizing Ab Assays
- **Tues PM SC2:** Overcoming Drug and Target Interference in ADA assays
- Happy Hour

All times are Eastern Daylight Time

Wednesday | October 7

- **C1:** Immunogenicity Assessment & Clinical Relevance
- **Wed AM *over lunch* | SC3:** Validation of ADA Assays and Cut Point Calculations
- Happy Hour

Thursday | October 8

- **C1:** Immunogenicity Assessment & Clinical Relevance
- **C2:** Immunogenicity Prediction & Control
- **C3:** Optimizing Bioassays for Biologics
- **Thurs AM *over lunch* | SC4:** Recent Advances with Gene and Cell Therapy
- Happy Hour

Friday | October 9

- **C2:** Immunogenicity Prediction & Control
- **C3:** Optimizing Bioassays for Biologics
- **Fri PM *over lunch* | SC5:** Advice on Putting Together an Integrated Summary of Immunogenicity

Benefits of Immunogenicity & Bioassay Summit Virtual

- **VIRTUAL CONFERENCE** accessible from the comfort of your home or office
- **INSPIRING KEYNOTE PRESENTATIONS** from world-renowned experts and visionaries
- **INTERACTIVE NETWORKING** with live Q&A sessions, breakout discussions, poster viewing, live chat with exhibitors, sponsors, and fellow delegates
- **RESEARCH POSTERS** engage with researchers presenting the latest in biotherapeutics discovery
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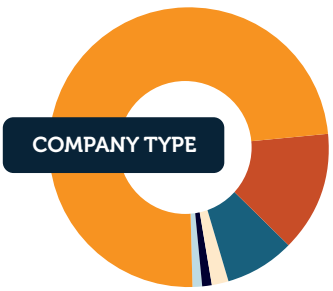
2019 ATTENDEE DEMOGRAPHICS



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5 FDA Speakers for 2020!

Distinguished Faculty

Barry Byrne, MD, PhD, Professor and Associate Chair, University of Florida

Etienne Caron, PhD, Assistant Professor, CHU Sainte-Justine Research Center, University of Montreal

Lukasz Chlewicki, PhD, Principal Research Scientist, Eli Lilly and Company

Shan Chung, PhD, Associate Director & Principal Scientist, Bioanalytical Sciences, Genentech

Sivan Cohen, PhD, Scientist, Genentech

Manuela Corti, PhD, Assistant Professor, Child Health Research Institute, University of Florida

Brandon DeKosky, PhD, Assistant Professor, The University of Kansas

Bo Feng, PhD, Associate Principal Scientist, Process R&D, Merck & Co., Inc.

Andrea Ferrante, MD, Principal Research Scientist, Eli Lilly and Company

Daron Forman, PhD, Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb

Dan Fowler, MD, CMO, Rapa Therapeutics

Theresa Goletz, PhD, President, Theresa Goletz Consulting

Boris Gorovits, PhD, Senior Director, Pharmacokinetics, Pharmacodynamics & Metabolism, Pfizer Inc.

Soumi Gupta, PhD, Director, Translational Sciences, BioMarin Pharmaceutical

Mohamed Hassanein, PhD, Senior Staff Scientist, Bioanalytical Sciences, Regeneron Pharmaceuticals

Timothy Hickling, PhD, Immunogenicity Sciences Lead, Pfizer Inc.

Wojciech Jankowski, PhD, Commissioner's Fellow, CBER, FDA

Emilee Knowlton, PhD, Senior Immunology Sales Specialist, ProImmune

Daniel LaGasse, PhD, Research Regulator, CBER, FDA

David Lansky, PhD, President, Precision Bioassay, Inc.

Catherine Liloia, Associate Director, Cell Lab, PPD, Inc.

Chang Liu, PhD, Assoc Scientist, BioAnalytical Sciences, Genentech Inc

Lilia Macovei, PhD, Bioanalytical Principal Investigator, Senior Scientist, Pfizer Inc.

Bernard Maillere, PhD, Research Director, Immunology, CEA

Ronit Mazor, PhD, Principal Investigator, CBER, FDA

Jim McNally, PhD, Principal, McNally Bioanalytical Consulting

Jos Melenhorst, PhD, Director, Product Development & Correlative Sciences, Center for Cellular Immunotherapies, University of Pennsylvania

Stephen Miller, PhD, Professor of Microbiology-Immunology, Feinberg School of Medicine, Northwestern University

Paul Moore, PhD, Vice President, Cell Biology & Immunology, MacroGenics, Inc.

Johanna Mora, PhD, Associate Director, Bristol-Myers Squibb

Kannan Natarajan, PhD, Staff Scientist, NIH NIAID

Simone Nicholson, PhD, DABT, Principal Toxicologist, Clinical Pharmacology and Safety Sciences, AstraZeneca

Michael Partridge, PhD, Associate Director, Bioanalytical Sciences, Regeneron Pharmaceuticals

Sofie Pattijn, Founder & CTO, ImmunXperts SA

Cheryl Pickett, MD, PhD, Associate Research Physician, Cancer Therapy Evaluation Program, Investigational Drug Branch, NIH NCI

Sandra Prior, PhD, Senior Scientist, National Institute for Biological Standards and Control (NIBSC, a centre of the MHRA)

Qiang Qu, Principal Scientist, EMD Serono

Theo Rispens, PhD, Head of Lab/PI, Sanquin

Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

Nancy Sajjadi, Independent Quality Consultant

Sumona Sarkar, PhD, Biomedical Engineer, Biosystems and Biomaterials Division, Biomaterials Group, National Institute of Standards and Technology

Tim Schofield, Owner & Consultant, CMC Sciences LLC

Ethan Shevach, MD, Senior Investigator, Cellular Immunology, Laboratory of Immune System Biology, NIH NIAID

Renu Singh, PhD, Scientific Leader, GSK

Perceval Sondag, Associate Principal Quantitative Scientist, Merck & Co., Inc.

Anish Suri, PhD, President and CSO, Cue Biopharma

Daniela Verthelyi, MD, PhD, Chief, Laboratory of Immunology, CDER, FDA

Eric Wakshull, PhD, CEO, Eric Wakshull Consulting

Steven Walfish, Principal Scientific Liaison, Global Science & Standards, USP

Wen Jin Wu, PhD, Senior Investigator, Biotechnology Products, CDER, FDA

Weifeng Xu, PhD, Principal Scientist & Group Leader, PPDM, Merck Research Labs

Tatyana Yun, PhD, Senior Scientist, Merck and Co., Inc.

Jeff Zhu, Senior Investigator, Immune System Biology, NIH NIAID

Short Courses*

October 6-8, 2020

**Separate registration is required, see Registration Page for pricing details*

TUESDAY, OCTOBER 6 11:35 AM-1:05 PM

SC1: Mechanism of Action and Risk-Based Approach for Developing Neutralizing Ab Assays

Instructors:

Shan Chung, PhD, Associate Director & Principal Scientist, Bioanalytical Sciences, Genentech

Jim McNally, PhD, Principal, McNally Bioanalytical Consulting

The development of neutralizing antibody assays is a daunting task that is complicated by the specific nature of each biotherapeutic. Many factors must be assessed to choose the proper assay format, to develop a robust assay and choosing when to invest in the development and implementation of these assays. This short course will focus on these topics and provide examples of current industry practices and publications. Specific focus will be given to a mechanism of action-based approach to selecting the assay format and relevant case studies will be provided.

TUESDAY, OCTOBER 6 2:35-4:35 PM

SC2: Overcoming Drug and Target Interference in ADA Assays

Instructors:

Weifeng Xu, PhD, Principal Scientist & Group Leader, PPDM, Merck Research Labs

Jim McNally, PhD, Principal, McNally Bioanalytical Consulting

Lynn Kamen, PhD, Senior Scientist, BioAnalytical Sciences, Genentech Inc.

Soluble drug, drug target and matrix can often interfere in the detection of anti-drug antibodies including neutralizing Abs. Although not always straightforward, it can be addressed and mitigated in a properly designed immunoassay. This short course will give an overview of the different types of interferences and current methodologies and approaches being utilized to resolve or reduce them.

WEDNESDAY, OCTOBER 7 11:55 AM-1:55 PM

SC3: Validation of ADA Assays and Cut Point Calculations

Instructors:

Johanna Mora, PhD, Associate Director, Bristol-Myers Squibb

Angela Yang, PhD, Scientist, Bioanalytical Sciences, Regeneron Pharmaceuticals, Inc.

This short course will focus on the validation of ADA assays and cut point evaluations. We will provide an in-depth overview of the basic considerations around ADA assay validation, with significant focus on the process of evaluating different types of cut-points, and the translation of the cut-point established during validation to the real-world implementation during a preclinical or clinical study.

THURSDAY, OCTOBER 8 11:40 AM-1:10 PM

SC4: Recent Advances with Gene and Cell Therapy

Instructors:

Soumi Gupta, PhD, Director, Translational Sciences, BioMarin Pharmaceutical

Jim McNally, PhD, Principal, McNally Bioanalytical Consulting

Topics to be Covered Include:

- Immunogenicity assessment of cell therapies
- Examining recent developments with CAR-T cells and edited stem cell
- Immunogenicity assessment of gene therapies
- Recent data on pre-existing reactivity for AAV
- Advances with redosing
- Application of current guidance to novel modalities
- What is your product? The vector, the expressed product?

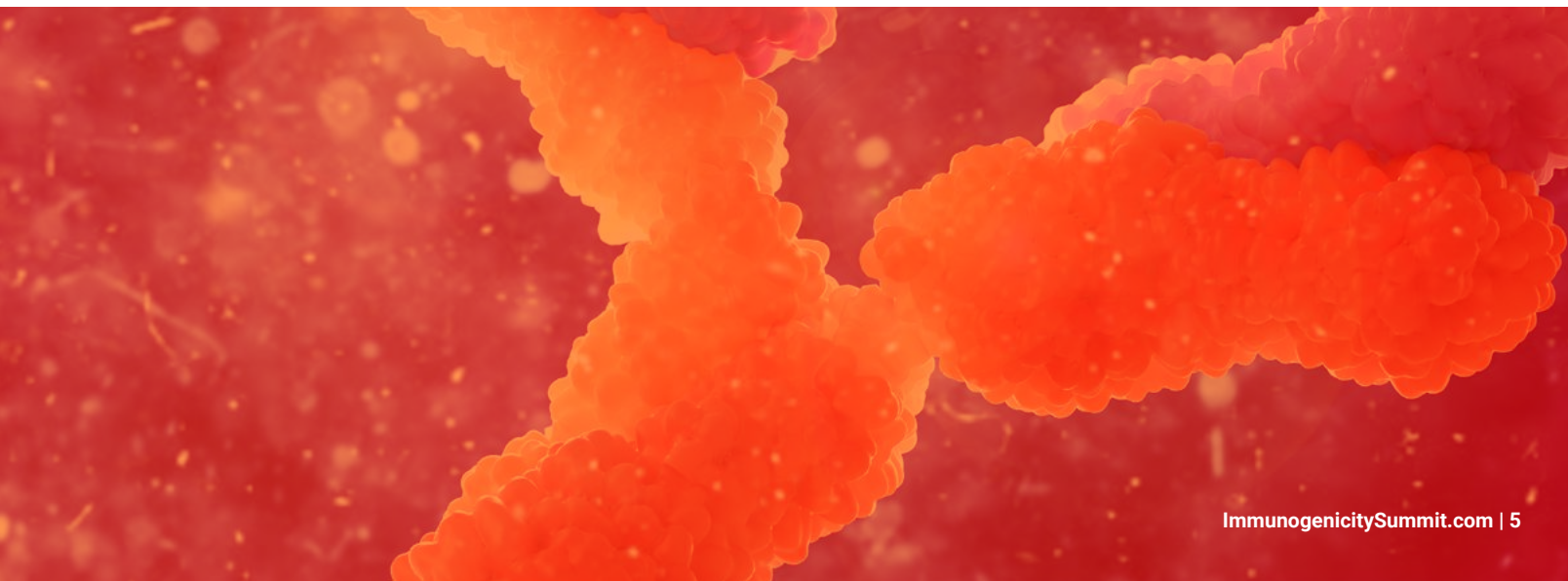
FRIDAY, OCTOBER 9 12:05-1:35 PM

SC5: Advice on Putting Together an Integrated Summary of Immunogenicity

Instructor:

Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

The purpose of this workshop is to share experience gained in preparing and reviewing the "Integrated Summary of Immunogenicity", with case examples to illustrate the multi-disciplinary information that is most useful for the regulator assessing the scale of risk of undesirable immunogenicity for overall clinical benefit vs. risk. It will examine the sponsor team's role and provide examples of how to address potential issues (and avoid introducing any new ones!) by generating a well-thought-out and constructed integrated summary.



Symposium: Immunology for Biotherapeutics

Understanding and Manipulating the Immune System for Therapeutic Advantage

October 6, 2020

TUESDAY, OCTOBER 6

CURRENT UNDERSTANDING OF IMMUNE MECHANISMS

9:00 am Symposium Overview

Ethan Shevach, MD, Senior Investigator, Cellular Immunology, Laboratory of Immune System Biology, NIH NIAID

9:05 am KEYNOTE PRESENTATION: Current Understanding of the Role of T Regulatory Cells and Their Modulation

Ethan Shevach, MD, Senior Investigator, Cellular Immunology, Laboratory of Immune System Biology, NIH NIAID

The immune system consists of several distinct cell types and each type plays a unique role. Dysregulation of the immune system can result in responses against self-antigens and in the development of autoimmune diseases. A specialized subset of T lymphocytes, termed T regulatory (Treg) cells, functions to suppress anti-self responses. Modulation of Treg function with drugs or biologics represents a major approach to the treatment of autoimmune disease.

9:25 Antigen Processing and Presentation: T Cell Activation and Interaction between the Cells of the Immune System

Kannan Natarajan, PhD, Staff Scientist, NIH NIAID

Antigen Presenting Cells process protein antigens into peptides for binding by either Major Histocompatibility Class I (MHC-I) or Class II (MHC-II) molecules, which are then displayed at the cell surface as peptide/MHC complexes, where they are recognized by T cell receptors leading to T cell activation. Cell biological, biochemical, and structural details of these processes as we now understand them will be discussed.

9:45 T Helper and Innate Lymphoid Cell Subsets

Jeff Zhu, Senior Investigator, Immune System Biology, NIH NIAID

Specific T helper and innate lymphoid cell subsets mediate crucial functions during different types of protective immune response. Inappropriate Th responses and ILC activation may lead to chronic infection and/or tissue damage. In addition, aberrant Th cell and ILC activation may result in many inflammatory allergic or autoimmune diseases. I will discuss the similarities and differences between Th cell and ILC subsets, and their functional crosstalk during immune responses.

10:05 Coffee Break - View Our Virtual Exhibit Hall

HARNESSING THE IMMUNE SYSTEM FOR BIOTHERAPEUTICS

10:20 Applying Bispecific Technology to Modulate the Immune Response for Therapeutic Intervention

Paul Moore, PhD, Vice President, Cell Biology & Immunology, MacroGenics, Inc.

Bispecific antibody-based molecules afford therapeutic opportunities not feasible with single-target antibodies or combinations. The most advanced clinical strategy in oncology exploits the ability of bispecific molecules to co-engage T cells with tumor cells, resulting in tumor cell lysis and T cell expansion. Additional approaches to leverage immune cells through bispecific targeting are being explored in oncology, autoimmunity, and infectious diseases. These will be discussed regarding molecule design and target selection.

10:40 Immunology Safety Considerations for Biotherapeutics

Simone Nicholson, PhD, DABT, Principal Toxicologist, Clinical Pharmacology and Safety Sciences, AstraZeneca

I shall examine the challenges of biotherapeutics impacting the immune response, and the challenges investigators face managing dose, scheduling, and satisfying the regulatory requirements. Checkpoint inhibitors used for immunotherapy have a natural role in controlling autoimmune diseases, such as Type 1 Diabetes and Lupus. Immunotherapies, in general, and technologies modifying T cell function and those involving cytokines present dangers of autoimmune disease, cardiovascular disorders, and additional challenges, especially in combination.

11:00 Biopharmaceutical Product Immunogenicity: What Causes It and What Are the Safety and Efficacy Consequences?

Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

Biopharmaceuticals contribute significantly to treatment of serious diseases, including chronic inflammatory and autoimmune diseases, genetic deficiencies, and cancer. Unwanted immunogenic responses against some of these products can occur, reducing efficacy and sometimes causing safety consequences, such as hypersensitivity, immune complex disease, and autoimmune syndromes. I will discuss factors that affect the degree to which the immune system responds, and the degree to which the response affects the efficacy and safety.

11:20 LIVE Q&A: Session Wrap-Up

11:35 Recommended Short Course*

SC1: Mechanism of Action and Risk-Based Approach for Developing Neutralizing Ab Assays

**Separate registration required. See short course page for details.*

11:35 Lunch Break - View Our Virtual Exhibit Hall

IMMUNO-ONCOLOGY

1:05 pm Harnessing the Body's Natural Immune Response to Fight Cancer

Daron Forman, PhD, Principal Scientist, Discovery Biotherapeutics, Bristol-Myers Squibb

Checkpoint inhibitors have shown remarkable response rates in some previously hard-to-treat cancers by redirecting the body's own immune system to recognize and eliminate tumor cells. Here, we will discuss the current state of checkpoint inhibitors in the clinic, challenges related to toxicities, biomarker approaches for patient stratification, and future directions of the field.

1:25 Adoptive T Cell Therapy

Jos Melenhorst, PhD, Director, Product Development & Correlative Sciences, Center for Cellular Immunotherapies, University of Pennsylvania

I will discuss the evolving field of adoptive T cell therapy, and compare and contrast tumor-targeting efforts with allogeneic, autologous, minimally manipulated to the TCR- and CAR-redirected T cells. Topics to discuss are safety, efficacy, toxicity; clinical trials in hematologic and solid tumors; and future directions to enhance immunogene therapy of cancer.

1:45 Oncolytic Viruses: Impact of the Virus on Tumor Cells, Local Microenvironment, and Systemic Adaptive Immune Response

Cheryl Pickett, MD, PhD, Associate Research Physician, Cancer Therapy Evaluation Program, Investigational Drug Branch, NIH NCI

Intratumorally injected oncolytic viruses infect, replicate, and lyse cancer cells. Through release of tumor-specific antigens and cytokines, they induce changes in local immune microenvironment, activating the adaptive immune system, and producing responses in non-injected lesions. These changes sensitize tumors to checkpoint inhibitors. We will review data on oncolytic viruses with attention to systemic responses and potential combination with other immunotherapy. We will also review delivery and safety issues.

2:05 LIVE Q&A: Session Wrap-Up

2:20 Refresh Break - View Our Virtual Exhibit Hall

2:35 Recommended Short Course*

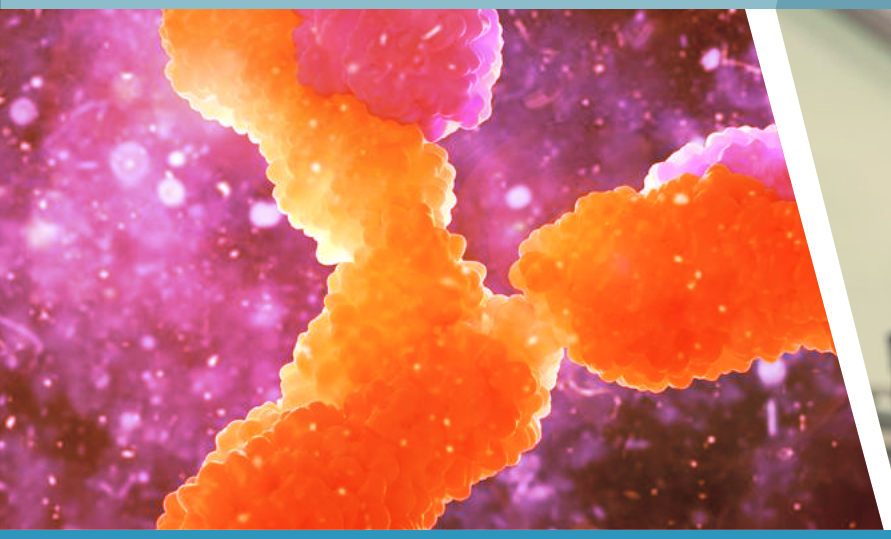
SC2: Overcoming Drug and Target Interference in ADA Assays

**Separate registration required. See short course page for details.*

4:35 Happy Hour - View Our Virtual Exhibit Hall

5:15 Close of Symposium

Testimonials



"I learned a lot about bioanalytical challenges and needs on novel modalities, which ultimately translates into faster drug products delivered to those that need them."

- Bioanalytical Principal Investigator, Senior Scientist, Pfizer

"The Summit was a fantastic meeting. It was an exciting opportunity to connect with colleagues and collaborators and to discuss the cutting-edge developments in protein drug immunogenicity."

- Assistant Professor, The University of Kansas

"The Immunogenicity & Bioassay Summit was a real success. It was a very nice opportunity to meet talented scientists in the field."

- Research Director, Immunology, CEA

C1: Immunogenicity Assessment & Clinical Relevance

Assay Strategy for Meaningful Evaluation

WEDNESDAY, OCTOBER 7

CLINICAL RELEVANCE OF ADA

9:00 am Conference Overview

Eric Wakshull, PhD, CEO, Eric Wakshull Consulting

9:05 FEATURED PRESENTATION: How to Determine if ADA Assays Are Clinically Relevant: If Clinical Impact of Immunogenicity Is Clear, Does Further Optimization of ADA Assay Performance Add Value Post-Marketing?

Soumi Gupta, PhD, Director, Translational Sciences, BioMarin Pharmaceutical

In this presentation, I will share a comparison of two case studies where 100% ADA incidence was detected in both sets of treated patients. I will highlight the methods used to investigate clinical relevance in each case and share the clinical decision-making and trial design changes that were made as a result.

9:25 Clinical Impact of ADA and Therapeutic Drug Monitoring

Theo Rispens, PhD, Head of Lab/PI, Sanquin

Immunogenicity is one of the factors that may impact efficacy and safety of therapeutic antibodies in patients. Nevertheless, linking immunogenicity assessment to clinical correlates has proved challenging. This presentation will discuss measurement of ADA to therapeutic monoclonal antibodies, and its clinical relevance in terms of drug tolerance, the relation with pharmacokinetics (PK), and the impact on efficacy.

9:45 Sponsored Presentation *(Opportunity Available)*

10:05 PANEL DISCUSSION: Assessing the Clinical Relevance of ADA

Moderator: Eric Wakshull, PhD, CEO, Eric Wakshull Consulting

- Cost of developing assays and new techniques
- Optimal methods for collecting good data
- Effectively detecting ADA
- Interaction and feedback from the FDA

Panelists:

Soumi Gupta, PhD, Director, Translational Sciences, BioMarin Pharmaceutical

Theresa Goletz, PhD, President, Theresa Goletz Consulting

Theo Rispens, PhD, Head of Lab/PI, Sanquin

10:25 Coffee Break - View Our Virtual Exhibit Hall

ASSAY DEVELOPMENT AND VALIDATION

10:55 KEYNOTE PRESENTATION: Selecting Optimal Format for ADA Assay to Ensure Fit-for-Purpose Assay Characteristics, including Assay Cut-Point

Boris Gorovits, PhD, Senior Director, Pharmacokinetics, Pharmacodynamics & Metabolism, Pfizer Inc.

Anti-drug antibody detecting assay characteristics significantly depend on the assay format and conditions chosen. Selecting appropriate assay set up will ensure that the assay delivers fit-for-purpose characteristics, including assay cut-point, sensitivity, and more. Methods allowing for relevant assay development, as well as alternative methodologies for assay cut-point calculation will be discussed.

11:15 A Case Study on an Alternative Approach for ADA Assay Cross-Validation for the Purpose of Supporting Global Clinical Studies

Qiang Qu, Principal Scientist, EMD Serono

Global clinical studies may utilize multiple bioanalytical labs at various geographical locations for sample analysis. Data comparability among labs is expected to be established before the decision of pooling or comparing immunogenicity results. Currently, there is no clear regulatory guidance on immunogenicity assay cross-validation and acceptance criteria. Here, a case study is presented on an alternative approach when using incurred study samples was not operationally feasible.

DEVELOPMENT OF NEUTRALIZING ANTIBODY ASSAYS

11:35 Challenges in Developing Alternative Formats of Neutralizing Antibody Assays

Tatyana Yun, PhD, Senior Scientist, Merck and Co., Inc.

11:40 LIVE Q&A: Session Wrap-Up

11:55 Recommended Short Course*

SC3: Validation of ADA Assays and Cut-Point Calculations

**Separate registration required. See short course page for details.*

11:55 Lunch Break - View Our Virtual Exhibit Hall

2:25 pm Immunogenicity Monitoring for Low-Risk Molecules: How Much Is Needed?

Michael Partridge, PhD, Associate Director, Bioanalytical Sciences, Regeneron Pharmaceuticals

Requirements for immunogenicity monitoring are applied to all biotherapeutics, regardless of the molecule's risk profile. This places an unnecessary burden on low-risk human mAbs. Frequent patient sampling and early collection times increase the detection of clinically irrelevant ADA. Furthermore, NAb assays implemented in registrational studies may add little value when information about low ADA incidence, as well as titer, persistence, PK, PD, etc., is available from other assays.

IMMUNOGENICITY OF IMMUNO-ONCOLOGY DRUGS

2:45 Bioanalytical Challenges in Patients with Prior Exposure to Class-Specific Biologics and Possible Mitigation Strategies

Mohamed Hassanein, PhD, Senior Staff Scientist, Bioanalytical Sciences, Regeneron Pharmaceuticals

Monoclonal antibodies (mAbs) are the leading biotherapeutic modality in the IO space. Patients experiencing disease recurrence, non-responders, or those developing resistance may enroll in new clinical trials involving mAbs specific for the same targets. Therefore, bioanalytical challenges may arise, including cross-reactivity in immunoassays from previous therapies, and increase the risk of developing pre-existing ADA. This talk will highlight some of these potential challenges and propose mitigation strategies to overcome them.

3:05 Sponsored Presentation *(Opportunity Available)*

ASSAY DEVELOPMENT AND VALIDATION

3:25 Development of an SPR-Based Assay for the Measurement of Purified Pre-Existing Antibodies against Biotherapeutic Proteins

Andrea Ferrante, MD, Principal Research Scientist, Eli Lilly and Company

We report a novel method based on a surface plasmon resonance (SPR)-measurement of the test molecule binding to immunoglobulins (Ig) purified from drug-naïve subjects' sera. Isolation of the Ig and concentration normalization eliminates matrix effect and enables comparison across subjects. By using a high-density surface, PRA of a wide range of affinity to the test molecule can be identified, making this approach a sensitive alternative to the ELISA-based methods.

3:40 Happy Hour - View Our Virtual Exhibit Hall

4:15 Close of Day

THURSDAY, OCTOBER 8

REGULATORY FEEDBACK

9:00 am KEYNOTE PRESENTATION: Peptides Identified on Monocyte-Derived Dendritic Cells: A Marker for Clinical Immunogenicity to FVIII

Wojciech Jankowski, PhD, Commissioner's Fellow, CBER, FDA

9:20 Immunogenicity Risk Assessments as Part of an IND Submission
Johanna Mora, PhD, Associate Director, Bristol-Myers Squibb
Scientists have been applying risk-based strategies for immunogenicity assessments of biotherapeutics and there is a 2019 publication providing advice on how to present this information in dossiers. However, practices across the industry on the content of immunogenicity risk assessments may vary. The goal of this presentation is to provide examples on the presentation of immunogenicity risk assessments and write a fictitious report with help from the audience.

9:40 Coffee Break - View Our Virtual Exhibit Hall

ADVANCES WITH NOVEL MODALITIES

10:10 Management of Immune Responses to AAV Gene Therapies and Redosing
Manuela Corti, PhD, Assistant Professor, Child Health Research Institute, University of Florida
Adeno-associated virus (AAV) gene therapy is a potential treatment for a variety of genetic disorders. A critical challenge for the success of AAV-mediated gene therapy is the host immune response, which may constitute a barrier to long-term efficacy and safety. Careful immunosurveillance following systemic administration of the vector demonstrates that immunomodulation can prevent the humoral response and activation of the complement classical-pathway, triggered by capsid antigen-IgM complexes.

10:30 Bioanalytical Support for Gene Therapy Programs: Strategies and Hurdles
Lilia Macovei, PhD, Bioanalytical Principal Investigator, Senior Scientist, Pfizer Inc.

10:50 Importance of Pre-Existing Abs to the Viral Capsid During Immunogenicity Assessment of Viral Vectors Based Gene Therapy
Jim McNally, PhD, Principal, McNally Bioanalytical Consulting

10:50 Coffee Break - View Our Virtual Exhibit Hall

11:05 Interactive Breakout Discussions - View Our Virtual Exhibit Hall

BREAKOUT: Assessing Vaccine Efforts for COVID-19
Theresa Goletz, PhD, President, Theresa Goletz Consulting

BREAKOUT: Value of Bioanalytical PMRs – Learnings from Late-Stage Clinical Studies
Soumi Gupta, PhD, Director, Translational Sciences, BioMarin Pharmaceutical

BREAKOUT: Preclinical Immunogenicity Risk Assessment
Andrea Ferrante, MD, Principal Research Scientist, Eli Lilly and Company

BREAKOUT: Assessing the Clinical Relevance of ADA
Eric Wakshull, PhD, CEO, Eric Wakshull Consulting

BREAKOUT: AAV Gene Therapies and Redosing
Barry Byrne, MD, PhD, Professor and Associate Chair, University of Florida

11:40 Recommended Short Course*

SC4: Recent Advances with Gene and Cell Therapy
**Separate registration required. See short course page for details.*

12:00 pm Lunch Break - View Our Virtual Exhibit Hall

1:25 Close of Immunogenicity Assessment & Clinical Relevance Conference

"The immunogenicity summit is one of the highlights of the year for me."
- Biotech Quality and Immunogenicity Reviewer, Biotechnology Products, CDER, FDA

"A great opportunity to meet FDA colleagues and interact with experts in different fields."
- Bioanalytical Principal Investigator, Senior Scientist, Pfizer

"I think your conference is one of the best ones focused on immunogenicity. Your ability to attract multiple FDA speakers is a big plus."
- CSO, Selecta Biosciences

C2: Immunogenicity Prediction & Control

Regulatory Perspectives, Risk Factors, and Management

THURSDAY, OCTOBER 8

TRANSLATION INTO THE CLINIC

1:25 pm Conference Overview

Bonnie Rup, PhD, Biotechnology Consultant, Bonnie Rup Consulting

1:30 Assessment and Prediction of Immunogenicity of Antibody-Drug Conjugates

Renu Singh, PhD, Scientific Leader, GSK

Presentation will focus on challenges associated with assessing and predicting clinical immunogenicity of antibody-drug conjugates (ADCs). ADCs are complex therapeutic modalities, with several bioanalytical species in systemic circulation which complicates *in vitro in vivo* correlation of immunogenicity data and its interpretation. Speaker will provide insight on this challenging topic with some case studies.

1:50 Validation of De-Immunization Strategies for Antibodies Using Cynomolgus Macaque as a Surrogate for Human

Lukasz Chlewicki, PhD, Principal Research Scientist, Eli Lilly and Company

There is little direct information on the predictability of *in silico*/*in vitro* tools to predict and reduce immunogenicity *in vivo*. We used *in silico* tools to de-immunize antibodies and used cynomolgus macaque as a surrogate for human. The resultant antibodies demonstrated similar biophysical properties, reduced ADA levels, and improved PK in primates; and points to the relevance of using non-human primates as an important *in vivo* model for antibody optimization.

2:10 Mastering Immunogenicity in Biologics Development PROIMMUNE www.proimmune.com

Emilee Knowlton, PhD, Senior Immunology Sales Specialist, ProImmune

Immunogenicity is one of the most complex issues to address in drug design and development and requires intelligent application of integrated platforms to mitigate the risk to your biologic. In this talk I will present case studies to illustrate the range of solutions that ProImmune provides including DC-T/T cell proliferation assays for lead selection/optimization, MAPPS assays for characterization of antigen presentation; HLA-peptide binding assays to characterize individual epitopes & undiluted whole blood cytokine storm assays.

2:30 LIVE Q&A: Session Wrap-Up

2:45 Refresh Break - View Our Virtual Exhibit Hall

PREDICTIVE STUDIES AND PREDICTIVE TOOLS

3:00 FEATURED PRESENTATION: T Cell Response to Biopharmaceuticals: From Basic Immunology to Immunogenicity Prediction

Bernard Maillere, PhD, Research Director, Immunology, CEA

ADA response to biopharmaceuticals (BP) is the frequent event, although their sequence is humani(zed) and expected to lead to T cell tolerance. Autoreactive T cells are indeed negatively selected in the thymus to self-peptides. Identification of immunogenic sequences in therapeutic antibodies and human hormones, from healthy donors and patients, reveals multiple mechanisms of tolerance, ignorance, and T cell activation, and contributes to anticipate immunogenicity risk.

3:20 Applying Immunopeptidomics Technologies to Control Tumor Immunogenicity

Etienne Caron, PhD, Assistant Professor, CHU Sainte-Justine Research Center, University of Montreal

Mass spectrometry profiling of peptides associated to human leukocyte antigen (HLA) – referred herein as immunopeptidomics – has become a dynamic new frontier in immunology, vaccine, and immunotherapy. In this presentation, we will describe the latest advances in the field. In particular, we will describe the importance of dissecting the molecular architecture that shapes the global composition of the immunopeptidome to understand and control tumor immunogenicity.

3:40 The Influence of T Cell Epitopes on Antibody Somatic Hypermutation Pathways

Brandon DeKosky, PhD, Assistant Professor, The University of Kansas

Next-generation sequencing (NGS) of paired-antibody heavy and light chains has opened up new possibilities for studying human antibody repertoires. Here, we applied high-throughput interrogation of human antibody responses and paired these data with large-scale T cell epitope prediction. We reveal new trends in antibody development that reduce antibody immunogenicity. These findings have broad implications for the identification and discovery of new antibody therapeutics with reduced immune rejection.

4:00 LIVE Q&A: Session Wrap-Up

4:15 Happy Hour - View Our Virtual Exhibit Hall

4:45 Close of Day

FRIDAY, OCTOBER 9

ADVANCES WITH NOVEL MODALITIES

9:00 am KEYNOTE PRESENTATION: Immunogenicity of AAV Vectors in Gene Therapy

Ronit Mazor, PhD, Principal Investigator, CBER, FDA

Adeno-associated viruses (AAV) are potent vectors used for gene delivery in gene therapy products. Recent clinical findings revealed immunogenicity related challenges including pre-existing antibodies, formation of neutralizing antibodies after the first administration, innate activation and formation of a cytotoxic immune response against transfected cells. In this talk I will provide a review of current state of the art of immunogenicity of AAV vectors and strategies for mitigation of it.

9:20 Immune-STATs: A Novel Biologics Platform for Selective and Specific T Cell Modulation in the Patient

Anish Suri, PhD, President and CSO, Cue Biopharma

A key consideration for successful immunotherapy of cancers, autoimmunity and chronic infectious disease is the selective and specific modulation of the immune repertoire while avoiding systemic immune modulation and related safety liabilities. To that end, we have developed a unique biologics platform termed Immuno-STAT that provides the opportunity to directly target and modulate the antigen-specific T cell repertoire in the patient.

9:40 Clinical Development of Immune-Tolerizing Therapy Using Hybrid TREG/Th2 Cells

Dan Fowler, MD, CMO, Rapa Therapeutics

Regulatory T (T_{REG}) cells hold promise for modulation of Th1-driven processes, including autoimmune and neurodegenerative disease, transplantation complications (graft rejection, GVHD), and foreign protein immunogenicity. Because T_{REG} and Th2-type cells counter-regulate Th1 responses, we developed an *ex vivo* manufacturing process that generates a T cell product of hybrid T_{REG}/Th2 phenotype. A phase I clinical trial of hybrid T_{REG}/Th2 cells has been developed for therapy of amyotrophic lateral sclerosis.

9:55 Coffee Break - View Our Virtual Exhibit Hall

10:10 Interactive Breakout Discussions - View Our Virtual Exhibit Hall

BREAKOUT: Overcoming Technical Issues with Assays to Assess Innate Immune Response Modulating Impurities

Daniela Verthelyi, MD, PhD, Chief, Laboratory of Immunology, CDER, FDA

BREAKOUT: Immunogenicity Prediction in the Real World: Feedback from the Users

Bernard Maillere, PhD, Research Director, Immunology, CEA

BREAKOUT: Mechanisms of Immunogenicity of Gene Therapy Products
Ronit Mazor, PhD, Principal Investigator, CBER, FDA

BREAKOUT: Different Strategies to Predict Immunogenicity
Sivan Cohen, PhD, Scientist, Genentech

BREAKOUT: Viability of Immune Tolerance Strategies for the Treatment of Human Disease
Stephen Miller, PhD, Professor of Microbiology-Immunology, Feinberg School of Medicine, Northwestern University

BREAKOUT: New Molecular Insights for Antibody and Protein Drug Immunogenicity
Brandon DeKosky, PhD, Assistant Professor, The University of Kansas

RISK ASSESSMENT STRATEGIES

11:05 KEYNOTE PRESENTATION: Assessing the Immunogenicity Risk of Impurities
Daniela Verthelyi, MD, PhD, Chief, Laboratory of Immunology, CDER, FDA

Product and process related impurities are critical quality attributes as they can modify the immunogenicity risk of biologics. This talk will discuss the role of impurities in product immunogenicity and the potential and limitations of clinical and preclinical studies designed to assess their risk.

11:25 Predicting Immunogenicity of Biopharmaceuticals through Integrating *in silico*, *in vitro*, and Immune Systems Data
Timothy Hickling, PhD, Immunogenicity Sciences Lead, Pfizer Inc.

Unwanted immune responses to therapeutic proteins can adversely affect clinical outcomes and may complicate product development. Reducing the risk of immunogenicity through application of 'predictive' assays during molecular design is appealing, though useful prediction via a single assay is not currently possible. I will describe an approach to integrate data relating to molecules and patients to simulate the outcome of clinical trials, including the introduction of an Immunogenicity Simulator consortium.

11:45 Sponsored Presentation *(Opportunity Available)*

12:05 pm LIVE Q&A: Session Wrap-Up

12:05 Recommended Short Course*

SC5: Advice on Putting Together an Integrated Summary of Immunogenicity
**Separate registration required. See short course page for details.*

12:20 Lunch Break - View Our Virtual Exhibit Hall

2:00 *In vitro* T Cell Assay to Predict Immunogenicity of Biotherapeutic Products
Sivan Cohen, PhD, Scientist, Genentech

Treatment of patients with biotherapeutic protein products may result in immune responses of varying clinical relevance, including development of life-threatening anti-drug antibodies (ADA) that can limit product efficacy. Predicting the risk for immunogenicity of biotherapeutic products at early stages is a crucial need. This presentation will focus on *in vitro* T cell assay studies to characterize the immunogenic potential of different biotherapeutic proteins and the clinically observed outcome.

2:20 FEATURED PRESENTATION: Fc-Fc Receptor Mediated Interactions: Implications for Modulating Fc-Fusion Protein Immunogenicity
Daniel LaGasse, PhD, Research Regulator, CBER, FDA

Fusing the human immunoglobulin G1 (IgG1) constant region (Fc-domain) to therapeutic proteins or peptides increases their circulating plasma half-life via neonatal Fc receptor (FcRn) binding and recycling. However, Fc-mediated interactions with other molecules including complement C1q and Fc gamma receptors (FcγR) can have immunological consequences. This presentation will highlight recent reports of Fc-Fc receptor interactions and discuss their implications for the modulation of Fc-fusion protein immunogenicity.

IMMUNE TOLERANCE

2:40 Specific Immune Tolerance for Facilitating Gene/Protein Replacement Therapy – Clinical Experience and Future Perspectives
Stephen Miller, PhD, Professor of Microbiology-Immunology, Feinberg School of Medicine, Northwestern University

The efficacy and mechanisms of action of negatively charged, antigen-encapsulating, carboxylated poly(lactide-co-glycolide) (PLG) nanoparticles (Ag-PLG) for gliadin tolerance induction in a Phase 2 clinical trial in celiac disease patients will be discussed. In addition, data showing the efficacy of Ag-PLG tolerance in inducing tolerance in a preclinical model of gene therapy using AAV-expressing green fluorescent protein will be presented and prospects for clinical translation for gene therapy discussed.

3:00 LIVE Q&A: Session Wrap-Up

3:15 Close of Summit

"Extremely high-quality presentations and excellent networking opportunities. Feedback from the FDA was invaluable."

- Professor, Head and Member, La Jolla Institute for Immunology

C3: Optimizing Bioassays for Biologics

Case Studies Demonstrating Successful Bioassay Development

THURSDAY, OCTOBER 8

INNOVATIVE STRATEGIES TO DESIGN BIOASSAYS

1:25 pm Conference Overview

Nancy Sajjadi, Independent Quality Consultant

1:30 A Simple Way to Select the Concentrations to Fit 4PL Curves for Potency Assays

Perceval Sondag, Associate Principal Quantitative Scientist, Merck & Co., Inc.

A challenging aspect of potency assays is choosing the ideal concentrations for the concentration-response curve analysis. Common optimal design methods are not suited for this type of analysis, as they fail to account for the constraint in a laboratory, as well as the variability between runs that affect the estimation of the relative potency and the similarity test. This talk proposes a simple way to find an efficient concentration range.

1:50 International Standards for Bioassays: A Global Effort to Harmonise the Bioactivity of Monoclonal Antibodies

Sandra Prior, PhD, Senior Scientist, National Institute for Biological Standards and Control (NIBSC, a centre of the MHRA)

As technical and regulatory tools for the development and control of biotherapeutic monoclonal antibody products evolve for new modalities and biosimilars, this fast-developing market encounters new challenges. Manufacturers' reference standards and reference medicinal products are insufficient to ensure product consistency between manufacturers, jurisdictions, and over time. The impact of using international standards on the harmonisation of complex bioassay data will be discussed in light of recent international collaborative studies.

2:10 Sponsored Presentation *(Opportunity Available)*

2:30 LIVE Q&A: Session Wrap-Up

Moderator: Nancy Sajjadi, Independent Quality Consultant

Panelists:

Perceval Sondag, Associate Principal Quantitative Scientist, Merck & Co., Inc.

Sandra Prior, PhD, Senior Scientist, National Institute for Biological Standards and Control (NIBSC, a centre of the MHRA)

2:45 Refresh Break - View Our Virtual Exhibit Hall

3:00 Ensuring Fitness for Use throughout the Bioassay Lifecycle

Tim Schofield, Owner & Consultant, CMC Sciences LLC

Many opportunities exist to ensure that bioassay measurement is fit for use. This includes but is not limited to strategic development, controls, suitability testing, and standard qualification. All of these must be linked to the bioassay ATP to deliver on their goal. This talk will describe the introduction and maintenance of these throughout the bioassay lifecycle, and how they differ across bioassay uses.

3:25 Strategic Ways to Create and Exploit Modularity in Bioassay Design and Analysis

David Lansky, PhD, President, Precision Bioassay, Inc.

Bioassays optimization is complex with many inputs and their application to different sized units. Combining practical laboratory constraints with design of experiments is easier with layered or modular design components. The properties of reported values for each of several different intended uses can be supported from a single efficient experiment. Modular design and analyses support efficient development and robustness experiments supporting adjustments to the assay format as the assay matures.

3:45 Talk Title to be Announced

Chang Liu, PhD, Assoc Scientist, BioAnalytical Sciences, Genentech Inc

4:05 LIVE Q&A: Session Wrap-Up

Moderator: Nancy Sajjadi, Independent Quality Consultant

Panelists:

Tim Schofield, Owner & Consultant, CMC Sciences LLC

David Lansky, PhD, President, Precision Bioassay, Inc.

Chang Liu, PhD, Assoc Scientist, BioAnalytical Sciences, Genentech Inc

4:15 Happy Hour - View Our Virtual Exhibit Hall

4:45 Close of Day

FRIDAY, OCTOBER 9

USP CHAPTERS

9:00 PANEL DISCUSSION: The USP Bioassay Chapters: How Can We Help?

Moderator: Steven Walfish, Principal Scientific Liaison, Global Science & Standards, USP

In this interactive panel discussion, members of the USP Bioassay Panel will discuss current issues and future goals of the USP suite of bioassay chapters. The audience will be able to interact through an open dialogue to ask questions and give feedback on areas where chapters can be improved to be more user-friendly. Do not miss your chance to be a part of the change!

Panelists:

Catherine Liloia, Associate Director, Cell Lab, PPD, Inc.

David Lansky, PhD, President, Precision Bioassay, Inc.

Tim Schofield, Owner & Consultant, CMC Sciences LLC

Perceval Sondag, Associate Principal Quantitative Scientist, Merck & Co., Inc.

9:55 Coffee Break - View Our Virtual Exhibit Hall

10:25 Interactive Breakout Discussions - View Our Virtual Exhibit Hall

BREAKOUT: Potency Assays

Catherine Liloia, Associate Director, Cell Lab, PPD, Inc.

POTENCY ASSAYS

11:05 Development of Enzymatic Functional Potency Assays for Antibody Therapeutic Product Development at Later Phase

Bo Feng, PhD, Associate Principal Scientist, Process R&D, Merck & Co., Inc.

Two functional bioassays which better reflect the MoA of antibody drug by measuring antibody binding-induced target protein enzymatic activity changes are developed to replace and/or supplement an early-phase binding ELISA potency assay. The enzymatical potency assays showed equivalent performance in comparison with binding assay regarding linearity/range, accuracy and precision. The stability-indicating capacity of the enzymatical functional bioassays has also been demonstrated using stability and force-degraded samples.

11:25 Building Bridges That Last: Working through Process and Method Changes for Potency and Viral Titer

Catherine Liloia, Associate Director, Cell Lab, PPD, Inc.

With higher expectations for potency assay performance, these analytical methods are refined earlier in drug development and have improved capability of detecting process-related differences. Clinical study design changes and evolving technologies for cell and gene therapies have introduced further instances where process, material, or method bridging are required later in development. Case studies will be reviewed with strategies to determine the most appropriate path to bridge these changes.

11:45 **Sponsored Presentation** *(Opportunity Available)*

12:05 pm **LIVE Q&A: Session Wrap-Up**

Moderator: Perceval Sondag, Associate Principal Quantitative Scientist, Merck & Co., Inc.

Panelists:

Bo Feng, PhD, Associate Principal Scientist, Process R&D, Merck & Co., Inc.

Catherine Liloia, Associate Director, Cell Lab, PPD, Inc.

12:05 **Recommended Short Course***

SC5: Advice on Putting Together an Integrated Summary of Immunogenicity

**Separate registration required. See short course page for details.*

12:20 **Lunch Break - View Our Virtual Exhibit Hall**

FDA INSIGHTS

1:45 **FEATURED PRESENTATION: Talk Title to be Announced**

Wen Jin Wu, PhD, Senior Investigator, Biotechnology Products, CDER, FDA

BIOASSAYS FOR NEW MODALITIES

2:05 **KEYNOTE PRESENTATION: Measurement Assurance, Control Strategies and Documentary Standards for the Development of Bioassays for Cell Therapy**

Sumona Sarkar, PhD, Biomedical Engineer, Biosystems and Biomaterials Division, Biomaterials Group, National Institute of Standards and Technology

2:25 **Development of *in vitro* Functional Bioassays for Potency and Immunogenicity Screening of Cell and Gene Therapy Products: Challenges and Opportunities**

Sofie Pattijn, Founder & CTO, ImmunXperts SA

Cell and gene therapies have the potential to cure previously untreatable diseases, and fundamentally alter the trajectory of many other diseases. However, the development of new therapeutics comes with a series of challenges and risks. In contrast to traditional therapeutics, large-batch manufacturing and quality testing for these individual batches of cell products, the selection and development of a suitable *in vitro* bioassay comes with certain challenges.

2:45 **LIVE Q&A: Session Wrap-Up**

Moderator: Sofie Pattijn, Founder & CTO, ImmunXperts SA

Panelists:

Sumona Sarkar, PhD, Biomedical Engineer, Biosystems and Biomaterials Division, Biomaterials Group, National Institute of Standards and Technology

Wen Jin Wu, PhD, Senior Investigator, Biotechnology Products, CDER, FDA

3:00 **Close of Conference**

"This event has a great atmosphere for networking and learning about new expectations in our always changing field."

- Senior Group Leader, Immunogenicity, PPD, Inc.

PRESENT A POSTER AND SAVE $50!

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the virtual poster sessions. To ensure your poster presentation is included in the conference materials, your full submission must be received, and your registration paid in full by September 4, 2020.

Virtual scientific poster presentation materials will include:

- **Poster title**
- **Text-only abstract.** It can be an in-depth, one-page abstract, or just a short description.
- **3-5 minute voice-over PowerPoint presentation.** You may substitute the PowerPoint with a one-page, static PDF of your poster
- Discuss your research and collaborate with other attendees during designated chat times

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