OCTOBER 7-10, 2025 | ALEXANDRIA, VA & VIRTUAL

HILTON ALEXANDRIA OLD TOWN | ALEXANDRIA VA

REGISTER EARLY AND **SAVE!**

17th Annual

Immunogenicity & Bioassay Summit

Elevating Clinical Products with Advanced Technologies and Strategies

Hear from top **industry, academia and the FDA** at 3 Conference Programs, Symposium, Training Seminar and Short Courses.

STREAMS	OCTOBER 7	OCTOBER 8 - 9	OCTOBER 9 - 10
IMMUNOGENICITY	Symposium: **Immunology for Biotherapeutics**	**Immunogenicity Assessment & Clinical Relevance**	**Immunogenicity Prediction & Control**
BIOASSAYS	DOWNLOAD THE **Conference At-A-Glance**	Training Seminar: **Biostatistics for Beginners**	**Optimizing Bioassays for Biologics**

FDA SPEAKERS

Yow-Ming Wang, PhD
CDER, FDA

Sophie Shubow, PhD
CDER, FDA

Ronit Mazor, PhD
CBER, FDA

Anurag Sharma, PhD
CBER, FDA

KEYNOTE & FEATURED SPEAKERS

Vibha Jawa, PhD
Epivax Inc

Alessandro Sette, PhD
La Jolla Institute for Allergy & Immunology

Amy Rosenberg, MD
Regeneron Pharmaceuticals, Inc.

Piyush Vyas, PhD
Eli Lilly and Company

Linlin Luo, PhD
Merck

Steven Walfish
Iovance Biotherapeutics

Organized by Cambridge Healthtech Institute

#ImmunoBio | ImmunogenicitySummit.com

Join us at the #1
Immunogenicity & Bioassay Event in the U.S.

RESOLVE the CHALLENGES of immunogenicity testing and risk assessment during preclinical and clinical development, bioassay design & analysis, and how to manipulate the immune system for therapeutic advantage by attending CHI's 17th Annual Immunogenicity & Bioassay Summit on October 7-10, 2025, at The Hilton Alexandria Old Town in Alexandria, VA. We'll examine challenges facing the industry with NEW case studies, NEW perspectives and NEW approaches. Hear from industry, academia and regulatory authorities at 3 Conference Programs, Symposium, Training Seminar and Short Courses. Once again, we'll host interactive breakouts on various niche topics so delegates can share experiences and generate new ideas. Plus, attend a vibrant exhibit/poster hall with innovative products & services. We hope to greet you this fall in Alexandria, VA.

Conference At-a-Glance*

Tuesday, October7	Wednesday, October 8	Thursday, October 9	Friday, October 10
10:00 AM - 4:30 PM Symposium: **Immunology for Biotherapeutics**	**8:30 AM - 5:30 PM Immunogenicity Assessment & Clinical Relevance**	**8:00 AM - 12:00 PM Immunogenicity Assessment & Clinical Relevance**	**8:30 AM - 4:30 PM Immunogenicity Prediction & Control**
9:00 AM - 12:00 PM Short Course 1: **Development of NAb Assays, Technical Considerations, Case Studies**	**8:30 AM - 5:30 PM** Training Seminar: **Biostatistics for Beginners**	**8:00 AM - 12:00 PM** Training Seminar: **Biostatistics for Beginners**	**8:30 AM - 4:30 PM Optimizing Bioassays for Biologics**
2:00 PM - 5:00 PM Short Course 2: **Overcoming Drug Target Interference in ADA and NAb Assays**		**1:00 PM - 5:30 PM Immunogenicity Prediction & Control**	
5:30 PM - 8:30 PM Short Course 3: **Validation of ADA Assays and Cut Point Calculations**		**1:00 PM - 5:30 PM Optimizing Bioassays for Biologics**	
5:30 PM - 8:30 PM Short Course 4: **Unlocking Immunity: Mastering Epitope Analysis and Prediction with IEDB and CEDAR Tools & Insights**		**6:00 PM - 9:00 PM** Short Course 5: **Insights on Developing an Integrated Summary of Immunogenicity**	

**Short Courses and Training Seminars are In-Person Only. See Registration Page for packages and pricing details.*

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About the
Immunogenicity Summit

The Immunogenicity & Bioassay Summit brings together experts from industry, academia, and regulatory authorities to address the challenges of immunogenicity testing and risk assessment during preclinical and clinical development. The summit focuses on bioassay design and analysis, as well as strategies to manipulate the immune system for therapeutic advantage. With its comprehensive agenda, high-level speakers, and cutting-edge content, the Immunogenicity & Bioassay Summit continues to be the go-to event for anyone working in the field of immunogenicity, bioassays, and biotherapeutics.

What Makes Us the #1 Immunogenicity Event in the U.S.?

Unparalleled speaker lineup featuring top scientists from leading biopharma companies, and renowned academic researchers.

- **Expert-Led Insights:** Gain cutting-edge knowledge from top industry experts, leading researchers, and regulatory authorities, addressing the biggest challenges in the field.
- **Regulatory Perspectives:** Get first-hand insights into evolving expectations from agencies like the FDA, helping you stay compliant and proactive.

A unique mix of deep-dive sessions, panels, training seminar, and networking events.

- **Innovative Solutions & Case Studies:** Learn from real-world case studies and emerging technologies that improve immunogenicity assessment and bioassay development.
- **Hands-On Learning:** Participate in specialized training seminar, short courses, and interactive breakout discussions designed to deepen your technical expertise.

High-quality engagement laser-focused on immunogenicity, ensuring in-depth and meaningful discussions with the right audience.

- **Networking & Collaboration:** Connect with global immunogenicity professionals, industry leaders, and regulatory experts to exchange ideas and foster new collaborations.
- **Exclusive Poster & Exhibit Hall:** Discover innovative products, technologies, and solutions showcased by leading companies in the immunogenicity and bioassay space.

With over 16 years of history, this is the most trusted and comprehensive event focused on immunogenicity.

- **Real-World Impact:** Showcases breakthrough research and new methodologies that directly impact the development of safe and effective biologics.
- **On-Demand Access:** Gain access to recorded sessions post-event, allowing you to revisit valuable insights at your convenience.

Register early and SAVE

Sponsorship & Exhibitor Opportunities

CHI offers comprehensive packages that can be customized to your budget and objectives. Sponsorship allows you to achieve your goals before, during, and long after the event. Packages may include presentations, exhibit space, and branding, as well as the use of delegate lists. Signing on early will maximize your exposure to qualified decision-makers and drive traffic to your website in the coming months.

Podium Presentations — Available within Main Agenda!

Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific program, breakfast, lunch, or a pre-conference workshop. Package includes exhibit space, onsite branding, and access to cooperative marketing efforts by CHI. Lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly! Sign on early to secure your talk.

Invitation-Only VIP Dinner/Hospitality Suite

Select specific delegates from the pre-registration list to attend a private function at an upscale restaurant or a reception at the hotel. From extending the invitations, to venue suggestions, CHI will deliver your prospects and help you make the most of this invaluable opportunity.

Focus Group

CHI will gladly provide you the opportunity of running a focus group. This exclusive gathering can be useful to conduct market research, collect feedback on a new product idea, and collect marketing intelligence from industry experts on a specific topic.

User Group Meeting/Custom Event

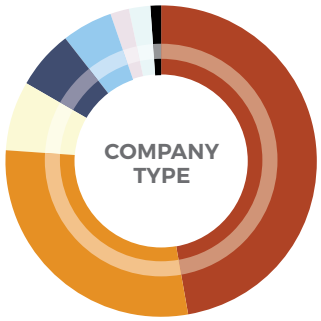
Co-locate your user group meeting or custom event. CHI will help market the event, manage logistical operations, develop the agenda, and more. CHI can handle the entirety of the meeting or select aspects.

Exhibit

Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve yours today! Additional branding and promotional opportunities are available, including:

- Conference Tote Bags
- Literature Distribution (Tote Bag Insert or Chair Drop)
- Badge Lanyards
- Conference Materials Advertisement
- Padfolios and More...

2024 ATTENDEE DEMOGRAPHICS



Biotech	46%
Pharma	28%
CRO	7%
Government	6%
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Academic	2%
Services	2%
Other	1%

USA	74%
Europe	12%
Asia	4%
Rest of World	1%

US BREAKDOWN

East Coast	74%
West Coast	12%
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For more information regarding exhibit and sponsorship, please contact:

Aimee Croke
Sr. Business Development Manager
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FDA Speakers

Sophie Shubow, PhD, Senior Biologist, **CDER, FDA**

Yow-Ming Wang, PhD, Associate Director for Biosimilars and Therapeutic Biologics, **CDER, FDA**

Ronit Mazor, PhD, Principal Investigator, **CBER, FDA**

Anurag Sharma, PhD, Gene Therapy Reviewer, **CBER, FDA**

Additional Distinguished Faculty

Jan Amstrup, PhD, Principal Scientist, **Novo Nordisk AS**

Kavitha Akula, PhD, Principal Scientist, **Bristol Myers Squibb Co.**

Javier Aguilera, PhD, Senior Scientist, Bioanalytical & Molecular Assays, **Moderna**

Nina Blazeska, Senior Project Manager, IEDB and CEDAR Resources, **La Jolla Institute for Immunology**

Priya Chockalingam, PhD, Vice President, Head of Clinical BioAnalytics & Translational Sciences, **Beam Therapeutics**

Rakesh Dixit, PhD, DABT, CEO & President, Bionavigen Oncology, LLC and CSO, TMAB Therapeutics, **Regio Biosciences**

Daron Forman, PhD, Senior Principal Scientist, Discovery Biotherapeutics, **Bristol Myers Squibb**

Christine Grimaldi, PhD, Director, Assay Development Group, **Regeneron**

Lora Hamuro, PhD, Senior Director, Clinical Pharmacology & Pharmacometrics, **Bristol Myers Squibb**

Robert Hamilton, PhD, Professor, Medicine & Pathology, Clinical Immunology & Allergy, **Johns Hopkins University**

Jin-Hee Han, PhD, Associate Principal Scientist, **Merck**

Timothy Hickling, PhD, Investigative and Immunosafety Chapter, **Roche**

Zicheng Hu, PhD, Principal Scientist, **Genentech**

Vibha Jawa, PhD, Executive Director, Nonclinical Disposition and Bioanalysis, **Bristol Myers Squibb**

Lynn Kamen, PhD, Scientific Officer, Executive Director, **BioAgilytix**

Zeynep Kosaloglu-Yalcin, PhD, Instructor, **La Jolla Institute for Immunology**

Natalia Kozhemyakina, PhD, Head, Bioassay Department, **JSC Biocad**

Daniel Leventhal, PhD, Head, Immunogenicity, **Xaira Therapeutics**

Linlin Luo, PhD, Senior Director, Regulated Bioanalytics, **Merck**

Chuyin Ma, PhD, Senior Scientist, Pharmacokinetics, Dynamics, Metabolism & Bioanalytics, **Merck**

Jim McNally, PhD, CSO, **Sword Bio**

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

Ashley Moore, PhD, Research Scientist II, Discovery Biology, **Alexion**

Paul Moore, PhD, CSO, **Zymeworks**

Kannan Natarajan, PhD, Staff Scientist, NIAID, **NIH**

Uchechukwu Okorji-Obike, PhD, Scientist, Bioassay, Biosafety and Impurities (BB&I), **AstraZeneca**

Krupa Ramani, Manager, **Johnson & Johnson**

Mohsen Rajabi Abhari, PhD, Director, Scientific Governance PK Sciences Drug Disposition, **Novartis**

Susan Richards, PhD, FAAPS, Immunogenicity Consultant, **Biopharma Immunogenicity Consulting LLC**

Amy Rosenberg, MD, Senior Director, Immunology and Protein Therapeutic, **Epivax, Inc.**

Laura Salazar-Fontana, PhD, Co-Founder, Immunogenicity Integrated and Founder, **LAIZ Regulatory Science Consulting SARL**

Nancy Sajjadi, Founder and Principal Consultant, **Sajjadi Consulting**

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

Alessandro Sette, PhD, Professor, Co-Director, Center for Vaccine Innovation, **La Jolla Institute for Allergy & Immunology**

Robert Siegel, PhD, Vice President, Laboratory for Experimental Medicine, **Eli Lilly and Company**

Han-Yu Shih, PhD, Investigator, NeuroImmune Regulome, NEI, **NIH**

Matthew Stephenson, PhD, Director of Statistics, **Quantics Biostatistics**

Gregory Steeno, PhD, Senior Director, Research Statistics, **Pfizer**

Melissa Taylor, PhD, Associate Director, Immunogenicity and LBA, **Moderna**

Jiangbo Tang, PhD, Principal Scientist, **Bristol Myers Squibb Co.**

Laura Santambrogio, PhD, Professor, Associate Director, Precision Immunology, **Weill Cornell Medicine**

Sophie Tourdot, PhD, Immunogenicity Sciences Lead, BioMedicine Design, **Pfizer**

Scott Umlauf, PhD, Senior Director, Bioassay and Impurities, **AstraZeneca**

Jenny Valentine, PhD, Senior Principal Scientist, Bioanalytical Sciences, **Regeneron**

Piyush Vyas, PhD, Director, Bioassay & Protein Therapeutics, **Eli Lilly & Co.**

Steven Walfish, Principal CMC Statistician, **Iovance Biotherapeutics**

Khaled Yamout, Analytical Sciences, Quality and Manufacturing Consultant, **Y-Chem Consulting LLC**

Zhaojun Yin, Principal Scientist, BioAnalytical Sciences gRED Development Sciences, **Genentech**

Weifeng Xu, PhD, Director, Bioanalytical, **Merck**

Xiaobin Zhang, PhD, Associate Director, **Takeda Pharmaceuticals**

Short Courses*

IN-PERSON ONLY

*Separate registration required, see registration page for details

TUESDAY, OCTOBER 7 9:00 AM-12:00 PM

SC1: Development of NAb Assays, Technical Considerations, and Case Studies

Instructors:

Lynn Kamen, PhD, Scientific Officer, Executive Director, BioAgilytix

Jim McNally, PhD, CSO, Sword Bio

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 choose 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.

TUESDAY, OCTOBER 7 2:00-5:00 PM

SC2: Overcoming Drug and Target Interference in ADA and NAb Assays

Instructors:

Lynn Kamen, PhD, Scientific Officer, Executive Director, BioAgilytix

Weifeng Xu, PhD, Director, Bioanalytical, Merck

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.

TUESDAY, OCTOBER 7 5:30-8:30 PM

SC3: Validation of ADA Assays and Cut-Point Calculations

Instructors:

Kavitha Akula, PhD, Principal Scientist, Bristol Myers Squibb Co.

Krupa Ramani, Manager, Johnson & Johnson

Jiangbo Tang, PhD, Principal Scientist, Bristol Myers Squibb Co.

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.

SC4: Unlocking Immunity: Mastering Epitope Analysis and Prediction with IEDB and CEDAR Tools & Insights - NEW FOR 2025!

Instructors:

Nina Blazeska, Senior Project Manager, IEDB and CEDAR Resources, La Jolla Institute for Immunology

Zeynep Kosaloglu-Yalcin, PhD, Instructor, La Jolla Institute for Immunology

This short course offers an in-depth introduction to the Immune Epitope Database and Analysis Resource (IEDB) and Cancer Epitope Database and Analysis Resource (CEDAR), designed to help scientists harness their full potential for immunological research. Participants will receive two focused presentations—one on navigating the IEDB (https://iedb.org/) and CEDAR (cedar.iedb.org) databases and another on using powerful prediction and analysis tools, including both the classic Analysis Resource (http://tools.iedb.org/main/) and the cutting-edge Next-Generation Tools (https://nextgen-tools.iedb.org/). The course will feature live demonstrations to guide attendees through real-world applications of these resources, empowering them to integrate epitope data and predictive modeling into their own research workflows.

THURSDAY, OCTOBER 9 6:00-9:00 PM

SC5: Insights on Developing an Integrated Summary of Immunogenicity - NEW FOR 2025!

Instructor:

Susan Richards, PhD, FAAPS, Immunogenicity Consultant, Biopharma Immunogenicity Consulting LLC

The purpose of this workshop is to share experience gained in preparing and reviewing the "Integrated Summary of Immunogenicity (ISI)" for submission in regulatory filings. We will overview examples of 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. We will also examine the sponsor team's role, the general format of an ISI, and provide examples of how to anticipate and address potential issues (and how to avoid introducing any new ones!) by generating a well-thought-out and constructed integrated summary.

> **"I liked the size of the event - it was large enough to engage in lively discussion and attend good quality presentations while small enough to stay focused and network with other attendees."**
>
> - JIM ZANGHI, GENENTECH

OCTOBER 7, 2025

Cambridge Healthtech Institute's 17th Annual

Immunology for Biotherapeutics

Understanding and Manipulating the Immune System for Therapeutic Advantage

TUESDAY, OCTOBER 7

8:30 am Registration & Morning Coffee

CURRENT UNDERSTANDING OF IMMUNE MECHANISMS

9:50 Chairperson's Opening Remarks

Robert Hamilton, PhD, Professor, Medicine & Pathology, Clinical Immunology & Allergy, Johns Hopkins University

Welcome to Current Understanding of Immune Mechanisms. The immune system is poised to distinguish self from foreign substances or non-self as a first line of defense. This session will examine areas of biology and medicine of the human immune system's structure, cell involvement, and function, all of which impact on states of health and disease.

10:00 Antigen Processing and Presentation by MHC-I Molecules: The Basis of T and NK Cell Activation

Kannan Natarajan, PhD, Staff Scientist, NIAID, NIH

Antigen presenting cells process proteins 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 will be discussed as well as data on strategies for human NK cell activation for immunotherapy.

10:30 Role of IgE and IgG/IgG4 in Modulating Type I Hypersensitivity Reactions in Human Allergic Disease

Robert Hamilton, PhD, Professor, Medicine & Pathology, Clinical Immunology & Allergy, Johns Hopkins University

This presentation will overview the four areas of hypersensitivity: immediate Type I IgE-mediated, Type II antibody-dependent cytotoxicity, Type III immune-complex-mediated, and delayed-Type hypersensitivity. Type I human allergic disease will then be examined, covering its pathophysiology, current diagnostic strategies, four modes of disease management, and special caveats relating to food, drug, venom, and respiratory allergic disease. Finally, the new discipline of molecular allergology will be discussed.

11:00 Networking Coffee Break

11:15 The Role of the Innate Immune System and Implications for Biotherapeutics

Han-Yu Shih, PhD, Investigator, NeuroImmune Regulome, NEI, NIH

The field of innate lymphoid cell (ILC) biology has progressed rapidly, highlighting these cells' roles in immunity, barrier tissue integrity, and homeostasis. ILCs can be classified based on cytokine production, mirroring patterns in CD4 T helper (Th) cell analogs. Unlike Th cells, ILCs respond promptly to pathogens without needing antigen-specific receptor recognition. Understanding ILC differentiation and immunoregulation is key to developing new treatments for autoimmunity, infection, and cancer.

HARNESSING THE IMMUNE SYSTEM FOR BIOTHERAPEUTICS

11:45 Harnessing the Body's Natural Immune Response to Fight Cancer

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

Immunotherapy has demonstrated impressive response rates in certain cancers that were historically challenging to treat by harnessing the body's own immune system to detect and destroy tumor cells. In this presentation, we will explore the current landscape of immunotherapy, highlighting key approaches such as cytokine therapies, cancer vaccines, adoptive cell therapies, and immunomodulation strategies.

12:15 pm Enjoy Lunch on Your Own

2:00 Chairperson's Remarks

Paul Moore, PhD, CSO, Zymeworks

2:05 Safety Considerations for Bispecifics and ADCs

Rakesh Dixit, PhD, DABT, CEO & President, Bionavigen Oncology, LLC and CSO, TMAB Therapeutics, Regio Biosciences

Bispecifics and antibody-drug conjugates (ADCs) are among the most advanced targeted therapies, offering significant potential for treating complex diseases such as cancer. Despite their high efficacy, understanding and addressing their safety profiles is crucial for improving patient outcomes and ensuring successful integration into clinical practice. The presentation will provide a high-level review with case studies of the safety concerns associated with these therapies and the strategies employed to improve them.

2:35 Pushing the Boundaries of Antibody-Based Therapeutics through Multispecifics and Drug Conjugates

Paul Moore, PhD, CSO, Zymeworks

Antibody-based therapeutics have provided great therapeutic benefit to many patients across various disease states. Multispecific antibodies afford therapeutic opportunities not feasible with single-target antibodies or combinations, while drug conjugates provide opportunity to extend therapeutic benefit through combining the targeting specificity of an antibody with a "payload." Examples of these advances will be summarized in the context of molecule design, target selection, biological characterization, and clinical benefit.

3:05 Networking Refreshment Break

3:30 Biopharmaceutical Product Immunogenicity: What Causes It and What Are the Safety and Efficacy Consequences?

Susan Richards, PhD, FAAPS, Immunogenicity Consultant, Biopharma Immunogenicity Consulting LLC

Biopharmaceuticals represent a diverse class of therapeutics, contributing significantly to advancing treatment of serious diseases, including chronic inflammatory and autoimmune diseases, genetic deficiencies, and cancer. Unfortunately, unwanted immunogenic responses against some of these products can occur. In this overview, factors that affect the degree to which the immune system responds, and the degree to which the response affects the efficacy and safety, are discussed.

4:00 The Cell-Autonomous Complement System as a Master Regulator of Homeostasis and Disease

Erin West, PhD, Associate Scientist, Complement and Inflammation Research Section, NHLBI, NIH

Our lab studies the role of cell-autonomous complement in immune and non-immune cells and its role in homeostasis and disease (infection, cancer and autoimmunity) to further our understanding of how this system can be targeted therapeutically.

4:30 Close of Symposium

5:00 Dinner Short Course Registration

Cambridge Healthtech Institute's 17th Annual

OCTOBER 8-9, 2025

Immunogenicity Assessment & Clinical Relevance

Assay Strategy for Meaningful Evaluation

WEDNESDAY, OCTOBER 8

7:45 am Registration & Morning Coffee

IMMUNOGENICITY OF PEPTIDES

8:25 Chairperson's Opening Remarks

Faye Vazvaei, Executive Director, Merck

8:30 KEYNOTE PRESENTATION: Immunogenicity Assessment Strategy for Peptides by Development Stage

Weifeng Xu, PhD, Director, Bioanalytical, Merck

Peptides, though smaller than full proteins, can provoke immune responses, potentially leading to anti-drug antibodies. Given the growing number of peptides in drug development, it's essential to establish immunogenicity evaluation strategies tailored to different development stages and clinical outcomes. A couple case studies will be presented to illustrate the diverse immunogenicity strategies implemented for different peptides.

9:00 Challenges and Perspectives on the Role of Impurities in the Immunogenicity Risk of Therapeutic Peptides

Montserrat Puig, PhD, Senior Principal Scientist, Merck

Despite significant advances in the analytical characterization of complex peptide drug products, gaps still exist in our understanding of the impact of impurities on a product immunogenicity risk. Currently available regulatory guidance does not put forward impurity qualification thresholds informed by immunogenicity risk and recommends qualification methods that present methodological challenges. This talk will provide an overview of these challenges and propose strategies to handle them.

9:30 Evaluating and Mitigating the Immunogenicity Risks of Peptide Products During Their Life Cycle

Laura Salazar-Fontana, PhD, Co-Founder, Immunogenicity Integrated and Founder, LAIZ Regulatory Science Consulting SARL

Peptide products, like therapeutic proteins, carry the risk of triggering immune responses that can modify relevant clinical outcomes. Their immunogenicity evaluation is intimately dependent on whether the peptide in question is developed as a new molecular entity or as a generic version of an approved drug. This presentation will discuss the preparation of a suitable immunogenicity assessment founded on prediction studies and clinical immunogenicity data from approved peptide drug products.

10:00 Networking Coffee Break

10:30 Bridging the Gaps Regarding Product-Related Factors with Risk to Impact Therapeutic Peptide Immunogenicity

Robert Siegel, PhD, Vice President, Laboratory for Experimental Medicine, Eli Lilly and Company

There is limited regulatory guidance on acceptable levels of API-related impurities in drug substances during clinical testing. A phase-appropriate, risk-based approach to evaluate the immunogenicity potential of impurities from an adaptive immune system perspective is presented. This approach frames the risk of the impurity in the context of the immunogenicity potential of API, dose level, and advocates for a shift from relative percentage to mass basis for impurity threshold considerations.

11:00 Integrated Summary of Immunogenicity (ISI) for Therapeutic Peptides

Mohsen Rajabi Abhari, PhD, Director, Scientific Governance PK Sciences Drug Disposition, Novartis

Health authorities recommend sponsors to consolidate immunogenicity results in an Integrated Summary of Immunogenicity (ISI) to facilitate the review. This presentation will discuss the costs and benefits of developing ISI from an industry perspective.

11:23 Immunogenicity Risk Assessment for Mitigation and Monitoring of Therapeutic Peptides During Development

Joanna Grudzinska-Goebel, PhD, Sr Project Lead & Immunogenicity Expert, DMPK, Bayer AG

Therapeutic peptides can elicit unwanted immune responses, potentially leading to safety implications and reduced patient benefits. The Immunogenicity Risk Assessment (IRA) identifies immunogenicity (IG) risk factors and establishes tailored mitigation and bioanalytical monitoring strategies. This presentation highlights the IRA's role in therapeutic peptide development and its integration into the ISI for marketing applications.

11:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:15 pm Session Break

ADVANCES WITH CELL AND GENE THERAPIES

1:15 Chairperson's Remarks

Amy Rosenberg, MD, Senior Director, Regulatory Affairs, Regeneron Pharmaceuticals, Inc.

1:20 The FDA Perspective on the Immunogenicity of Gene Therapy Products

Anurag Sharma, PhD, Chief, Gene Therapy Branch, CBER, FDA

Immunological responses to gene therapies continue to challenge the field, despite remarkable therapeutic advances. These immune reactions threaten safety profiles, therapeutic efficacy, and sustained clinical benefits. Effective immunogenicity management remains crucial for realizing the full clinical potential of gene-based treatments. This talk will present the FDA's perspective on immunogenicity considerations in gene therapy development and approval processes.

1:50 FEATURED PRESENTATION: CAR T Approaches to Treatment of Autoimmunity and Prevention of ADA to Biological Therapeutics

Amy Rosenberg, MD, Senior Director, Regulatory Affairs, Regeneron Pharmaceuticals, Inc.

This presentation will focus on non-engineered as well as engineered Treg cellular therapies for treatment of autoimmune disease, a theoretical exploration of prevention of allergy, and induction of tolerance to novel protein and gene therapies.

2:20 Interactive Discussions

These in-person group discussions are open to all attendees, speakers, sponsors, and exhibitors. Participants choose a specific discussion group to join. Each group has a moderator to ensure focused discussions around key issues within the topic. This format allows participants to meet potential collaborators, share examples from their work, vet ideas with peers, and be part of a group problem-solving endeavor. The discussions provide an informal exchange of ideas and are not meant to be a corporate or specific product discussion. All group discussions will be offered **IN-PERSON ONLY**. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY DISCUSSION: Strategies for Peptide Immunogenicity Assessment

Mohsen Rajabi Abhari, PhD, Director, Scientific Governance PK Sciences Drug Disposition, Novartis

Faye Vazvaei, Executive Director, Merck

IN-PERSON ONLY BREAKOUT: Designing ADA Assays for Detection of

OCTOBER 8-9, 2025

Cambridge Healthtech Institute's 17th Annual

Immunogenicity Assessment & Clinical Relevance

Assay Strategy for Meaningful Evaluation

Clinically Relevant Responses
Lauren Stevenson, PhD, CSO & Head, Translational Sciences, Immunologix Labs

IN-PERSON ONLY BREAKOUT: Clinical Context of 100 ng/mL ADA: Do We Always Need Highly Sensitive Immunogenicity Assays?
Kamalika Mukherjee, PhD, Principal Scientist, Bioanalytical Strategy, Regeneron Pharmaceuticals Inc

3:10 **Grand Opening Refreshment Break in the Exhibit Hall with Poster Viewing**

4:00 **The Impact of Biological Sex on AAV Immunogenicity**
Ronit Mazor, PhD, Principal Investigator, CBER, FDA
The success of AAV gene therapy has been hindered by pre-existing and post treatment immune response against the AAV. Our studies show that females exhibit substantially higher preexisting antibody titers and neutralizing activities against multiple AAV serotypes compared to males. Beyond humoral immunity, we identified specific patterns in innate immune activation following AAV exposure in human peripheral blood mononuclear cells, where females demonstrate enhanced and accelerated cytokines production.

IMPLEMENTATION OF AI AND DEEP LEARNING

4:30 **Overcoming Pre-Existing Antibodies and Implementing AI**
Melissa Taylor, PhD, Associate Director, Immunogenicity and LBA, Moderna
Using development of an anti-LNP assay to illustrate the concepts, strategies to address pre-existing antibodies will be discussed. While some strategies will be experimental, others will include different ways of approaching the analysis, including use of AI.

ASSAY DEVELOPMENT AND VALIDATION

5:00 **A Strategic Approach to Cell-Based Neutralizing Antibody Assays for Bispecific Peptide**
Kelly Ngoc Pham, PhD, Associate Principal Scientist, Merck
Innovative multiplexed cell-based assays were designed to detect neutralizing antibodies (NAbs) against efinopegdutide, a dual GLP-1R/GCGR agonist peptide drug. Multiple assay formats were rigorously evaluated to develop assays that detect NAbs against the drug and its endogenous peptides, which carry the highest immunogenicity risk. Our multiplexing approach significantly reduces resource use, accelerates validation, and we established two cut points to effectively address matrix interference.

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

6:30 **Close of Day**

THURSDAY, OCTOBER 9

7:30 am **Registration & Morning Coffee**

CLINICAL RELEVANCE OF ADA

8:00 **Chairperson's Remarks**
Jenny Valentine, PhD, Senior Principal Scientist, Bioanalytical Sciences, Regeneron

8:05 KEYNOTE PRESENTATION: **Clinical Pharmacology Evaluations of Immunogenicity Impact: Ongoing Efforts to Facilitate Harmonization**
Yow-Ming Wang, PhD, Associate Director for Biosimilars and Therapeutic Biologics, CDER, FDA
Clinical pharmacology data have emerged as a sensitive measure for evaluating potential impact on efficacy measures. Heterogeneity observed in regulatory submissions indicates the need for continued harmonization efforts to increase the consistency in evaluating immunogenicity information and assessing clinical impact. This presentation will share ongoing efforts in the Office of Clinical Pharmacology at the FDA aiming to facilitate harmonization from data submission to data analysis and data reporting.

8:35 **ADA Responses to Multidomain Proteins are Primarily against T Cell Binding Domains**
Jenny Valentine, PhD, Senior Principal Scientist, Bioanalytical Sciences, Regeneron
A survey of domain specificity for ADA responses to numerous T cell engaging bispecific antibodies was conducted. Data showed ADA were specific for either both domains or only the T cell binding domain, indicating that immune cell-binding arm is more likely to elicit a response. The domain mapping showed that ADA responses can evolve.

9:05 **'Tiering' down the paradigm: Single-tiered immunogenicity assay validation and implementation**
Lauren Stevenson, CSO & Head of Translational Sciences, Translational Sciences, Immunologix Labs
Rethinking the immunogenicity paradigm is a hot topic with S/N gaining traction as an alternative to titers and means to fully describe subject response profiles in a single tier. Greater depth of understanding, time and cost savings are recognized as advantageous, but questions remain regarding how to validate such assays. This presentation proposes assay validation approaches to support implementation of single-tiered testing that provides greater clarity for clinical interpretation.

9:35 **Coffee Break in the Exhibit Hall with Poster Viewing**

10:20 **Investigation of Clinically Relevant Consequences of Anti-Insulin Icodec Antibodies by *in vitro* Testing of Neutralizing Effect as Well as Correlation of Antibody Titres with Efficacy and Safety Parameters**
Henrik Toft-Hansen, PhD, Principal Scientist, Novo Nordisk
Insulin icodec is a new weekly basal insulin. A neutralizing antibody (NAb) assay assessed samples in insulin-naïve Type 2 diabetes patients. Of 270 anti-drug antibody (ADA) positive subjects, 13% tested NAb positive. Higher ADA titers correlated with NAb detection. ADA presence or NAb status did not impact the efficacy or safety of insulin icodec. *In vitro* NAb testing added limited value to correlation of titer with clinical parameters.

ASSAY DEVELOPMENT AND VALIDATION

10:50 **Immunogenicity Strategy for a Multidomain Masked Cytokine Therapeutic**
Joshua Zylstra, PhD, Associate Director, Assay Development, Regeneron Pharmaceuticals
This presentation will discuss the immunogenicity strategy for a multidomain biotherapeutic that includes a masked cytokine moiety. It will focus on our experiences with developing preclinical and clinical assays, highlighting the challenges encountered during assay development and explaining how a fit-for-purpose assay was implemented to support first-in-human studies.

11:20 **Development and Validation of a Titer-Only Assay for Quasi-Quantitative Detection of Anti-Protein Antibodies in Human Sera**
Javier Aguilera, PhD, Senior Scientist, Bioanalytical & Molecular Assays, Moderna
mRNA-based therapies provide promising platforms for protein replacement in rare diseases involving dysfunctional intracellular proteins. We developed and validated a *de novo* anti-protein antibody (APA) assay using a titer-only approach due to limited reference protein availability. This assay achieved high sensitivity (50ng/mL) and precision within ±2 dilutions of median titer. We discuss when a titer-only format is more practical than the standard 3-tier design, and cross-reactivity in orphan diseases.

11:50 **Close of Immunogenicity Assessment & Clinical Relevance Conference**

OCTOBER 9-10, 2025

Cambridge Healthtech Institute's 17th Annual

Immunogenicity Prediction & Control

Regulatory Perspectives, Risk Factors, and Management

THURSDAY, OCTOBER 9

12:00 pm Registration Open

RISK ASSESSMENT AND MITIGATION

1:15 Chairperson's Opening Remarks

Sophie Tourdot, PhD, Immunogenicity Sciences Lead, BioMedicine Design, Pfizer

1:20 KEYNOTE PRESENTATION: Risk to Readiness: Integrating Risk Assessment Outputs to Inform IND Bioanalytical Strategies

Vibha Jawa, PhD, Chief Scientific Officer, Epivax Inc

This talk explores how integrated risk assessments—encompassing sequence-based intrinsic risks such as neoepitope formation from engineered domains, and extrinsic risks arising from post-translational modifications, process-related attributes, and formulation changes—inform the development of bioanalytical and clinical strategies for complex biologics. We will also discuss product and patient-specific risk factors and how these multifaceted insights are articulated in IND submissions to support immunogenicity risk management, assay design, and clinical monitoring plans.

1:50 Immunogenicity Risk Assessment as a Guide for Clinical Immunogenicity Testing Approaches

Christine Grimaldi, PhD, Director, Assay Development Group, Regeneron

Since the finalization of the 2019 FDA Guidance on immunogenicity testing, many companies have adopted the practice of conducting an immunogenicity risk assessment (IRA) to assess the potential for unwanted immunogenicity. This presentation will discuss the evolution of the IRA and case studies that highlight how it can support a sound assay development and sample analysis strategy for molecules with varying degrees of risk.

2:20 Impurities and Host Cell Protein Contaminants and Immunogenicity Risk

Timothy Hickling, PhD, former Immunogenicity Expert Scientist, Investigative & Immunosafety Chapter, Roche

Unwanted immune responses to biologics occur due to factors from patients, products, and treatments. The purity of the product is important for understanding immunogenicity risks, with impurities and contaminants, such as host cell proteins, contributing to the overall risk profile. Uncertainty over acceptable product quality attributes can add time to development cycles and add risk to clinical trials. The presentation will discuss identifying and mitigating these risks.

2:50 Designing Safer Biotherapeutics: Evaluating Adaptive and Innate Immune Risk PROIMMUNE www.proimmune.com

Andrew Isidoridy PhD, Immunology Sales Specialist, ProImmune Inc

Preclinical immunogenicity risk assessment is a crucial consideration in the development of biotherapeutics. Learn about best practices in this field from real-world case studies applying MAPPs, T cell proliferation, MHC-peptide binding and cytokine release assays. Additionally, the field of protein binding reagents will be explored, with a focus on the limitations of antibodies as a research reagent. Furthermore, success of Ankyrons, a next-generation, monoclonal target binding reagent in a diverse range of applications will be highlighted.

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

4:00 Assessing Immunogenicity Risks of Biotherapeutics with Dendritic-Cell-Based Assays

Zhaojun Yin, Principal Scientist, BioAnalytical Sciences gRED Development Sciences, Genentech

The emergence of anti-drug antibodies can significantly impact drug safety and efficacy. Dendritic cells (DCs) play a vital role in priming CD4 T cells, which are essential for robust antibody production. Characterizing DC activities serves as a valuable tool to inform the immunogenicity risk associated with biotherapeutics. I will discuss our recent advancements and experiences in employing DC-based assays for immunogenicity risk assessment in the early drug discovery and development.

4:30 Unlocking the Immunogenicity Toolbox: Comprehensive Risk Analysis for ADC Programs

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

Assessing immunogenicity risk for antibody-drug conjugates (ADCs) presents unique challenges due to the impact of the drug conjugate on T cell proliferation. This presentation highlights an integrated approach combining *in silico* algorithms, *in vitro* MAPPs, and DC-PBMC proliferation assays to evaluate the immunogenicity risk of ADC therapeutics, illustrated through an ADC case study.

RISK ASSESSMENT AND MITIGATION

5:00 Synergized Efforts to Improve Risk Assessment and Mitigation by Design of Biologics

Sophie Tourdot, PhD, Immunogenicity Sciences Lead, BioMedicine Design, Pfizer

Effective mitigation of the immunogenicity of biologics necessitates a comprehensive understanding of its underlying mechanisms and multiple risk factors, enabling the identification of potential intervention points. Numerous academic and industrial organizations, along with US- and Europe-based scientific societies, have formed collaborations to address these issues. This presentation will provide an overview of ongoing and emerging initiatives within various frameworks.

5:40 Dinner Short Course Registration

5:40 Close of Day

6:00 Recommended Dinner Short Course*

SC5: Insights on Developing an Integrated Summary of Immunogenicity

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

FRIDAY, OCTOBER 10

8:00 am Registration & Morning Coffee

8:25 Chairperson's Remarks

Laura Santambrogio, PhD, Professor, Associate Director, Precision Immunology, Weill Cornell Medicine

8:30 FEATURED PRESENTATION: Protein Regions That are Immunogenic and Conserved within Viral Families of Potential Pandemic Concern

Alessandro Sette, PhD, Professor, Co-Director, Center for Vaccine Innovation, La Jolla Institute for Immunology

We developed a general pipeline for identification of Conserved T cell Epitope Regions from viral families of potential pandemic concern. For each viral family we select a prototype virus and determine the sequence conservation across different viral species and variants. In parallel, actual or predicted immunogenicity is established. The cross-reactivity of regions that are conserved and immunogenic can be tested with homologous peptides from representative viral species of interest.

9:00 The growing importance of human *in vitro* systems in preclinical development and how they can be used to support regulatory filings. Lonza

Noel Smith, Director, Head of Immunology, Lonza

Immunogenicity poses a critical risk to all biologics - including monoclonal antibodies, ADCs, recombinant proteins, cell & gene therapies, and mRNA-based therapies. The consequences of immunogenicity can not only endanger patients, but also reduce the effectiveness of the treatment. Recent changes to the regulatory landscape have meant that there is a much heavier reliance on human *in vitro* systems to support regulatory filings.

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Immunologenicity Prediction & Control

Regulatory Perspectives, Risk Factors, and Management

The complexity of the human immune system means that several arms of the immune response need to be assessed with the molecule format and mode of action particularly important to consider when deciding how to design and execute the preclinical immunogenicity risk assessment.
This presentation will outline the *in vitro* assays that can be used to support preclinical development and include some examples of how these are applied to common drug modalities being widely developed.

9:30 Interactive Discussions

These in-person group discussions are open to all attendees, speakers, sponsors, and exhibitors. Participants choose a specific discussion group to join. Each group has a moderator to ensure focused discussions around key issues within the topic. This format allows participants to meet potential collaborators, share examples from their work, vet ideas with peers, and be part of a group problem-solving endeavor. The discussions provide an informal exchange of ideas and are not meant to be a corporate or specific product discussion. All group discussions will be offered **IN-PERSON ONLY**. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

IN-PERSON ONLY DISCUSSION: AI and Machine Learning to Predict Protein Immunogenicity

Yuri Iozzo, PhD, Head of Digital Biology, Biologics Drug Discovery, ModeX Therapeutics

IN-PERSON ONLY BREAKOUT: *In Vitro* Immunogenicity Assays: Time for Standardization and Benchmarking

Sofie Pattyn, Founder & CTO, IQVIA Laboratories

10:20 Coffee Break in the Exhibit Hall & Last Chance for Poster Viewing

TRANSLATION INTO THE CLINIC

11:00 The Landscape of the MHC Immunopeptidome

Laura Santambrogio, PhD, Professor, Associate Director, Precision Immunology, Weill Cornell Medicine

Preclinical and clinical data demonstrate that novel antigenic determinants efficiently recognized by mature T cells can emerge from a variety of non-mutational mechanisms, encompassing epitope mimicry, upregulation of cryptic epitopes, the usage of non-canonical initiation codons, alternative RNA splicing, and enzymatic and non-enzymatic post-translational protein modifications. Here, I will discuss the mechanisms underlying the formation of non-mutational neoantigens, as well as their implications in increasing MHC-restricted immunogenicity.

11:30 Evaluating the Translatability of Immunogenicity Data from Cynomolgus Monkey Studies to Human Trials

Zicheng Hu, PhD, Principal Scientist, Genentech

The translatability of immunogenicity data from Cynomolgus monkey models to humans has been debated. This study analyzes detailed immunogenicity data of 53 molecules and shows that Cyno monkeys provide valuable information on the incidence, magnitude, and clinical impact of ADA responses in humans. Despite species differences, Cyno immunogenicity data is crucial for immunogenicity risk assessment.

STATISTICAL METHODS AND ADVANCED MODELING TECHNIQUES

12:00 pm Immunogenicity T Cell Assay Fit-for-Purpose Validation: Application of a Statistical Path to Enhance Confidence in Decision-Making Data

Gregory Steeno, PhD, Senior Director, Research Statistics, Pfizer

Drug immunogenicity mitigation by design consists of minimizing product-related risks, including CD4 T cell epitope sequence content. *In silico* and *in vitro* tools can guide removal of such liabilities, though data interpretation can be challenging because of the lack of assay standardization across laboratories. The presentation will describe the statistical methods used for a T cell assay qualification, aimed at enhancing confidence in producing high-quality decision-making data and robust inferences.

12:30 Advanced Modeling Techniques for Evaluating Immunogenicity Impact for Combined Biotherapeutics

Lora Hamuro, PhD, Senior Director, Clinical Pharmacology & Pharmacometrics, Bristol Myers Squibb

This seminar explores the use of statistical and mechanistic QSP models to evaluate immunogenicity for a nivolumab-ipilimumab combination therapy in melanoma. By analyzing clinical study data, these models reveal increased ADA occurrence with combination therapy but minimal effects on efficacy and safety. The findings enhance our understanding of the immunogenicity mechanism, provide critical guidance for optimizing dosing strategies and support clinical trial design.

1:00 Networking Luncheon

1:30 Session Break

IMMUNE TOLERANCE

2:25 Chairperson's Remarks

Daniel Leventhal, PhD, Principal Consultant, Tactyl

2:30 Translation of a Nanoparticle Delivery System for the Induction of Therapeutic Tolerance

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

The cellular and molecular mechanisms underlying the induction of immune tolerance using the intravenous infusion of biodegradable antigen-encapsulation PLGA nanoparticles and their similarity to natural tolerance induced by uptake of apoptotic debris will be discussed. In addition, the results of initial human Phase 1a/2 clinical translational studies in treatment of celiac disease and primary biliary cholangitis will be reviewed.

AI AND ML IN PRACTICE

3:00 Quantifying Intuition: What Can Human and Machine Learning Tell Us About Immunogenicity Risk?

Daniel Leventhal, PhD, Principal Consultant, Tactyl

Immunogenicity risk assessment is a complex challenge requiring robust clinical data and predictive tools. The Immunogenicity Database Collaborative (IDC) addresses this need by curating a standardized dataset linking clinical immunogenicity outcomes to key risk factors. We present IDC V1 and demonstrate its utility in evaluating preclinical risk assessments, including *in vitro* assays and machine learning-based predictors. This effort supports improved benchmarking, risk modeling, and community collaboration across the biotherapeutics industry.

3:30 Critical Assessment of Computational Tools for Immunogenicity Prediction

Kunal Kundu, PhD, Principal Scientist, Bioinformatics, Regeneron

Immunogenicity of biotherapeutics arises from both drug- and patient-related factors, with CD4+ T cell/B cell epitopes playing a pivotal role. Numerous computational tools have been developed to predict these epitopes. I will discuss the performance of these tools through a blind assessment, offering critical insights into their strengths and limitations for advancing immunogenicity prediction in biotherapeutics.

4:00 PANEL DISCUSSION: Statistical Models, Immune Tolerance, AI, and ML

Moderator: Daniel Leventhal, PhD, Principal Consultant, Tactyl
Panelists:
Stephen Miller, PhD, Professor Emeritus of Microbiology-Immunology, Feinberg School of Medicine, Northwestern University
Kunal Kundu, PhD, Principal Scientist, Bioinformatics, Regeneron
Gregory Steeno, PhD, Senior Director, Research Statistics, Pfizer
Lora Hamuro, PhD, Senior Director, Clinical Pharmacology & Pharmacometrics, Bristol Myers Squibb

4:30 Close of Summit

Register early and SAVE

OCTOBER 9-10, 2025

Cambridge Healthtech Institute's 13th Annual

Optimizing Bioassays for Biologics

Successful Bioassay Development in an Era of Emerging Modalities

THURSDAY, OCTOBER 9

12:00 pm Registration Open

RECENT ADVANCES WITH NOVEL MODALITIES

1:15 Chairperson's Opening Remarks

Matthew Stephenson, PhD, Director of Statistics, Quantics Biostatistics

1:20 KEYNOTE PRESENTATION: Ligand Qualification Strategy for Abeta Peptides for Alzheimer Therapeutics

Piyush Vyas, PhD, Director, Bioassay & Protein Therapeutics, Eli Lilly & Co.

Substantial differences in the potencies of Abeta peptide batches have been demonstrated leading to bioassay failures for Alzheimer therapeutics. Analytical studies suggested that Abeta peptides do exist in different aggregated states. A robust qualification strategy was designed to qualify this critical reagent to mitigate bioassay failures.

1:50 Novel Clinical Bioassay Approaches for Genome Editing Therapies

Priya Chockalingam, PhD, Vice President, Head of Clinical BioAnalytics & Translational Sciences, Beam Therapeutics

Bioassays are key to evaluate potency and safety of genome editing therapies and ensure they accurately target and modify the genome with minimal off-target effects. We developed a clinical bioassay using exosomal RNA/protein as non-invasive pharmacodynamic biomarkers to assess treatment response and proof-of-drug mechanism. We also developed methods to assess germline editing with a sensitive assay to provide reassurance for the absence of editing in human sperms.

BIOASSAY CONTROL AND MAINTENANCE

2:20 Statistical Process Control in the Presence of Correlated Observations

Matthew Stephenson, PhD, Director of Statistics, Quantics Biostatistics

Statistical Process Control techniques are often used to monitor bioassays. These techniques typically assume that values of the monitored metric (often model parameter) are independent. However, dependence structures often exist in bioassay data (i.e., replicate observations of a metric within an assay tend to be more similar to one another than between assays). In this talk, we explore various strategies for the valid application of SPC techniques in bioassay monitoring.

2:50 Designing Safer Biotherapeutics: Evaluating Adaptive and Innate Immune Risk

PROIMMUNE www.proimmune.com

Andrew Isidoridy PhD, Immunology Sales Specialist, ProImmune Inc

Preclinical immunogenicity risk assessment is a crucial consideration in the development of biotherapeutics. Learn about best practices in this field from real-world case studies applying MAPPs, T cell proliferation, MHC-peptide binding and cytokine release assays. Additionally, the field of protein binding reagents will be explored, with a focus on the limitations of antibodies as a research reagent. Furthermore, success of Ankyrons, a next-generation, monoclonal target binding reagent in a diverse range of applications will be highlighted.

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

REFERENCE STANDARDS AND REGULATORY CONSIDERATIONS

4:00 Standards Development and Measurement Assurance Strategies for Cell Characterization Assays

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

4:30 Re-Designing a Cell-Based Assay for Potency Testing of Plasmid API after Regulatory Feedback: Challenges and Solutions

Jan Amstrup, PhD, Senior Specialist, Novo Nordisk AS

The rise of new non-protein drug modalities, like plasmids, is thrilling. However, it also brings challenges in creating appropriate bioassays and fulfilling validation standards. This case study details the creation of a cell-based assay for potency testing of a plasmid active pharmaceutical ingredient (API), highlighting the difficulties faced throughout the development and validation process.

RISK ASSESSMENT AND MITIGATION

5:00 Synergized Efforts to Improve Risk Assessment and Mitigation by Design of Biologics

Sophie Tourdot, PhD, Immunogenicity Sciences Lead, BioMedicine Design, Pfizer

Effective mitigation of the immunogenicity of biologics necessitates a comprehensive understanding of its underlying mechanisms and multiple risk factors, enabling the identification of potential intervention points. Numerous academic and industrial organizations, along with US- and Europe-based scientific societies, have formed collaborations to address these issues. This presentation will provide an overview of ongoing and emerging initiatives within various frameworks.

5:40 Dinner Short Course Registration

5:40 Close of Day

6:00 Recommended Dinner Short Course*

SC5: Insights on Developing an Integrated Summary of Immunogenicity

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

FRIDAY, OCTOBER 10

8:30 am Registration & Morning Coffee

BIOASSAY DESIGN AND POTENCY ASSAY DEVELOPMENT

8:55 Chairperson's Remarks

Natalia Kozhemyakina, PhD, Head, Bioassay Department, JSC Biocad

9:00 Analytical Control Strategy for the Stability of Human Serum Albumin Binding Domain in Biotherapeutics

Jin-Hee Han, PhD, Associate Principal Scientist, Merck

A key element of drug safety and efficacy is developing therapeutic protein with extended half-life to deliver desired therapeutic outcomes. Historically, attaching Fc region (Fc-fusion protein) to the drug molecule has been implemented for recycling drug circulation in the serum. Another approach for pharmacokinetic (PK) enhancement is connecting drug molecule to the human serum albumin (HSA). We propose to compare and contrast the analytical control strategy for the two methodologies.

9:30 Interactive Discussions

These in-person group discussions are open to all attendees, speakers, sponsors, and exhibitors. Participants choose a specific discussion group to join. Each group has a moderator to ensure focused discussions around key issues within the topic. This format allows participants to meet potential collaborators, share examples from their work, vet ideas with peers, and be part of a group problem-solving endeavor. The discussions provide an informal exchange of ideas and are not meant to be a corporate or specific product discussion. All group discussions will be offered **IN-PERSON ONLY**. Please visit the Interactive Discussions page on the conference website for a complete listing of topics and descriptions.

Cambridge Healthtech Institute's 13th Annual

OCTOBER 9-10, 2025

Optimizing Bioassays for Biologics

Successful Bioassay Development in an Era of Emerging Modalities

IN-PERSON ONLY BREAKOUT: Development and Use of Potency Assays for the Right Purpose
Jan Amstrup, PhD, Senior Specialist, Novo Nordisk AS

IN-PERSON ONLY BREAKOUT: Bioassays for Demonstrating Drug Mechanism-of-Action (MoA): Approaches and Challenges
Natalia Kozhemyakina, PhD, Head, Bioassay Department, JSC Biocad

IN-PERSON ONLY BREAKOUT: Streamlining and Revolutionizing Bioanalytical Workflows with AI, Machine Learning, and Natural Language Processing
Chuying Ma, PhD, Senior Scientist, Pharmacokinetics, Dynamics, Metabolism & Bioanalytics, Merck
Weifeng Xu, PhD, Director, Bioanalytical, Merck

10:20 **Coffee Break in the Exhibit Hall & Last Chance for Poster Viewing**

11:00 **Analytical Strategy for Characterizing Mechanisms of Action of Innovative Biopharmaceuticals Using Reporter Cell Lines**
Natalia Kozhemyakina, PhD, Head, Bioassay Department, JSC Biocad
The development of innovative biopharmaceuticals requires a comprehensive understanding of their mechanisms of action (MoA) to ensure their effectiveness and safety. Understanding the MoA of these agents is critical for optimizing their therapeutic use and predicting patient responses. This presentation focuses on our efforts to design and implement cell-based assays that provide deeper insights into the MoA of biotherapeutic agents, thereby optimizing the drug development process.

11:30 **A Patient Cell Assay to Test Antibody-Immune Checkpoints Fusion Therapeutics in Autoreactive T Cell Disease**
Ashley Moore, PhD, Research Scientist II, Discovery Biology, Alexion
Various autoimmune diseases are driven or worsened by autoreactive T cells attacking organs, tissues, or transplants. We created an assay system using patient-derived PBMCs and artificial antigen presentation cells to model T cell activation against a particular tissue. We demonstrated targeting antibodies fused to Ig-like domains from various immune checkpoints can block T cell activation, demonstrating the promise of selectively potent and specific T cell modulation biotherapeutics.

12:00 pm **Bioassay Development to Support Biopharmaceutical Development**
Uchechukwu Okorji-Obike, PhD, Scientist, Bioassay, Biosafety and Impurities (BB&I), AstraZeneca
Bioassays are essential analytical tools for quantifying the biological activity of biotherapeutic products. For complex mAbs or modalities, bioassays work with other analytical assays to support the process. Here, various types of bioassay formats are explored, as well as the impact of aggregation. The case study highlights the importance of method selection and interpretation in bioassay design, emphasizing the need for comprehensive characterization of aggregation and its potential impact on bioactivity measurements.

SUCCESSFUL IMPLEMENTATION OF DEEP-LEARNING

12:30 **Deep-Learning Driven Colony Counting for Vaccine Bioassays**
Chuying Ma, PhD, Senior Scientist, Pharmacokinetics, Dynamics, Metabolism & Bioanalytics, Merck
The multiplex opsonophagocytic assay, with colony counting as the assay endpoint, is critical for assessing pneumococcal vaccine immunogenicity. Current counting methods are time-consuming and prone to variability. We developed a deep-learning pipeline for automated colony segmentation and counting, which achieves superior accuracy and minimizes human intervention. This scalable solution is targeted at enhancing the efficiency of the assay workflow by 30% to support faster and data-driven development of pneumococcal vaccines.

1:00 **Networking Luncheon**

1:30 **Session Break**

ESTABLISHING POTENCY RELATED CRITICAL QUALITY ATTRIBUTES FOR COMPLEX PRODUCTS

2:25 **Chairperson's Remarks**
Nancy Sajjadi, Founder and Principal Consultant, Sajjadi Consulting

2:30 **mRNA Products: An Overview on Strategy for Potency for DS vs DP**
Khaled Yamout, Analytical Sciences, Quality and Manufacturing Consultant, Y-Chem Consulting LLC
The development of mRNA-based medicines requires robust potency assays to assess both translatability and biological activity. These assays can be either cell-free or cell-based assays; each provide a different assessment but are complementary to each other. As such, we will discuss various strategies for assessing mRNA DS and DP potency evaluation and the advantages and disadvantages between cell-free and cell-based assays.

3:00 FEATURED PRESENTATION: **Autologous TIL Products: Statistical Considerations**
Steven Walfish, Principal CMC Statistician, Iovance Biotherapeutics
Setting acceptance criteria for autologous therapies creates statistical challenges based on patient-to-patient variability. This talk discusses approaches to estimate patient-to-patient variability to set acceptance criteria based on process variability. Tolerance intervals will be explained for setting statistically-based acceptance criteria. Examples will be presented highlighting the methodology. Challenges will be discussed to help the participants to solve common issues.

3:30 **Advancing Drug Development: Utilizing T-cell Activation Reporter Gene Assays for Potency Monitoring from the Pre-Clinical to the Commercial Stages**
Felix Feng, Senior Scientist, Bioassay Development, AstraZeneca
Accurate potency monitoring is vital in drug development for efficacy and safety. This presentation highlights T cell activation reporter gene assays, which more accurately reflect a drug's mechanism of action than single target binding assays. By measuring immunological activity, T cell reporter assays offer reliable and reproducible potency assessments. We will discuss assay optimization and development, showing how these advanced assays are shaping potency monitoring and enhancing drug development strategies.

4:00 **Interpreting Phase Appropriateness for Lot Release Criteria and Assay Qualification for Potential CQAs**
Nancy Sajjadi, Founder and Principal Consultant, Sajjadi Consulting
Product potency is a critical quality attribute but not all assays designed to measure it will correlate with clinical outcomes. Regulatory guidance indicates that potency assurance for a product should include acceptance criteria throughout development and result in rejection of sub-potent lots. To establish criticality, product batches with different potencies need to be evaluated clinically for their impact on effectiveness and safety. Phase appropriateness will be discussed in this context.

4:30 **Close of Summit**

TRAINING SEMINAR

Biostatistics for Beginners

WEDNESDAY, OCTOBER 8, 2025
8:30 AM - 5:30 PM

THURSDAY, OCTOBER 9, 2025
8:00 AM - 12:00 PM

Training Seminar Will Be Held In Person Only

To ensure a cohesive and focused learning environment, moving between conference sessions and the training seminar is not allowed.

TS2B: Biostatistics for Beginners

Instructor:

Nancy Sajjadi, Founder and Principal Consultant, Sajjadi Consulting

Statistical analysis is an integral part of designing, developing, validating, and monitoring performance of a bioassay after it is implemented. Statistical tools and techniques are required for experimental design, selecting an appropriate model for the dose response curve, evaluating system and sample suitability, and to measure, control, and communicate the uncertainty of reported potency results. Fundamental concepts are also integral to developing product specifications and making decisions for lot release. This training seminar is intended for people who generate or review bioassay data but have minimal training in statistics. A slower-paced interactive course helps participants understand the meaning of commonly encountered statistical information in context and expand their knowledge of fundamental concepts and tools that are applicable to their daily work. Time is built into the agenda to allow for review of specific topics and open discussion in response to participant questions.

TOPICS TO BE COVERED:

- Statistics: Definition and its application to assay development
- The arithmetic mean, the standard deviation and how to prove differences
- Assay intended use, hypothesis testing and evaluating fitness-for-purpose
- Inferential statistics: terminology and symbols explained
- Standard error of the mean, t values, and p values
- Reported mean values, margin of error, and confidence interval of a mean
- Statistical Significance: Difference vs. Equivalence Testing
- Type I and Type II Errors and Statistical Power
- Dose response curve- model selection, system and sample suitability evaluation
- Log transformation of response readouts and relative potency values
- Calculating relative potency values: parallel line vs. 4 PL
- Quality by Design (QbD): Assays as processes to be optimized and evaluated against target performance requirements
- Overview of available guidance: FDA, USP and ICH documents

THE COMMITMENT TO PARTICIPANTS:

Each participant is likely to arrive at the course with the expectation of examples or explanations to address issues that are specific to them or their organization. To ensure that participants are satisfied, the instructor is open to receiving non-confidential questions in advance for consideration in customizing the course material. The instructor will assess each question to ensure it matches the scope of the training seminar. If you have any questions you would like the instructor to address at the training seminar, please email them to Gemma Smith: gsmith@cambridgeinnovationinstitute.com

WHO SHOULD ATTEND:

- Laboratory scientists, technicians and others with limited statistical knowledge who are involved in generating and reporting data
- Managers in QA, QC and Regulatory functions who review data and statistical analyses
- Non-statisticians who engage with statisticians in the design and interpretation of studies
- Technicians involved in design, execution or review of assay qualification protocols
- Anyone interested in increasing their understanding of basic statistical concepts and improving their comprehension of conference presentations that include statistical analyses

INSTRUCTOR BIOGRAPHY

Nancy Sajjadi, M.Sc. is Founder and Principal Consultant of Sajjadi Consulting. She has over 30 years of experience in biopharmaceutical product development. She began her career as a bench scientist doing malaria vaccine research then joined a start-up company developing cell and gene-using therapies for infectious disease, cancer, and cell therapy applications. Her responsibilities included research, assay development, and quality control. In 2000, she left her position as Director of QC at Chiron Technologies Center for Gene Therapy to start her own consulting business. For over 20 years, Ms. Sajjadi has provided services to biopharmaceutical companies, contract laboratories, non-profit organizations, universities, and US government agencies. She has assisted clients in the development, implementation, and improvement of quality programs for a range of cutting-edge products and provides technical expertise in assay development, qualification, and validation. Ms. Sajjadi has authored several articles pertaining to bioassays and viral gene therapy and has served on 5 advisory panels for the United States Pharmacopeia (USP). She enjoys teaching introductory courses in bioassay design, development, and validation for non-statisticians. Her company has recently expanded services to include leadership development and executive coaching to guide organizations toward sustaining a culture of quality.

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CONFERENCE HOTEL AND VENUE:
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Discounted Room Rate: $279 s/d
Discounted Room Rate Cut-off Date: September 11, 2025

Visit the Travel page of ImmunogenicitySummit.com
to make your hotel reservations and for additional information

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Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure an onsite poster board and/or ensure your poster is included in the conference materials, your full submission must be received, and your registration paid in full by **September 5, 2025.**

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PRICING AND REGISTRATION INFORMATION

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Two short courses	$599	$299
Three short courses	$799	$399
Four short courses	$999	$499

TRAINING SEMINAR ONLY PRICING *In-Person only

Early Registration Discount until July 25	$1099	$599
Advance Registration Discount until September 5	$1149	$699
Registrations after September 5, and on-site	$1199	$899

SYMPOSIUM ONLY PRICING *In-Person only

Early Registration Discount until July 25	$1099	$599
Advance Registration Discount until September 5	$1149	$699
Registrations after September 5, and on-site	$1199	$899

CONFERENCE PRICING

PREMIUM PRICING - BEST VALUE! Save 10% off your short course registration (Includes access to ALL programming and network events Tuesday-Friday, on-demand access to all presentations for one year.)

Early Registration Discount until July 25	$3099	$1299
Advance Registration Discount until September 5	$3299	$1499
Registrations after September 5, and on-site	$3499	$1599

STANDARD PRICING
(Includes access to TWO programs and all networking events. Plus on-demand access to all presentations for one year. Excludes short courses)

Early Registration Discount until July 25	$2599	$1049
Advance Registration Discount until September 5	$2799	$1149
Registrations after September 5, and on-site	$2999	$1249

GROUP DISCOUNTS

Have your colleagues or entire team attend the 17th Annual Immunogenicity & Bioassay Summit.

Purchase a full price registration here and participants from the same organization will receive a 20% discount when registering through the Group Registration page.

For more information on group discounts contact Elizabeth Lemelin at 781-972-5488.

Alumni Discount: SAVE 20%

CHI appreciates your past participation at our events. Because of the loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

**Alumni, Twitter/X, LinkedIN, Facebook or any other promotional discounts cannot be combined. Discounts not available on Short Courses.*

POSTER DISCOUNT: $50 OFF

Poster materials are due by September 5, 2025. Once your registration has been fully processed, we will send an email containing a unique link and instructions for submitting your abstract and other materials. If you do not receive your link within 5 business days, please contact jring@healthtech.com.

CHI reserves the right to publish your poster content in various marketing materials and products.

Flexible Registration – Seamlessly switch between In-person and/or Virtual

Select In-Person or Virtual option and you have the flexibility to switch your preferred event experience at any time leading up to the Conference.

How to Register: **ImmunogenicitySummit.com**

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode **2527F** when registering!

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