

Keynote Line-up and Seven FDA Speakers Confirmed for Immunogenicity and Bioassay Summit 2015, Organized by CHI

Seventh annual event to focus on technologies and strategies for safe and efficacious products in the clinic

NEEDHAM, MASSACHUSETTS, UNITED STATES, August 26, 2015 /EINPresswire.com/ -- Cambridge Healthtech Institute (CHI) today announced the FDA and keynote speakers confirmed to present at its seventh annual Immunogenicity and Bioassay Summit 2015 being held on November 17-19, 2015 at the Hilton Baltimore in Baltimore, MD.

FDA and keynote presenters include:

- William Hallett, Ph.D., product quality & immunogenicity reviewer at FDA, will give a regulatory perspective on how product quality attributes of biotherapeutics affect immunogenicity
- Maura C. Kibbey, Ph.D., senior scientific liaison, biologics & biotechnology at United States Pharmacopeia, will cover compendial potency assays and associated biological reference materials – challenges in assay bridging
- Susan Kirshner, Ph.D., associate chief, laboratory of immunology, therapeutic proteins, biotechnology at FDA, will discuss regulatory perspectives on setting up the clinical immunogenicity study for a biosimilar
- Xiaobin (Victor) Lu, Ph.D., CMC reviewer, division of cellular & gene therapies at FDA, will outline a product life-cycle approach for developing potency assays for a CGT product from preclinical studies to the Biological License Application (BLA)
- Joao Pedras-Vasconcelos, Ph.D., biotech quality and immunogenicity reviewer at FDA, will explain how to identify and mitigate immunogenicity-related risks for different product types
- Valerie Quarmby, Ph.D., staff scientist, bioanalytical sciences at Genentech, Inc., will provide a harmonized approach to interpretation and reporting of clinical immunogenicity data
- Jack Ragheb, Ph.D., principal investigator, therapeutic proteins at FDA, will explore relevance of animal models for [immunogenicity prediction](#)
- Theo Rispens, Ph.D., senior scientist, immunopathology at Sanquin, will discuss immunogenicity testing in patients treated with anti-TNF
- Amy S. Rosenberg, M.D., division director, office of biotechnology products at FDA, will address immunologic sabotage of dystrophin replacement therapies in duchenne muscular dystrophy
- Daniela Verthelyi, M.D., Ph.D., chief, immunology lab, at FDA, will describe different approaches for the detection of innate immune response modifying impurities in therapeutic proteins

In addition, the summit features several other opportunities for attendees to gain up-to-the-minute, implementable intelligence to overcome immunogenicity and bioassay challenges. The summit also includes more than 45 sessions, 4 dinner short courses, 12 roundtable breakouts and panel discussions, and an exhibit/poster hall showing the latest solutions. The summit is organized into 3 tracks: [Immunogenicity Assessment](#) & Clinical Relevance, Immunogenicity Prediction & Mitigation, and Optimizing [Bioassays for Biologics](#).

“CHI’s Immunogenicity and Bioassay Summit 2015 brings together FDA, academic and industry experts in the field of originator and biosimilar biotherapeutics,” said Dr. Nicole Lyscom, CHI Team Leader and Senior Conference Director. “Since the event’s inception, I am amazed by the in-depth, lively discussions in the breakout groups and sessions. Our speakers take a genuine interest in helping others overcome their difficulties with immunogenicity and bioassay development.”

Important Dates:

Poster abstract submission deadline: October 16, 2015

Advanced registration discount deadline: October 16, 2015

Writers and editors are invited to attend. To request a press pass, email Lisa Scimemi, lscimemi@healthtech.com.

Prospective attendees can view a complete agenda, learn more about sponsorship and exhibitor opportunities, and register at <http://www.immunogenicitysummit.com>.

About Cambridge Healthtech Institute (www.chicorporate.com)

Cambridge Healthtech Institute (CHI), founded in 1992, is the industry leader in providing superior-quality scientific information to eminent researchers and business experts from top pharmaceutical, biotech, and academic organizations. Delivering an assortment of resources such as events, reports, publications and eNewsletters, CHI's portfolio of products include Cambridge Healthtech Institute Conferences, Barnett Educational Services, Insight Pharma Reports, Cambridge Marketing Consultants, Cambridge Meeting Planners, Knowledge Foundation and Cambridge Healthtech Media Group, which includes Bio-IT World and Clinical Informatics News.

Media Contact:

James Prudhomme
Cambridge Healthtech Institute
781-972-5400
jprudhomme@healthtech.com

James Prudhomme
CHI
7819725400
email us here

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