

Vaccine Technology VI

June 12-17, 2016

Oral Session Descriptions

Session I: Break Through Developments in Vaccinology

Chairs: Florian Krammer, The Mount Sinai Hospital, USA, and Haru Pujar, Moderna Therapeutics, USA

This session will highlight new basic research findings and enablers of vaccine development. Examples could be new immunology discoveries relevant for vaccine technology, new clinical assays/correlates, new vectoring (nanoparticles) or new adjuvants to steer immune response.

Session II: Issues and Case Studies in Process Development

Chairs: Udo Reichl, Max Planck, Germany and Charles Lutsch, Shantha Biologics, India

Production of efficacious and safe vaccines poses significant challenges in upstream and downstream processing as well as in formulation. To reduce costs per dose and to cope with ever increasing demands, this session will focus on further steps towards process intensification to increase product yields, the establishment of platform technologies to speed up process development, advances in process analytics, and the use of disposables for campaign-based vaccine manufacturing. Examples from mature markets and developing Countries will be highlighted.

Session III: Formulating and Delivering Vaccines

Chairs: David Volkin, Kansas University, USA

"I have a great candidate for a vaccine that will solve an unmet medical need.... But how do I get it tested to demonstrate its value?" This session deals with the different steps that need to be taken in order to bring a concept to the first clinical trial, from the definition of the vaccine form (formulation, route of administration) to the various steps that need to be taken before entering into humans. Each vaccine candidate is unique and will require specific approach, nonetheless a common path can be defined and followed to maximize the chances of reaching a fast go/no go decision. Those paths will be discussed, including from how to select the formulation and validate its choice, to discussing the new emerging delivery technologies that are being brought to the field of vaccines. Finally, this session will be concluded by a discussion among the speakers on the various avenues, their benefit and challenges.

Session IV: Vaccine Characterization and Analytics

Chairs: Linda Lua, University of Queensland, Australia, and Indresh Srivastava, Protein Sciences, USA

Vaccine characterization applies to all phases of vaccine development, final release vaccine product and process consistency during manufacture. It encompasses all in vitro and in vivo assays to evaluate the biological, chemical and physical properties of a vaccine. In-depth characterization of vaccines provides an understanding on the function, potency and toxicity issues, and improves vaccine efficacy and safety. In addition, bio-analytical characterization plays a critical role in establishing comparability of the product produced with process, scale and site changes. This session will focus on testing strategies and case studies highlighting the pivotal role of analytical characterization in vaccine development, licensure, and post-licensure life cycle management.

Session V: Therapeutic Vaccines

Chairs: Laurent Huemau, Inovio, USA, and Tony Hitchcock, Cobra Biologics, United Kingdom

The recognition of the key role of the immune system and of viruses in a wide range of diseases is increasing every day. In this session, new approaches for the development of therapeutic vaccines will be discussed. Of special interest is the identification of new immunological targets, therapies for oncology and addictions, the role of tolerization, and others.

Session VI: Getting Vaccines to the Market: Case studies

Chairs: Rebecca Sheets, Grimalkin Partners, USA and Danny Casimiro, Merck, USA

Session VII: New Challenges and Technologies in Vaccine Development

Chairs: Odile Leroy, European Vaccine Initiative, Germany, and Albert Price, Medimmune, USA

The next wave of vaccines to be developed will need to overcome new challenges, such as rapidly responding to emerging pathogens, eliciting effective immune responses against “difficult” targets that evade the immune system, and prevention and treatment of various diseases including non-communicable diseases. To address these challenges, the application of multiple new technologies to vaccine strategies will be required. Our quickly growing understanding of both the immune system and the molecular biology of pathogens, pathogenesis and risk factors, all enable new strategies for prevention and treatment. New vectors, synthetic biology, and specific immune modulation are examples that will play prominent roles for the vaccinology of the 21st century. This session will feature examples of new technologies and approaches that will address major challenges in vaccinology.

Session VIII. One World, One Health

Chairs: Monica Dias Figueiredo, Merial, USA, Ab Osterhaus, University of Veterinary Medicine Hannover, Germany, and Juan Garza, UNAM, Mexico

The vast majority of emerging and re-emerging pathogens in humans is of animal origin. Most of this growing number of threats has its origin in wildlife, while humans are exposed either directly or through indirect domestic animal contacts. Effective and economical ways of protecting mankind from emerging diseases are best based on combatting zoonotic pathogens at the animal source. The “One Health” concept creates awareness of the major opportunities that exist to protect public health through policies aimed at controlling these pathogens at the level of their animal hosts, or more specifically, at the interface between humans, animals and their environments. Implementation of these policies places those who have regular contacts with domestic animals, like owners, handlers and veterinarians, in the front line together with those who regularly come into contact with wildlife and their environment. This session will highlight the importance of the integration between medical and veterinary disciplines within the One Health concept.