REGISTER BY 31ST MARCH AND RECEIVE A £400 DISCOUNT
REGISTER BY 29TH APRIL AND RECEIVE A £200 DISCOUNT

SMi
LINKING BUSINESS *with* INFORMATION

SMi Present the 3rd Annual Conference on...

Immunogenicity

13 - 14 JUNE 2016

Holiday Inn Kensington Forum, London, UK

Accelerating commercialisation of your next gen biotherapeutics – adopt advanced immunogenicity assessments for successful regulatory approval

Chairs for 2016:

Annie De Groot,
CEO and CSO,
EpiVax, Inc.

Adnan Khan,
Senior Scientist Immunology/Pharmacology,
UCB

Featured Speakers:

- **Meenu Wadhwa,** Section Leader, Cytokines and Growth Factors, NIBSC, **MHRA**
- **Kei Kishimoto,** Chief Scientific Officer, **Selecta Biosciences**
- **Daniel Sikkema,** Executive Director, Head of Immunogenicity and Clinical Immunology, **GlaxoSmithKline**
- **Jochem Gokemeijer,** Associate Director, **Bristol-Myers Squibb**
- **Tim Hickling,** Immunogenicity Sciences Discipline Lead, **Pfizer**

Key Sessions:

- **MHRA: Towards harmonisation of immunogenicity assays**
- **Integration of immunogenicity risk data to forecast clinical outcomes**
- **A harmonised approach to interpretation and reporting of clinical immunogenicity data**
- **Development and validation of cell based antibody neutralisation assays**

Sponsored by

ABZENA
Enabling better biopharmaceuticals

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS
Wednesday 15th June 2016, Holiday Inn Kensington Forum, London, UK

A: Approaches to standardising assays for measuring drug levels and anti drug antibodies to biotherapeutics in clinical practice

Workshop Leaders:
Hishani Kirby, Founder and Director, **Hishani Kirby Associates Ltd**
Daniel Sikkema, Executive Director, Head of Immunogenicity and Clinical Immunology, **GlaxoSmithKline**
08.30 – 12.30

B: Unwanted immunogenicity from bench to bedside

Workshop Leaders:
Arno Kromminga, CEO/CSO, **IPM Biotech**
Sofie Pattijn, Chief Technology Officer, **ImmunXperts**
13.30 – 17.30

www.immuno.co.uk

Register online or fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711
ACADEMIC & GROUP DISCOUNTS AVAILABLE

CPD CERTIFIED
The CPD Certification Service

@SMIPHARM
#immunosmi

Immunogenicity

Day One | Monday 13th June 2016

08.30 **Registration & Coffee**

09.00 **Chairman's Opening Remarks**
Annie De Groot, CEO and CSO, **EpiVax, Inc.**

OPENING ADDRESS

09.10 **Improving the efficacy and safety profile of biotherapeutics by addressing product immunogenicity with tolerogenic nanoparticles**

- The development of anti-drug antibodies (ADAs) is a common cause for treatment failure and adverse events associated with biologic therapies.
- Addressing product immunogenicity has the potential to improve efficacy and safety profile of novel biologics; reduce catastrophic late stage clinical failure due to ADAs; provide life cycle management for existing products; and differentiate products from biosimilars.
- Selecta Biosciences is a clinical stage company that has developed a novel platform of Synthetic Vaccine Particles (SVP) to induce durable antigen-specific immune tolerance for the prevention of ADAs

Kei Kishimoto, Chief Scientific Officer, **Selecta Biosciences**

09.50 **Redefining the well-defined: unwanted immune responses**

- What is an unwanted immune response?
- What can we define as tolerance?
- Therapeutic innervation and innovation

Adnan Khan, Senior Scientist Immunology/Pharmacology, **UCB**

10.30 **Morning Coffee**

EXPLORING IMMUNOGENIC ASSESSMENT TECHNIQUES

11.00 **A harmonised approach to interpretation and reporting of clinical immunogenicity data**

- How can we harmonise data?
- Should we be able to compare trial results that use different ranking methods
- The benefits a harmonised approach can bring to the reporting of clinical immunogenicity data

Daniel Sikkema, Executive Director, Head of Immunogenicity and Clinical Immunology, **GlaxoSmithKline**

KEYNOTE ADDRESS

11.40 **Towards harmonisation of immunogenicity assays**

- Wide variation in ADA incidence and titres often reported for a therapeutic
- Should we produce reference panels or standardise methods to harmonise data?
- Availability of a WHO reference panel for erythropoietin antibody assays

Meenu Wadhwa, Section Leader, Cytokines and Growth Factors, NIBSC, **MHRA**

12.20 **Networking Lunch**

13.20 **Immunogenicity risk assessment tools for biologics**

- Immunogenicity risk assessment tools to inform biologics development programs
- Utilisation of immunogenicity tools to guide critical quality attributes (CQA) for product attributes
- Challenges in clinical validation of immunogenicity risk assessment

Jochem Gokemeijer, Associate Director, **Bristol-Myers Squibb**

NEXT GENERATION BIOLOGICS

14.00 **Integrating best-in-class in vitro and ex vivo assays to manage immunogenicity risk in biologics**

- Learn how data from cell-based assays, physical MHC-peptide binding assays and mass spectrometry antigen presentation assays can be integrated to characterize immune responses against, or caused by, biotherapeutic drugs
- Mitigate the risk of first infusion reactions using whole-blood cytokine release assay
- Improve decision-making in lead selection, lead characterisation and re-engineering options

Jeremy Fry, Director of Sales, **ProImmune Ltd.**

14.40 **Afternoon Tea**

15.10 **Nanobodies, a promising new class of biopharmaceuticals. What about their immunogenicity?**

- Nanobodies originate from camelids, but does their humanisation make sense?
- Different methods for anti-drug antibodies (ADA) assessment towards nanobodies
- In vitro immunogenicity risk assessment of nanobodies

Chloé Ackaert, Postdoctoral Researcher, **Free University of Brussels**

15.50 **Understanding the role of aggregation in the immunogenicity of biotherapeutic proteins**

- Comparison of the immunological responses to immunisation with recombinant biologics in monomeric and aggregated forms in a mouse model
- The results were generally indicative of skewing towards a Th1-type response
- Can HCPs also play a role in modulating the immune response?

Jeremy Derrick, Professor, **University of Manchester**

16.30 **Chairman's Closing Remarks and Close of Day One**
Annie De Groot, CEO and CSO, **EpiVax, Inc.**

08.30 Registration and Coffee

09.00 **Chairman's Opening Remarks**
Adnan Khan, Senior Scientist Immunology/Pharmacology, **UCB**

OPENING ADDRESS / KEYNOTE ADDRESS

09.10 **Development and validation of cell based antibody neutralisation assays**
- Examples of validation of cell based neutralisation assays
- Their application to release / stability testing of vaccines
- Consideration of the assay life cycle

Sue Charlton, Scientific Lead, Vaccine Research Group, **Public Health England**

09.50 **Integration of immunogenicity risk data to forecast clinical outcomes**
- Immune responses to biologics as a normal response to drug exposure
- Identifying key risk factors for immunogenicity
- Working with protein engineers to reduce immunogenicity of biotherapeutics
- Utilising non-clinical assays for immunogenicity assessment

Tim Hickling, Immunogenicity Sciences Discipline Lead, **Pfizer**

10.30 **Morning Coffee**

A CLOSER LOOK AT ADAPTIVE T CELLS

11.00 **Influence of aggregates on in vitro T cell responses**
- Immunogenicity of therapeutic protein products can elicit unwanted ADA
- Protein aggregation can result in enhanced immunogenicity
- In vitro methods that measure the impact of these aggregates on enhanced immunogenicity will be useful tools in screening processes to avoid or reduce problems associated with ADA

Mark Fogg, Immunology Group Leader, **Abzena**

11.40 **T-cell amplification assays for immunogenicity prediction: T-cell repertoire and epitopes**
- Why are T cell assays performed to predict immunogenicity?
- What kind of data do they produce?
- Do they have been already confronted to clinical observations?
- Are they really useful as compared to other predictive approaches?

Machteld Tiemessen, Senior Scientist, **Janssen**

12.20 **Networking Lunch**

INNOVATIONS IN IMMUNOGENICITY

13.20 **Correlation of T-cell responses induced by therapeutic cancer vaccines with clinical responses**
- In premalignant disease caused by high risk HPV, therapeutic vaccination-induced T-cell responses correlate with clinical responses
- In late stage HPV-induced cancer myeloid cell depletion by standard chemotherapy fosters robust vaccine-induced T cell responses
- Therapeutic vaccines works as monotherapy in pre-malignant disease, but treatment of late stage cancer requires combination of vaccination with immuno-modulation

Kees Melief, Chief Scientific Officer, **ISA Pharmaceuticals**
Ronald Loggers, Chief Executive Officer, **ISA Pharmaceuticals**

14.00 **A computational pipeline for personalised cancer vaccine development**
- Checkpoint inhibitors are changing cure rates for cancer and generating excitement in the cancer field
- While cure rates are improving, personalised cancer vaccines may improve cure rates even further
- Personalised cancer vaccines are feasible using available computational tools
- Participants will learn how personalised cancer vaccines will move the needle on cancer cures of the future

Annie De Groot, CEO, **EpiVax**

14.40 **Afternoon Tea**

15.10 **Immunogenicity of biosimilar monoclonal antibodies**
- Unexpected immunogenicity linked to biosimilar monoclonal antibodies
- The challenge of assessing similarity between originator and biosimilar mAb
- Developing a characteriation strategy for proving comparability with biosimilars

Andreas Herrmann, CEO, **Baliopharm AG**

15.50 **Protein aggregates: Why do we need to study them? Quantification and characterisation of sub-visible particles in protein therapeutics**
- Biopharmaceutical and problems never seen with non-protein substances
- Protein aggregates structure and function
- Strategy in analysis and characterization of protein aggregates

Mantas Malisauskas, Manager R&D, **Baxalta**

16.30 **Chairman's Closing Remarks and Close of Day Two**
Adnan Khan, Senior Scientist Immunology/Pharmacology, **UCB**

Official Publications


Supported by

HALF-DAY POST-CONFERENCE WORKSHOP
Wednesday 15th June 2016
08.30 – 12.30
Holiday Inn Kensington Forum, London, UK

A: Approaches to standardising assays for measuring drug levels and anti drug antibodies to biotherapeutics in clinical practice

Workshop Leaders:
Hishani Kirby, Founder and Director,
Hishani Kirby Associates Ltd
Daniel Sikkema, Executive Director, Head of Immunogenicity and Clinical Immunology, **GlaxoSmithKline**

Overview of Workshop:

The assay requirements for rapid decision making with licenced biotherapeutics in clinical practice can be very different from the best practice applied during regulated studies. The growing trend for therapeutic drug monitoring (TDM) with biotherapeutics has highlighted the need for harmonisation of assays and associated data throughout the lifecycle of a given drug.

In this workshop, an overview of historical approaches to validating methods to quantify biopharmaceuticals and to detect, monitor, and characterise anti-drug antibodies will be presented. The current best practices, terminology, and future insights for standardisation of methods and associated technological developments will be discussed.

You will be able to learn about the latest trends and developments for quantifying biotherapeutics and monitoring anti-drug antibodies will be presented in the context of assay harmonisation, associated challenges and possible solutions.

Programme:

08.30 **Registration**

09.00 **Workshop Leaders Introduction**

09.10 **Overview of historical approaches for drug and ADA measurement: Fit for purpose?**
- Which format?
- What are the parameters?
- Constraints and challenges

10.30 **Morning Coffee**

11.00 **Looking beyond – technological developments**
- Future standardisation of methods
- Advanced quantification techniques for biotherapeutics and application on immunogenicity
- Associated challenges and solutions

12.00 **Q&A**

12.30 **End of Workshop**

About the Workshop Leader:

Hishani Kirby, PhD, Founder and Director,
Hishani Kirby Associates Ltd

With over 25years in the biopharmaceutical industry, Hishani has gained wide experience in the development of biopharmaceutical products. This has been mainly with Mab and Mab-based fragments, where she has utilised her extensive protein analytical and bioanalytical expertise, in the characterisation and measurement of complex biotherapeutics. Hishani first estalished her career at Celltech in Mab therapeutics and then joined UCB, where she was responsible for providing expert guidance on bioanalytical strategy in PK, PD and immunogenicity in support of the company's portfolio from discovery through to post licencing phases of development, as well as leading the team responsible for execution of analytical and bioanalytical services.

More recently, Hishani has formed her own consulting company providing expertise in scientific aspects of bioanalysis, immunogenicity risk assessment and testing strategies, and in regulatory considerations in biopharmaceutical development. Her strengths are in designing and implementing practical/ innovative analytical solutions to enable rapid decision making through development to post license life cycle management.

Daniel Sikkema, Executive Director, Head of Immunogenicity and Clinical Immunology, **GlaxoSmithKline**

Dan joined GlaxoSmithKline (GSK) as Executive Director and Head of the Clinical Immunology group in BioPharm R&D in August 2010. Prior to this, he had held various positions of increasing responsibility at Bristol-Myers Squibb, Wyeth Vaccines, Merck Vaccines and Biologics, and Sanofi Pasteur. Dan has contributed to the clinical immunology and microbiology assessments leading to licensure of Prev(e)nar, Meningitec, Gardasil, Rotavax, ProQuad, and Zostavax, and has worked extensively with the WHO, US Centers for Disease Control, National Institute for Biological Standards and Controls, US FDA, and EMA. Now at GSK he is heading the Immunogenicity and Clinical Immunology group assessing immunogenicity of administered biotherapeutics and the quantitation of target-engaged biomarkers in the clinical setting, as well as leading the Innovative Medicines Initiative (www.abirisk.eu) to further understand the underlying mechanisms and basic biology around induction of immunogenicity to biotherapeutics and their clinical relevance. July 1, 2015, he assumed the Chair Elect position for Division V at American Society for Microbiology.

HALF-DAY POST-CONFERENCE WORKSHOP
Wednesday 15th June 2016
13.30 – 17.30
Holiday Inn Kensington Forum, London, UK

B: Unwanted immunogenicity from bench to bedside

Workshop Leaders:
Arno Kromminga, CEO/CSO, **IPM Biotech**
Sofie Pattijn, Chief Technology Officer, **ImmunXperts**

Overview of Workshop:
This workshop will give an insight on the rapid growing field of unwanted immunogenicity and the science behind it. The immunology of an unwanted immune response will be addressed and discussed. Also, an overview of the tools for early immunogenicity assessment will be given. Finally, the emerging trends and clinical impact of neutralising anti-drug antibodies will be discussed followed by a summary of the lessons learned and future challenges.

Programme:

13.30	**Registration**
14.00	**The immunology of immunogenicity**
14.45	**Tools for early non-clinical immunogenicity assessment**
15.30	**Afternoon Tea**
16.00	**Neutralising anti-drug antibodies: Emerging trends and clinical impact**
16.45	**Lessons learned and future challenges**
17.20	**Closing remarks**
17.30	**Close of workshop**

About the Workshop Leaders:
Dr Arno Kromminga is currently CSO of GLP-certified IPM Biotech. In addition, he is a faculty member at the Institute of Immunology at the University of Kiel. He studied Biochemistry and Immunology and has 20+ years experience in assay development, is author of multiple publications in peer-reviewed journals and books and is a co-founder and board member of the European Immunogenicity Platform (EIP). He and his team have developed and validated numerous immunological binding and cellular functional assays for immunogenicity testing and PK/PD analysis for pre-clinical and clinical studies. His major interest besides the validation of assays, is the interpretation of results to obtain clinically meaningful data

Sofie Pattijn (CTO, ImmunXperts) has over 20 years of experience in the field of immunogenicity assessment (vaccines and biotherapeutics). She has extensive hands-on lab experience and has managed and coached several In Vitro teams over the last decade. From 2008 till 2013 she was Head of the In Vitro Immunogenicity group at AlgoNomics (Ghent, Belgium) and Lonza Applied Protein Services (Cambridge, UK). Prior to that, she worked at Innogenetics, Belgium for over 15 years.

IMMUNOGENICITY

Conference: Monday 13th & Tuesday 14th June 2016, Holiday Inn Kensington Forum, London, UK **Workshops: Wednesday 15th June 2016, London, UK**

4 WAYS TO REGISTER

www.immuno.co.uk

FAX your booking form to +44 (0) 870 9090 712
PHONE on +44 (0) 870 9090 711

POST your booking form to: Events Team, SMi Group Ltd, 2nd Floor South, Harling House, 47-51 Great Suffolk Street, London, SE1 0BS, UK

Unique Reference Number	
Our Reference	LVP-176

DELEGATE DETAILS

Please complete fully and clearly in capital letters. Please photocopy for additional delegates.

Title: **Forename:**

Surname:

Job Title:

Department/Division:

Company/Organisation:

Email:

Company VAT Number:

Address:

Town/City:

Post/Zip Code: **Country:**

Direct Tel: **Direct Fax:**

Mobile:

Switchboard:

Signature: **Date:**

I agree to be bound by SMi's Terms and Conditions of Booking.

ACCOUNTS DEPT

Title: **Forename:**

Surname:

Email:

Address (if different from above):

Town/City:

Post/Zip Code: **Country:**

Direct Tel: **Direct Fax:**

VENUE Holiday Inn Kensington Forum, 97 Cromwell Rd, London SW7 4DN, UK

☐ **Please contact me to book my hotel**
Alternatively call us on +44 (0) 870 9090 711,
email: events@smi-online.co.uk or fax +44 (0) 870 9090 712

Terms and Conditions of Booking

Payment: If payment is not made at the time of booking, then an invoice will be issued and must be paid immediately and prior to the start of the event. If payment has not been received then credit card details will be requested and payment taken before entry to the event. Bookings within 7 days of event require payment on booking. Access to the Document Portal will not be given until payment has been received.

Substitutions/Name Changes: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. Two or more delegates may not 'share' a place at an event. Please make separate bookings for each delegate.

Cancellation: If you wish to cancel your attendance at an event and you are unable to send a substitute, then we will refund/credit 50% of the due fee less a £50 administration charge, providing that cancellation is made in writing and received at least 28 days prior to the start of the event. Regretfully cancellation after this time cannot be accepted. We will however provide the conferences documentation via the Document Portal to any delegate who has paid but is unable to attend for any reason. Due to the interactive nature of the Briefings we are not normally able to provide documentation in these circumstances. We cannot accept cancellations of orders placed for Documentation or the Document Portal as these are reproduced specifically to order. If we have to cancel the event for any reason, then we will make a full refund immediately, but disclaim any further liability.

Alterations: It may become necessary for us to make alterations to the content, speakers, timing, venue or date of the event compared to the advertised programme.

Data Protection: The SMi Group gathers personal data in accordance with the UK Data Protection Act 1998 and we may use this to contact you by telephone, fax, post or email to tell you about other products and services. Unless you tick here ☐ we may also share your data with third parties offering complementary products or services. If you have any queries or want to update any of the data that we hold then please contact our Database Manager databasemanager@smi-online.co.uk or visit our website www.smi-online.co.uk/**updates quoting the URN as detailed above your address on the attached letter.**

EARLY BIRD DISCOUNT

☐ **Book by 31st March to receive £400 off the conference price**
☐ **Book by 29th April to receive £200 off the conference price**

CONFERENCE PRICES

I would like to attend: (Please tick as appropriate)	**Fee**		**Total**
☐ Conference & 2 Workshops	**£2697.00**	**+ VAT**	**£3236.40**
☐ Conference & 1 Workshop A ☐ B ☐	**£2098.00**	**+ VAT**	**£2517.60**
☐ Conference only	**£1499.00**	**+ VAT**	**£1798.80**
☐ 2 Workshops	**£1198.00**	**+ VAT**	**£1437.60**
☐ 1 Workshop only	**£599.00**	**+ VAT**	**£718.80**
Workshop A ☐ Workshop B ☐			

PROMOTIONAL LITERATURE DISTRIBUTION

☐ Distribution of your company's promotional literature to all conference attendees	**£999.00**	**+ VAT**	**£1198.80**

The conference fee includes refreshments, lunch, conference papers, and access to the Document Portal. Presentations that are available for download will be subject to distribution rights by speakers. Please note that some presentations may not be available for download. Access information for the document portal will be sent to the e-mail address provided during registration. Details are sent within 24 hours post conference.

DOCUMENTATION

I cannot attend but would like to purchase access to the following

Document Portal/paper copy documentation	**Price**		**Total**
☐ Access to the conference documentation on the Document Portal	**£499.00**	**+ VAT**	**£598.80**
☐ The Conference Presentations – paper copy (or only £300 if ordered with the Document Portal)	**£499.00**	**-**	**£499.00**

PAYMENT

Payment must be made to **SMi Group Ltd,** and received before the event, by one of the following methods **quoting reference P-176 and the delegate's name. Bookings made within 7 days of the event require payment on booking, methods of payment:**

☐ **UK BACS** Sort Code **300009**, Account **00936418**
☐ **Wire Transfer** Lloyds TSB Bank plc, 39 Threadneedle Street, London, EC2R 8AU
Swift (BIC): **LOYDGB21013,** Account **00936418**
IBAN **GB48 LOYD 3000 0900 9364 18**
☐ **Cheque** We can only accept Sterling cheques drawn on a UK bank.
☐ **Credit Card** ☐ Visa ☐ MasterCard ☐ American Express

All credit card payments will be subject to standard credit card charges.

Card No: ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Valid From ☐☐/☐☐ Expiry Date ☐☐/☐☐

CVV Number ☐☐☐☐ 3 digit security on reverse of card, 4 digits for AMEX card

Cardholder's Name:

Signature: **Date:**

I agree to be bound by SMi's Terms and Conditions of Booking.

Card Billing Address (If different from above):

VAT

VAT at 20% is charged on the attendance fees for all delegates. VAT is also charged on Document portal and literature distribution for all UK customers and for those EU Customers not supplying a registration number for their own country here.

If you have any further queries please call the Events Team on tel +44 (0) 870 9090 711 or you can email events@smi-online.co.uk