Analyse, Interpret, Improve

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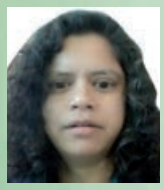
# BioANALYTICAL & FORMULATION CONGRESS

Tuesday 15th - Wednesday 16th September 2015 • Maritim proArte Hotel, Berlin, Germany

## Key Speakers



**Dr Disha Dadke**
Director, Biological and Biotech,
**USP, India**

**Annick Gervais**
Director, Analytical Development
**UCB, Belgium**

**Dr Alistair Kippen**
Director, Analytical Biotechnology
**MedImmune, UK**

**Dr Atanas Koulov**
Group Head, Analytical Development
**Roche, Switzerland**

**Dr Yelena Lyubarskaya**
Senior Principal Scientist
**Biogen Idec, USA**

**Dr Fabienne Deckert-Salva,**
Head of Outsourced Bioanalytics
**Novartis, Switzerland**

1. **Protein Characterisation**
2. **Formulation, Particles and Aggregation**
3. **Immunogenicity and Bioanalysis**
4. **Biological Assays**

Conference Sponsors

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# Pre-Conference Symposiums

## Host Cell Proteins

*Registration 13.00 • Start 14.00 • End 20.00 • The workshop will finish no later than 20.00. Workshop documentation, refreshments and an evening meal will be provided.*

**Workshop Objectives:**

A major portion of biotherapeutics today are produced by recombinant DNA technology using a well-selected host cell system. Host cells express a large number of their own proteins that can easily contaminate the recombinant protein drug. This interactive workshop will provide information on applications and methods for HCP monitoring, mass spectrometry techniques, orthogonal methods as well as the latest input from the USP on HCP guidance.

**Topics to be covered include:**

- Regulatory updates: feedback on the new usp/ep guidance
- Immunoassays for hcp monitoring - how are the assays actually developed?
- Applications of hcp monitoring
- Applications of mass spec
- Gmp aspects of hcp monitoring
- Orthogonal methods

Confirmed Speakers:

**Part 1: Latest feedback on the USP HCP guideline - what are the expectations?**

**A member of the US Pharmacopea's Expert Committee on Host Cell Proteins**

**Part 2: HCPs from an assay perspective - monitoring applications**

**Oliver Anderka**
Laboratory Head
**Novartis, Switzerland**

**Part 3: Immunoassays for HCPs**

**Aurelie Delangle**
Senior Scientist
**UCB, Belgium**

**Part 4: Q&A**

*"Host-cell protein (HCP) analysis is a big issue when it comes to early clinical testing, design of downstream processes, and quality control of biopharmaceuticals."*

**BioProcess International Magazine**

## Immunogenicity Masterclass

*Registration 13.00 • Start 14.00 • End 20.00 • The workshop will finish no later than 20.00. Workshop documentation, refreshments and an evening meal will be provided.*

**Workshop Objectives:**

Early detection of immunogenicity reactions is a key component of a drug development programme. pre-conference workshop shows you how to detect, reduce and characterise unwanted immunogenicity, interpret the last regulatory guidelines and formulate a winning strategy that you can implement into your business immediately.

**Topics to be covered include:**

**Introduction to Immunogenicity:**

- What is immunogenicity
- Factors affecting immunogenicity with regards to therapeutic proteins/ novel molecules

**Immunogenicity Testing:**

- The need to test for immunogenicity
- Current challenges facing the industry
- PK and how it changes during immunogenicity
- How to assess samples and evaluate safety

**Measuring Unwanted Immunogenicity:**

- Screening assays, confirmatory assays, characterisation assays and neutralising assays
- Assay methodologies and how they compare including new and old technologies

**Non-Clinical and Clinical Consequences of Immunogenicity :**

- Predictability of animal models
- Patient safety
- Reduced efficacy
- Altered PK

**Regulatory Updates and Expectations**

Confirmed Leaders:

**Arno Kromminga**
CEO/CSO
**IPM Biotech, Germany**

**Roy Jeffries**
Molecular Immunology Professor
**University of Birmingham, UK**

**Bernard Malliere**
Head of Immunochemistry
**Institute of Biology and Technologies, France**

**Daniel Kramer**
Global Scientific Advisor Clinical Immunogenicity
**Sanofi, Germany**

# Evening Seminar: Tuesday 15th September 2015

## Analytical and Formulation Strategies for ADCs

*Registration is at 18.15 for a 18.30 start. The seminar will finish no later than 20.30. Networking dinner to follow.*

The analysis and formulation of ADCs poses some of the biggest challenges in analytical and formulation development. This evening seminar, comprising a series of short presentations and in-depth discussion, will help you devise and implement and winning ADC characterisation.

**Agenda includes:**

- Analytical strategies for Antibody-Drug-Conjugates
- QbD/setting CQAs for ADCs, including method development
- Drug product formulations
- Liquid vs. lypholised strategies
- Stabilising ADCs
- Higher Order Structures for ADCs

**Lead:**

**Dr Alex Lazar**
*Head of Analytical and Pharmaceutical Sciences*
**Immunogen, USA**

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# Day One: Tuesday 15th September

## Latest Updates on Host Cell Proteins

08:00 **Morning coffee and registration**

08.55 **Chairperson's opening remarks**

09:00 **Latest updates on forthcoming USP host cell protein paper**

A member of the US Pharmacopea's Expert Committee on Host Cell Proteins

## Plenary Discussion Panel: Current Challenges and Opportunities in Bioanalytics and Formulation

09:40

- Current challenges in analytical methods for biologics
- Lifecycle management for analytics
- Analytical / Formulation support for regulatory filings and accelerated programmes
- Real time release testing
- New technologies – what gaps still remain?

**Dr Alistair Kippen**
*Director*
**Analytical Biotechnology**
**MedImmune, UK**

**Dr Bernardo Perez-Ramirez**
*Senior Director*
**BioFormulations, Sanofi, USA**

**Dr Annick Gervais**
*Director, Analytical Development*
**UCB, Belgium**

**Dr Alex Lazar**
*Head of Analytical and Pharmaceutical Sciences,*
**Immunogen, USA**

**Dr Yelena Lyubarskaya**
*Senior Principal Scientist*
**Biogen Idec, USA**

A member of the US Pharmacopea's Expert Committee on Host Cell Proteins

10:30 **Morning Coffee and Networking**

| Protein Characterisation 1 | Formulation 2 | Immunogenicity 3 | Biological Assays 4 |
|---|---|---|---|
| **Chairpersons' Opening Remarks** | | | |
| Characterisation and Quantification of Biologics | De-Risking Candidate Molecules | Immunogencity Strategies for Novel Products and Non-Innovators | Regulatory Update and Assay Development |
| 11:15 **Improving the speed, quantification and quality of biological characterisation**  Dr Jonathon Bones *Principal Investigator* **NIBRT, Ireland** | **FEATURED PRESENTATION: De-risking candidate molecules and identification of critical quality attributes**  Bernardo Perez-Ramírez, *Senior Scientific Director, BioFormulations Development, Global Biotherapeutics,* **Sanofi** | **FEATURED PRESENTATION: Current status of immunogenicity** Dr Daniel Kramer, *Global Scientific Advisor of Clinical Immunogenicity,* **Sanofi, Germany** | **Compendial potency assays and associated biological reference materials**  Dr Disha Dadke *Director, Biological and Biotech* **USP, India** |
| 11:45 **The analysis and characterisation of biosimilars**  Dr Lowell Brady *Scientist, Protein Characterisation* **Sandoz, Germany** | **High-throughput analysis of stability samples**  Melanie Hofmann *Formulation Scientist* **Merck Serono, Germany** | **Immunogenicity strategies for novel products and non-innovators; in vitro biological comparability of biosimilar anti-tnf antibodies**  Dr Zoltan Urbanyi *Deputy Head, Bioanalytics PK/PD,* **Gedeon Richter, Hungary** | **Case study: applications of QbD principles when developing assays**  Dr Franci Weijts *Lead Scientist* **Synthon, Netherlands** |
| 12:15 **Key analytical strategies for the development of biosimilars** Dr. Donna Potts, *Biopharma Market Specialist – EMEA,* **Agilent Technologies** | **The light scattering toolbox for biophysical screening and characterisation of proteins** Felix Deluweit *Application Scientist* **Wyatt Technology Europe** | Please contact luke.pickering@informa.com if you would like to present a spotlight presentation | This presentation will be given by Gyros |

BioANALYTICAL & FORMULATION CONGRESS

# Day One: Tuesday 15th September

| | Protein Characterisation 1 | Formulation 2 | Immunogenicity 3 | Biological Assays 4 |
|---|---|---|---|---|
| 12:45 | **LUNCH** | | | |
| 13:00 | LiveLabs **Bringing the Bioanalytical Industry to Life** For more information please contact luke.pickering@informa.com |  | **Current Participants** Malvern GYROS Immunoassays Miniaturized Productivity Maximized. | |
| 14:00 | **Novel methods for rapid PTM profiling and developability assessment of biologics candidates**  Dr Christian Graf *Biologics Technical Development & Manufacturing,* Novartis Pharma AG Switzerland | **Pre-formulation challenges - ipsen's story**  Dr Tanvir Tabish, *Associate Director,* Ipsen, Denmark | **Immunogenicity strategies for novel products and non-innovators: petides**  Sufyan Maqbool, *Associate Scientist I,* MedImmune, UK | **Assay method development, validation and transfer lifecycle of a gene reporter bioassay**  Julie Svennberg, *Scientist – Bioassay Development Lab,* UCB, Belgium |
| 14:30 | **Analytical development and formulation of early control strategy for a small therapeutic protein**  Dr Abbas Razvi *Principle Scientist* Novartis, Switzerland | **Discussion panel: Early stage formulation strategies**  Dr Shahid Uddin *Head, Formulation* MedImmune, UK  Dr Ahmed Yasin *Head, Formulation and Stability* GSK,UK | **Discussion panel: Immunogenicity strategies for novel molecules** Dr Daniel Kramer *Global Scientific Advisor of Clinical Immunogenicity* Sanofi, Germany Dr Zoltan Urbanyi *Deputy Head, Bioanalytics PK/PD* Gideon Richter, Hungary Sufyan Maqbool *Associate Scientist I* MedImmune, UK | **Validation of cell based neutralisation assays** Dr Sue Charlton, *Senior Project Team Leader,* Public Health England, UK |
| 15:00 | This presentation will be given by Bruker | This presentation is reserved for Unchained Labs | Please contact luke.pickering@informa.com if you would like to present a spotlight presentation | Please contact luke.pickering@informa.com if you would like to present a spotlight presentation |
| 15:30 | **Afternoon Tea and Networking Time** | | | |
| | QbD, Control Strategies and CQAs | | Assay Sensitivity and Assessment | |
| 16:00 | **Analysing protein quality attributes and their change with time**  Dr Yelena Lyubarskaya *Senior Principal Scientist* Biogen Idec, USA | **Protein stability in aqueous solutions; Mechanisms for excipient behaviour**  Professor Robert Falconer *Senior Lecturer* The University of Sheffield, UK | **Assay sensitivity & specificity throughout the drug development life cycle**  Michael G. Tovey *Ph.D., INSERM Director of Research, Laboratory of Biotechnology & Applied Pharmacology, Ecole Normale Supérieure de Cachan* Cachan, France | |
| 16:45 | **Discussion panel: Control strategies for mabs and non-mabs:** Dr Yelena Lyubarskaya *Senior Principal Scientist* Biogen Idec, USA Dr Abbas Razvi, *Principle Scientist,* Novartis, Switzerland | **Monitoring product stability during development**  Katie Tingey, *Formulation Scientist,* MedImmune, UK | **Current methods in immunogenicity assessment of next generation biologics-nanobodies** Annelies Coddens *Scientist* Ablynx, Belgium | |
| 17:15 | **Conclusions from Day One's Chairs** | | | |
| 17:20 | **Networking Drinks and Treasure Hunt** By registering for the congress you are invited to join Informa's BioAnalytical Treasure Hunt. In teams of 10 collect clues to decipher and solve the final anagram to claim the prize | | |  |
| 18:15 | **Registration for Evening Seminar** | | | |

| | Protein Characterisation 1 | Formulation 2 | Bioanalysis 3 | Biological Assays 4 |
|---|---|---|---|---|
| 08:55 | **Chairpersons' Opening Remarks** | | | |
| | Particles, Protein Aggregation and Immunogenicity | | PK/PD Bioanalysis and Biomarkers | Assay Robustness and Method Development |
| 09:00 | **FEATURED SESSION:**<br>**Particles particularised: Particle sources, particulate formulations, particle analytics & biological consequences, in particular**<br>Professor Wim Jiskoot<br>Leiden University, The Netherlands & Coriolis Pharma, Germany | | **Comparability of analytical methods for PK and ADA analysis- HUMIRA A case study**<br>Dr Mario Richter, *Group Leader*<br>Abbvie, Germany | **Optimization of cell based potency assays**<br>Dr Fionola Fogarty, *Cell Based Assay Lead,*<br>MSD, Ireland |
| 09:30 | **Factors governing the performance of established and emerging SVPs characterization methods**<br>Dr Atanas Koulov<br>*Group Head at Analytical Development*<br>Roche, Switzerland | | **Aggregation, immune-complexes and the immunogenicity of antibody therapeutics**<br>Roy Jeffries<br>*Molecular Immunology*<br>Professor University of Birmingham, UK | **Optimization and robustness study of a potency assay using DoE**<br>Dr Jan Amstrup, *Principle Scientist, CMC Bioassay,* Novo Nordisk, Denmark |
| 10:00 | **Discussion panel: The link between particle analysis, protein aggregation and immunogenicity - latest findings**<br>Professor Wim Jiskoot<br>Leiden University, The Netherlands & Coriolis Pharma, Germany<br>Dr Atanas Koulov<br>*Group Head at Analytical Development Roche Biologics,*<br>Roche, Switzerland | | **Generic and specific PK immunoassay formats: what can the quantitation difference tell you about your therapeutic molecule?**<br>Dr Yanmei Lu, *Scientist*<br>Genentech, USA | **Phase appropriate approach for Bioassay development, validation, and new technology implementation in Quality Control laboratories**<br>Dr Elena Belitsky, *Associate Director,*<br>Biogen Idec, USA |
| 10:30 | **Morning Coffee and Networking Break** | | | |
| | Biophysical analysis and higher order structures | Formulation strategies for novel therapies and formulations | PK/PK Bioanalysis and Biomarkers | Assay Robustness and Method Development |
| 11:15 | **Determining the aggregation properties for scFv mutant proteins using fluorescence, NMR, calorimetry, and light scattering methods**<br>Dr Robin Curtis, *Senior Lecturer,*<br>University of Manchester, UK | **Formulation and stability strategies for ADCs**<br>Shan Jiang, *Senior Director, Formulation and Drug Product Sciences,* Seattle Genetics, Inc, USA | **Impact of target interference in PK and ADA assays**<br>Dr Giane Sumner *Director, Assay Development Preclinical Development Department*<br>Regeneron Pharmaceuticals, Inc | **Outsourcing Assay Method Development, Validation and Transfer**<br>Dr Fabienne Deckert-Salva, *Head of Outsourced Bioanalytics,* Novartis, Switzerland |
| 11:45 | **High order structure of biotherapeutic proteins using a combination of biophysical mass spectrometry techniques**<br>Christel Veyssier, *Scientist I, Analytical Biotechnology Science & Strategy,*<br>MedImmune, UK | **Formulation strategies for ADCs – liquid formulations**<br>Dr Alex Lazar, *Head of Analytical and Pharmaceutical Sciences,* Immunogen, USA | **Discussion Panel: Bioanalysis/Biomarkers**<br>Dr Yanmei Lu, *Scientist,* Genentech, USA<br>Dr. Robert Nelson, *Head of Bioanalytical Assay Laboratory,* NovImmune SA<br>Dr Fabienne Deckert-Salva, *Head of Outcourced Bioanalytics,* Novartis, Switzerland<br>Dr Giane Sumner, *Director, Assay Development, Preclinical Development Department* Regeneron Pharmaceuticals, Inc | **Discussion panel: assay method development, validation and optimisation**<br>Dr Elena Belitsky, *Associate Director,* Biogen Idec, USA<br>Julie Svennberg, *Scientist – Bioassay Development Lab,* UCB, Belgium<br>Dr Jan Amstrup, *Principle Scientist, CMC Bioassay,* Novo Nordisk, Denmark<br>Dr Disha Dadke, *Director, Biological and Biotech,* USP, USA |
| 12:15 | This presentation will be given by Europa and Prozyme | **SVP characterisation: Why simply counting shadows leaves you in the dark**<br>Dr Amber Fradkin *Associate Director*<br>KBI Biopharma, USA | Spotlight presentations - please contact luke.pickering@informa.com for more information | Spotlight presentations - please contact luke.pickering@informa.com for more information |

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# Day Two: Wednesday 16th September

| Protein Characterisation 1 | Formulation 2 | Bioanalysis 3 | Biological Assays 4 |
|---|---|---|---|

12:45 **Lunch and Poster Presentations, Including:**

## BioAnalytical Congress Poster Award

**Confirmed poster presenters include:**

**Development and characterisation of a higher throughput N-glycan profiling method for antibodies**
Wilco Brusselaars, MSD, The Netherlands

**Influence of glycerol on lyophilized mab formulations**
Jacqueline Horn, Ludwig-Maximilians-Universität München, Pharmaceutical Technology and Biopharmaceutics; Germany

**Analysis of the physical stability of antibody conjugates**
Corinna Duerr, Ludwig-Maximilians-Universität München, Germany

**In-line filtration of liquid biotech drugs – an easy approach to reduce the immunogenicity risk?**
Benjamin Patrick Werner, Ludwig-Maximilians-University, Germany

To submit a poster please visit the website
www.bioanalyticalcongress.com

## Roundtable discussions

13:00

| Roundtable 1: Biosimilars | | Roundtable 2: Bioanalysis | |
|---|---|---|---|
| The Return of CE | Formulating Novel Biologics | Biomarker Assays and Predictive Biomarkers | Automation and Highthroughput |

14:00

**Enriching the analytical toolbox for viral vaccines with capillary electrophoresis**
Dr Lars Geurink, *Associate Scientist, Analytical Development,* Janssen, Netherlands

**14.20 CE and UPLC are complementary high-hand tools to tune N-glycosylation of therapeutic proteins**
Dr Ana Krstanovic-Anastassiades, *Assistant Scientist, Biotech Process Science Analytics,* Merck Serono, Italy

**Formulation strategies for novel therapies**
Dr John Grimshaw, *Fellow,* Novartis, Switzerland

**Glycans and anti-glycan antibodies – novel biomarkers for diagnostics**
Prof. Dr. Bernd Lepenies, *Professor for Infection Immunology,* University of Veterinary Medicine, Hannover, Germany

**High-throughput assays to detect antibody biophysical properties**
Dr Tingwan Sun, *Scientist,* Adimab, LLC, USA

14:30

**14:40 Enhanced detection of product-related variants and impurities in recombinant glycoproteins**
Francois Griaud *Post-Doctoral Scientist, Biologics Process Research and Development,* Novartis Pharma

**Head-to-head comparison of HESylated and PEGylated proteins**
*Compliance Expert PG Technology/ Site Frankfurt Pharma,* Sanofi, Germany

**Fit-for-purpose inflammatory biomarker assay development and validation**
Dr Robert Nelson, *Head of Bioanalytical Assay Laboratory,* NovImmune SA

**Automation Discussion Panel - New high-throughput methods**
Dr Fabienne Deckert-Salva *Head of Outsourced Bioanalytics,* Novartis, Switzerland
Julie Svennberg, *Scientist – Bioassay Development Lab,* UCB, Belgium

15:00 Please contact luke.pickering@informa.com if you would like to present a spotlight presentation

15:30 **Afternoon Tea and Poster Award Winners Announced**

## Congress Take-Home Messages

16:00

This closing session will address the key take home messages for each stream in an open forum, taking into account the discussions had over the past 2 days.

The main objective is to provide all attendees with information and input from all areas of biopharmaceutical analytics to implement in their business moving forward.

17:00 **End of Congress**

BioANALYTICAL & FORMULATION CONGRESS

Post-Conference Symposium:
Thursday 17th September

# The Challenge of Protein Aggregation and Sub Visible Particles in Biopharmaceuticals

*Registration at 8:30 for a 9.00 start ending no later than 15:00. Morning and lunch breaks are included*

## Introduction

The workshop will address the mechanism of aggregation and the implications on product development. New analytical methods will be presented and discussed and strategies to avoid and reduce aggregation in biopharmaceuticals will also be highlighted. Attendees will gain a critical overview of the complexity and diversity of the aggregation and sub-visible particles of peptide and protein biopharmaceuticals and on strategies to overcome these issues.

## Agenda

- Different aggregation mechanisms will focus on peptide and protein examples
- Available techniques for detection of aggregation and impurities (leachables) and how these methods can be applied. Combining analytical methods to ensure detection of aggregates across a range of particle sizes. New technologies for characterisation of aggregates will be presented.
- Strategies for developing stable peptide drug formulations. High-throughput analysis (HTA) and high-throughput formulation (HTF) platforms will be presented. Using case studies, potential causes of aggregation and prevention strategies will be discussed.
- Aggregation of biopharmaceuticals in human plasma depends on formulation: a new development and research field
- Regulatory aspects and concerns

## Workshop leaders

**Professor Tudor Arvinte,**
Chairman, School of Pharmacy, **Geneva-Lausanne,** Switzerland
and Chairman, CEO,**Therapeomic Inc.** Switzerland

*"An excellent workshop. Very enthusiastic and very experienced in the field."*

**Novo Nordisk**

# Practical Quality By Design for Biopharmaceuticals

*Registration at 8:30 for a 9.00 start ending no later than 15:00. Morning and lunch breaks are included*

## Introduction

Quality by Design is positively encouraged by the EMA and FDA and is now becoming increasingly adopted by biopharmaceutical companies. It has also been coined by some as 'Smart Design'.

Although indicative regulatory guidelines are in place, they tend to only scratch the surface and the devil of course then lies in the detail.

In this workshop we will lift Quality by Design off the page and put it into a tangible context so that the attendees will be able to take way what they have learnt and translate this into real and practical action.

Using a combination of fundamental understanding, case studies and interactive team challenges based on 'real life' Quality by Design scenarios, the workshop will build into a useful framework that can be used to underpin putting Quality by Design into place in the workplace.

## Agenda

- Quality by Design strategies
- Dissection of component QbD parts
- Adaptation to different product classes
- Defining the target product profile
- Process and material risk evaluations and control
- Derivation and Validation of Design Spaces
- Establishing a final Control Strategy
- Incorporating QbD as part of the quality and operational systems
- Meeting regulatory expectation
- Incorporation of QbD into dossier submissions
- Approaches and experience with the EMA and FDA
- Leveraging Quality and Regulatory flexibilities

## Workshop leader:

**Dr Richard Dennett,** Director,
**Voisin Consulting Life Sciences,**
France

# Present a Poster at BioAnalytical Poster Hall - €100 prize for top two posters

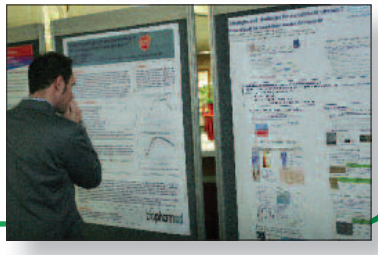
Sponsored and judged by BioANALYTICAL & FORMULATION CONGRESS

Why not consider presenting a poster at this conference to derive more value from attending. Share your research with your peers and learn from other posters as well. Many attendees tell us that being selected for a poster presentation helps to facilitate their company approve process to attend the conference.

All poster abstracts received by Wednesday 9 September 2015 and presented at the 2015 BioAnalytical & Formulation Congress are automatically eligible for the Poster Award competition sponsored by the BioAnalytical and Formulation Congress.

Posters will be reviewed and judged by our Scientific Advisory Board.

To submit your poster and for additional details on deadlines and the poster size and regulations, please visit: www.bioanalyticalcongress.com or email sarah.lintern@informa.com



# BioANALYTICAL & FORMULATION CONGRESS

Co-located with Analytical Method Development & Validation

## Accelerate your business at the International BioAnalytical & Formulation Congress 2015

## **Vital Statistics** from 2014

**5** conferences

**1** location

**75:25**
buyer vs seller attendee ratio

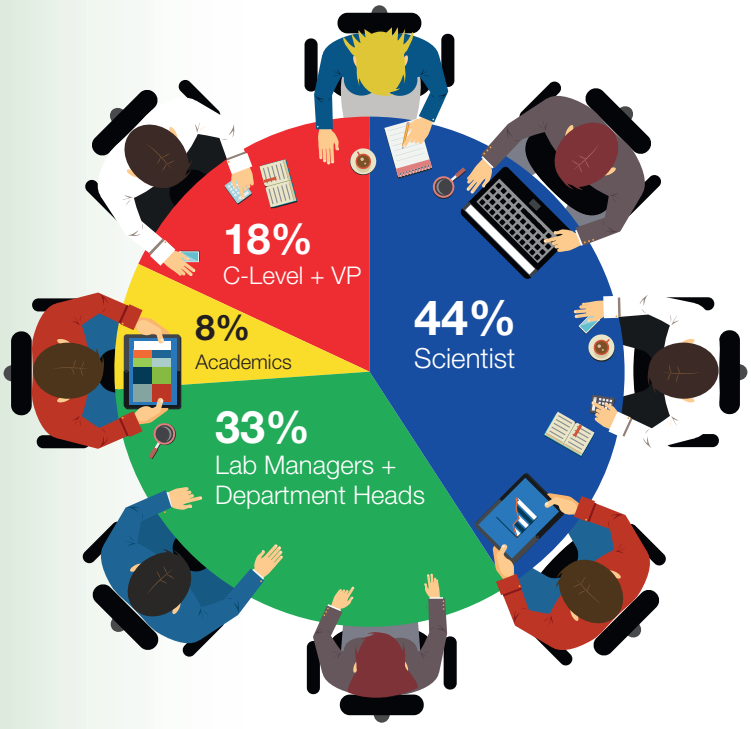
**9/10** Top 10 Pharma companies were present

**130+**
Companies

**10%**
Event Growth

**280+**
Attendees

## Primary Audience Breakdown




## Industry Partners Already in Attendance

MERCK, SANOFI, Intertek, Gedeon Richter, nibrt, ucb, MedImmune, WYATT, Manchester 1824, IPSEN, USP, UNCHAINED LABS, KBI, novo nordisk, Ablynx, NOVARTIS, REGENERON, GENOVIS, ImmunoGen, Inc., Adimab, biogen idec, Roche, novimmune, MSD, Genentech, Biogen, Agilent Technologies, SeattleGenetics, gsk, Public Health England, Malvern, BRUKER, ANA RIO TEC, anacura, QUALITY ASSISTANCE, atlanbio, GYROS

To register or for the latest information, please visit: www.bioanalyticalcongress.com Tel: +44 (0)20 7017 7481 Email: registrations@informa-ls.com

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*" Very good opportunity to meet leaders in the field"*

*" Overall the conference was very good with great presentations"*

NOVARTIS

Crucell

BRUKER

*"Good meeting for europe (we need more of these!) Nice to meet a broad mix of people"*

## Attendee job title break down

Bioanalytics • Bioassay development • Quality control • Quality Assistance R&D • CMC • Principle Scientist • Method Development • Biophysical Analytics • Characterisation Production & Analysis • Analytical Development • Preclinical Development • Formulation Scientist • Protein Analytics • Protien Biophysics & Formulation Bioanalytical Assay • Pharmacology • BioFormulations • Researcher

For more information on the opportunities available please contact Luke Pickering

Email: luke.pickering@informa.com

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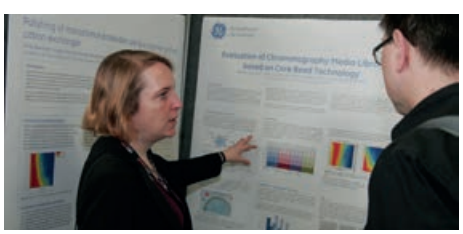

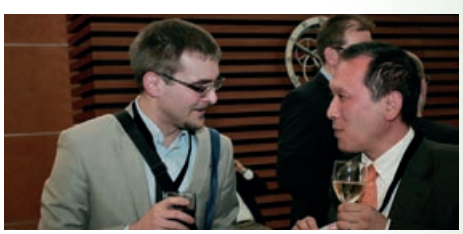

BioANALYTICAL & FORMULATION CONGRESS

15th-16th September 2015
Maritim proArte Hotel, Berlin, Germany
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| 2 day pass: Conference only | £1599 + VAT | £200 | £1699 + VAT | £100 | £1799 + VAT | - |
| 2 day pass: Conference + Evening Seminar | £2098 + VAT | £200 | £2198 + VAT | £100 | £2298 + VAT | - |
| 3 day pass: Conference + 1 symposium | £2298 + VAT | £200 | £2398 + VAT | £100 | £2498 + VAT | - |
| 3 day pass : Conference + 1 symposium + 1 Evening Seminar | £2697 + VAT | £300 | £2797 + VAT | £200 | £2897 + VAT | £100 |
| 4 day pass: Conference + 2 symposiums + FREE evening seminar | £2997 + VAT | £700 | £3097 + VAT | £600 | £3197 + VAT | £500 |

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| ☐ Immunogenicity Masterclass | | ☐ Practical Quality By Design for Biopharmaceuticals |

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APPENDIX

# Conference Abstracts

## Latest Updates on Host Cell Proteins

08:00 **Morning coffee and registration**

08.55 **Chairperson's opening remarks**

09:00 **Latest updates on forthcoming USP host cell protein paper**

A member of the US Pharmacopea's Expert Committee on Host Cell Proteins

## Plenary Discussion Panel: Current Challenges and Opportunities in Bioanalytics and Formulation

09:40

- Current challenges in analytical methods for biologics
- Lifecycle management for analytics
- Analytical / Formulation support for regulatory filings and accelerated programmes
- Real time release testing
- New technologies – what gaps still remain?

**Dr Alistair Kippen**
*Director*
**Analytical Biotechnology**
**MedImmune, UK**

**Dr Bernardo Perez-Ramirez**
*Senior Director*
**BioFormulations, Sanofi, USA**

**Dr Annick Gervais**
*Director, Analytical Development*
**UCB, Belgium**

**Dr Alex Lazar**
*Head of Analytical and Pharmaceutical Sciences,*
**Immunogen, USA**

**Dr Yelena Lyubarskaya**
*Senior Principal Scientist*
**Biogen Idec, USA**

A member of the US Pharmacopea's Expert Committee on Host Cell Proteins

10:30 **Morning Coffee and Networking**

# Protein Characterisation 1

**Chairpersons' Opening Remarks**

Characterisation and Quantification of Biologics

11:15 **Improving the speed, quantification and quality of biological characterisation**

**Dr Jonathon Bones**
*Principal Investigator*
**NIBRT, Ireland**

11:45 **The analysis and characterisation of biosimilars**

**Dr Lowell Brady**
*Scientist, Protein Characterisation*
**Sandoz, Germany**

12:15 **Key analytical strategies for the development of biosimilars**

**Dr. Donna Potts,** *Biopharma Market, Specialist – EMEA,*
**Agilent Technologies**

12:45 **LUNCH**

13:00

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**Current Participants**
Malvern GYROS

14:00 **Novel methods for rapid PTM profiling and developability assessment of biologics candidates**

Early profiling of critical post-translational modifications is important for developability risk assessment and lead selection of biotherapeutic drug candidates. This talk presents workflows and case studies using antibody subunit analysis with novel automated UPLC-MS methods and software, allowing for a rapid modification screening and quantification of low concentrated IgG candidate samples in much higher throughput.

**Dr Christian Graf**
*Biologics Technical Development & Manufacturing,* **Novartis Pharma AG Switzerland**

14:30 **Analytical development and formulation of early control strategy for a small therapeutic protein**

**Dr Abbas Razvi,**
*Principle Scientist*
**Novartis, Switzerland**

15:00 This presentation will be given by Bruker

# Protein Characterisation 1

15:30 **Afternoon Tea and Networking Time**

## QbD, Control Strategies and CQAs

16:00 **Analysing protein quality attributes and their change with time**

Understanding of critical quality attributes (CQAs) of biologics is essential in biopharmaceutical development and production. Often, the CQA assignment is built upon prior knowledge and results derived from In Vitro studies, although the relevance of those may be incomplete. In this work, we are investigating the quality attributes of biopharmaceuticals using clinical samples. This approach will allow us to obtain dynamic In Vivo proteoform information. This information will enable more thorough understanding of the product quality attributes, will guide the development of appropriate process control strategy, optimize quality and yield of biopharmaceutical manufacturing, establish scientifically based specifications. As biopharmaceuticals have a large number of quality attributes, it is challenging to fully evaluate the impact of these attributes on safety and efficacy. Residual uncertainties in the CQA identification may impact the development of the process control strategy. This issue is becoming more pressing as the increasing process yields result in the limited number of batches used in clinical trials, which narrows the clinical experience. In order to gain more insights into the criticality of product attributes in relevant systems, we are characterizing quality attributes' changes in vivo, i.e. in clinical samples. Due to the complexity of human serum and similarities between endogenous and recombinant IgGs, specific enrichment of the drug is necessary. Affinity purification has been used for target enrichment. Enzymatic digestion, and on-line LC/MS is utilized for sample characterization due to its sensitivity, selectivity, and ability to provide rich qualitative and quantitative information

**Dr Yelena Lyubarskaya**
*Senior Principal Scientist*
**Biogen Idec, USA**

16:45 **Discussion panel: Control strategies for mabs and non-mabs:**

**Dr Yelena Lyubarskaya**
*Senior Principal Scientist,* **Biogen Idec, USA**
**Dr Abbas Razvi,** *Principle Scientist*
**Novartis, Switzerland**

17:15 **Conclusions from Day One's Chairs**

17:20 **Networking Drinks and Treasure Hunt**

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18:15 **Registration for Evening Seminar**

08:55 **Chairpersons' Opening Remarks**

## Particles, Protein Aggregation and Immunogenicity

09:00 **FEATURED SESSION:**
**Particles particularised: Particle sources, particulate formulations, particle analytics & biological consequences, in particular**

**Professor Wim Jiskoot**
**Leiden University, The Netherlands &**
**Coriolis Pharma, Germany**

09:30 **Factors governing the performance of established and emerging SVPs characterization methods**

**Dr Atanas Koulov,**
*Group Head at Analytical Development*
**Roche, Switzerland**

10:00 **Discussion panel: The link between particle analysis, protein aggregation and immunogenicity - latest findings**

**Professor Wim Jiskoot**
**Leiden University, The Netherlands &**
**Coriolis Pharma, Germany**

**Dr Atanas Koulov**
*Group Head at Analytical Development Roche Biologics,* **Roche, Switzerland**

10:30 **Morning Coffee and Networking Break**

## Biophysical analysis and higher order structures

11:15 **Determining the aggregation properties for scFv mutant proteins using fluorescence, NMR, calorimetry, and light scattering methods**

Predicting aggregation propensity from knowledge of protein structural properties and experimental measures remains a challenging task. In this work, we have generated a series of scFv mutants by introducing salt bridges, overcharging, reducing hydorphobicity, and by charge neutral mutations of arginine to lysine. The aggregation behaviour under accelerated conditions has been characterized extensively using a suite of experimental methods. The results provide insight into the limitations of assessing aggregation propensity from traditional measures of conformational and colloidal stability, and point towards developing novel approaches for characterizing interactions between partially folded states.

**Dr Robin Curtis,** *Senior Lecturer,* **University of Manchester, UK**

# Protein Characterisation 1

11:45 **High order structure of biotherapeutic proteins using a combination of biophysical mass spectrometry techniques**

Christel Veyssier
*Scientist I, Analytical Biotechnology Science & Strategy,* **MedImmune, UK**

12:15 This presentation will be given by Europa and Prozyme

12:45 **Lunch and Poster Presentations, Including:**

## BioAnalytical Congress Poster Award

**Confirmed poster presenters include:**

**Development and characterisation of a higher throughput N-glycan profiling method for antibodies**
Wilco Brusselaars, MSD, The Netherlands

**Influence of glycerol on lyophilized mab formulations**
Jacqueline Horn, Ludwig-Maximilians-Universität München, Pharmaceutical Technology and Biopharmaceutics; Germany

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**In-line filtration of liquid biotech drugs – an easy approach to reduce the immunogenicity risk?**
Benjamin Patrick Werner, Ludwig-Maximilians-University, Germany

To submit a poster please visit the website
www.bioanalyticalcongress.com

## Roundtable discussions

13:00 Roundtable 1: Biosimilars

The Return of CE

14:00 **Enriching the analytical toolbox for viral vaccines with capillary electrophoresis**

Dr Lars Geurink, *Associate Scientist, Analytical Development,*
**Janssen, Netherlands**

14.20 **CE and UPLC are complementary high-hand tools to tune N-glycosylation of therapeutic proteins**

Dr Ana Krstanovic-Anastassiades, *Assistant Scientist, Biotech Process Science Analytics,* **Merck Serono, Italy**

14:40 **Enhanced detection of product-related variants and impurities in recombinant glycoproteins**
Monitoring and controlling post-translational modifications (PTMs) in recombinant glycoproteins is a requirement to ensure manufacturing process consistency and product quality. Aside the well-described examples like glycosylation or deamidation of amide groups the analyst may face the challenging task of detecting less predictable product-related variants and impurities. This presentation will focus on different mass spectrometry and data analysis approaches to enable the semi-automated detection of such variants and impurities during technical development.

Francois Griaud
*Post-Doctoral Scientist, Biologics Process Research and Development*
**Novartis Pharma**

15:00 Please contact luke.pickering@informa.com if you would like to present a spotlight presentation

15:30 **Afternoon Tea and Poster Award Winners Announced**

## Congress Take-Home Messages

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**Analytical Biotechnology**
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*Senior Director*
**BioFormulations, Sanofi, USA**

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**UCB, Belgium**

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*Senior Principal Scientist*
**Biogen Idec, USA**

A member of the US Pharmacopea's
Expert Committee on Host Cell Proteins

10:30 **Morning Coffee and Networking**

# Formulation 2

**Chairpersons' Opening Remarks**

### De-Risking Candidate Molecules

11:15 **FEATURED PRESENTATION: De-risking candidate molecules and identification of critical quality attributes**

**Bernardo Perez-Ramírez**
*Senior Scientific Director, BioFormulations Development, Global Biotherapeutics,* **Sanofi**

11:45 **High-throughput analysis of stability samples**
Focusing on early candidate selection and formulation development of high concentration protein formulations, low volume high throughput tools for simultaneous assessment of thermal and colloidal stability were developed and fitted to the requirements of limited sample volumes and the need for increased sample throughput.

**Melanie Hofmann**
*Formulation Scientist*
**Merck Serono, Germany**

12:15 **The light scattering toolbox for biophysical screening and characterisation of proteins**

**Felix Deluweit**
*Application Scientist*
**Wyatt Technology Europe**

12:45 **LUNCH**

13:00

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**Current Participants**
Malvern GYROS

14:00 **Pre-formulation challenges - ipsen's story**

**Dr Tanvir Tabish,** *Associate Director,* **Ipsen, Denmark**

# Formulation 2

14:30 **Discussion panel: Early stage formulation strategies**


Dr Shahid Uddin
*Head, Formulation*
MedImmune, UK


Dr Ahmed Yasin
*Head, Formulation and Stability,* GSK,UK

15:00 This presentation is reserved for Unchained Labs`

15:30 **Afternoon Tea and Networking Time**

## QbD, Control Strategies and CQAs

16:00 **Protein stability in aqueous solutions; Mechanisms for excipient behaviour**


Professor Robert Falconer
*Senior Lecturer*
The University of Sheffield, UK

16:45 **Monitoring product stability during development**


Katie Tingey
*Formulation Scientist*
MedImmune, UK

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Dr Atanas Koulov
*Group Head at Analytical Development Roche Biologics,* Roche, Switzerland

10:30 **Morning Coffee and Networking Break**

## Biophysical analysis and higher order structures

11:15 **Formulation and stability strategies for ADCs**


Shan Jiang, *Senior Director, Formulation and Drug Product Sciences,*
Seattle Genetics, Inc, USA

11:45 **Formulation strategies for ADCs – liquid formulations**


**Dr Alex Lazar**
*Head of Analytical and Pharmaceutical Sciences,*
Immunogen, USA

12:15 **SVP characterisation: Why simply counting shadows leaves you in the dark**

Dr Amber Fradkin
*Associate Director*
KBI Biopharma, USA

# Formulation 2

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## BioAnalytical Congress Poster Award

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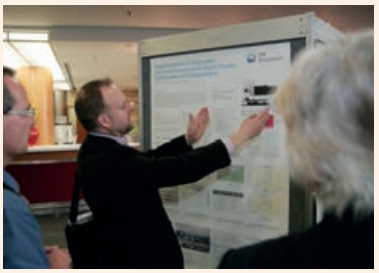

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## Roundtable discussions

13:00 Roundtable 1: Biosimilars

Formulating Novel Biologics

14:00 **Formulation strategies for novel therapies**

Dr John Grimshaw, *Fellow,* Novartis, Switzerland

NOVARTIS

14:30 **Head-to-head comparison of HESylated and PEGylated proteins**

*Compliance Expert PG Technology/ Site Frankfurt Pharma,* Sanofi, Germany

SANOFI

15:00 Please contact luke.pickering@informa.com if you would like to present a spotlight presentation

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**Immunogen, USA**

**Dr Yelena Lyubarskaya**
*Senior Principal Scientist*
**Biogen Idec, USA**

A member of the US Pharmacopea's Expert Committee on Host Cell Proteins

10:30 **Morning Coffee and Networking**

# Immunogenicity 3

**Chairpersons' Opening Remarks**

Immunogencity Strategies for Novel Products and Non-Innovators

11:15 **FEATURED PRESENTATION: Current status of immunogenicity**

**Dr Daniel Kramer,** *Global Scientific, Advisor of Clinical Immunogenicity,* **Sanofi, Germany**

11:45 **Immunogenicity strategies for novel products and non-innovators; in vitro biological comparability of biosimilar anti-tnf antibodies**

**Dr Zoltan Urbanyi**
*Deputy Head, Bioanalytics PK/PD,* **Gedeon Richter, Hungary**

12:15 Please contact luke.pickering@informa.com if you would like to present a spotlight presentation

12:45 **LUNCH**

13:00



14:00 **Immunogenicity strategies for novel products and non-innovators: petides**

Assessment of Immunogenicity is vital to understanding the immunogenic potential of a drug. Additionally this provides an indication of the safety and efficacy of a drug and is thus a regulatory requirement during preclinical and clinical testing. This first peptide molecule at MedImmune presented unique bioanalytical challenges compared to traditional molecules; the construct required careful consideration when developing a bridging immunogenicity assay on the Meso Scale Discovery (MSD®) platform, the preferred choice for anti-drug antibody (ADA) assays. In this assay, biotin and SULFO-TAG–labelled drug served as the capture and detection reagents respectively and were incubated together with samples containing ADA. The relatively small size of peptide molecule presented unique challenges in ensuring that drug could be adequately labelled and to result in a reliable and robust ADA assay. With careful consideration to these challenges, peptide molecule was successfully labelled and characterised to allow development of robust assays for both the preclinical and clinical assays, with the required sensitivity and drug tolerance for each. The assays supported rat and cyno GLP toxicology studies and the ongoing First-Time in Human Single Ascending Dose (SAD) study.

**Sufyan Maqbool**
*Associate Scientist I*
**MedImmune, UK**

MedImmune
A member of the AstraZeneca Group

14:30 **Discussion panel: Immunogenicity strategies for novel molecules**

**Dr Daniel Kramer,** *Global Scientific Advisor of Clinical Immunogenicity,* **Sanofi, Germany**
**Dr Zoltan Urbanyi,** *Deputy Head, Bioanalytics PK/PD,* **Gideon Richter, Hungary**
**Sufyan Maqbool,** *Associate Scientist I* **MedImmune, UK**

# Immunogenicity 3

15:00 Please contact luke.pickering@informa.com if you would like to present a spotlight presentation

15:30 **Afternoon Tea and Networking Time**

Assay Sensitivity and Assessment

16:00 **Assay sensitivity & specificity throughout the drug development life cycle**

Michael G. Tovey, *Ph.D., INSERM Director of Research, Laboratory of Biotechnology & Applied Pharmacology, Ecole Normale Supérieure de Cachan,* **Cachan, France**

16:45 **Current methods in immunogenicity assessment of next generation biologics-nanobodies**
Nanobodies® are a novel class of therapeutic proteins derived from naturally occurring mammalian single-chain antibodies. Combinable as modular compounds based on single-domain antibody fragments, Nanobodies are developed for a range of serious human diseases, including inflammation, hematology, oncology and pulmonary disease. Immunogenicity of the Nanobodies is assessed during pre-clinical and clinical studies using anti-drug antibody (ADA) assays, neutralizing Ab assays and/or characterization assays (isotyping). These ADA assays are developed based on a fit-for-purpose strategy with special focus to improve drug and target tolerance characteristics using various strategies (i.e. optimized master mixture concentrations of biotinylated and sulfo-tagged drug in a homogeneous bridging ADA assay, protein G pre-treatment, BEAD, target-capturing strategies, etc.), as illustrated by different case studies.

Annelies Coddens
*Scientist*
**Ablynx, Belgium**

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PK/PD Bioanalysis and Biomarkers

09:00 **Comparability of analytical methods for PK and ADA analysis- HUMIRA A case study**

Dr Mario Richter
*Group Leader*
**Abbvie, Germany**

09:30 **Aggregation, immune-complexes and the immunogenicity of antibody therapeutics**
Many parameters may potentiate the development of anti-drug antibodies (ADA) to recombinant protein therapeutics. The presence of aggregated protein is considered a particular risk and much effort is expended to characterize and eliminate aggregated material. However, IgG antibody therapeutics are administered with the purpose of forming immune complexes (aggregates) that may be directed to cellular compartments that process antigen for presentation and ADA generation. Increased attention should be given to characterizing immune complexes formed on administration of antibody drugs whilst developing protocols to induce immune tolerance and/or immunosuppression, in order to circumvent the development of ADA.

Roy Jeffries
*Molecular Immunology*
**Professor University of Birmingham, UK**

10:00 **Generic and specific PK immunoassay formats: what can the quantitation difference tell you about your therapeutic molecule?**
During the development of large molecule therapeutics, measuring drug concentrations in biological fluid or tissues are required for PK, PK/PD and efficacy studies in preclinical animal models. When using both generic and specific immunoassay formats, the assay result discrepancy and agreement often provides early indication of molecule stability as well as target engagement in vivo. Case studies of in vivo degradation, aggregation, deamination and soluble target interference for therapeutic Fc fusion proteins and monoclonal antibodies will be presented.

Dr Yanmei Lu
*Scientist*
**Genentech, USA**

10:30 **Morning Coffee and Networking Break**

PK/PD Bioanalysis and Biomarkers

11:15 **Impact of target interference in PK and ADA assays**

Dr Giane Sumner
*Director, Assay, Development, Preclinical Development Department*
**Regeneron Pharmaceuticals, Inc**

# Immunogenicity 3

11:45 **Discussion Panel: Bioanalysis/Biomarkers**
Dr Yanmei Lu, *Scientist,* Genentech, USA
Dr. Robert Nelson, *Head of Bioanalytical Assay Laboratory,* NovImmune SA
Dr Fabienne Deckert-Salva, *Head of Outcourced Bioanalytics,* Novartis, Switzerland
Dr Giane Sumner, *Director, Assay Development, Preclinical Development Department* Regeneron Pharmaceuticals, Inc

12:15 Spotlight presentations - please contact luke.pickering@informa.com for more information

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## Roundtable discussions

13:00 Roundtable 2: Bioanalysis

### Biomarker Assays and Predictive Biomarkers

14:00 **Glycans and anti-glycan antibodies – novel biomarkers for diagnostics**

Prof. Dr. Bernd Lepenies, *Professor for Infection Immunology,* University of Veterinary Medicine, Hannover, Germany

14:30 **Fit-for-purpose inflammatory biomarker assay development and validation**
The clinical phases of novel drug development are associated with a high attrition rate and so it is essential to have measurable endpoints that predict desired or undesired clinical outcomes. The combination of target engagement and disease-related biomarkers enhances understanding of the mechanism of action, facilitates early proof-of-concept and increases the efficiency of early clinical development with improved quality of decision-making. Here, we describe a tiered approach to biomarker assay development and validation to support a monoclonal antibody (mAb) clinical development program for the treatment of an inflammatory disorder. During an observational study in the intended disease-state population, screening of a large panel of inflammatory biomarkers of interest was performed to assess which best correlated with disease activity. To support Phase II studies, where small numbers of patients were treated to assess the safety and efficacy of the therapeutic mAb, a multiplex assay was developed and qualified on the Luminex® platform to allow verification of the 6 lead biomarkers. For Phase III studies, further development and validation of key biomarker assays, of target engagement and disease activity, was performed on the Meso Scale Discovery (MSD®) platform.

Dr Robert Nelson, *Head of Bioanalytical Assay Laboratory,* NovImmune SA

15:00 Please contact luke.pickering@informa.com if you would like to present a spotlight presentation

15:30 **Afternoon Tea and Poster Award Winners Announced**

## Congress Take-Home Messages

16:00 This closing session will address the key take home messages for each stream in an open forum, taking into account the discussions had over the past 2 days.

The main objective is to provide all attendees with information and input from all areas of biopharmaceutical analytics to implement in their business moving forward.

17:00 **End of Congress**

## Latest Updates on Host Cell Proteins

08:00 **Morning coffee and registration**

08.55 **Chairperson's opening remarks**

09:00 **Latest updates on forthcoming USP host cell protein paper**

A member of the US Pharmacopea's
Expert Committee on Host Cell Proteins

## Plenary Discussion Panel: Current Challenges and Opportunities in Bioanalytics and Formulation

09:40

- Current challenges in analytical methods for biologics
- Lifecycle management for analytics
- Analytical / Formulation support for regulatory filings and accelerated programmes
- Real time release testing
- New technologies – what gaps still remain?

**Dr Alistair Kippen**
*Director*
**Analytical Biotechnology**
**MedImmune, UK**

**Dr Bernardo Perez-Ramirez**
*Senior Director*
**BioFormulations, Sanofi, USA**

**Dr Annick Gervais**
*Director, Analytical Development*
**UCB, Belgium**

**Dr Alex Lazar**
*Head of Analytical and Pharmaceutical Sciences,*
**Immunogen, USA**

**Dr Yelena Lyubarskaya**
*Senior Principal Scientist*
**Biogen Idec, USA**

A member of the US Pharmacopea's
Expert Committee on Host Cell Proteins

10:30 **Morning Coffee and Networking**

# Biological Assays 4

**Chairpersons' Opening Remarks**

Regulatory Update and Assay Development

11:15 **Compendial potency assays and associated biological reference materials**
USP, regulators, and manufacturers share a common goal of reducing in vivo testing yet, replacing animal assays with suitable in vitro assays may be challenging. This presentation will highlight USP's current efforts to include modern bioassays in the USP-NF as well as bridging expectations for revision sponsors who would like to propose a modern assay for the compendium.

**Dr Disha Dadke**
*Director, Biological and Biotech,* **USP, India**

11:45 **Case study: applications of QbD principles when developing assays**
Principles of quality by design can be applied to development of biological assays and offer advantages over conventional biological assay development procedures. This will be illustrated by a case study on the development of a cell based potency method for an immune modulating compound aimed at treatment of MS symptoms. During method optimization the design space was determined using DOE strategy to allocate main effects and interactions between parameters. Since qualification and setting of system suitability limits, the method has been operational and in control for over 1.5 years. Control charts are in place to monitor curve fit parameters, control sample recovery, and method variation in real time.

**Dr Franci Weijts**
*Lead Scientist*
**Synthon, Netherlands**

12:15 This presentation will be given by Gyros

12:45 **LUNCH**

13:00

# Biological Assays 4

14:00 **Assay method development, validation and transfer lifecycle of a gene reporter bioassay**

**Julie Svennberg**, *Scientist – Bioassay Development Lab*, **UCB, Belgium**

14:30 **Validation of cell based neutralisation assays**
PHE have established cell based assays to support the development, manufacture and release of anthrax vaccines. These can be applied to measure the potency of vaccines and the functional activity of anti-Bacillus anthracis antibodies raised in vaccinees and therefore have a role in vaccine development, pre-clinical studies, stability testing, batch release and clinical trials. This talk will describe the validation of one such cell based assay.

**Dr Sue Charlton**, *Senior Project Team Leader*, **Public Health England, UK**

15:00 Please contact luke.pickering@informa.com if you would like to present a spotlight presentation

15:30 **Afternoon Tea and Networking Time**

## Assay Sensitivity and Assessment

14:30 **Assay sensitivity & specificity throughout the drug development life cycle**

**Michael G. Tovey**, *Ph.D., INSERM Director of Research, Laboratory of Biotechnology & Applied Pharmacology, Ecole Normale Supérieure de Cachan*, **Cachan, France**

14:30 **Drug tolerant assays for anti-drug antibodies**

**Annelies Coddens**
*Scientist*
**Ablynx, Belgium**

17:15 **Conclusions from Day One's Chairs**

17:20 **Networking Drinks and Treasure Hunt**
By registering for the congress you are invited to join Informa's BioAnalytical Treasure Hunt. In teams of 10 collect clues to decipher and solve the final anagram to claim the prize

18:15 **Registration for Evening Seminar**

08:55 **Chairpersons' Opening Remarks**

## Assay Robustness and Method Development

09:00 **Optimization of cell based potency assays**

**Dr Fionola Fogarty**
*Cell Based Assay Lead*
**MSD, Ireland**

09:30 **Aggregation, immune-complexes and the immunogenicity of antibody therapeutics**
**Optimization and robustness study of a potency assay using DoE**
Potency determination is an important part of the quality assessment/control. According to ICH Guideline Q6B, potency must be evaluated by using well-characterized and validated bioactivity assays. A bioassay is often validated at phase I/II, but during the biologic's life cycle, the assay often needs optimization and refinement, to fulfil both internal and external requirements. Here the optimization of a bioassay used at Novo Nordisk A/S for potency determination of a biopharmaceutical protein will be shown. By implementing Design of Experiments (DoE) in the optimization process, nine assay factors and four factor interactions based on time consumption and complexity of buffers were evaluated. By using DoE the factors were simultaneously evaluated in an efficient and effective manner. The conclusions drawn from statistical analysis of the results obtained from the DoE provided improved assay conditions and settings that were successfully evaluated in a proof of concept assay. Furthermore, how to implement the optimizations will be discussed with regard to validation status of the assay.

**Dr Jan Amstrup**
*Principle Scientist, CMC Bioassay*
**Novo Nordisk, Denmark**

10:00 **Phase appropriate approach for Bioassay development, validation, and new technology implementation in Quality Control laboratories**

**Dr Elena Belitsky**
*Associate Director*
**Biogen Idec, USA**

10:30 **Morning Coffee and Networking Break**

## Assay Robustness and Method Development

# Biological Assays 4

11:15 **Outsourcing Assay Method Development, Validation and Transfer**

Dr Fabienne Deckert-Salva, *Head of Outsourced Bioanalytics*, **Novartis, Switzerland**

11:45 **Discussion panel: assay method development, validation and optimisation**
Dr Elena Belitsky, *Associate Director,* **Biogen Idec, USA**
Julie Svennberg, *Scientist – Bioassay Development Lab,* **UCB, Belgium**
Dr Jan Amstrup, *Principle Scientist, CMC Bioassay,* **Novo Nordisk, Denmark**
Dr Disha Dadke, *Director, Biological and Biotech,* **USP, USA**

12:15 Spotlight presentations - please contact luke.pickering@informa.com for more information

12:45 **Lunch and Poster Presentations, Including:**

## BioAnalytical Congress Poster Award

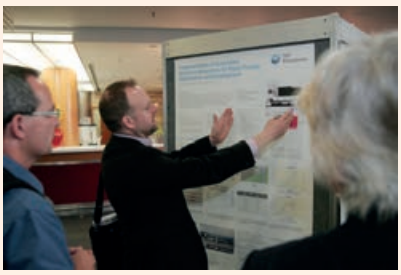
**Confirmed poster presenters include:**

**Development and characterisation of a higher throughput N-glycan profiling method for antibodies**
Wilco Brusselaars, MSD, The Netherlands

**Influence of glycerol on lyophilized mab formulations**
Jacqueline Horn, Ludwig-Maximilians-Universität München, Pharmaceutical Technology and Biopharmaceutics; Germany

**Analysis of the physical stability of antibody conjugates**
Corinna Duerr, Ludwig-Maximilians-Universität München, Germany

**In-line filtration of liquid biotech drugs – an easy approach to reduce the immunogenicity risk?**
Benjamin Patrick Werner, Ludwig-Maximilians-University, Germany



To submit a poster please visit the website
www.bioanalyticalcongress.com

## Roundtable discussions

13:00 Roundtable 1: Biosimilars

## Automation and Highthroughput

14:00 **High-throughput assays to detect antibody biophysical properties**
Antibody drug discovery is often challenged for selection of highly developable leads with minimum downstream issues. Here we reported using high-throughput assays to detect antibody biophysical properties including self-interaction and cross-interaction for more than 100 approved, Ph3, & Ph2 antibody drugs. Approved mAbs exhibit lower levels of self- and cross-interaction than mAbs earlier in development. Cross-interaction can be reduced by directed evolution. These measures may be helpful in clone prioritization for development in the future.

Dr Tingwan Sun
*Scientist*
**Adimab, LLC, USA**

14:30 **Automation Discussion Panel - New high-throughput methods**

Dr Fabienne Deckert-Salva
*Head of Outsourced Bioanalytics*
**Novartis, Switzerland**

Julie Svennberg
*Scientist – Bioassay Development Lab,*
**UCB, Belgium**

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