

11<sup>th</sup> Edition

# Biologics Formulation Development and Drug Delivery

Foster the stability and robustness of your formulation through all the processes to ensure a safe delivery to patients

Amsterdam, The Netherlands

22<sup>nd</sup> – 23<sup>rd</sup> October 2020

Firms should focus on developing a **holistic vision** as well as utilising **new modelling** and analytical tools to enhance their **formulation process**

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## Attending This Premier **marcus evans** Conference Will Enable You to

- **Discover** how you can design robust formulation by developing quality model processes and predicting the behaviour of proteins throughout their lifecycle
- **Learn** how to improve the formulation stability for various vaccines, molecules, and high-concentration liquid forms
- **Consider** manufacturing and scale-up challenges to fostering your formulation
- **Explore** how to optimise drug delivery for biologics

## Learn from Key Practical Case Studies

- **Sanofi Pasteur** explore how to optimise formulation and stability prediction for biologics
- **Coriolis Pharma** examine the challenges of measuring aggregation and conformational changes for biologics
- **Janssen** address challenges around the formulation and stability of non-protein biological molecules
- **Queen's University Belfast** explain how 3D printed devices can improve biopharmaceutical drug delivery

## Media Partners



the **Medicine Maker**

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## Expert Speaker Panel

### Carsten Worsøe

Principal Scientist, Extractables and Leachables  
**Novo Nordisk**

### Dr. Martin Hülsmeier

Senior Principal Scientist, Head of HTS Operations and Analytics  
**AbbVie**

### Jonas Fransson

Director, Drug Product Development  
**Swedish Orphan Biovitrum**

### Olivier Brass

Senior Scientist, Head of Research Unit  
**Sanofi Pasteur**

### Dr. Klaus Richter

Expert Scientist and Group Leader AUC  
**Coriolis Pharma**

### Dimitrios Lamprou

Reader in Pharmaceutical Engineering  
**Queen's University Belfast**

### Jörg Plaschke

Lab Head, Biologics Formulation Development  
**Merck**

### Dr. Raj Singh Thakur

Reader in Pharmaceutics  
**Queen's University Belfast**  
Founder, CTO  
**Re-Vana Therapeutics**

### Philip Corner

Scientist, Downstream Processing, Biologics  
**Centre for Process Innovation Limited**

### Benjamin Werner

Scientist, Formulation Development  
**Boehringer Ingelheim**

### Vasco Filipe

Section Head, Drug Development of Biologics  
**Sanofi**

### Dr Driton Vllasaliu

Lecturer in Pharmaceutics  
**King's College London**

### Yinan Chen

Scientist, Formulation Development  
**Janssen**

### Geoff Smith

Professor of Pharmaceutical Process Analytical Technology  
**De Montfort University**

### Joël Richard

Chief Development Officer, Drug Development Operations  
**MedinCell**

### Florie Schild

BRD Europe – Formulation and Stability Unit  
**Sanofi R&D**

## Thursday 22<sup>nd</sup> October 2020

08.30 Registration and Coffee

09.00 Opening Address from the Chair

DESIGN ROBUST FORMULATION PROCESSES BY DEVELOPING QUALITY MODELS AND ASSURING THE BEHAVIOUR OF BIOLOGICS THROUGHOUT THEIR LIFECYCLE

09.15 **High-throughput platform for vaccine development**

- Formulation development strategy
- Vaccine formulation screening
- Antigen/adjuvant interactions characterisation

**Florie Schild**

BRD Europe – Formulation and Stability Unit

**Sanofi R&D**

IMPROVE FORMULATION STABILITY FOR VARIOUS MOLECULES, VACCINES, AND HIGH-CONCENTRATION LIQUID FORMS

10.00 **Thermokinetic modelling to derisk stability studies**

**Dr. Martin Hülsmeier**

Senior Principal Scientist, Head of HTS Operations and Analytics

**AbbVie**

10.45 **Refreshme**

11.15 **Case Study**

**Formulation and stability prediction for biologics**

- Models and molecular dynamics used for excipient formulation assessment
- Dedicated stability prediction and adapted methodology for biologics
- Regulatory and agency requirements
- Case studies

**Olivier Brass**

Senior Scientist, Head of Research Unit

**Sanofi Pasteur**



PANEL DISCUSSION

12.00 **Consider how to predict and limit protein aggregation**

- What are the main challenges in attempting to limit aggregation?
- Which methods and techniques can help to control aggregation?
- How can the quality of the product be maintained while limiting aggregation?

**Olivier Brass**

Senior Scientist, Head of Research Unit

**Sanofi Pasteur**

12.45 Lunch

13.45 **Case Study**

**The challenges of measuring aggregation and conformational changes of biopharmaceuticals**

**Dr. Klaus Richter**

Expert Scientist and Group Leader AUC

**Coriolis Pharma**

14.30 **From formulation screening to early manufacturing**

**Jörg Plaschke**

Lab Head, Biologics Formulation Development

**Merck**

15.15 **Refreshme**

POSTER PRESENTATIONS

15.45 *There will be an opportunity for three presenters to display posters, with each presentation lasting 15 minutes. Delegates will be able to study the posters and engage in Q&A with the speakers.*

VIDEO PRESENTATION

16.30 **Long acting injectables of fragile molecules: Opportunities from new technologies for the delivery of small specific antibodies**

- Formulation of Long-Acting Injectables (LAIs) for fragile molecules: What are the challenges and drivers?
- What technologies have been successful so far for formulating LAIs of fragile molecules?
- Limitations of current technologies for formulation of fragile molecules
- BEPO technology: A highly versatile technology for development of innovative LAIs
- Case study: LAI BEPO-based formulation for the delivery of a small Bispecific T-Cell Engager (BiTE) antibody for immunotherapy treatment in prostate cancer

**Joël Richard**

Chief Development Officer, Drug Development Operations

**MedinCell**

17.15 **The AMECRYS project: Revolutionising downstream processing**

- Use membrane assisted crystallisation for the purification of monoclonal antibodies
- Implications of enabling purification of mAbs without the use of a chromatograph
- Challenges and future potential for collaboration in downstream processing

**Philip Corner**

Scientist, Downstream Processing, Biologics

**Centre for Process Innovation Limited**

18.00 Closing Remarks from the Chair

**Who Should Attend**

**From pharmaceuticals, those responsible for:**

- Formulation
- Process Development
- Biologics
- Drug Delivery

## Friday 23<sup>rd</sup> October 2020

08.30 Registration and Coffee

09.00 Opening Address from the Chair

09.15 **Case Study**  
**Address challenges around the formulation and stability of non-protein biological molecules**

**Yinan Chen**

Scientist, Formulation Development  
**Janssen**

10.00 **The ICH Q3E extractables and leachables guidelines process**

- Introduction and history of the ICH Q3E extractables and leachables guideline
- Description of the ICH Q3E outline, process and expected timeline
- How to deal with the quality aspect of leachables interacting with biologics
- E&L risk assessments during development and life cycle management for biologics

**Carsten Worsoe**

Principal Scientist, Extractables and Leachables  
**Novo Nordisk**

10.45 **Refreshme**

**CONSIDER MANUFACTURING AND SCALE-UP CHALLENGES TO FOSTER YOUR FORMULATION**

11.15 **What can be done to ensure compatibility between biologics, delivery devices, and packaging?**

- Ensure that new biologic products can be scaled up and stored effectively
- Optimise container closure systems for storage and shipping
- Integrate improved fill-finish methods into the formulation and packaging process
- Consider the shelf-life of biologics during formulation

**Benjamin Werner**

Scientist, Formulation Development  
**Boehringer Ingelheim**

**VIDEO PRESENTATION**

12.00 **Lyophilization Process Development for Biopharmaceuticals: Applications for EISPAT**

- Electrical impedance spectroscopy – basic considerations
- Impedance enabled freeze-drying microscopy (Z-FDM) for formulation development
- Through Vial Impedance spectroscopy (TVIS) for process development
- Applications in freezing and primary drying

**Geoff Smith**

Professor of Pharmaceutical Process Analytical Technology  
**De Montfort University**

12.45 Lunch

**OPTIMISE DRUG DELIVERY FOR BIOLOGICS**

13.45 **Non-invasive delivery of biologics**

- Barriers to mucosal delivery of biologics
- Strategies for mucosal delivery of biologics with focus on oral
- Latest progress in the field of mucosal delivery of biologics

**Dr Driton Vllasaliu**

Lecturer in Pharmaceutics  
**King's College London**

14.30 **Case Study**  
**3D printed devices for the delivery of biologics**

- 3D printed microneedle arrays
- Insulin skin delivery
- In vitro and in vivo evaluation
- Implantable devices

**Dimitrios Lamprou**

Reader in Pharmaceutical Engineering  
**Queen's University Belfast**

15.15 **Refreshme**

15.45 **Innovate solutions for delivery of biologics to the eye**

- Challenges with ocular delivery of biologics via intraocular injections and eye drops
- Generate innovative solutions to address the unmet need in ocular delivery of biologics
- Develop devices to alter ocular barrier function
- Engineer biodegradable sustain release systems

**Dr. Raj Singh Thakur**

Reader in Pharmaceutics  
**Queen's University Belfast**  
Founder, CTO  
**Re-Vana Therapeutics**

**POSTER PRESENTATIONS**

16.30 *There will be an opportunity for three presenters to display posters, with each presentation lasting 15 minutes. Delegates will be able to study the posters and engage in Q&A with the speakers.*

17.15 Closing Remarks from the Chair

**Testimonials**

**"A great experience to learn more about what other companies are doing"**

**Merck**

**"Extremely high quality content and agenda"**

**GSK**

**Business Development Opportunities**

Does your company have services, solutions or technologies that the conference delegates would benefit from knowing about? If so, you can find out more about the exhibiting, networking and branding opportunities available by contacting:

**Rob Taylor**, General Manager

Business Development & Strategic Accounts

**marcus evans** Barcelona

Tel: +34 (0)93 393 4632, E-Mail: [RobT@marcusevanses.com](mailto:RobT@marcusevanses.com)

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the

### Medicine Maker

The development and manufacture of small molecules, biologics, and advanced therapies draws on the talent, passion and experience of a wide range of professionals. **The Medicine Maker** is a global publication that brings these people into the limelight, showcasing the pharma industry's success stories and examining its biggest points of contention. Engaging content covers the entire spectrum of drug development, keeping all medicine makers up to date with the most pressing topics, trends and technologies driving the drug development and manufacturing industry forward.

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