

# Digital Week

22<sup>nd</sup> – 26<sup>th</sup> June 2020

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



Those who learned to **collaborate**  
and **improvise** most effectively  
have **prevailed**.

Charles Darwin

Whilst many things in the world have changed since the COVID-19 outbreak, one thing here at marcus evans has remained very much the same. We remain committed to delivering our customers the information they need to make sense of the business world around them. Never before have businesses faced such unprecedented challenges and we are focussed on ensuring you continue to get the insights you need to drive your business forward and emerge stronger than ever.

We recognise that in today's world our clients need information delivered in a different way; one that recognises that fluid working hours and flexible working environments are the "new normal". Our **Digital Week** format is designed to compliment this new way of working by delivering three hours of highly focused, practitioner driven content per day, spread across your working week through our innovative **Live+** online streaming platform.

Insightful – Flexible – Impactful

Your Content, Your Way!

## 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**

### Bernhard Valldorf

Lab Head, Biologics Formulation  
Development  
**Merck**

### Dr. Raj Singh Thakur

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

### Vicky Smith

Senior Analytical Scientist  
**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**

## MONDAY 22<sup>ND</sup> JUNE

13.30

### Address logistical challenges within formulation development and drug delivery

- Determine the issues caused by the limited availability of molecules
- Understand the challenges within biologics delivery
- Use integration, miniaturisation, and automation to improve formulation efficiency

**Dr. Raj Singh Thakur**

Reader in Pharmaceutics

**Queen's University Belfast**

Founder, CTO

**Re-Vana Therapeutics**

14.15

### From formulation screening to early manufacturing

- Ensure the entire lifecycle of biologics is mapped effectively
- Improve the screening and formulation process by using better data
- Utilise AI and machine learning to enhance biologics modelling
- Integrate manufacturing within the overall formulation cycle

**Bernhard Valldorf**

Lab Head, Biologics Formulation Development

**Merck**

## TUESDAY 23<sup>RD</sup> JUNE

13.30

### Approach formulation development on a holistic basis

- Consider manufacturing and delivery implications during formulation development
- Cooperate across units and foster a collective vision of the process
- Use QbD standards and PAT to optimise formulation processes

**Jonas Fransson**

Director, Drug Product Development

**Swedish Orphan Biovitrum**

14.15

### 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**

## WEDNESDAY 24<sup>TH</sup> JUNE

13.30 **Case Study**

### Address challenges around the formulation and stability of non-protein biological molecules

- Establish the main challenges in attempting to maintain the stability of non-proteins
- What are the differences between non-proteins and proteins in the context of formulation?
- Determine the methods and techniques which can help to ensure stability

**Yinan Chen**

Scientist, Formulation Development

**Janssen**

14.15

### 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**

## THURSDAY 25<sup>TH</sup> JUNE

13.30

### 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 Worsøe**

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

14.15

### 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**

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

## FRIDAY 26<sup>TH</sup> JUNE

13.30

### Improve the delivery of parenterals to enhance the patient experience

- Examine how to improve patient safety and comfort while maintaining drug potency
- Use subcutaneous delivery to help with the effectiveness of injections and improve bioavailability
- Consider how the formulation development and manufacturing process affects drug delivery options and half-lives

**Dr Driton Vllasaliu**

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

14.15

### Emerging technologies within the fight against pandemics

- Actual and theoretical use cases for different technological innovations
- Examples from the 2020 COVID-19 pandemic

**Dimitrios Lamprou**

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

## Testimonials

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

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

"A great experience, learned many good things. Good networking opportunity"  
**Janssen**

# Digital Week



## Don't Listen In, Participate!

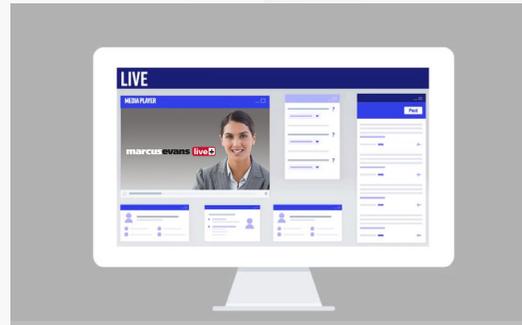
Our passion is connecting people through our events; we firmly believe a virtual event experience should be no different. Our **Live+ content platform** will of course give you access to all the presentations as they happen and beyond, but we have to do much better than that! Our focus is on unlocking the incredible knowledge, experience and value within our entire event delegation, not just our world class speakers. That is why our **Live+ platform** is loaded with features to ensure you get your full participation.

## Your content, your way!

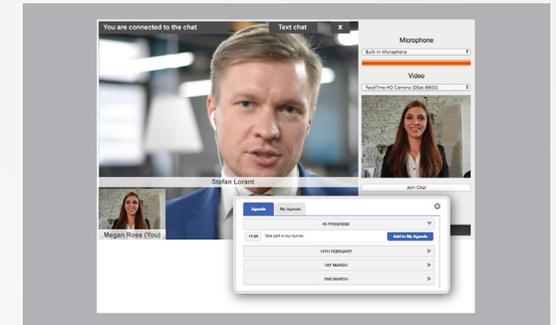


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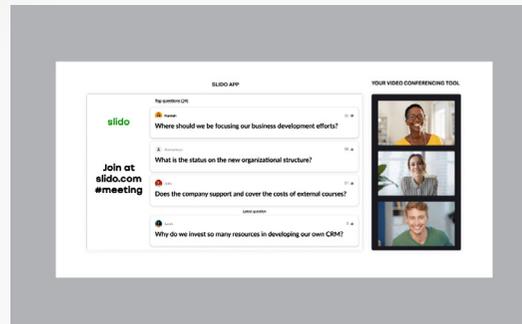
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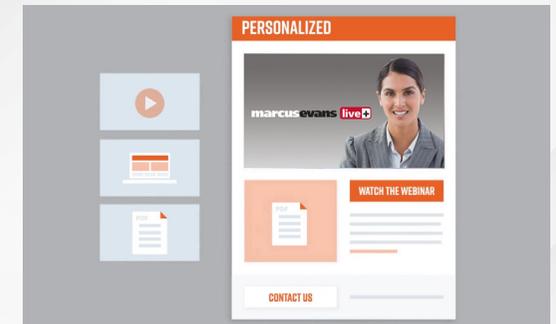
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It's not all about you... well kind of! But we want to share your insights and experience with others. Our online in-event **chat rooms, open and closed breakout rooms** and meeting scheduler means you don't have to miss out on those connections that have always made our events so valuable. Meet who you want, when you want. Virtual. Flexible. Efficient.



Good online events don't just happen; they need to be prepared. We understand this and have designed an event that seeks out **attendee engagement**. Take advantage of interactive live polling and Q&A throughout the event to understand where you sit on the key issues compared to your peers. All insights from these interactions will be posted to your content hub post event for you to refer back to.



Attending an event should be much more than the content delivered onsite, it needs to last and needs to continue to add value to you and your business once the show is over. Our **content hub** is where you go to download event presentations and additional content but also a place to share content with fellow delegates and reconnect post event as you wish.

**Sharing knowledge is our passion.** Our event content is therefore designed to be shared with your broader network. Our goal is to provide you and your team with the insights you need to be a success. Share live from the event or refer back to the content hub where we will distribute further content way beyond the live event.