

Digital Week

22nd – 26th June 2020

11th 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 complement 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

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Expert Speaker Panel

Carsten Worsø

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

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

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MONDAY 22ND JUNE

13.30

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

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

Jörg Plaschke

Lab Head, Biologics Formulation Development

Merck

TUESDAY 23RD 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 24TH 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 25TH 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 26TH JUNE

13.30

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

14.15

Emerging technologies in the fight against pandemics

- 3D printing of drug delivery systems and medical devices
- Microfluidics for rapid diagnosis and drug delivery
- MEMS for diagnostics and monitoring applications
- Examples from the COVID-19 pandemic
- Actual and theoretical cases

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



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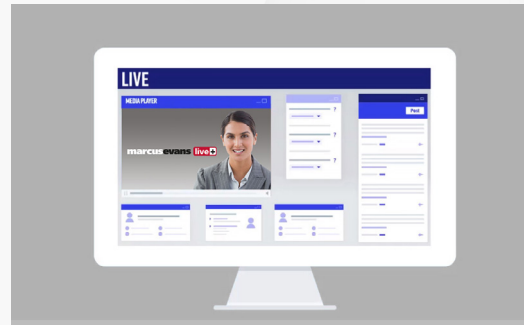
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Your content, your way!

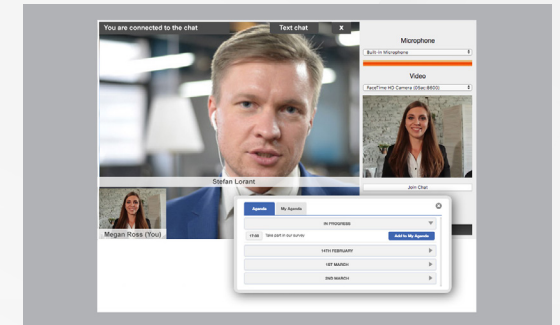


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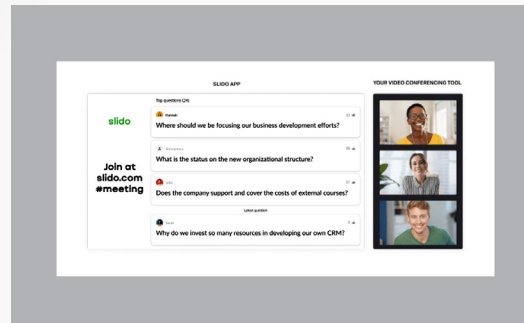
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