

SMi Present the 14th Annual Conference on...

Controlled Release Delivery

Strengthening innovation and overcoming the challenging regulatory landscape

COPTHORNE TARA HOTEL, KENSINGTON, LONDON, UK



CONFERENCE:
3RD - 4TH

WORKSHOP: 5TH
APRIL 2017



CHAIRMEN:

- **Howard Stevens**, Professor, **University Of Strathclyde**
- **Sudhakar Garad**, Global Head of Chemical and Pharmaceutical Profiling, **Novartis Institutes for BioMedical Research**

FEATURED SPEAKERS:

- **Markham Luke**, Director, Division of Therapeutic Performance, **FDA**
- **René Holm**, Head and Scientific Director, Liquids & Parenterals, **Janssen**
- **Mark Wilson**, Director, Technology Licensing, PTS, **GSK**
- **Patrick Garidel**, Associate Director Protein Science, **Boehringer Ingelheim**
- **Stephan Buchmann**, Head Preformulation & Preclinical Galenics, **Actellion**
- **John Fox**, Chief Executive Officer, **Merrion Pharmaceuticals**

HIGHLIGHTS IN 2017:

- Listen to **FDA** evaluate **generic drug development**
- **Novartis** optimise the success of **biopharmaceutical approaches** for controlled release delivery
- Can lipid suspensions **improve oral bioavailability?**
Answers from **Janssen**
- Insights into the **opportunities and limitations to improving solubility and bioavailability** with **Actellion**
- Hear **InnoCore Pharmaceuticals** discuss microparticles and hydrogels for **parenteral drug delivery**

PLUS AN INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOP | WEDNESDAY 5TH APRIL 2017, COPTHORNE TARA HOTEL, KENSINGTON, LONDON, UK

Challenges in Inhaled Drug Delivery

Workshop Leaders:

David Harris, Leading Respiratory Drug Delivery, **PA Consulting Group**
Phil Seeney, Inhalation and Drug Delivery Specialist, **PA Consulting Group**

08.30am - 12.30pm

www.controlledreleasedelivery.com

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@SMIPHARM

08.30 Registration & Coffee

09.00 **Chairman's Opening Remarks**
Howard Stevens, Professor, University Of Strathclyde

INNOVATIONS IN DRUG DELIVERY

OPENING ADDRESS / KEYNOTE ADDRESS

09.10 **Lipid suspensions - how, when and with what?**

- What is a lipid based suspension and how could it look from a commercialisation perspective?
- When can lipid based suspensions be used to improve the oral bioavailability?
- How large a proportion of the compound needs to be solubilised in the lipid phase?
- What excipients to use for lipid based formulation?

René Holm, Head and Scientific Director, Liquids & Parenterals, Janssen

09.50 **Novel injectable formulations for postoperative pain with opioid sparing**

- NSAID analgesics administered concomitantly with opioids have been shown to greatly decrease the amounts of opioid required for effective treatment (so-called opioid sparing) but in many cases are poorly delivered.
- We are using our proprietary SmartCelle technology to develop a range of low volume, high concentration NSAID and COX-II products for the treatment of postoperative pain.
- Unlike today's treatments which are quickly cleared from the body, the pharmacokinetics imparted by SmartCelle technology can maintain drug concentrations in the blood sufficient to double exposure versus non-formulated drug.

Damon C. Smith, CEO, Polymeric Particles & Altus Formulation

10.30 Morning Coffee

11.00 **Controlled erosion facilitates development of complex oral delivery profiles**

- Therapeutic opportunities for Complex Oral Delivery Profiles ?
- How to harness in-vivo erosion to achieve CODPs ?
- In-vivo Evaluation of CODPs ?

Howard Stevens, Professor, University Of Strathclyde

11.40 **From ideas to novel drug products - parenteral and oral controlled release drug delivery strategies**

- Controlled release formulation design, scale-up and GMP manufacturing of PLGA-based microparticles
- Multi-unit oral dosage form with EUDRATEC® PEP for oral delivery of macromolecules and poorly permeable small drugs.
- Evonik platform technologies offer a combination of synergistic modules for improved bioavailability in combination with a tailored drug release profile

Hans Baer, Senior Project Manager, Evonik Nutrition and Care GmbH

12.20 Networking Lunch

NANOPARTICLES/NANOMEDICINE & QbD

13.20 **Parenteral delivery of nano-carriers**

- Hurdles in the design of parenteral drug delivery systems for insoluble compounds
- Summary of solubilization and parenteral delivery technologies
- The key considerations in design of parenteral drug delivery system
- Case studies in development of nanocarriers

Jim Jingjun Huang, Founder and CEO, Ascendia Pharmaceuticals LLC

14.00 **Delivery and release of small molecules and biologics using Nanocin technology**

- Overview of Nanocin technology
- Discussion of mechanisms of Nanocin-mediated cell entry and release
- Examples of small molecule and biologics delivery
- Examples of collaborative projects

Liam Good, Director, Tecrea Ltd

14.40 Afternoon Tea

15.10 **The nanomedicine experience**

- The talk will explore the design and synthesis of nanomedicine forming materials
- Their fabrication into differentiated nanomedicines.
- Case studies will include data on peptide brain delivery

Ijeoma Uchegbu, Chair in Pharmaceutical Nanoscience, University College London & CEO, Nanomerics

15.50 **Examining how Quality by Design (QbD) can aid formulation and controlled release delivery**

- Assessing the importance of QbD in controlled release delivery
- Implementation of QbD principles in the development of microsponges as drug delivery carriers
- The advantages of implementing QbD into controlled release systems

David Elder, Consultant, David P Elder Consultancy

16.30 **Biodegradable polymeric microparticles and hydrogels for parenteral drug delivery**

- Whereas PLGA has its limitations for protein delivery causing e.g. burst, pH drop and instability, a different biodegradable polymer platform will be shared to solve the issues
- Demonstrating excellent control over release kinetics and effective preservation of protein bioactivity
- Several case studies will be presented to exhibit all requirements to develop sustained release formulations for parenteral delivery of biologic therapeutics
- Our hydrogel technology will be shared as a solution for site specific sustained delivery of small molecules and peptides. The technique as such is unique, straight forward in processing and very scalable in comparison to other techniques

Rob Steendam, Chief Technology Officer, InnoCore Pharmaceuticals

17.10 **Chairman's Closing Remarks and Close of Day One**
Howard Stevens, Professor, University Of Strathclyde

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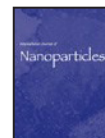
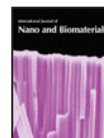
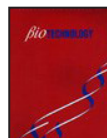
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08.30 Registration & Coffee

09.00 Chairman's Opening Remarks

Sudhakar Garad, Global Head of Chemical and Pharmaceutical Profiling, **Novartis Institutes for BioMedical Research**

OPENING ADDRESS

09.10 The development and commercialisation of drug delivery systems: Challenges and opportunities

- GSK's experiences in developing technologies
- The collaborative "open innovation" approach
- Commercialisation challenges – finding the breakthrough application
- Examples of successful development and exploitation projects
- GSK's approach to working with other organisations

Mark Wilson, Director, Technology Licensing, PTS, **GlaxoSmithKline**

CNS DRUG DELIVERY

09.50 NEUWAY Pharma: Qualified for CNS drug delivery

- Treatment of CNS diseases is not limited by drugs, but by delivery.
- The majority of active substances is excluded from the CNS by the blood-brain-barrier
- NEUWAY is focusing on providing a gateway for drugs via this natural border
- NEUWAY's engineered protein capsules (EPCs) consist of the natural VP1 protein of JV Virus - a virus that knows how to overcome the blood-brain barrier.
- EPCs are non-infectious and can be filled with a variety of therapeutic molecules

Heiko Manniga, Managing Director, **NEUWAY Pharma**

10.30 Morning Coffee

11.00 Matrix-binding fusions for local delivery of therapeutics

- Challenges in delivery to tissues with dense matrix and poor vasculature
- Nature-inspired solutions using binding to matrix components
- Matrix-binding fusions for intra-articular delivery with extended retention

Parth Patwari, Founder & Chief Scientific Officer, **ProteoThera**

11.40 Biopharmaceutical approaches for controlled release delivery

- Why controlled drug delivery – pros and cons
- Past, today and future for controlled delivery
- What biopharmaceutical properties needs to be considered for designing a controlled release dosage form
- Pharmaceutical consideration for oral, topical or parenteral controlled delivery
- Patient preference and commercial impact

Sudhakar Garad, Global Head of Chemical and Pharmaceutical Profiling, **Novartis Institutes for BioMedical Research**

12.20 Networking Lunch

THERAPEUTIC APPLICATIONS

KEYNOTE ADDRESS

13.20 Generic drug development and evaluation: A U.S. FDA perspective

- Bioequivalence in the setting of pharmaceuticals
- Definitions – what are complex drug products
- How FDA assists generic drug development

Luke Markham, Director, Division of Therapeutic Performance, **FDA**

14.00 Improving solubility and bioavailability

- Basic principles to be considered
- Opportunities and limitations to improve solubility and bioavailability
- Presentation of case studies

Stephan Buchmann, Head Preformulation & Preclinical Galenics, **Actelion**

14.40 Afternoon Tea

15.10 Hydrogel formulations for biologics

- Rational for sustained release formulations for biologics
- Influence of gel network properties on release kinetics
- Impact of molecular format on release kinetics
- Drug-delivery system compatibility
- Case studies

Patrick Garidel, Associate Director Protein Science, **Boehringer Ingelheim**

15.50 Utilizing novel technology to accelerate drug development

- Apply new technology to accelerate drug development pipeline and develop novel formulations
- Delivering benefit to the patient while creating novel formulations
- Translating the technology from use in R&D to clinical output

John Fox, Chief Executive Officer, **Merrion Pharmaceuticals**

16.30 Chairman's Closing Remarks and Close of Day Two

Sudhakar Garad, Global Head of Chemical and Pharmaceutical Profiling, **Novartis Institutes for BioMedical Research**

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Contact Zoe Gale, SMi Marketing on

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HALF DAY POST-CONFERENCE WORKSHOP

Wednesday 5th April 2017

Copthorne Tara Hotel, Kensington, London, UK

8.30am - 12.30pm

Challenges in Inhaled Drug Delivery

Workshop Leaders:

David Harris, Leading Respiratory Drug Delivery,

PA Consulting Group

Phil Seeney, Inhalation and Drug Delivery Specialist,

PA Consulting Group

Workshop overview:

In this workshop, focusing on inhaled drug delivery, we aim to cover the requirements of an ideal inhaler and why this is so difficult to achieve in practice. We will explore the underlying scientific and engineering principles, and move on to cover the variety of tools and techniques that are available to help scientists, engineers and designers create inhaler products that are safe, efficient and easy and intuitive to use. This will be an interactive session, and we will actively encourage audience participation, with the hope that it will be useful, interesting and enjoyable!

Agenda

08.30	Registration & Coffee
09.00	Introduction from Workshop Leaders
09.20	The Ideal inhaler – what is required?
10.10	The challenges – why is the ideal so difficult?
11.00	Morning Coffee & Networking
11.30	Tools and techniques to achieve your inhaled drug delivery objectives
12.20	Q&A
12.30	End of Workshop

About the Workshop Leader:

David leads the Respiratory Drug Delivery sector at PA Consulting and enjoys the challenge of balancing commercial and technical activities.

"One of the best things about working at PA is being surrounded by like-minded and intelligent people – many of whom are leaders in their field. Drug delivery is a hugely exciting sector to work in and it offers a wide range of technical and scientific challenges. It's also very rewarding – the products that we and others like us develop have the potential to massively improve people's lives. It's a great pleasure working with clients who share these aspirations." David is a physicist and has been working in the field of medical device development since 1994, where he started his career in the Respiratory Physics group at Fisons. He specialises in respiratory drug delivery and enjoys applying solid aerosol science and fluid dynamics to improve the efficacy of inhaler technology. David has numerous patents and publications in this area and regularly presents at conferences.

Phil Seeney is a technology expert at PA Consulting Group. Phil developed strong engineering skills in industry, transitioning to product design and medical device development after studying at Imperial College and the Royal College of Art. He has over 40 years of product development experience covering healthcare, consumer durable and fast moving consumer goods sectors. For the last 25 years, Phil has specialised in drug delivery and the development of medical devices. His experience extends beyond the development of products and he has conducted numerous technology identification and due diligence projects for blue chip pharmaceutical clients.

About PA Consulting:

PA is a consulting, technology and innovation firm. We define success as achieving exceptional results that have a lasting impact on businesses, communities and individuals worldwide. This principle has remained the cornerstone of our ethos since 1943 - and it continues to underpin everything we do. Our clients choose us because we challenge convention to find the solutions that really work - in practice, not just on paper. Then we roll up our sleeves and get the job done. Our specific expertise is in energy and utilities, financial services, health, life sciences, consumer and manufacturing, government, defence and security, transport and logistics. We operate globally from our principal offices in the Americas, Europe, the Nordics, the Gulf and wider Middle East and North Africa region (MENA) and Asia Pacific. So wherever the challenge is, we have a team nearby.



JANUARY

Pharmaceutical Microbiology

18th - 19th January 2017, London, UK

Social Media In The Pharma Industry

18th - 19th January 2017, London, UK

Pre-Filled Syringes Europe

18th - 19th January 2017, London, UK

FEBRUARY

Parallel Trade

6th - 7th February 2017, London, UK

3D Cell Culture

22nd - 23rd February 2017, London, UK

RNAi Therapeutics

22nd - 23rd February 2017, London, UK

MARCH

Superbugs & Superdrugs - A Focus on Antibacterials

20th - 21st March 2017, London, UK

Paediatric Clinical Trials

20th - 21st March 2017, London, UK

Drug Discovery

27th - 28th March 2017, London, UK

Asthma & COPD

29th - 30th March 2017, London, UK

APRIL

Controlled Release

3rd - 4th April 2017, London, UK

Adaptive Designs

3rd - 4th April 2017, London, UK

Pre-Filled Syringes East Coast

26th - 27th April 2017, Boston, USA

MAY

Lyophilisation

8th - 9th May 2017, London, UK

Orphan Drugs Europe

15th - 16th May 2017, Berlin, Germany

Pharma Logistics and Supply Chain

18th - 19th May 2017, London, UK

Pain Therapeutics

22nd - 23rd May 2017, London, UK

Highly Potent Active Pharmaceutical Ingredients

22nd - 23rd May 2017, London, UK

JUNE

Pre-Filled Syringes West Coast

5th - 6th June 2017, San Diego, USA

Microbiology USA

8th - 9th June 2017, San Diego, USA

ADMET

12th - 13th June 2017, London, UK

Immunogenicity

12th - 13th June 2017, London, UK

BioBanking

14th - 15th June 2017, London, UK

Molecular Diagnostics

14th - 15th June, London, UK

JULY

Allergies

6th - 7th July 2017, London, UK

Peptides

6th - 7th July 2017, London, UK

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Conference: 3rd - 4th April 2017, Copthorne Tara Hotel, Kensington, London, UK Workshop: 5th April 2017, London

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- ☐ Book by 28th February to receive £100 off the conference price

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P-201

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TOTAL

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