

SMi Presents the 13th Annual Conference on...

Controlled Release

Uniting innovation and science to improve controlled release formulation and delivery for next generation drugs

Holiday Inn Regents Park, London, UK

18 - 19
APRIL
2016

ADVISORY BOARD:

- **Howard Stevens**, Professor, **University of Strathclyde**
- **David Elder**, Due Diligence Director, **GlaxoSmithKline**

FEATURED SPEAKERS:

- **Marion Westwood**, Pharmaceutical Assessor, **MHRA**
- **Andy Lewis**, Director Novel Drug Delivery Technologies, **Ipsen**
- **Sachin Mittal**, Senior Principal Scientist, **Merck**
- **Marianne Ashford**, Principal Scientist Drug Targeting, **AstraZeneca**
- **Sune Andersen**, Principal Scientist, **Novo Nordisk**
- **Mark Wilson**, Director Platform Technology and Science, **GlaxoSmithKline**
- **Saif Shubber**, Formulation Scientist, **MedImmune**
- **Rene Holm**, Senior Director, **Lundbeck**

Key Sessions:

- **MHRA: Supporting innovation in controlled release and combination products**
- **Examining how Quality by Design (QbD) can aid formulation and controlled release delivery**
- **The future of controlled release peptide drug delivery**
- **Parenteral controlled release: Revival for increased adherence**
- **Multi-particulates – formulation factors and challenges during development and transfer**

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS

Wednesday 20th April 2016, Holiday Inn Regents Park, London, UK

A: QbD/PAT-Driven Controlled Release Design and Development

08.30 – 12.30

Leaders: **Jérôme Mantanus**, Senior Scientist QbD/PAT Drug Product Formulation, **UCB Pharma**
Cristiana Campa, Head, Quality by Design Integration, **GlaxoSmithKline**

B: Exploring Controlled Release Drug Delivery Methods

13.30 – 17.30

Leaders: **Rene Holm**, Senior Director, **Lundbeck**
Clive Wilson, Professor of Pharmaceuticals, **University of Strathclyde**
Ijeoma Uchegbu, Chair in Pharmaceutical Nanoscience, **University College London & CEO, Nanomeric**

Sponsored by:

SOTAX
Solutions for Pharmaceutical Testing

www.controlledrelease.co.uk

Register online or fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711

Controlled Release

Day One | Monday 18th April 2016

08.30 Registration & Coffee

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

OPENING ADDRESS

09.10 MHRA: Supporting innovation in controlled release and combination products

- Discuss the latest innovations surrounding controlled release
- Gain key regulatory updates from leading competent authorities talking specifically on grey areas such as the regulatory environment surrounding combination products
- Case study on work with OxSonic

Marion Westwood, Pharmaceutical Assessor, MHRA

09.50 An industrial perspective on novel oral dose controlled release technologies

- GSK's activities to develop new platform drug delivery technologies
- Approaches to collaboration and partnering with external organisations
- The application and implementation of new technologies within GSK

Mark Wilson, Director Platform Technology and Science, GlaxoSmithKline

10.30 Morning Coffee

THE IMPORTANCE OF QbD

KEYNOTE ADDRESS

11.00 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, Due Diligence Director, GlaxoSmithKline

11.40 Application of QbD during spray drying scale-up

- Examining the use of spray drying in controlled release
- Linking lab-scale QbD with production scale QbD
- Scale-up impact on solid dosage forms

Sune Andersen, Principal Scientist, Novo Nordisk

12.20 Networking Lunch

INNOVATIONS IN CONTROLLED RELEASE

13.50 Controlling peptide stability to unlock their therapeutic potential

- Peptides as pharmaceutical drugs
- Challenges to their formulation and delivery
- Overcoming the challenges; formulation development and drug delivery
- Future directions and conclusions

Saif Shubber, Formulation Scientist, MedImmune

14.30 How are combination products altering the drug delivery landscape?

- Current issues with the combination of drugs with different release mechanisms
- The regulatory environment surrounding combination products with different controlled release mechanisms
- Who can support you with regulatory compliance?

Howard Stevens, Professor, University of Strathclyde

15.10 Afternoon Tea & Speed Networking
An ice breaking session for you to exchange business cards with your industry colleagues



15.40 The importance of controlled release in nanomedicine design

- Predicting modelling for nanomedicine design
- Optimising drug release from a nanomedicine to improve therapeutic index
- Comparison of different nanomedicines in improving therapeutic index

Case studies and data sharing
Marianne Ashford, Principal Scientist Drug Targeting, AstraZeneca

16.20 Imaging for the characterisation of controlled-release drug delivery applications

- How to incorporate imaging techniques into the R&D stage of controlled release drug delivery
- Discussing the application of molecular imaging techniques to enhance the development and optimisation of controlled release systems
- An analysis of the current molecular imaging techniques on the market

Hakan Keles, Senior Imaging Scientist, GlaxoSmithKline

17.00 Interactive discussion: Overview of Day One

- Summary of the day's presentations
- Has Day One achieved your expected learning goals?
- What to expect from Day Two

Moderated by:

Howard Stevens, Professor, University of Strathclyde

17.30 Chairman's Closing Remarks & Close of Day One
Howard Stevens, Professor, University of Strathclyde

Sponsored by:



SOTAX is a global leader in providing innovative solutions for pharmaceutical testing. The company offers high-quality dissolution testing systems, physical tablet testing instruments, automated sample preparation workstations for composite assay and content uniformity testing, as well as associated technical and application services. www.sotax.com

Supported by



Want to know how you can get involved? Interested in promoting your services to this market?
Contact Vinh Trinh, SMI Marketing on +44 (0) 207 827 6140 or email: vtrinh@smi-online.co.uk

Register online at: www.controlledrelease.co.uk • Alternatively fax

Controlled Release

Day Two | Tuesday 19th April 2016

08.30 Registration & Coffee

09.00 Chairman's Opening Remarks David Elder, Due Diligence Director, GlaxoSmithKline

KEYNOTE ADDRESS

09.10 The future of controlled release peptide drug delivery

- Review of routes of delivery of currently marketed peptide products
- Novel peptide dosage forms currently in development
- Future innovations in peptide delivery

Andy Lewis, Director Novel Drug Delivery Technologies, Ipsen

09.50 Microfluidics and drug delivery systems for controlled release: Production, characterisation and industrial translation

- Production of nanoscale and microscale drug delivery vehicles using microfluidic technology
- Development of acoustofluidic platforms for ultrasound-mediated intracellular delivery of therapeutic compounds
- Biomimetic microfluidic architectures to investigate drug release processes within physiologically-relevant microenvironments
- Industrial translation of microfluidic technology: Challenges and future perspectives

Dario Carugo, Research Fellow, University of Oxford & University of Southampton

10.30 Morning Coffee

A CLOSER LOOK AT PRODUCT DESIGN

11.00 Dissolution testing: A key tool for a better product design

- Principles of dissolution
- How does dissolution relate to Biopharmaceutical Classification System (BCS) and In Vitro/In Vivo Correlation (IVIVC)
- API characterisation and dissolution
- Case studies

Samir Haddouchi, Managing Director, SPS Pharma Services

11.40 Parenteral controlled release: Revival for increased adherence

- Parenteral controlled release and adherence
- Development of parenteral controlled release dosage forms: Design and manufacture
- Understanding the performance of controlled release dosage forms

Sachin Mittal, Senior Principal Scientist, Merck

12.20 Networking Lunch

13.50 How to formulate poorly soluble drugs

- Available pharmaceutical technologies for formulating low soluble compounds
- Technical and biopharmaceutical considerations of the technologies
- Future trends in the formulation of low soluble compounds

Rene Holm, Senior Director, Lundbeck

14.30 Multi-particulates – formulation factors and challenges during development and transfer

- Advantage of multi-unit particulate dosage form over single unit dosage form
- Formulation components for Multi-Unit Particulate System (MUPS)
- Equipment for manufacturing of MUPS
- Process transfer for MUPS

Inder Gulati, Formulation R&D Lead, Merck

15.10 Afternoon Tea

NEW PLATFORMS IN CONTROLLED RELEASE DELIVERY

15.40 CriticalMix platform technology: A novel platform technology for sustained delivery of small and large API's

- Overview of who Critical Pharmaceuticals are
- Issues with current technologies surrounding microparticles for API's of all sizes
- Overview and advantages of the CriticalMix process
- Case studies

Anjum Shabir-Ahmed, Head of Pharmaceutical Science, Critical Pharmaceuticals

16.20 Selection and development of controlled release technology suitable for adult and paediatric dosing

- Multiparticulate controlled release formulations are well known for providing superior controlled release compared to the monolithic systems due to lower food effect and uniform gastric emptying
- The advantages of multiparticulate system was further extended to maximise the dosing flexibility during development for adult and paediatric dosing
- Product development including the selection of technology, release mechanism, and development of IVIVR/IVIVC will be discussed

Harpreet Sandhu, Senior Director, Kashiv Pharma, LLC

17.00 Optimising drug delivery systems to mimic the human circadian rhythm

- The influence of circadian rhythm on human physiological systems and disease state
- Optimising drug release to reflect the natural human circadian cycle
- Controlled release therapies for circadian therapeutic areas of interest: Chronocort® - a case study

Daniel Margetson, CMC Director, Diurnal Ltd

17.40 Chairman's Closing Remarks & Close of Day Two David Elder, Due Diligence Director, GlaxoSmithKline

SPONSORSHIP AND EXHIBITION OPPORTUNITIES

Smi offer sponsorship, exhibition, advertising and branding packages, uniquely tailored to complement your company's marketing strategy. Prime networking opportunities exist to entertain, enhance and expand your client base within the context of an independent discussion specific to your industry.

Should you wish to join the increasing number of companies benefiting from sponsoring our conferences please call:

Alia Malick on +44 (0) 20 7827 6168
or email: amalick@smi-online.co.uk

Smi Pharmaceutical 2016 Planner:

JANUARY

Pharmaceutical Microbiology
20th - 21st January 2016
London, UK

Social Media In The Pharmaceutical Industry
20th - 21st January 2016
London, UK

Pre-Filled Syringes
27th - 28th January 2016
London, UK

FEBRUARY

Parallel Trade
8th - 9th February 2016
London, UK

Advances and Progress in Drug Design
15th - 16th February 2016
London, UK

RNAi Therapeutics
15th - 16th February 2016
London, UK

MARCH

Superbugs & Superdrugs - A Focus on Antibacterials
16th - 17th March 2016
London, UK

Paediatric Clinical Trials
16th - 17th March 2016
London, UK

APRIL

Asthma & COPD
11th - 12th April 2016
London, UK

Controlled Release
18th - 19th April 2016
London, UK

Adaptive Designs
18th - 19th April 2016
London, UK

Pre Filled Syringes USA
25th - 26th April 2016
New Jersey, USA

Lyophilisation USA
27th - 28th April 2016
New Jersey, USA

For further information visit us at www.smi-online.co.uk/pharmaceuticals

your registration to +44 (0)870 9090 712 or call +44 (0)870 9090 711

HALF-DAY POST CONFERENCE WORKSHOP A

Wednesday 20th April 2016

08.30 – 12.30

Holiday Inn Regents Park, London, UK

QbD/PAT- Driven Controlled Release Design and Development

Workshop Leaders:

Jérôme Mantanus, Senior Scientist QbD/PAT Drug Product Formulation, **UCB Pharma**

Cristiana Campa, Head, Quality by Design Integration, **GlaxoSmithKline**

Overview of the Workshop:

This workshop aims to enhance attendees' understanding on how to adopt the core principles of Quality by Design (QbD) for controlled release development and manufacturing. The QbD framework has many implications for manufacturers and regulators alike. The workshop defines how QbD concepts can be applied to improve both method validation and transfer. Its goal is to stimulate thinking and discussion on how analytical method validation and transfer could evolve as industry increasingly adopts Quality by Design concepts.

Programme:

08.30 Registration & Coffee

09.00 Introduction from Workshop Leaders

09.30 Introduction to QbD

- Assessing the implementation of an integrated Quality by Design approach

10.00 Selection of DoE approach answering QTP Requirements

- Taking advantage of design space to identify robust formulation
- Case study on modified release formulation development
- Case study on the improvement of a tablet formulation using design space approach

10.30 Morning Coffee & Networking

11.00 PAT to gain process understanding

- PAT for process monitoring and end-point detection
- PAT for real time release

12.20 Q&A

12.30 End of Workshop

About the Workshop Leaders:



Dr. Jérôme Mantanus graduated in Pharmaceutical Sciences in 2007 at the Liège University in Belgium. He obtained his PhD at the same university in 2011. His research activities focused on the use of Near Infrared spectroscopy as a PAT compliant process analyzer. In 2012 he joined UCB Pharma as a QbD/PAT scientist. He is now responsible for ensuring and realizing Quality by Design (QbD) and Process Analytical Technology (PAT).



Cristiana Campa is currently Head of Quality by Design Integration at GSK Vaccines. In this role, Cristiana is leading a team with members in Belgium, Italy and US sites, aimed at the definition of an integrated approach for product, process and analytical development according to QbD principles, after acquisition of Novartis Vaccines by GSK. In her role, she is sharing her experience as technical lead for the implementation of QbD in Technical Development and Manufacturing Science and Technology at Novartis Vaccines since 2012. Cristiana has a PhD in Chemistry (2000, University of Basilicata, Italy) with a focus on analytical chemistry of carbohydrates.

Exploring Controlled Release Drug Delivery Methods

Workshop Leaders:

Rene Holm, Senior Director, **Lundbeck**

Clive Wilson, Professor of Pharmaceutics, **University of Strathclyde**

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

Overview of the workshop:

When designing controlled-release systems, it is important to understand the different drug delivery systems available and identify which mechanism is best suited to your release process. At times more than one mechanism may be involved at different stages in the drug delivery process. This workshop aims to explore different drug delivery methods that can be utilised in controlled release drug delivery.

Programme:

13.00 Registration & Coffee

13.30 Introduction from Workshop Leaders

14.00 What does the industry need now?

- Industry perspective from Lundbeck: What's hot in industry?
- Latest developments in drug delivery

15.00 Afternoon Tea & Networking

15.30 The biological:

What can we and can't we do in the gut?

- Challenges involved with delivering to the gut
- Impact of controlled release formulations on gut wall metabolism

16.30 The chemical: Will nanotechnology solvate all our problems?

- Nanotechnology to overcome the limitations of current drugs to develop products that deliver patient benefit in areas of unmet medical need
- Offering the possibility to exert unprecedented control on drug activity

17.00 Q&A

17.30 End Of Workshop

About the Workshop Leaders:



René Holm received his pharmaceutical training at the Royal Danish School of Pharmacy, now the school of pharmacy at University of Copenhagen, Denmark, in 1998 and his PhD in biopharmaceutics from the same institution in 2002. Dr. Holm joined Lundbeck in 2001, and worked within pharmaceutical development, formulations for non-clinical testing in drug discovery, physical chemistry and material science and is now divisional director for the functional unit responsible the CMC development of biological development and pharmaceutical research and preformulation, i.e. in practice tasks from drug discovery, over development and trouble shooting in production.



Prof. Dr. Clive G. Wilson is the J. P. Todd Chair of Pharmaceutics, based at Strathclyde Institute of Pharmacy & Biomedical Sciences, Glasgow, U.K. He pioneered applications of imaging in research on physiological and pathophysiological effects of transit on drug absorption following oral, nasal, pulmonary and ophthalmic delivery. He has supervised 61 Ph.D. students, authored 6 books, more than 170 papers and 97 review papers.



Ijeoma Uchegbu, is Professor of Pharmaceutical Nanoscience at the UCL School of Pharmacy, University College London (UCL), Pro-Vice Provost for Africa and The Middle East, UCL and Chief Scientific Officer of Nanomerics, a spin out company from the UCL School of Pharmacy in London.

She obtained her PhD from the School of Pharmacy, University of London in 1994, was appointed to a lectureship within the Department of Pharmaceutical Sciences, Strathclyde University in 1997 and a Chair in Drug Delivery at Strathclyde University in 2002. Nanomerics was founded in 2010 by Ijeoma and Andreas G. Schätzlein. Nanomerics is a speciality pharmaceutical company focused on exploiting pharmaceutical nanotechnology platforms for medicines development.

CONTROLLED RELEASE

Conference: Monday 18th & Tuesday 19th April 2016, Holiday Inn Regents Park, London, UK Workshops: Wednesday 20th April 2016, London, UK

4 WAYS TO REGISTER

www.controlledrelease.co.uk

FAX your booking form to +44 (0) 870 9090 712
PHONE on +44 (0) 870 9090 711

POST your booking form to: Events Team, SMi Group Ltd, 2nd Floor
South, Harling House, 47-51 Great Suffolk Street, London, SE1 0BS, UK

EARLY BIRD DISCOUNT

- ☐ Book by 18th December 2015 to receive £400 off the conference price
- ☐ Book by 29th January 2016 to receive £200 off the conference price
- ☐ Book by 29th February 2016 to receive £100 off the conference price

CONFERENCE PRICES

I would like to attend: (Please tick as appropriate)	Fee	Total
<input type="checkbox"/> Conference & 2 Workshops	£2697.00 + VAT	£3236.40
<input type="checkbox"/> Conference & 1 Workshop AM <input type="checkbox"/> PM <input type="checkbox"/>	£2098.00 + VAT	£2517.60
<input type="checkbox"/> Conference only	£1499.00 + VAT	£1798.80
<input type="checkbox"/> 1 Workshop only AM <input type="checkbox"/> PM <input type="checkbox"/>	£599.00 + VAT	£718.80
<input type="checkbox"/> 2 Workshops	£1198.00 + VAT	£1437.60

PROMOTIONAL LITERATURE DISTRIBUTION

- ☐ Distribution of your company's promotional literature to all conference attendees **£999.00 + VAT £1198.80**

The conference fee includes refreshments, lunch, conference papers, and access to the Document Portal. Presentations that are available for download will be subject to distribution rights by speakers. Please note that some presentations may not be available for download. Access information for the document portal will be sent to the e-mail address provided during registration. Details are sent within 24 hours post conference.

DOCUMENTATION

I cannot attend but would like to purchase access to the following Document Portal/paper copy documentation	Price	Total
<input type="checkbox"/> Access to the conference documentation on the Document Portal	£499.00 + VAT	£598.80
<input type="checkbox"/> The Conference Presentations – paper copy (or only £300 if ordered with the Document Portal)	£499.00 -	£499.00

PAYMENT

Payment must be made to **SMi Group Ltd**, and received before the event, by one of the following methods **quoting reference P-166 and the delegate's name**. Bookings made within 7 days of the event require payment on booking, methods of payment are below. Please indicate method of payment:

- ☐ **UK BACS** Sort Code **300009**, Account **00936418**
- ☐ **Wire Transfer** Lloyds TSB Bank plc, 39 Threadneedle Street, London, EC2R 8AU
Swift (BIC): **LOYDGB21013**, Account **00936418**
IBAN **GB48 LOYD 3000 0900 9364 18**
- ☐ **Cheque** We can only accept Sterling cheques drawn on a UK bank.
- ☐ **Credit Card** ☐ Visa ☐ MasterCard ☐ American Express
All credit card payments will be subject to standard credit card charges.

Card No:

Valid From / Expiry Date /

CVV Number 3 digit security on reverse of card, 4 digits for AMEX card

Cardholder's Name:

Signature:

Date:

I agree to be bound by SMi's Terms and Conditions of Booking.

Card Billing Address (if different from above):

VAT

VAT at 20% is charged on the attendance fees for all delegates. VAT is also charged on Document portal and literature distribution for all UK customers and for those EU Customers not supplying a registration number for their own country here.

Unique Reference Number

Our Reference

LVP-166

DELEGATE DETAILS

Please complete fully and clearly in capital letters. Please photocopy for additional delegates.

Title: Forename:

Surname:

Job Title:

Department/Division:

Company/Organisation:

Email:

Company VAT Number:

Address:

Town/City:

Post/Zip Code: Country:

Direct Tel: Direct Fax:

Mobile:

Switchboard:

Signature: Date:

I agree to be bound by SMi's Terms and Conditions of Booking.

ACCOUNTS DEPT

Title: Forename:

Surname:

Email:

Address (if different from above):

Town/City:

Post/Zip Code: Country:

Direct Tel: Direct Fax:

VENUE Holiday Inn Regents Park, Carburton Street, London, W1W 5EE

☐ Please contact me to book my hotel

Alternatively call us on +44 (0) 870 9090 711,

email: events@smi-online.co.uk or fax +44 (0) 870 9090 712

Terms and Conditions of Booking

Payment: If payment is not made at the time of booking, then an invoice will be issued and must be paid immediately and prior to the start of the event. If payment has not been received then credit card details will be requested and payment taken before entry to the event. Bookings within 7 days of event require payment on booking. Access to the Document Portal will not be given until payment has been received.

Substitutions/Name Changes: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. Two or more delegates may not 'share' a place at an event. Please make separate bookings for each delegate.

Cancellation: If you wish to cancel your attendance at an event and you are unable to send a substitute, then we will refund/credit 50% of the due fee less a £50 administration charge, providing that cancellation is made in writing and received at least 28 days prior to the start of the event. Regrettably cancellation after this time cannot be accepted. We will however provide the conference documentation via the Document Portal to any delegate who has paid but is unable to attend for any reason. Due to the interactive nature of the Briefings we are not normally able to provide documentation in these circumstances. We cannot accept cancellations of orders placed for Documentation or the Document Portal as these are reproduced specifically to order. If we have to cancel the event for any reason, then we will make a full refund immediately, but disclaim any further liability.

Alterations: It may become necessary for us to make alterations to the content, speakers, timing, venue or date of the event compared to the advertised programme.

Data Protection: The SMi Group gathers personal data in accordance with the UK Data Protection Act 1998 and we may use this to contact you by telephone, fax, post or email to tell you about other products and services. Unless you tick here ☐ we may also share your data with third parties offering complementary products or services. If you have any queries or want to update any of the data that we hold then please contact our Database Manager databasemanager@smi-online.co.uk or visit our website www.smi-online.co.uk/updates quoting the URN as detailed above your address on the attached letter.

If you have any further queries please call the Events Team on tel +44 (0) 870 9090 711 or you can email events@smi-online.co.uk