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

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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 OxSonics

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 imagining 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 Imagining 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**

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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

Anjumn 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 compare 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**

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 QTTP 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.

HALF-DAY POST CONFERENCE WORKSHOP B
Wednesday 20th April 2016
13.30 – 17.30
Holiday Inn Regents Park, London, UK

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.

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