From: Gemma Redmond <pharma@smiconferences.co.uk>
To: Kester, Tonykester@aging.sc.gov
Date: 3/21/2016 8:44:12 AM
Subject: MHRA and US FDA to discuss innovation in Controlled Release

Controlled Release

18 - 19 April 2016 | Holiday Inn Regent's Park, London, UK

Sponsored by: **Sotax**

Register online and join attendees including Novartis, Debiopharm, Hovione, Colorcon, Lucideon, University of Pavia and more!

Contact Matthew Apps on Tel: +44 (0) 20 7827 6093 or Email: mapps@smi-online.co.uk

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Dear Mr Tony Kester,

Could you benefit from hearing exclusive presentations and briefings from 11 global pharma companies covering, in detail, their own experiences in driving Controlled Release innovation?

If the answer is yes, book now to learn from your industry peers and gain valuable insight into their current strategies and future outlook to improve CR formulation and delivery for next generation drugs.

In addition to the array of pharma case studies, SMi is proud to announce that the **MHRA** and **US FDA** will be sharing their own unique perspectives at the 13th annual Controlled Release conference, highlighting scientific and regulatory challenges, along with how these have been overcome:

MHRA's Pharmaceutical Assessor, Marion Westwood, will share an opening address on Day One titled, *'Supporting innovation in controlled release and combination products'*. Her presentation will cover the following key points:

- 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

US FDA's Pharmacologist, Mohammad Absar, will be delivering a presentation at 13:50 on Day One titled *'Regulatory perspective on innovative systems for controlled release'*. Key points covered include:

- An overview of current innovative controlled release systems in the US market
- Scientific and regulatory challenges in developing generic controlled release systems
- FDA/OGD's ongoing research programme

Additionally, the two-day programme also promises to bring you the cutting-edge developments highlighting:

- New platforms in Controlled Release delivery

CriticalMix platform technology: A novel platform technology for sustained delivery of small and large APIs by **Critical Pharmaceuticals**

Diurnal on optimising drug delivery systems to mimic the human circadian rhythm

- Innovations in Controlled Release

MedImmune talks about controlling peptide stability to unlock therapeutic potential

AstraZeneca presents nanomedicine design for controlled release

- The importance of QbD

GSK examines how Quality by Design (QbD) can aid formulation and controlled release delivery

Novo Nordisk demonstrates application of QbD during spray drying scale-up

- Product Design

Parenteral controlled release: Revival for increased adherence – case study by **Merck**

Lundbeck showcases how to formulate poorly soluble drugs

Don't forget to extend your stay to join the 2 post-conference interactive workshops taking place on Wednesday 20th April 2016:

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

Hosted by by Daniela Stranges, Senior Scientist, Quality by Design Integration, **GlaxoSmithKline** and Jerome Mantanus, Senior Scientist QbD/PAT Drug Product Formulation, **UCB Pharma**

Enhance understanding on the adoption of core principles of Quality by Design (QbD) for controlled release development and manufacturing. This workshop defines how QbD tools (DoEs, PAT) can be applied to support formulation and process development.

WORKSHOP B: Exploring Controlled Release Drug Delivery Methods

Hosted by Rene Holm, Senior Director, **Lundbeck**; Clive Wilson, Professor of Pharmaceutics, **University of Strathclyde**; Ijeoma Uchegbu, Scientific Secretary CRS, Chair in Pharmaceutical Nanoscience, University of London and CEO, **Nanometrics**

This workshop will explore drug delivery technologies that can be utilised in controlled release drug delivery and will consider some of the newer concepts in the drug delivery world including nanotechnology.

SPONSORSHIP INFORMATION

For details on tailored sponsorship and branding packages, please contact Alia Malick, Director on Tel: +44 (0) 20 7827 6168 or Email: amalick@smi-online.co.uk

HOW TO REGISTER

Register online: **www.controlledrelease.co.uk**

Contact Matthew Apps on Tel: +44 (0) 20 7827 6093 or Email: mapps@smi-online.co.uk