From: Mike Giles <pharma@smiconferences.co.uk>
To: Kester, Tonykester@aging.sc.gov
Date: 3/21/2016 10:41:47 AM
Subject: 3 Key Updates Showcased Next Month in an Industry Spotlight at Lyophilization USA

Lyophilization USA | April 27th & 28th 2016
Renaissance Woodbridge Hotel, Iselin, New Jersey, USA

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3 Key Industry Updates Showcased Next Month: Hear more from Lyophilization Technology Inc, PAREXEL and FDAPharma Consulting

Dear Mr Tony Kester,

Lyophilization USA will strengthen knowledge of lyophilization productivity as well as look at the practicalities of QbD and scale up, keeping attendees at the forefront of cutting edge technology for viable and cost efficient manufacturing.

As well as hearing case studies from a selection of leading pharmaceutical companies currently implementing freeze drying processes, this year's event will feature **3 key updates** from industry pioneers at the heart of freeze drying technology and regulation.

1. Controlling nucleation with Lyophilization Technology Inc.

Are improvements truly seen in processing characteristics and finished product attributes? **Dr. Karen Bossert**, Vice President of Scientific Affairs presents exclusive data highlighting uniformity of ice nucleation within a batch through controlled nucleation.

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FEATURED SPEAKERS INCLUDE:

Jim Searles, Ph.D.
Technical Fellow, **Pfizer**

Sune Klint Andersen
Principal Scientist, **Novo Nordisk**

Dr. Mark Yang
Director of Fill/Finish Development,

2. Regulation ready with strategic guidance from PAREXEL

Emphasising on QbD elements, Principal Consultant, **Lotte McNamara**, looks at QbD applications during early and late stage lyophilization development. Regulatory QbD filings will also be discussed providing attendees with the knowledge on what information is required and how it should be presented during early and late stage development.

3. Taking a systematic approach with FDAPharma Consulting

What kind of information may be included in a pharmaceutical development section of an NDA or BLA? With a focus on QbD principles, the presentation by **Ravi S. Harapanhalli**, Principal at FDAPharma Consulting, will explain how ICH Q8 (R2) can be applied in the development and optimization of lyophilization processes.

These are just some of the unmissable program highlights for 2016. Visit the website to see a **full speaker line-up** and detailed conference agenda.

Late Stage Process Development,
Genzyme Corp

Dr Evgenyi Shalaev
Research Investigator, **Allergan**

Prakash Sundaramurthi
Senior Scientist, **Teva Biologics**

Dr. Vineet Kumar
Senior Scientist, **J&J**

Lisa Hardwick
Research Scientist
Baxter Healthcare

Dr Salman Mazummil
Drug Product Development,
Janssen

Jamie Tsung
Principle Scientist,
Drug Product Development
Momenta Pharmaceuticals

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GET IN TOUCH:

For tailored sponsorship packages contact Alia Malick on +44 (0)20 7827 6168 or email amalick@smi-online.co.uk

For delegate enquiries contact Fateja Begum on +44 (0)20 7827 6184 or email fbegum@smi-online.co.uk

OTHER EVENTS OF INTEREST:

3rd Annual Conference: **Pre-Filled Syringes East Coast**
April 25th & 26th 2016 | Renaissance Woodbridge Hotel, Iselin, New Jersey, USA
http://www.pfsamericas.com

4th Annual Conference: **Lyophilisation Europe**
July 4th & 5th 2016 | Holiday Inn Kensington Forum, London, UK
BOOK BY 31ST MARCH TO SAVE £400
http://www.lyophilisation-europe.com

Register online at www.lyophilization-usa.com