

From: Daniel Gilchrist <pharma@smiconferences.co.uk>
To: Kester, Tonykester@aging.sc.gov
Date: 4/18/2016 6:04:01 AM
Subject: Freeze Drying Highly Concentrated Biologics: Hear from Boehringer Ingelheim, Merck and GSK

Boehringer Ingelheim Case Study: Freeze Drying Highly Concentrated Biologics at Specific Formulation Conditions Explained!

SMi Presents the 4th Annual Event:

Lyophilisation Europe

Conference: 4th - 5th July | Interactive Workshop: 6th July

Holiday Inn Kensington Forum, London, UK

www.lyophilisation-europe.com

£200 EARLY BIRD ENDS 29TH APRIL

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EVENT UPDATE:

New speakers added onto the stellar line-up for 2016 including:

Donna Williams, Associated Principal Scientist from **Merck & Co Inc**, who will present on "Formulation and Drying Strategies for Stabilising Biologics and Vaccines."

Perceval Sondag, Senior Statistician from **Arlenda**, who will present on the "Application of Statistics across the Lyo Product Lifecycle."

[VIEW AGENDA >>](#)

Dear Mr Tony Kester,

Join us this July at SMi's forthcoming conference, **Lyophilisation Europe**, when it returns to London for its 4th annual show to the latest regulatory and industry updates in pharmaceutical freeze drying from an array of experts such as **NIBSC**, **Novo Nordisk**, **GSK**, **Sanofi-Aventis** + many more.

With a focus on drug formulation, one of the event highlights this year will include a featured keynote address on highly concentrated biologics by Patrick Garidel, Head of Pharmaceutical Basic Development at **Boehringer Ingelheim**.

The development of high-concentration protein formulations result in several stability, analytical, and delivery challenges. The presentation will arm you with the strategic guidance you need to overcome manufacturing problems by delving further into the freeze drying of highly concentrated protein formulations, buffer-free formulations, impact on stability and by providing detailed insight through an informative case study on monoclonal antibodies. Presentation details.

Scroll down for **agenda highlights** or visit the [website](#) today to take a look at the full conference agenda.

GET INVOLVED:

£200 EARLYBIRD EXPIRES 29TH APRIL

Register online at: www.lyophilisation-europe.com

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

For delegate enquiries and pharma/biotech rates, contact:
Fateja Begum on +44 (0)20 7827 6184 or email fbegum@smi-online.co.uk

AGENDA HIGHLIGHTS: [View Agenda](#)

| DAY ONE: 4th July 2016 | | DAY TWO: 5th July 2016 | |
|------------------------|---|------------------------|--|
| 8.30 | Registration & Coffee | 8.30 | Registration & Coffee |
| 9.00 | Chairman's Opening Remarks Sune Andersen , Principal Scientist Drying Processes, Novo Nordisk A / S | 9.00 | Chairman's Opening Remarks Sune Andersen , Principal Scientist Drying Processes, Novo Nordisk A / S |
| 9.10 | Application of QbD principles to design lyophilisation process robustness studies in support tech transfer of a freeze-dried vaccine component Daniela Stranges , Senior Scientist, GSK | 9.10 | Challenges in spray drying process and formulation development Sune Andersen , Principal Scientist Drying Processes, Novo Nordisk A / S |
| 9.50 | Constructing a robust design space based on product and process limitations Kevin Ward , Director of R&D , BioPharma Technology | 9.50 | ATEX regulation applied to a manufacturing workshop of high potent injectables Franck Pavan , Outsourcing Business Manager, Pierre Fabre |
| 10.30 | Morning Coffee | 10.30 | Morning Coffee |
| 11.00 | Formulation and drying strategies for stabilising biologics and vaccines Donna Williams , Associated Principal Scientist, Merck & Co Inc | 11.00 | Sponsor session: Establishing the correct safety margins to prevent temperature collapse |
| 11.40 | Freeze-drying protein and vaccine formulations Paul Matejtschuk , Principal Scientist, NIBSC | 11.40 | On the use of PAT tools and statistical analysis to determine optimal freeze drying cycle parameters for scale-up Erwan Bourles , Freeze dryer scientist, GSK |
| 12.20 | Networking Lunch | 12.20 | Networking Lunch |
| 1.30 | Through vial impedance spectroscopy : A process analytical technology (PAT) to develop a rational lyophilization cycle Geoff Smith , Professor of Pharmaceutical Process Analytical Technology , De Montfort University | 1.30 | Panel discussion: Challenges of optimising filling processes and maintaining freeze dryers Erwan Bourles , Freeze dryer scientist, GSK |
| 2.10 | Optimisation of industrial freeze drying cycle - Two case studies Mostafa Nakach , Head of Pharmaceutical Engineering Group, Sanofi-Aventis R&D | 2.10 | Freeze-Drying of highly concentrated biologics at specific formulation conditions Patrick Garidel , Head of Pharmaceutical Basic Development, Boehringer Ingelheim |
| 2.50 | Afternoon Tea | 2.50 | Afternoon Tea |
| 3.20 | Continuous freeze drying of (Bio-) pharmaceuticals Jos Corver , Founder, RheaVita BV | 3.20 | Modern process of lyophilisation Andrea Weiland , Pharmacist, Ph.D.Managing Director, Explicat Pharma GmbH |
| 4.00 | Application of Statistics across the Lyo Product Lifecycle Perceval Sondag , Senior Statistician, Arlenda | 4.00 | Uncertainty and global sensitivity analysis (GSA) for the (dynamic) design space determination of a traditional and continuous freeze-drying process Thomas De Beer , Professor and Head of PAT, University Of Ghent |
| 4.40 | Panel discussion: Designing formulations for lyophilized products Jos Corver , Founder, RheaVita BV | 4.40 | Chairman's Closing Remarks and Close of Day Two |
| 5.20 | Chairman's Closing Remarks and Close of Day One | | |

POST CONFERENCE INTERACTIVE WORKSHOP:

08.30 – 12.30, July 6th 2016

Get hands on training through an **interactive session** on the **design and scale up of a freeze drying process**, hosted by Paul Matejtschuk, Principal Scientist and Section Head, **NIBSC**; and Kevin Ward, Director of R&D, **Biopharma Process Systems Ltd**.

Contact us today and arrange a package to attend all 3 days!

Register online at: www.lyophilisation-europe.com

You are registered as: kester@aging.sc.gov Your Unique Reference Number: 92804565

To update your contact preferences please go to <http://www.smi-online.co.uk/update-preferences>