

From: Benjamin Jones <pharma@smiconferences.co.uk>

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Subject: Lyophilisation Europe | A Focus on Pharmaceutical Freeze Drying | A Debate on QbD Principles

Lyophilisation Europe 2016

4th Annual Conference: 4th & 5th July

Interactive Workshop: 6th July

4 WEEKS REMAIN: www.lyophilisation-europe.com

Dear Mr Tony Kester,

SMi's Lyophilisation portfolio of events have now firmly become established as the industry's only leading shows on pharmaceutical freeze drying and **Lyophilisation Europe** is already shaping up to be a success.

WHO WILL YOU HEAR FROM?

Bringing in voices from some of the most senior market experts in formulation science and freeze drying, **Lyophilisation Europe** provides the perfect platform to discuss pioneering technological developments and address the latest updates in regulation and cost efficient processes without compromising drug quality.

Our expert panel of speakers includes: **Boehringer Ingelheim, NIBSC, Sanofi, GSK Vaccines**, plus many more.

[See the full line-up.](#)

PANEL DISCUSSIONS:

What are the challenges of optimising filling processes and maintaining freeze dryers? Join the debate led by Erwan Bourles, Freeze Drying Scientist from **GSK** and moderated by Sune Klint Anderson, Principle Scientist from **Novo Nordisk**.

Attendees will be invited to discuss integrating risk-based approaches into **QbD principles**, maintaining continuous **process validation** and control of **process parameters**, and be presented with a case study on **material flow**.

[Download a brochure](#) to take a look at the detailed conference programme and speaker line-up or scroll down for agenda highlights.

Register online at:
www.lyophilisation-europe.com

For sponsorship packages contact
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Day One - 4th July 2016

Day Two - 5th July 2016

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|-------|---|-------|--|
| 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 , Head of Injection Manufacturing Site, AMATSIGROUP |
| 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 | | DOWNLOAD BROCHURE |

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