

From: Benjamin Jones <pharma@smiconferences.co.uk>
To: Kester, Tonykester@aging.sc.gov
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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

8.30	Registration & Coffee	8.30	Registration & Coffee
9.00	Chairman's Opening Remarks	9.00	Chairman's Opening Remarks
	Sune Andersen , Principal Scientist Drying Processes, Novo Nordisk A / S		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	9.10	Challenges in spray drying process and formulation development
	Daniela Stranges , Senior Scientist, GSK		Sune Andersen , Principal Scientist Drying Processes, Novo Nordisk A / S
9.50	Constructing a robust design space based on product and process limitations	9.50	ATEX regulation applied to a manufacturing workshop of high potent injectables
	Kevin Ward , Director of R&D , BioPharma Technology		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	11.00	Sponsor session: Establishing the correct safety margins to prevent temperature collapse
	Donna Williams , Associated Principal Scientist, Merck & Co Inc		
11.40	Freeze-drying protein and vaccine formulations	11.40	On the use of PAT tools and statistical analysis to determine optimal freeze drying cycle parameters for scale-up
	Paul Matejtschuk , Principal Scientist, NIBSC		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	1.30	Panel discussion: Challenges of optimising filling processes and maintaining freeze dryers
	Geoff Smith , Professor of Pharmaceutical Process Analytical Technology , De Montfort University		Erwan Bourles , Freeze dryer scientist, GSK
2.10	Optimisation of industrial freeze drying cycle - Two case studies	2.10	Freeze-Drying of highly concentrated biologics at specific formulation conditions
	Mostafa Nakach , Head of Pharmaceutical Engineering Group, Sanofi-Aventis R&D		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	3.20	Modern process of lyophilisation
	Jos Corver , Founder, RheaVita BV		Andrea Weiland , Pharmacist, Ph.D.Managing Director, Explicat Pharma GmbH
4.00	Application of Statistics across the Lyo Product Lifecycle	4.00	Uncertainty and global sensitivity analysis (GSA) for the (dynamic) design space determination of a traditional and continuous freeze-drying process
	Perceval Sondag , Senior Statistician, Arlenda		Thomas De Beer , Professor and Head of PAT, University Of Ghent
4.40	Panel discussion: Designing formulations for lyophilized products	4.40	Chairman's Closing Remarks and Close of Day Two
	Jos Corver , Founder, RheaVita BV		
5.20	Chairman's Closing Remarks and Close of Day One		DOWNLOAD BROCHURE

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