

**From:** Tom McAllister <pharma@smiconferences.co.uk>  
**To:** Kester, Tonykester@aging.sc.gov  
**Date:** 3/30/2016 9:55:37 AM  
**Subject:** Lyophilized Biologics: New Windows of Opportunity in a Market Projected to Reach US \$4.8 Billion by 2020

## LYOPHILIZATION USA

Renaissance Woodbridge Hotel, Iselin, New Jersey, USA

Conference: April 27th & 28th 2016 | Interactive Workshops: April 29th 2016

Proudly Sponsored by: **Emergent Biosolutions, Kamat Pharmatech, Millrock Technology, One2One, SP Scientific**

1 Exhibition Booth Remains - [Contact us](#) for details

**FINAL EARLY BIRD: \$200 saving expires tomorrow on March 31st**  
[Register Online](#) | [View Agenda](#)

### Lyophilized Biologics: Discover New Windows of Opportunity in a Market Projected to Reach US \$4.8 Billion by 2020

Dear Mr Tony Kester,

Do you have a competitive edge over your peers? Can you afford not to attend [Lyophilization USA](#) when it returns to New Jersey next month? In just **4 weeks** time the pharmaceutical freeze-drying industry will gather at SMI's 2nd annual event **Lyophilization USA**, to receive cutting edge updates on technology, manufacturing and emerging developments in drug for

Highlights will include a keynote opening address on day 2 from **Genzyme Corp's Director of Fill/Finish Development & Lifecycle Process Development**, Dr Mark Yang. The presentation will explore current trends into the growing market of lyophilized biologics and offer strategic guidance into reducing lyophilization cycles and costs for commercial manufacturing. Mark will also discuss technologies designed to increase efficiency in development times and provide a progressive outlook into future developments [here](#) for details.

#### STAY AT THE FOREFRONT OF YOUR MARKET:

- Benefit from an agenda tailored towards **driving efficiency** and commercial competitiveness through reducing your manufacturing costs and shortening lyophilization cycle time.
- Stay at the cusp of emerging developments with 11 hours of content delivered by senior industry thought leaders such as **Pfizer, Novo Nordisk, Allergan, J&J** + more.
- Gain an overview of the **latest innovations** in freeze drying technology, protein stabilization and aseptic spray drying
- Escape regulatory risk through informed guidance on **QbD submissions**.
- Create a competitive edge and customize your drying process through understanding **key parameters** such as temperature and ideal water content for drug products.
- Increase **product shelf life** through unique insight into interaction with API's.

This is just a small overview of what to expect next month. Scroll down for an agenda summary or visit the website to download [brochure](#) and full itinerary.

#### GET INVOLVED: \*\* BOOK BY MARCH 31ST FOR THE LAST EARLY BIRD OFFER AND SAVE \$200 \*\*

- REGISTER ONLINE: [www.lyophilization-usa.com](http://www.lyophilization-usa.com)
- SPONSORSHIP INFORMATION: - **ONLY 1 BOOTH REMAINS**  
For details on tailored branding packages, contact Alia Malick on: +44 (0) 207 827 6168 or email [amalick@smi-online.com](mailto:amalick@smi-online.com).
- DELEGATE ENQUIRIES: For delegate enquiries and pharma rates, contact Fateja Begum on: +44 (0)20 7827 6148 or email [fbegum@smi-online.co.uk](mailto:fbegum@smi-online.co.uk)

## AGENDA SUMMARY:

DAY ONE APRIL 27TH 2016		DAY TWO APRIL 28TH 2016	
8.30	<b>Registration &amp; Coffee</b>	8.30	<b>Registration &amp; Coffee</b>
9.00	<b>Chairman's Opening Remarks</b>	9.00	<b>Chairman's Opening Remarks</b>
9.10	<b>Effect of Pressure and Dryer Load upon Secondary Drying Rates</b> <b>Jim Searles</b> , Technical Fellow, Global Technical Services, <b>Pfizer</b>	9.10	<b>Commercial Competitiveness of Lyophilized Products</b> <b>Mark Yang</b> , Director, <b>Genzyme</b>
9.50	<b>QbD Principles — How Can This Help with Topical Dosage Formula?</b> <b>Naveen Kanthamneni</b> , Formulation Scientist, R&D Development, <b>Endo Pharmaceuticals Inc.</b>	9.50	<b>Clearing the Fog: Characterization of the Fogged Layer in Lyophilized Products and Studies with Hydrophobic-Coated Vials</b> <b>Chris Heynes</b> , Senior Engineer, <b>Genentech</b>
10.30	<b>Morning Coffee</b>	10.30	<b>Morning Coffee</b>
11.00	<b>Load Them Properly: Lessons Learnt from the Condenser Coil Temperature Alarms</b> <b>Vineet Kumar</b> , Senior Scientist, <b>Johnson And Johnson</b>	11.00	<b>Validation of Filling Operations</b> <b>Accurate and Reliable Determination of Collapse Temperature by Optical Coherence Tomography-Freeze Drying Microscope (OCT-FDM)</b> <b>Vamsi Mudhivarathi</b> , Postdoctoral Fellow, <b>University Of Connecticut</b>
12.20	<b>Protein Stability: Change in the Apparent Acidity During Freezing and Drying</b> <b>Ke Wu</b> , Senior Scientist, <b>Allergan</b>	11.40	<b>Freeze Dried Medical Device Products</b> <b>Mrinal Shah</b> , Senior Engineer, Process Development, <b>LifeCell Corporation</b>
12.20	<b>Networking Lunch</b>	12.20	<b>Networking Lunch</b>
1.20	<b>ControLyo™ Nucleation on Demand: The Impact of Controlling Nucleation on Finished Material Attributes and Processing Characteristics for Bulk Material and Vial Product</b> <b>Dr. Karen Bossert</b> , Vice President, Scientific Affairs, <b>Lyophilization Technology, Inc</b>	1.20	<b>Looking at Lyophilization from ICH Q8(R2) Perspective</b> <b>Ravi S. Harapanhalli</b> , Principal, <b>FDAPharma Consulting</b>
2.00	<b>Residual Water Content in a Lyophilized Drug Product — Optimizing Secondary Drying</b> <b>Lisa Harwick</b> , Research Scientist, <b>Baxter BioPharma Solutions</b>	2.00	<b>Freeze Thaw for Protein Stabilization</b> <b>Jamie Tsung</b> , Principal Scientist, <b>Momenta Pharmaceuticals Inc</b>
2.40	<b>Afternoon Tea &amp; Networking Break</b>	2.40	<b>Afternoon Tea &amp; Networking Break</b>
3.10	<b>Phase-Appropriate Regulatory Strategies: A Focus on QbD Elements</b> <b>Lotte McNamara</b> , Principal Consultant, <b>PAREXEL</b>	3.10	<b>Comparability Studies for Tech Transfer in Lyophilization</b>
3.50	<b>Aseptic Spray Drying as an Alternative to Lyophilization?</b> <b>Sune Andersen</b> , Principal Scientist Drying Processes, <b>Novo Nordisk A / S</b>	3.50	<b>Looking Beyond — Is Drying the Only Way to Go?</b> <b>Sune Andersen</b> , Principal Scientist Drying Processes, <b>Novo Nordisk A / S</b>
4.30	<b>Panel Discussion: Is Lyophilization the Way to Go Forward?</b> <b>Padam Sharma</b> , Sterile Drug Products, Injectables, External Contract Manufacturing, Aseptic Processing, <b>Allergan Inc</b> <b>Salman Muzammil</b> , Drug Product Development, <b>Janssen</b>	4.30	<b>Chairman's Closing Remarks and Close of Day Two</b>
5.10	<b>Chairman's Closing Remarks and Close of Day One</b>		
		PLUS 2 interactive workshops on April 29th 2016.	
		<b>WORKSHOP A: 08:30 - 12:30</b> Lyophilization – Development through Tech Transfer Hosted by Steritech Solutions LLC	
		<b>WORKSHOP B: 13:30 - 17:00</b> An Empirical Approach to Formulation and Lyophilization Cycle Development of Parenteral and Diagnostic Products Hosted by AB BioTechnologies, Inc.	
		<a href="#">DOWNLOAD BROCHURE</a>	

Lyophilization USA is Proudly Sponsored by:

Register online at [www.lyophilization-usa.com](http://www.lyophilization-usa.com)

YOU MAY ALSO BE INTERESTED IN THE BELOW CONFERENCES:

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

**4th Annual Conference: Lyophilisation Europe**

4th & 5th July 2016 | Holiday Inn Kensington Forum, London UK

**BOOK BY 31ST MARCH TO SAVE £400**

[www.lyophilisation-europe.com](http://www.lyophilisation-europe.com)

You are registered as: kester@aging.sc.gov/ Your unique contact code is: 92804565 (P-169 EM - LC4WK 92804565)  
If you do not wish to receive further email messages, please go to <http://www.smi-online.co.uk/unsubscribe/>