

Freeze-Drying of Pharmaceuticals and Biologicals

Dorint Sporthotel
Garmisch Partenkirchen,
Germany

September 28 - October 1
2010

Symposium and Short Course



Presented by
University of Munich (LMU),
University of Connecticut,
Dane O. Kildsig Center for Pharmaceutical
Processing Research (CPPR), a National Science
Foundation Industry/University Cooperative
Research Center

Meeting Description

Researchers from all relevant areas of freeze-drying of pharmaceuticals and biologicals get together to discuss the critical aspects and new developments in the field. The topics include: material sciences, biotech formulation, technical operations and PAT. Special emphasis of the meeting is on exchange and networking in a relaxing but focused atmosphere.

The symposium will begin with an informal snack lunch welcome reception on Wednesday, September 29th. An exhibition with short presentations by vendors accompanies the meeting.

Potential vendors should contact
Gerhard Winter, University of Munich
Tel. +49 89 2180 77022
gerhard.winter@lrz.uni-muenchen.de

Short Course – Fundamentals of Pharmaceutical Freeze Drying

Mike Pikal and Steve Nail, two of the most distinguished mentors of the science of freeze drying introduce into basics of the physics, process engineering, formulations aspects etc of the technology spiced with their personal anecdotes of more than 60 years of practical experience. The short course will be held on Tuesday September 28th and Wednesday 29th prior to the symposium.

Meeting Registration

A registration form is attached to this brochure. You can also register at our conference website

or at <http://www.lyo-garmisch.de>
or at <http://www.cppr.purdue.edu/>

The registration fee includes refreshments at the receptions along with coffee breaks and lunch each day of the conference. A social event including dinner and a buffet dinner with the exhibitors are included, as well.

A discounted registration fee is available for students. The professor's signature is required on the registration form. Further information on registration, payment, cancellation, logistics etc. can be found on the conference website.

Please register early as the number of spaces is limited !!

An acknowledgment of registration and a receipt will be mailed to you. Conference documentation and name badges will be handed out at the conference.

Registration fees (Conference only):

Registration: 850 €
Student Registration: 400 €

Registration fees (Short course and Conference, combined):

Registration: 1200 €
Student Registration: 450 €

Registration Form

Freeze-Drying of Pharmaceuticals and Biologicals
September 28-October 1, 2010

Dorint Sporthotel, Garmisch-Partenkirchen, Germany

Name: _____

Address: _____

Zip/ City: _____

State: _____

Country: _____

Phone: _____

Fax: _____

Email: _____

Short course participation: Yes _____ No _____

I plan to submit an abstract: Yes _____ No _____

I am a student: Yes _____ No _____

If yes, professor's signature: _____

Mail or fax the completed registration form to

Ms. Elizabeth Anderson
School of Pharmacy
University of Connecticut
69 North Eagleville Rd.
Storrs, CT 06269-3092
Liz.Anderson@UConn.edu
Fax +1 (860) 486-2076

Cancellation Policy:

Only requests for cancellation received prior to August 15, 2010 will receive a refund. The refund will consist of the registration fee minus 150 €.

[Hotel Registration](#)

A limited contingent of hotel rooms is reserved at a special rate at the **Dorint Sporthotel and the nearby Mercure Hotel in Garmisch-Partenkirchen**. The reserved block of rooms for the Conference will only be held until June 30, 2010. Requests for accommodations after this date will be subject to availability.

Please make reservations directly at the hotel and refer to our reservation contingents.

Dorint Resort

Mittenwalder Str. 59
D-82467 Garmisch-
Partenkirchen, Germany
Tel. +49 8821 706516
Fax +49 8821 706540

“LMU-Lyophilisation Conference”
www.dorintresorts.com

Mercure Hotel

Mittenwalder Str. 2
D-82467 Garmisch-
Partenkirchen, Germany
Tel. +49 8821 7560
Fax +49 8821 74268

“Contingent 61818 LMU”
www.mercure.com

[Call for Papers](#)

Contributed papers will be considered for posters. Please follow the abstract template found on the conference website. Abstracts will be reproduced exactly as received.

The deadline for receipt of abstracts is August 15, 2010.

Please mail two hard copies or the electronic version of the abstract as pdf-file to:

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Department of Pharmacy; Pharmaceutical Technology and
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Butenandtstrasse 5
D-81377 Muenchen, Germany
Gabriele.Hartl@cup.uni-muenchen.de

[Organizing Committee](#)

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Tuesday, September 28

13:00 – 17:30 Short Course: Fundamentals of pharmaceutical freeze-drying – I
A short course in the basics taught by Michael Pikal and Steve Nail for those new to the subject

Wednesday, September 29

8:00 – 11:00 Short Course: Fundamentals of pharmaceutical freeze-drying – II
A short course in the basics taught by Michael Pikal and Steve Nail for those new to the subject

11:00 – 12:30 Registration, Welcome Snack Lunch

12:30 – 12:30 Introduction

Keynote Lecture

12:45 – 13:30 Lyophilization: the historical saga of a mere technical curiosity
Professor Louis Rey, Lausanne, Switzerland

Introductory Lecture

13:30 – 14:00 Lyophilized Therapeutics: Past, Present, and Future
Ed Trappler, Lyophilization Technology Inc., Ivyland PA, US

Material Sciences

14:00 – 14:30 Stability of Freeze-Dried Proteins: Causal and Correlating Factors
Marc Cicerone, NIST, Gaithersburg MD, US

14:30 – 15:00 Perspective on driven molecular materials

15:00 – 16:00 Break / Exhibition

16:00 – 16:30 Phase Separation in Amorphous Protein Systems: Detection and Implications for Stability
Mike Pikal, University of Connecticut, Storrs CT, US

16:30 – 17:00 Monitoring Phase Transitions During Freeze-Drying: Potential Implications on Product Performance
Raj Suryanarayanan, University of Minnesota, Minneapolis MN, US

17:00 – 17:30 Panel Discussion with audience participation
Moderator: Alan MacKenzie, Mercer Island WA, US

19:00 – open end Social event evening at Gasthaus Rassen

Thursday, September 30

Biotech formulations

8:30 – 9:00 Stabilization of freeze-dried inactivated polio virus
Pierre Chouvenec, Sanofi-Pasteur, Lyon, France

9:00 – 9:30 Freeze-Drying of lipoplexes, storage stability
Tom Anchordoquy, University of Colorado Denver, Aurora CO, US

9:30 – 10:00 Freeze-Drying of Nanosuspensions: From Theory to Practical Formulation and Process Design
Henning Gieseler, University of Erlangen, Germany

10:00 – 10:30 Break

10:30 – 11:00 Freeze Drying of Adjuvanted Vaccines
Ted Randolph, University of Colorado, Boulder, CO

11:00 – 11:30 New insights into freeze-drying with collapse
Kathrin Schersch, Novartis, Basel, Switzerland

11:30 – 12:00 Effects of Lyophilization on Thiol-Disulfide Exchange
Liz Topp, Purdue University, West Lafayette IN, US

12:00 – 12:30 Panel Discussion with audience participation
Moderator: Alan MacKenzie, Mercer Island WA, US

12:30 – 15:30 Lunch / Poster Session / Exhibition

Technical Operations and PAT I

15:30 – 16:00 Modeling and Simulation of Vapor/Ice Dynamics in Pharmaceutical Freeze-Drying
Alina Alexeenko, Purdue University, West Lafayette IN, US

16:00 – 16:30 Experimental and modeling studies of freeze-drying of API with organic co-solvent formulations
Julien Andrieu, University of Lyon, France

16:30 – 19:00 Exhibitors Soap Box Session with Bavarian Buffet/Exhibition

Friday, October 1

Technical Operations and PAT II

8:30 – 9:00 Guidelines for Operation of Freeze Dryers When Using Non-Aqueous Solvents
Dan Gunderud, IMA Edwards, Tonawanda NY, US

9:00 – 9:30 The Application of TDLAS in Measuring Equipment Capability and Establishing a Process Design Space
Steve Nail, Baxter, Bloomington IN, US

9:30 – 10:00 Monitoring lyophilization with optical fiber sensors
Michael Wiggenhorn, Coriolis, Martinsried, Germany

10:00 – 10:30 Process understanding by spectroscopy
Thomas de Beer, University of Gent, Belgium

10:30 – 11:00 Break

11:00 – 11:30 Modeling for risk assessment of quality failures
Stephanie Passot, AgroParisTech, INRA, Thiersval-Grignon, France

11:30 – 12:00 Residual water in freeze-dried materials: why and how to control it and at what levels
Evgenyi Shalaev, Pfizer, Groton CT US

12:00 – 12:30 Controlling Nucleation in Lyophilization: Effects on Process and Product
Robert Sever, Praxair, Burr Ridge IL, US

12:30 – 13:00 Panel Discussion with audience participation/ Conference Wrap-Up

Lunch