

APV Experts' Workshop on Lyophilization of Biologicals

- Current trends of freeze-drying for biologicals
- Advanced formulation concepts
- IP considerations for freeze-drying
- Platform technologies for early development
- Scale-up and transfer
- Case studies

21st to 22nd November 2012
Munich, Germany
Course No. 6472

Making
Science
Work

Arbeitsgemeinschaft für Pharmazeutische
Verfahrenstechnik e. V.
Gemeinnütziger wissenschaftlicher Verein
International Association for
Pharmaceutical Technology
Kurfürstenstraße 59
55118 Mainz/Germany
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<http://www.apv-mainz.de>

Target Group

Scientists in the area of pharmaceutical research working on freeze-drying of biological drug products. Scientists, Manufacturing Managers and Process Development Engineers involved in the pharmaceutical development of freeze-dried products. Project Managers who wish to out-source or coordinate the development of such formulations. Regulatory Affairs Managers who wish to learn more about the particular issues related to development of freeze-dried products.

Programme

Wednesday, 21st November 2012
11.00 to 18.00 h

Welcome address

Dr. Michael Wiggenhorn
 Coriolis Pharma Service GmbH
 Martinsried, Germany

Current trends of freeze-drying of biologicals

Prof. Dr. Gerhard Winter
 Ludwig-Maximilians-Universität
 Munich, Germany

Process Analytical Technologies (PAT) from laboratory to production

Prof. Dr. Thomas de Beer
 University of Ghent
 Ghent, Belgium

Advanced formulation concepts

Dr. Michael Wiggenhorn

Scale-up and transfer consideration

Dr. Ingo Presser
 (not yet confirmed)
 Boehringer Ingelheim GmbH & Co. KG
 Biberach, Germany

Freeze-Drying in Dual Chamber Systems

Dr. Frank Böttger
 Vetter Pharma-Fertigung GmbH & Co. KG
 Ravensburg, Germany

Thursday, 22nd November 2012
09.00 to 16.00 h

IP considerations for freeze-drying

Dr. Jan Zillies
 Hoffmann Eitle München-London
 Munich, Germany

Solid state characterization of freeze-dried protein formulations

Dr. Marco van de Weert
 University of Copenhagen
 Copenhagen, Denmark

Vaccine stabilization using freeze-drying

Dr. Jean Pierre Amorij
 National vaccine institute
 Bilthoven, The Netherlands

Platform technologies for lyophilization in early development phases of biological products

Dr. Michael Siedler
 Abbott Bioresearch Center
 Worcester, United States

Modern lyophilization cycle developments and design

Jörg Lümke
 (not yet confirmed)
 F Hoffmann-La Roche AG
 Basle, Switzerland

Lyophilization of highly concentrated protein formulations

Prof. Dr. Wolfgang Frieß
 Ludwig-Maximilians-Universität
 München
 Munich, Germany

Case studies presented and discussed together

All speakers

Programme is subject to change

APV Experts' Workshop on Lyophilization of Biologicals

A seminar organised by the APV focus group Pharmaceutical Biotechnology

Course Leader

Dr. Michael Wiggenhorn graduated in Engineering and in Biopharmaceutical Science (MSc) at the Division of Drug Delivery Technology at Leiden University (Leiden/Amsterdam Centre for Drug Research). His master thesis was related to the development and testing of chitosan microparticles prepared by the supercritical anti-solvent (SAS) method under supervision of Prof. Dr. Gerrit Borchard. Mid 2007 he finished his PhD thesis entitled "Scale-Up of Liposome Manufacturing: Combining High Pressure Liposome Extrusion with Drying Technologies" in Prof. Dr. Gerhard Winter's group at the Department of Pharmacy, Pharmaceutical Technology and Biopharmaceutics at the Ludwig-Maximilians-University (LMU), Munich, Germany. In January 2008 he received an Exist grant to set the course for starting up a company.

He is a co-founder and the chief executive officer (CEO) of the Coriolis PharmaService GmbH in Munich, Germany. Coriolis is a research oriented service provider, which offers formulation development and analytics of pharmaceutical proteins and colloidal drug formulations, with a strong focus on freeze drying and other drying technologies. Michael has published several publications, book chapters and patents in the field of processing and freeze-drying developments.

Objectives

The APV Experts' Workshop on "Lyophilization of biologicals" will take up and discuss with internationally renowned speakers from academia and industry current topics in the context of development, manufacturing, characterization and patenting of freeze-dried biological products.

Topics:

- Formulation concepts
- Scale-up and transfer
- Lyophilization cycle development
- PAT applications for use in laboratory and production
- Solid state characterization techniques
- IP issues and patenting
- Freeze-drying of prefilled syringes
- Vaccine stabilization
- Lyophilization of highly concentrated protein solutions

Date

Course No. 6472
from 21st Nov. 2012 11.00 h
to 22nd Nov. 2012 16.00 h

Location

IZB GmbH
Am Klopferspitz 19
82152 Planegg/Martinsried,
Germany
Phone: +49 89 700 65-670
Telefax: +49 89 700 65-677

Registration fee

APV member 1360 EUR
Non-member 1490 EUR
(free of VAT according § 4,22
UStG)

Coffee breaks, lunches, dinner
and proceedings included.

Members of authorities pay
half of the APV member's and
non-member's registration fee
respectively.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone +49 6131 9769-0
Telefax +49 6131 9769-69
e-mail: apv@apv-mainz.de

You will receive a confirmation
of your registration with the
invoice.

Hotel reservation

**ACHAT Premium Hotel
München-Süd**
Perchtinger Straße 3
81379 München, Germany
Phone: +49 89 780 676-0
Telefax: +49 89 780 676-888

Participants should make
their own hotel reservation
referring to the APV seminar.

Deadline for special conference
rate: 23rd October, 2012.

Special rate:
Single room incl. breakfast
buffet from EUR 85,00 per
night.

Hotel Ambiance Rivoli & Rivoli
Albert-Rosshaupter-Str. 18-22
81369 München, Germany
Phone: +49 89 743 515-152
Telefax: +49 89 743 515-999

Participants should make
their own hotel reservation
referring to the APV seminar.

Deadline for special conference
rate: 20th September, 2012.

Special rate:
Single room incl. breakfast
buffet from EUR 98,00 per
night.

Mainz, June 2012

Registration

Anmeldung

Seminaranmeldung/Registration by fax +49 6131 9769-69

oder per Post an/or by postal service to:

APV Arbeitsgemeinschaft für
Pharmazeutische Verfahrenstechnik e. V.
Kurfürstenstraße 59
D-55118 Mainz

Veranstaltung/Course No. 6472

Titel/Title: APV Experts' Workshop on Lyophilization
of Biologicals

Munich, Germany from 21st to 22nd November 2012

Titel, Vorname, Name
Title, First Name, Name

Firmenname
Company Name

Firmenadresse
Company Address

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Purchase Order Number

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e-mail Adresse
e-mail Address

Stellung im Betrieb
Position in Company

Abteilung
Department

APV-Mitglied
APV Member

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Date

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