ECA Academy
Your GMP/GDP Information Source

Spray Drying

Solutions for the Pharmaceutical Industry

Includes Guided Tour at the Hovione Site
The Hands-On Spray Drying Session is fully booked

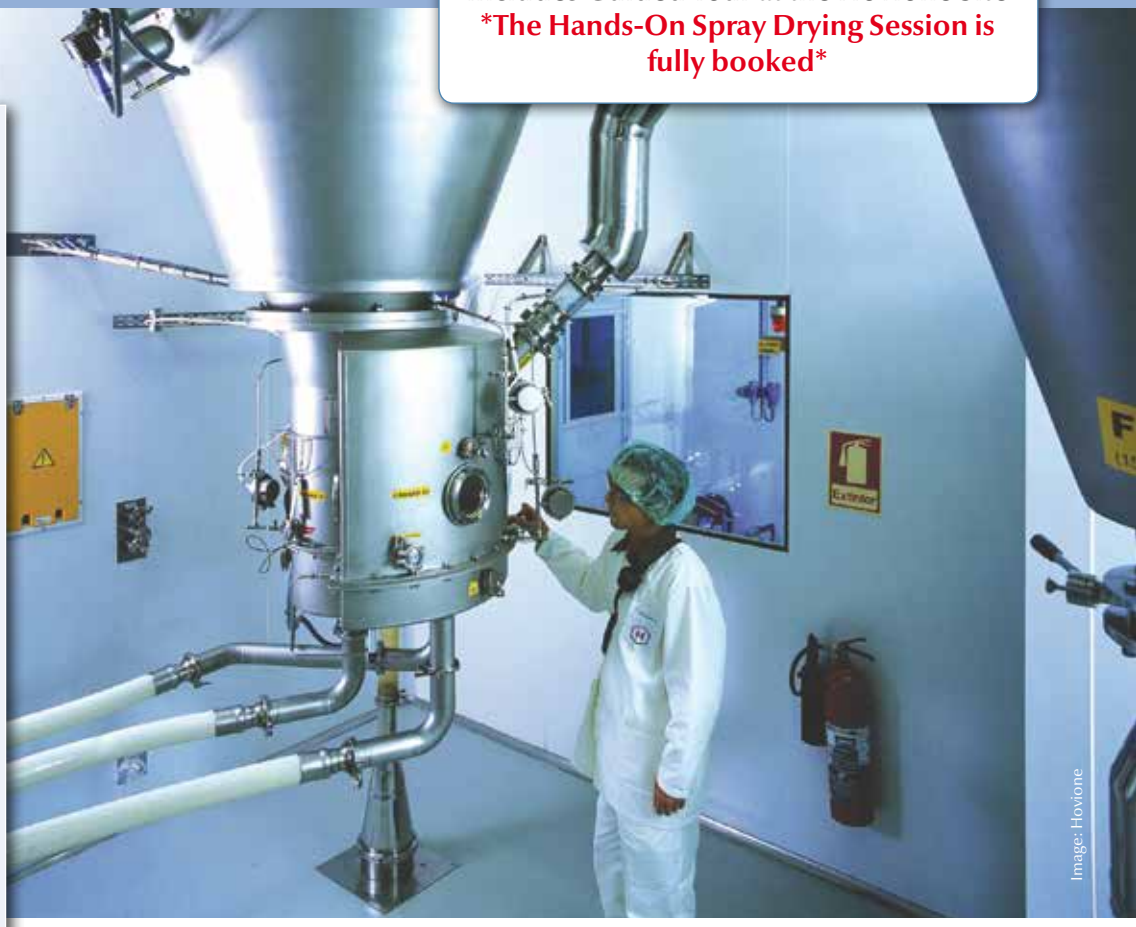
Image: Hovione

SPEAKERS


DR SUNE KLINT ANDERSEN
Novo Nordisk, Denmark


DR RUI FERREIRA
Hovione, Portugal


DR FILIPA MAIA
Hovione, Portugal


DR ULRICH MEIER
Novartis, Switzerland


DR THOMAS QUINTEN
Janssen Pharmaceutica, Belgium


HENRIK SCHWARTZBACH
GEA, Denmark


DR HARALD STAHL
GEA, Germany


DR JOAO VICENTE
Hovione, Portugal

7-9 June 2016, Lisbon, Portugal

HIGHLIGHTS:

- Fundamentals of Spray Drying
- Formulation development: Spray vs Freeze Drying
- Quality-by-Design for Spray Drying Processes
- Scale up of a pharmaceutical Spray Drying Processes
- Validation of Spray Drying Processes in an cGMP Environment
- Case Studies from Pharmaceutical Industry:
  - Increasing Bioavailability
  - Solid Dosage Forms
  - Inhalation Products

This conference is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager“.
Please find details at www.gmp-certification.eu

Spray Drying

7-9 June 2016, Lisbon, Portugal

Objectives

Take advantage of the opportunity to **focus on spray drying technology and process** and get a first hand demonstration of solutions for diverse requirements. Further, benefit from the **post-conference session** where you can get a **hands-on experience in spray drying yourself**. You will learn in small groups how the spray drying result is affected by different equipment, parameter changes, solvents etc.

Background

Spray drying is presently one of the most exciting technologies for the pharmaceutical industry, being an ideal process where the end-product must comply with precise quality standards regarding particle size distribution, residual moisture/solvent content, bulk density and morphology.

One advantage of spray drying is the remarkable versatility of the technology, evident when analysing the multiple applications and the wide range of products that can be obtained. From very fine particles for pulmonary delivery to big agglomerated powders for oral dosages, from amorphous to crystalline products and the potential for one-step formulations, spray drying offers multiple opportunities that no other single drying technology can claim.

Benefits of Spray Drying

- High precision control over:
  - Particle size
  - Bulk density
  - Degree of crystallinity
  - OVIs and residual solvents
- Typical application in pre-formulated products
  - Microencapsulations
  - Solid solutions
  - Improved bioavailability and stability
- For products with unusual or difficult characteristics
  - Sticky or hygroscopic products
  - Slowly crystallizing products
  - Difficult to isolate products
- Rapid drying for temperature sensitive materials

Target Audience

This conference addresses specialists and executives working in the fields of pharmaceutical manufacture, research and development and quality control as well as technicians, planners and plant designers, especially those involved with the manufacture of powders and granules, as e.g. in the manufacture of solid dosage forms for oral or pulmonary administration.

Moderator

Dr Harald Stahl

Programme

Fundamentals of Spray Drying

- Identification of Critical Process Parameters
- Control of those Process Parameters
- Influence of these Process Parameters on Product Quality
- Example of setting up a Spray Drying Process

Spray drying from a particle perspective

- Gas temperature and humidity
- Drying at particle level
- Stickiness (time, temperature and humidity)
- CFD models and drying kinetic analysis

Spray Drying vs Freeze Drying – How to choose the right technique?

- Fundamentals of Freeze Drying
- Spray Drying of Pharmaceuticals
  - Formulation via spray drying
  - Scientific basics
  - Review of spray-dried pharmaceutical products
- How to conclude: Spray Drying or Freeze Drying

Programme (cont'd)

Development of Scaleable Spray Drying Processes for Solid Drug Product Manufacture

The presentation starts from the target properties of pharmaceutical intermediates and products for oral solid dosage forms and for dry powder inhalation, viewing SD as a particle design tool. Examples of various product types, such as amorphous drug substances, solid dispersions, granulates and inhalable powder, are given. SD is then compared to other drying/ agglomeration processes more common in the pharma industry. A systematic approach for development of products/ processes by means of spray drying is illustrated. , A special focus is given to the scaleability of the SD processes.

Validation and the usage of QbD for Spray Drying

- Risk assessment in the context of qualification and validation
- Development of spray drying process using DoE
- Three stage DoE
  - Parameter screening (CCF design with 3 variables + extension)
  - Raw material variability
  - Process Validation
- PAT: Inline particle sizing and NIR used to monitor the spray drying process
- Special test during qualification and validation

Scale-up of a Spray Drying Process

The bench scale spray drying units can be found in most of the material characterisation and drug development teams, being also used as production units of high-value low-volume drugs. However, it is often underestimated the valuable information that lab experiments can give to help in a successful process scale-up. In this presentation a scale-up methodology will be presented where insight will be given on what and how lab scale data can be used, as well as, how scaling-up can be used to improve product properties.

- Usage of lab scale data
- Product improvement during scale up
- Methodology for scale up of SD processes

Trouble Shooting Session

In this interactive session, all the key elements of the preceding lectures are brought together.

What to do if:

- Particles are too fine/coarse
- Yield is too low
- Final product moisture content is too high
- Different product characteristics after scale up

Case study: Enhancing the bioavailability of poorly soluble drugs using spray drying: scaling up from lab scale to commercial scale

- Short introduction on amorphous solid dispersions
- Manufacturing technologies
- Case study of itraconazole (Sporanox®)
- Case study of etravirine (Intelence®)

Case study: Application of Spray Drying for oral dosage forms

- Case-study 1 – Laboratory scale challenges
  - Focus on laboratory scale unit limitations
  - How to improve powder properties at laboratory scale
  - Strategies to formulate poor flowing SD powders
- Case-study 2 – Commercial challenges
  - Focus on adjusting powder properties for locked formulations
  - How to develop a commercial process
  - Strategies to cope with challenging targets (e.g. density, PS)

Case study: Application of Spray Drying for Inhalation Products

- Critical quality attributes: an overview for composite formulations via spray drying
- Spray drying process: Thermodynamics aspects specific of Inhalation products
- Spray drying process: Atomization aspects (controlling particle size and morphology)
- Composite DPI formulations through spray drying

Site Visit at Hovione on Thursday, 9 June 2016
cGMP Spray Drying Equipment and Facility

Part of the programme on the third day of the conference is a guided tour at the Hovione site.

In line with the latest developments on spray drying technologies and with the increasing demand for highly defined particles properties in the pharmaceutical industry, Hovione has installed and commissioned a range of spray drying units able to operate under the most stringent cGMP conditions.

These laboratorial, pilot and industrial scale units allow Hovione to offer from a few grams to full scale commercial production. With FDA-inspected plants Hovione is capable to manufacture spray dried material under cGMP conditions.

The guided tour will include a visit of the spray dryer building where pilot, small and full commercial scale equipment can be seen. Moreover the production control room and the analytical labs will be part of the guided tour.

Fully booked

Hands-on Spray Drying Session

Thursday, 9 June 2016

On the third conference day you will have the opportunity to **take advantage of an exclusive hands-on training**. For that purpose several spray dryers will be available at Hovione. Experienced Trainers will lead you in small groups, providing an intensive experience and directly applicable know-how.

You will see how scale-up is done through mathematical modelling and how to take advantage of scale-up to significantly improve powder properties. You will have the chance to spray dry a material both at lab and commercial scale. You will learn how to develop a process under QbD, how to optimise production parameters and how to proceed a scale-up from laboratory to industrial scale. Furthermore, you will learn how to analyse and evaluate your product.

Target group of the Session

Process Engineers, Pharmaceutical Technologists, Pharmaceutical Formulation Scientists, Application Chemists, Drug Development Engineers, Particle Design Engineers

In certain cases a participation in the workshop may not be possible due to competitive reasons.

Experiments

- Definition of scale-up conditions with the aid of macroscopic heat and mass balance and Computational Fluid Dynamics
- Laboratory scale spray drying – how to set up a stable lab scale process. Tips and tricks
- Upscale to pilot/commercial-scale spray dryer. Details on system configuration and basic controls
- Comparison of powders in terms of flowability, particle size, morphology and other relevant powder/particle attributes

A shuttle bus will bring you back to the hotel with a prior stop at the airport.
Airport arrival is scheduled for approximately 15.30 h.

The course is held in small groups, so number of participants is strongly limited.
Early booking is recommended.

Social Event

On 7 June you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Speakers

DR SUNE KLINT ANDERSEN, NOVO NORDISK A/S, DENMARK

Dr Andersen studied at the Technical University of Denmark and gained his Ph.D. in Particle Technology. From 1999-2007 he worked for Niro A/S as Spray Drying specialist and is now working for Novo Nordisk A/S also in the position of a Spray Drying Specialist.

DR RUI FERREIRA, HOVIONE FARMACIENCIA SA, PORTUGAL

Rui Ferreira is graduated in Chemical Engineering and holds a Ph. D. in Engineering Sciences and Technology. At Hovione, he is working in the Drug Product Development group as Process Development Scientist and has participated in the scale-up of multiple spray drying processes for the production of amorphous solid dispersions. His main interests are in the areas of oral dosage forms, pharmaceutical technology and particle engineering.

DR FILIPA MAIA, HOVIONE FARMACIENCIA SA, PORTUGAL

Filipa Maia has a degree in chemical engineering. She works in the Inhalation Development Team of Hovione were she is working in particle design projects, applying spray drying and other techniques for the design of particles intended for inhalation.

DR ULRICH MEIER, NOVARTIS PHARMA AG, SWITZERLAND

Ulrich Meier is a Senior Process and Particle Engineer in Technical R&D at Novartis Pharma. His main interests include development of drug substance finishing processes, as well as the development of continuous spray drying processes for pharmaceutical intermediates and inhalable particles by means of conventional and fluidized bed spray-drying and supercritical fluid processes. He is also teaching at Novartis workshops and at the University of Applied Sciences in Luzern.

DR THOMAS QUINTEN

Janssen Pharmaceutica NV, Belgium
Thomas Quinten is a pharmacist with a PhD in Pharmaceutical Technology. He works a Senior Scientist for J&J in the Development of Oral Solid Dosage forms.

HENRIK SCHWARTZBACH, GEA, DENMARK

Henrik Schwartzbach has been working for GEA Niro since 1992 with R&D and process optimisation. The focus has been process optimisation within pharmaceutical spray drying. Henrik Schwartzbach has detailed and in-depth knowledge about cutting edge pharmaceutical spray drying. As the GEA Senior Process Technologist he is deeply involved in setting the industry standards for pharmaceutical spray drying.

DR HARALD STAHL, GEA, GERMANY

Dr.Harald Stahl worked in the Pharmaceutical Development of Schering AG in Germany. At that time his main interest was the aseptic production of pellets. Since 1995 he served within GEA Process Technology in various positions. Presently he owns the position of a Group Director Application & Strategy Management of GEA. He has published more than 20 papers on various aspects of pharmaceutical production.

DR JOAO VICENTE, HOVIONE FARMACIENCIA SA, PORTUGAL

João Vicente has an academic background in Chemical Engineering and Pharmaceutical Technology. , His PhD thesis, entitled Modeling and Optimization of Spray Drying Processes under QbD Principles, was sponsored by Hovione and performed under industrial conditions. During the research João has developed predictive tools to support scale-up activities. Since then, João Vicente has been working at Hovione as Scientist in the Drug Product Development Group and has participated in the Development and Validation of several spray drying processes.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Tuesday, 7 June 2016,
10.00 to approx 17.45 h,
(Registration and coffee 09.30 – 10.00 h)
Wednesday 8 June 2016,
08.30 to approx 16.45 h
Thursday, 9 June 2016 2016,
8.30 - 13.00[1]/13.30[2] h)

End times for the guided tour
[1] approx. airport arrival
[2] approx. return to hotel

Venue


Lisbon Marriott Hotel
Avenida dos Combatentes
1600-042 Lisbon
Portugal
Phone +351 217 325 400
Fax +351 217 264 281

Fees (per delegate plus VAT, including guided tour, without workshop)
ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 7 June, lunch on 7 and 8 June, a business lunch on 9 June and all refreshments.
VAT is reclaimable.

There will be a bus transfer after the guided tour to the hotel via the airport. w

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event.
Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservations should be made directly with the hotel.
Early reservation is recommended.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0)62 21/84 44-0
Fax +49 (0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Robert Eicher (Operations Director) at +49(0)62 21 / 84 44 12, or per e-mail at eicher@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Rouwen Schopka (Organisation Manager) at +49(0)62 21 / 84 44 13, or per e-mail at schopka@concept-heidelberg.de.

If the bill-to-address deviates from the specification to the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

Reservation Form (Please complete in full)

+49 6221 84 44 34

Spray Drying with Guided Tour at Hovione
7-9 June 2016, Lisbon, Portugal

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number **Purchase Order Number, if applicable**

Street / P.O. Box

City Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

wa/vers1/07072015

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.

If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing.

The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.