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!

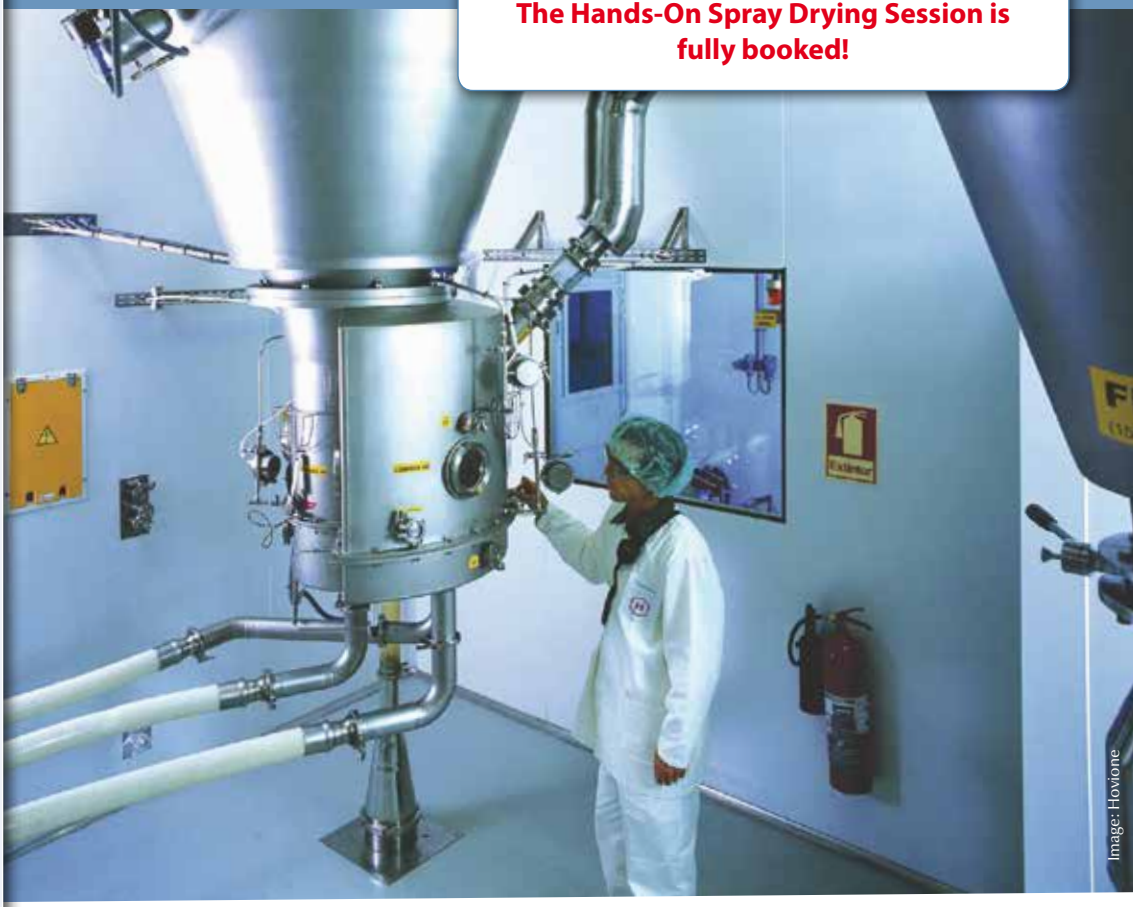

Image: Hovione

Speakers

Dr Sune Klint Andersen
Janssen Pharmaceutica

Dr Eunice Costa
Hovione

João Henriques
Hovione

Dr Eline Hermans
Janssen Pharmaceutica

Dr Ulrich Meier
Novartis

Dr Andrew Parker
Juniper Pharma Services

Dr Harald Stahl
GEA

Dr Joao Vicente
Hovione

Marianne Van Steenwinckel
Janssen Pharmaceutica

10-12 April 2018, Lisbon, Portugal

HIGHLIGHTS:

- Fundamentals of Spray Drying
- Formulation development: Spray vs Freeze Drying
- Analytics and characterisation of spray dried products
- QbD 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:
  - Amorphous Solid Dispersions
  - Usage of PAT Tools
  - 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

10-12 April 2018, 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

Analytics and characterisation of spray dried products

- Short Overview of Solid dispersions:
- Analytical tools
- Novel screening methods – single droplet spray drying
- Screening protein formulations
- Understanding cohesion/adhesion balances
- Correlating structure with performance

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

- 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.

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 and lab-scale limitations
- Product improvement during scale up
- Scale-up methodology
- Process development strategy

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

Amorphous Solid Dispersions – Manufacturing Technologies

- Amorphous solid dispersions: a way to improve the aqueous solubility and oral bioavailability
- Spray drying from lab scale to commercial scale: end to end process development
- Case study: upscaling form lab scale equipment to commercial scale equipment

Case Study: PAT Technology for Spray Drying

- PAT to support a theoretical spray dry model in scale-up
- FDA's request for PAT to ensure product quality
- In line measurement of particle size and relative saturation

Integration of Quality-by-Design into Qualification and Validation of Spray Drying Processes

- Development of spray drying process using Quality-by-Design
  - Design of Experiments (DoE)
  - Critical Process Parameters
  - Critical Material Attributes
- Risk assessments:
  - Spray Drying Process
  - Spray Dryer Design
- Qualification and Validation of a Spray Dryer
- Process Validation
  - Scale-up
  - Control Strategy
- Special tests during qualification and validation

Supporting the development of oral dosage forms with Spray Drying

- Specific challenges of the formulation of Amorphous Solid Dispersions into tablets
- Bridging spray drying and tablet development
- Advantages and challenges of integrated ASD tablet development

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, 12 April 2018
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. The guided tour will end with a lunch snack at 12.30 h. Afterwards there will be a transfer to airport & hotel (for those participants not taking part in the workshop).

Fully booked

Hands-on Spray Drying Session

Thursday, 12 April 2018

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

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 10 April, 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, JANSSEN PHARMACEUTICA NV, BELGIUM

Dr Andersen studied at the Technical University of Denmark and gained his Ph.D. in Particle Technology and has an MBA in Management & Technology. He worked for Niro A/S for seven and for Novo Nordisk for 10 years as spray drying specialist. Now he is working at Janssen Research & Development, Belgium as Principal Scientist in Spray Drying.

DR EUNICE COSTA, HOVIONE, PORTUGAL

Eunice Costa is a Process Development Scientist at Hovione, working on particle design and formulation development for both oral and inhalation drug products. Eunice holds a PhD in Bioengineering from the MIT-Portugal Program, New University of Lisbon. Prior to her PhD, Eunice worked at the Early Stage Pharmaceutical development group at Genentech US, and at the Human Physiology department at TNO, The Netherlands.

JOÃO HENRIQUES, HOVIONE FARMACIENCIA SA, PORTUGAL

João is the Team Leader for the Formulation and Particle Design group at Hovione. His team is responsible for the development, scale-up and validation of spray drying, jet milling, spray congealing and drug product processes. He joined Hovione in 2008 as a PAT specialist and has worked in Manufacturing Operational Excellence before he joined the R&D Group.

DR ELINE HERMANS, JANSSEN PHARMACEUTICA NV, BELGIUM

Eline Hermans has a master and a PhD in Chemical Engineering. She works a Janssen Pharmaceutica in Beerse as Sr. Scientist is the field of new processes and technologies, for example Continuous Manufacturing, Spray Drying and 3D Printing.

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 ANDREW PARKER, JUNIPER PHARMA SERVICES, UK

Andrew is Director of Project Management at Juniper Pharma Services. He has a degree in Physical Chemistry/Biotechnology from the University of Bristol and has been working as a research chemist in the Bristol Colloid Center.

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. He developed predictive tools to support scale-up activities. Since then, João Vicente has been working at Hovione as Scientist in Drug Product Development and has participated in the Development and Validation of several spray drying processes. He is the team leader of the Particle Engineer and Solubility Enhancement Group at Hovione.

MARIANNE VAN STEENWINCKEL, JANSSEN PHARMACEUTICA

Marianne Van Steenwinckel holds Master Degrees in Pharmaceutical Sciences and Industrial Pharmacy and is an Senior Scientist in Drug Product Development at Janssen R&D in Beerse, Belgium. Her expertise is in the area of OSD development and especially in amorphous solid dispersions. She has worked on numerous development projects and she has extensive experience within spray drying with application of DoE, Scale-up through modeling, and implementation of PAT.

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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, 10 April 2018,
10.00 to approx 17.30 h,
(Registration and coffee
09.30 – 10.00 h)
Wednesday 11 April 2018,
09.00 to approx 17.30 h
Thursday, 12 April 2018,
8.30 -13.00[1]/13.30[2] h)

[1] approx. airport arrival
[2] approx. return to hotel

There will be a shuttle service after the guided tour for those participants who cannot take part in the workshop. This shuttle will leave at 12.30 h and arrive at the airport at approx. 13.00 h and approx. at 13.30 at the 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)
ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 10 April, lunch on 10 and 11 April, a business lunch on 12 April and all refreshments. VAT is reclaimable.

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

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
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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:

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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
10-12 April 2018, Lisbon, Portugal

☐ Mr ☐ Ms

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Title, first name, surname

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Company

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Department

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

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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).

German law shall apply. Court of jurisdiction is Heidelberg.

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.