Spray Drying
Solutions for the Pharmaceutical Industry

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

10-12 April 2018, Lisbon, Portugal

Speakers

Dr Sune Klint Andersen
Janssen Pharmaceutica

João Henriques
Hovione

Dr Eline Hermans
Janssen Pharmaceutica

Dr Filipa Maia
Hovione

Dr Ulrich Meier
Novartis

Dr Andrew Parker
Juniper Pharma Services

Dr Harald Stahl
GEA

Dr João Vicente
Hovione

Marianne Van Steenwinckel
Janssen Pharmaceutica

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
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.

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.
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.

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 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 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.
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,
12 April 2018,
8.30 - 15.30/16.00 h

The event will be a shuttle service after the
guided tour for those participants who can-
not 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. The other shuttle will arrive at the
airport at 15.30 h.

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

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

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to notify us in writing. If you cannot take part, you have to
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General terms and conditions
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Privacy Policy: By registering for this event,
accept the processing of my Personal Data.

Fees (per delegate plus VAT, including
workshop & guided tour)
ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995

The conference fee is payable in advance
after receipt of invoice and includes con-
ference documentation, dinner on 10 April,
lunch on 10 and 11 April, a business lunch
on 12 April and all refreshments. VAT is re-
claimable.

There will be a bus transfer after the guided
tour and after the hand-on session to the
hotel via the airport.

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

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 lim-
ited 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 negoti-
ated rate for the duration of your stay. Res-
evations 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.

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.

Spray Drying - with Guided Tour and Workshop at Hovione
10-12 April 2018, Lisbon, Portugal

Company

Department

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

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German law shall apply. Court of jurisdiction is
Heidelberg.