ECA Academy
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GMP Certification Programme
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Speakers


Dr Sune Klint Andersen
Janssen Pharmaceutica


João Henriques
Hovione


Dylan Jones
formerly Sanofi


Prof Geoffrey Lee
Erlangen University, Germany


Mafalda Paiva
Hovione


Dr Tiago Porfirio
Hovione


Dr Thomas Quinten
Janssen Pharmaceutica


Henrik Schwartzbach
Niro A/S, Denmark


Dr Harald Stahl
GEA

Spray Drying

Solutions for the Pharmaceutical Industry

12 - 14 May 2020 | Copenhagen, Denmark


Image: Hovione

Highlights

- Fundamentals of spray drying
- Formulation development: Spray vs Freeze Drying
- Analytics and characterisation of spray dried products
- Development and spray drying on lab scale
- 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
  - Drying of biopharmaceuticals
  - Inhalation products

Includes Hands-On Spray Drying Workshop at the GEA Niro Site

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 **practical day at the GEA Niro Site** 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?

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

Spray drying, an enabling and versatile technology– From solubility enhancement to dry powder Inhalation

- Overview of spray drying applications in the pharmaceutical industry
- Spray drying as an enabling technology for low solubility APIs and pulmonary delivery
- Bridging particle engineering, formulation and performance

Spray Drying on Laboratory Scale

- Lab-scale & micro-scale spray dryers
- Design & process conditions
- Enthalpy calculations
- Advantages & limitations
- Examples

Scale up of SD processes – How to develop a robust commercial process

The scale-up of a spray drying process is often considered a resource-intensive challenge requiring large quantities of expensive drugs. Nevertheless, the use of a proper scale-up methodology overcomes this difficulty by the adoption of suitable mathematical modelling tools and lab experimentation approach. This presentation will focus on:

- Scale up methodology
- Establishment of scale-independent correlations
- Modelling tools for spray drying development
- Troubleshooting during scale up

Case Study Sanofi: PAT for Control and Optimisation of a Large Scale Spray Dryer

An optimised process for spray drying often operates close to boundaries of failure. Operating close to these boundaries requires well-controlled critical process parameters and critical product attributes.

- Development of timely, meaningful, and reliable measurements
- Practical examples of using PAT tools in spray drying

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

Enhancing the bioavailability of poorly soluble drugs using spray drying: Amorphous Solid Dispersions

- Introduction to ASD
- Manufacturing technologies (focusing on spray drying and melt extrusion)
- Case studies

Spray Drying of Biopharmaceuticals

For biopharmaceutical formulations, spray drying has only been used sparingly with freeze drying being the overwhelming choice as drying technology. However, over the last decade several developments within the pharmaceutical industry have taken place resulting in spray drying becoming a more accepted technology and more generally considered as an feasible technology for drying of biopharmaceuticals. In the presentation the challenges in spray drying of biopharmaceuticals will be discussed together with the possible solutions to overcome these.

- Biopharmaceuticals vs. Small Molecules
- Traditional Biopharmaceutical Drying Processes
- Spray Drying of Biopharmaceuticals
  - Oral Delivery
  - Parenteral Delivery (Aseptic Spray Drying)
- Outlook for Biopharmaceutical Drying Processes

Addressing the Analytical Challenges of Spray dried materials

- The importance of a reliable evaluation of physical stability
- Quantifying improvements in solubility – biorelevant assessment of in vitro performance

Hands-On Spray Drying Workshop

on Thursday, 14 May 2020

On the third conference day you will have the opportunity to **take advantage of an exclusive hands-on training**. With that purpose three different spray dryers will be disposed at the GEA Niro Test Station. Experienced Trainers will lead you in very small groups, providing an intensive experience and directly applicable know-how.

You will **see how different spray drying equipment, different solvents, products, and variation of process parameters affect the yield, residual moisture, bulk density and particle size**. You will learn how to design feasibility studies, 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 and the process by using methods like Laser Diffraction, Microscopy and LoD.

Target group of the Course:
Pharmaceutical Technologists Pharmaceutical Formulation Scientists Application Chemists Drug Development Engineers, Particle Design Engineers.

Experiments

- Labscale spray drying in once-through operation of aqueous/organic solvent applications under contained conditions and influence of process parameters on drying conditions
- Upscale to pilot-scale spray drying of aqueous/organic solvent applications and influence of process parameters on particle size in closed-cycle operation
- Upscale from pilot-scale to industrial scale spray drying of aqueous/organic solvent applications and influence of process parameters on particle size, bulk density and residual moisture/solvent content

A shuttle bus will bring you back to the hotel with a prior stop at the airport. Airport arrival is scheduled for approximately 16.15 h.

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

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

Speakers

Dr Sune Klint Andersen
Janssen Pharmaceutica NV, Belgium

Sune gained his PhD 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.

Dylan Jones
formerly Sanofi, UK

Dylan is director at Baythorne UK. Before he has been R&D Manager at Sanofi in Suffolk. The site hosts the largest continuous processing plant in the world for pharmaceutical manufacturing and very large spray dryers. He led a team specialised in process development, spectroscopy, and multivariate data analysis to develop real time measurements for automation and control.

Prof Geoffrey Lee
Erlangen University, Germany

After being Assistant Professor at the Univiversity of Illinois, Chicago, Geoffrey Lee was appointed Associate Professor in Pharmaceutics at the University of Heidelberg. In 1993 he was given the Chair in Pharmaceutics at Erlangen University. Prof Lee's major research interests are the drying of proteins, and the transdermal delivery of drugs.

Mafalda Paiva
Hovione FarmaCiencia, Portugal

Mafalda has a MSc in Pharmaceutical Sciences and Quality Control and is working for Hovione as group leader in the R&D Analytical Development. Her main area of expertise are performance methodologies to forecast in vivo behaviour of amorphous based drug products.

Speakers

Dr Tiago Porfirio
Hovione FarmaCiencia, Portugal

Tiago is a Chemical Engineer and working as Scientist responsible for the development of manufacturing processes and implementation of new technologies in the area of Particle Engineering. His research is focused in the development of modelling tools to support the scale-up activities of SD processes.

Dr Thomas Quinten
Janssen Pharmaceutica, Belgium

Thomas is a pharmacist with a PhD in Pharmaceutical Technology. He works as Senior Scientist for J&J in the Development of Oral Solid Dosage forms.

Henrik Schwartzbach
Niro, Denmark

Henrik has been working for Niro A/S since 1992 with R&D and process optimisation. His focus has been development and process optimisation within pharmaceutical spray drying. As the Niro Pharma Division Senior Process Technologist he is deeply involved in setting the industry standards for pharmaceutical spray drying.

Dr Harald Stahl
GEA, Germany

Harald started his career in the Pharmaceutical Development of Schering in Germany. Since 1995 he served within GEA Process Technology in various positions. Presently he owns the position of a Vice President and is Head of Application Development and Strategy.

Social Event

On 12 May 2020, 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.

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

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CONCEPT HEIDELBERG
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GERMANY

Reservation Form (Please complete in full)

Spray Drying, 12-14 May 2020, Copenhagen, Denmark

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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 HEIDELBERGwill 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 https://www.gmp-compliance.org/privacy-policy). 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.

Date
Tuesday, 12 May 2020, 10.00 to approx 17.30 h,
(Registration and coffee 09.30 – 10.00 h)
Wednesday 13 May 2020, 09.00 to approx 17.30 h
Thursday, 14 May 2020, 8.30 -16.15[1]/16.45[2] h)

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

Venue
Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
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Scandinavia.meetings.events@radissonblu.com

Fees (per delegate, plus VAT, including Workshop)
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 conference documentation, dinner on 12 May, lunch on 12 and 13 May, a business lunch on 14 May and all refreshments. VAT is reclaimable.

There will be a bus transfer after the hands-on session to the hotel via the airport. The shuttle will arrive at the airport at approx. 16.15 h and 16.45 h at the hotel

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

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/ POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

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

Conference language
The official conference language will be English.

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