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Speakers


Dr Sune Klint Andersen
Janssen Pharmaceutica


Dylan Jones
formerly Sanofi


Paulo Lino
Hovione FarmaCiencia


Dr Tiago Porfirio
Hovione


Dr Thomas Quinten
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Henrik Schwartzbach
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Luis Sousa
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Dr Harald Stahl
GEA

Spray Drying

Solutions for the Pharmaceutical Industry

Live Online Conference on 15/16 March 2022


Image: Hovione

Highlights

- Fundamentals of spray drying
- Formulation development: Spray vs freeze drying
- Analytics and characterisation of spray dried products
- 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

Objectives

In this Live Online Conference you will get to know the different spray drying applications and what you have to consider when you implement them into your manufacturing process. You will learn

- how to identify critical process parameters
- how to weigh up the pros and cons of spray drying and freeze drying and how to choose the right technique
- how to scale up and develop a robust commercial SD process
- how to control and optimize a Large Scale Spray Dryer
- how to enhance the bioavailability of poorly soluble drugs by a SD technique

You will get first hand information by experts from industry. Benefit from their experience in applying the spray drying technology in the manufacture of various pharmaceutical products.

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 analyzing 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.

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

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

Moderator

Dr Harald Stahl, GEA

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.

Dylan Jones, Baythorne 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.

Paulo Lino, Hovione FarmaCiencia, Portugal

Paulo Lino is a Scientist in the R&D Drug Product Development area. Pharmacist by training, did a PhD and Post-Doc in Pharmaceutical Technology spanning complex biopharmaceutical formulation/engineering, freeze-drying and particulate polymeric drug delivery systems. At Hovione he has led since 2017 multivariate formulation screening and several development/scale up campaigns of solubility enhancement and particle engineering projects.

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.

Luis Sousa, Hovione FarmaCiencia, Portugal

Dr Luis Sousa is a Senior Analytical Chemist in the R&D Analytical Development area. He is a pharmacist by training and holds a PhD in Thermal Analysis and Pharmaceutics from the UCL School of Pharmacy, London, UK. After his PhD, Dr. Sousa did a two-year post-doc at Purdue University, West Lafayette, USA, before joining Hovione in 2015.

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.

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Reservation Form (Please complete in full)

Spray Drying, Live Online Conference on 15/16 March 2022

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Date of the Live Online Conference

Tuesday, 15 March 2022,
09.30 to approx 17.15 h CET
Wednesday, 16 March 2022,
09.00 to approx 16.30 h CET

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Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice.

Registration

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

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering Recordings

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These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

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

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