ECA Academy
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Speakers


Dr Sune Klint Andersen
Janssen Pharmaceutica


Dr Jean-René Authelin
Sanofi


Dr Rainer Nicolai
F. Hoffmann La-Roche


Simon Phillips
Nova Laboratories


Dr João Pires
Hovione


Dr Thomas Quinten
Janssen Pharmaceutica


Dr Inês Ramos
Hovione


Dr Harald Stahl
GEA


Dr João Vicente
Hovione


Dr Ann-Cathrin Willmann
Boehringer Ingelheim Pharma

Spray Drying

Solutions for the Pharmaceutical Industry

24-26 September 2024 | Lisbon/Porto Salvo, Portugal


Image: Spray Drying Facilities at Hovione

Highlights

- Fundamentals of Spray Drying
- Development of a Spray Drying Process
- Advanced Characterization of Spray Dried Particles
- Scale Up of a Pharmaceutical Spray Drying Processes
- Validation of Spray Drying Processes in a CGMP Environment
- Manufacturing Technologies for Amorphous Solutions
- Aseptic Spray Drying
- Tailoring Spray Drying Processes for Biopharmaceutical and Respiratory Formulations
- Case Studies from Pharmaceutical Industry:
  - Sanofi: Spray Drying of Biologics
  - Roche: Spray Drying of highly active Substances
  - Hovione: Amorphous Solid Dispersions by Spray Drying

Includes Guided Tour at the Hovione Sites

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 **site visit** where you can get a **hands-on experience in spray drying yourself**. You will learn how the spray drying result is affected by different equipment, parameter changes 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 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.

Moderator

Dr Harald Stahl, GEA

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

Development of a Spray Drying Process

- Scientific basics
- Lab equipment
- Material selection
- Scaleability
- Design of the test series
- Case studies
  - Dry powder for inhalation
  - Amorphous solid dispersions

Advances in Characterization of Morphology of spray dried Particles

- Elucidation of spray drying particle microstructure like wall thickness, porosity
- Application of Tomography and FIB-SEM
- Application of Machine Learning/AI to subdivide particles in morphology classes
- Impact of this new knowledge on formulation and process development

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

A spray drying process will be subjected to multiple scale-up steps throughout the product's life-cycle, thus requiring a robust process understanding to control the products properties. The scope of this talk is to describe the knowledge and risk-based methodology that guides the stages from the process design up to qualification and commercial phase of a spray drying manufacturing process. The lecture will focus on predictive tools used to support process/product development and scale-up activities.

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

Amorphous solid Dispersions by Spray Drying from a Formulation Perspective

The manufacturing of Amorphous solid dispersions (ASD) has become an established and commercially demonstrated strategy to improve the bioavailability of poorly water-soluble drugs. ASD formulation typically requires the definition of multiple factors that can amount to extensive lab experimentation, hindering fast-to-market. This lecture will provide an overview of how to design a successful formulation for amorphous solid dispersions produced by spray drying, using a streamlined approach and a proprietary technology to expedite the screening phase with minimal API requirements. An overview of Hovione's methodology, the evaluation process, and the studies typically utilized, insights on alternative excipients, as well as key information needed to make a formal assessment of the best candidates will be provided resorting to case studies.

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

Tailoring Spray Drying Processes for Biopharmaceutical and Respiratory Formulations

- Requirements & challenges when applying spray drying for biopharmaceutical and respiratory products
- Adaptation of specifications and de-risking of the process during its development from laboratory scale to commercial production
- Optimisation of the spray drying process
  - overall product quality
  - lowest risk
  - shortest time to market

Case Study Sanofi: Spray Drying of Biologics

Aseptic Spray Drying as an enabling Technology for novel Sterile Presentations

- Sterile Processing and Isolator technology
- Aseptic validation and sterility assurance
- Aseptic spray drying as stabilisation platform and alternative to aseptic lyophilisation
- Sterile finished drug product presentations based on sterile spray dried powder
- Emerging trends and case studies

Case Study Roche: Spray Drying of highly active Substances

- Large scale containment technologies
- Operating conditions versus containment
- Cleanability in regard to containment performance

Trouble Shooting Session

In this interactive session, all the key elements of the preceding lectures are brought together.
What to do if:

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

26 September 2024

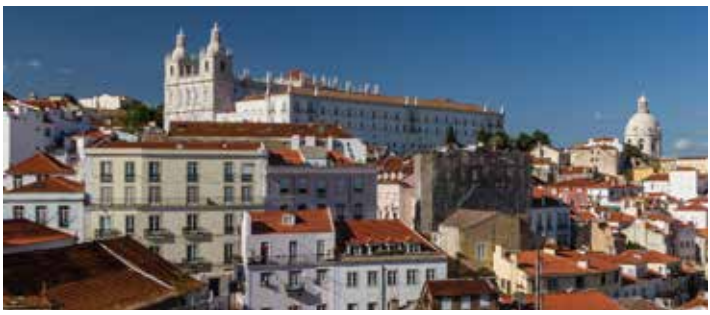
Visit of the Hovione Spray Drying Facilities in Lisbon

As part of the conference you will have a unique opportunity to visit Hovione's labs and manufacturing facilities in Lisbon, where research, development and manufacturing activities take place. In the labs you will gain access to Particle Engineering facilities, explore some of the most advanced analytical PAT tools, and get a close look at the specialized equipment used in spray drying development. You will also have the chance to observe analytical and process development operations in an engaging hands-on workshop, guided by Hovione experts.
During the visit to the manufacturing facilities, you will witness a state-of-the-art facility in action, showcasing a commercial spray drying unit.
Please note that availability for this exclusive site visit is limited, so securing your spot early is highly recommended to ensure you don't miss out on this opportunity to experience Pharmaceutical innovation at Hovione.

- We provide bus transfer from the conference hotel to the Hovione sites. After the site visit there will be transfers to the airport and back to the conference hotel
- Due to competition reasons, individual participants may be excluded from the site visit
- Participants are required to sign a Confidential Disclosure Agreement (CDA) before entering Hovione sites

Social Event

On Tuesday 24 September 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

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 and particle engineering.

Dr Jean-René Authelin, Sanofi

Jean René Authelin joined Rhone Poulenc in 1988 as a Chemical Engineer. In the 90's he founded the Physical Quality function, dedicated to the API crystallization, drying, polymorphism, particle engineering for which he was for 10 years Global Head in Rhone Poulenc Rorer (now Sanofi). Later he became Global Head of Pharmaceutical Engineering, now he is Senior Scientific Advisor, global CMC.

Dr Rainer Nicolai, F. Hoffmann La-Roche

Rainer Nicolai has been involved in the handling of high purity and high activity substances since 1998. With a total of 15 years of experience as a project manager and containment expert at Roche, he is involved in a wide range of issues with high practical relevance.

Simon Phillips, Nova Laboratories

As Head of Sterile Manufacturing at Nova Laboratories, Simon is responsible for all aspects of a Nova's Sterile Contract Manufacturing business, including manufacturing in three sterile manufacturing facilities, technical operations and business development. He and his teams are responsible for manufacture of both clinical and commercial sterile products filled in a range of presentations.

Dr João Pires, Hovione

João Pires obtained his PhD degree in the field of Engineering Design and Advanced Manufacturing. In 2018, he joined Hovione as a Drug Product Development Scientist. Since 2021, he has been working as R&D Manager, leading the Process Development team in the Inhalation and Advanced Drug Delivery group, which focus on the process development and industrialization of technologies such as spray drying, jet milling, wet polishing and microfluidics.

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GERMANY

Reservation Form (Please complete in full)

Spray Drying
24-26 September 2024, Lisbon/Porto Salvo, Portugal

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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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 July 2022).
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 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.

Dr Thomas Quinten, Janssen Pharmaceutica

Thomas 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.

Dr Inês Ramos, Hovione

Inês Ramos is R&D Manager/Scientist for Formulation in Oral Drug Product Development. Her core expertise includes preformulation, ASD formulation, spray drying and tableting process development. Inês has an academic background in Pharmaceutical Sciences, holding a PhD degree in the same field on the development of green immunoanalytical methods using miniaturized fluidic devices.

Dr Harald Stahl, GEA

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

João Vicente has an academic background in Chemical Engineering, holding a Masters in Biological Engineering and a Ph. D. in Pharmaceutical Technology. Over the last 15 years, João has been focused on the development of tools and scale-up methods to expedite process development. João Vicente has been working at Hovione R&D in the Drug Product Development Department and has participated in the Development and Qualification of several spray drying manufacturing processes. More recently João has been responsible for the continuous improvement and post-approval changes throughout the commercial stage of the product's life-cycle.

Dr Ann-Cathrin Willmann, Boehringer Ingelheim Pharma

Ann-Cathrin Willmann is a pharmacist by training and holds a PhD in Pharmaceutical Technology focusing on particle engineering for respiratory drug delivery. She works as Senior Scientist in Pharmaceutical Development at Boehringer Ingelheim, Germany.

Date

Tuesday, 24 September 2024, 13.00 to approx 17.45 h,
(Registration and coffee 12.30 – 13.00 h)
Wednesday 25 September 2024, 08.30 to approx 17.15 h
Thursday 26 September 2024, 8.30 to approx. 16.00[1]/16.30[2]/17.00[3] h)

[1] approx. end of the site visit
[2] approx. airport arrival
[3] approx. return at the conference hotel

There will be a shuttle after the site visit. This shuttle will arrive at the airport at approx. 16.30 h and approx. at 17.00 at the hotel.

In certain cases a participation in the site visit may not be possible due to competitive reasons.
Participants are required to sign a Confidential Disclosure Agreement (CDA) before entering Hovione sites

Venue

TD Hotels Lagoas Park
Lagoas Park, Edíficio 2, 2º Piso
2740-265 Porto Salvo
Portugal
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email: lagoaspark@tdhotels.com

Fees (per delegate, plus VAT)

ECA Members EUR 2090.- per delegate plus VAT
APIC Members EUR 2190.- per delegate plus VAT,
(does not include ECA Membership)
Non-ECA Members EUR 2290.- per delegate plus VAT
EU GMP Inspectorates EUR 1145.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 24 September, lunch on 25 September and a business lunch on 26 September and all refreshments. VAT is reclaimable.

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.

Presentations/Certificate

The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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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