ECA ACADEMY

Image: Hovione

Includes Guided Tour at the Hovione Site
The Hands-On Spray Drying Session is fully booked

Spray Drying

Solutions for the Pharmaceutical Industry

14-16 May 2014, Lisbon, Portugal

SPEAKERS

DR SUNE KLINT ANDERSEN
Novo Nordisk, Denmark

ANDREW BIRKMIRE
GEA Process Engineering, USA

DR EUNICE COSTA
Hovione, Portugal

DR FILIPE GASPAR
Hovione, Portugal

DR MICHELLE MADSEN
Chr. Hansen, Denmark

DR ULRICH MEIER
Novartis, Switzerland

DR JOSÉ LUÍS SANTOS
Hovione, Portugal

DR HARALD STAHL
GEA Pharma Systems, Germany

DR GEERT VERRECK
Janssen Pharmaceutica, Belgium

HIGHLIGHTS:

- Fundamentals of Spray Drying
- Development of Spray Drying processes
- Quality-by-Design for Spray Drying processes
- Using Spray Drying as a Tool in Formulation Development
- Scale up of a pharmaceutical Spray Drying processes
- Validation of Spray Drying processes in an cGMP environment
- Spray Drying of sensitive biological material
- Spray Drying as an alternative to Lyophilisation
- Case Studies from Pharmaceutical Industry:
  - Increasing Bioavailability
  - 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

14-16 May 2014, 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

Dr Harald Stahl, GEA Pharma Systems, Germany

- 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 Scaleable Spray Drying Processes for Solid Drug Product Manufacture

Dr Ulrich Meier, Novartis, Switzerland

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, following the methodology proposed e.g. in a publication by Dobry et al. A special focus is given to the scaleability of the SD processes. Scale-up of pharma manufacturing processes asks some specific requirements from developers as well as from equipment to be used.

Programme (cont'd)

Scale-up of a Spray Drying Process

Dr Filipe Gaspar, Hovione, Portugal

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
- Product improvement during scale up
- Methodology for scale up of SD processes

Application of Quality-by-Design for the Optimisation of Spray Drying Processes

Dr Sune Klint Andersen, Novo Nordisk, Denmark

- Development of spray drying process using DoE
- Three stage DoE
  - Parameter screening (CCF design with 3 variables + extension)
  - Raw material variability
  - Process Validation
- PAT: Inline particle sizing and NIR used to monitor the spray drying process

Using Spray drying as a Tool in Formulation Development

Dr Michelle Madsen, Chr. Hansen A/S, Denmark

- The place of spray drying in the value chain of drug development
- Drug delivery forms supported by spray drying - An overview with details
- The concept of particle engineering applied on the formulation development of :
  - Oral solid dose
  - Pulmonary solid dose
  - Sterile parenteral dose

Spray Drying of Proteins – A Valid Alternative to Lyophilisation

Andrew Birkmire, GEA Process Engineering, USA

- Comparison of Spray Drying and Lyophilization
- Functional property preservation of proteins by SD compared to Lyophilisation
- Formulation/stabilisation aspects of SD compared to Lyophilisation
- Aseptic spray drying process design

Case study: Enhancing the bioavailability of poorly soluble drugs using spray drying: scaling up from lab scale to commercial scale

Dr Geert Verreck, Janssen Pharmaceutica, Belgium

- Short introduction on amorphous solid dispersions
- Manufacturing technologies
- Case study of itraconazole (Sporanox®)
- Case study of etravirine (Intelence®)

Case study: Application of Spray Drying for oral dosage forms

Dr José Luís Santos, Hovione, Portugal

- Improving oral dosage forms performance through spray drying
- Case study 1 – Laboratory scale challenges
  - Focus on laboratory scale unit limitations
  - How to improve powder properties at laboratory scale
  - Strategies to formulate poor flowing SD powders
- Case study 2 – Commercial challenges
  - Focus on adjusting powder properties for locked formulations
  - How to develop a commercial process
  - Strategies to cope with challenging targets (e.g. density, PS)

Case study: Application of Spray Drying for Inhalation Products

Dr Eunice Costa, Hovione, Portugal

- Introduction: applications of spray drying for inhalation products (carrier-based and composite formulations);
- 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 Friday, 16 May 2014
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 D[illegible]ession

Fully booked

Friday, 16 May 20[illegible]

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.

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

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 Wednesday, 14 May 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, Novo Nordisk A/S, Denmark
Dr Andersen studied at the Technical University of Denmark and gained his Ph.D. in Particle Technology. From 1999-2007 he worked for Niro A/S as Spray Drying specialist and is now working for Novo Nordisk A/S also in the position of a Spray Drying Specialist.

ANDREW BIRKMIRE, GEA PROCESS ENGINEERING, USA
Andrew is the Process Development Manager for GEA Process Engineering. He has supervised over 230 spray drying development tests for pharmaceutical and biotech products, concentrating on proteins and peptides, spray dried dispersions for enhancing the bioavailability of poorly-soluble APIs, products for inhalation, and room temperature stable vaccines. He currently is in charge of the Pharmaceutical Process Development Center in Columbia, MD, USA.

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, USA, and at the Human Physiology department at TNO, The Netherlands.

DR FILIPE GASPAR, HOVIONE, PORTUGAL
Filipe has a degree and a PhD in Chemical Engineering. At Hovione he was involved in more than 120 pharmaceutical development projects involving advanced particle engineering technologies. He was the Lead Scientist on 4 projects that reached commercial stage, including the first project developed and submitted under QbD. He has published more than 20 papers and 5 patents. Currently he is Director of Drug Product Technologies of the Particle Design Business Unit.

DR ULRICH MEIER, NOVARTIS PHARMA AG, SWITZERLAND
Ulrich Meier is a Senior Process and Particle Engineer in Technical R&D at Novartis Pharma headquarters in Basel. His main interests and professional experience include development of drug substance finishing processes including crystallization, filtration, drying and post-micronization conditioning, 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 professional networks' seminars, at the University of Applied Sciences in Luzern.

DR MICHELLE MADSEN, CHR. HANSEN A/S, DENMARK
Michelle studied Mechanical/Chemical Engineering and holds a master in Industrial Drug Development. For over 20 years she worked for GEA Niro in development and engineering projects. She also worked for Novozymes, responsible for the process characterization and production of several bio-pharmaceutical molecules. She is currently working for the Cultures and Enzymes Division of Chr. Hansen A/S as a Senior Drying Scientist, developing next generation alternative/hybrid drying methods for future live lactic acid bacteria formulations and supporting existing full scale freeze drying processes in production.

DR JOSÉ LUÍS SANTOS, HOVIONE, PORTUGAL
José Luís Santos is a Process Development Scientist at Hovione. He has worked on a number of projects involving the development of spray dried dispersions, manufacturing of micro and nanoparticles using integrated milling and membrane technologies, and the implementation of scale-up and modeling methodologies. José holds a PhD in Chemical Engineering in the field of membrane technology and numerical methods.

DR HARALD STAHL, GEA PHARMA SYSTEMS, GERMANY
Dr Harald Stahl worked for 3 years 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 Senior Pharmaceutical Technologist of GEA Pharma Systems. He has published more than 20 papers on various aspects of pharmaceutical production.

DR GEERT VERRECK, JANSSEN PHARMACEUTICA NV, BELGIUM
Geert Verreck is a Scientific Director and Fellow in Drug Product Development at Janssen R&D in Beerse, Belgium. His expertise is in the area of oral solid development and more specifically in amorphous solid dispersions prepared via melt extrusion or spray drying. He started working for J&J in 1995 after graduating as a chemical engineer. In 2005 he received his Ph.D. in Pharmaceutical Sciences at the Catholic University of Leuven, Belgium.

Easy Registration

Reservation Form:
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Wednesday, 14 May 2014,
14.00 to approx 18.30 h
(Registration and coffee 13.30 – 14.00 h)
Thursday, 15 May 2014,
09.00 to approx 17.30 h
Friday, 16 May 2014, 8.30 -12.30 h

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* (including guided tour)
ECA Members € 1,390.-
APIC Members € 1,490.-
Non-ECA Members € 1,590.-
EU GMP Inspectorates € 795.-
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on 14 May, lunch on 15 May, a business lunch on 16 May and all refreshments.
VAT is reclaimable.

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.

*per delegate plus VAT

Conference language
The official conference language will be English.

Organisation and Contact
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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 Ronny Strohwald (Organisation Manager) at +49(0)62 21 / 84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

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69007 Heidelberg
Germany

Reservation Form (Please complete in full)

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Spray Drying with Guided Tour at Hovione
14 - 16 May 2014, Lisbon, Portugal

☐ Mr ☐ Ms

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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)!