ECA
European Compliance Academy

Guided Tour and Hands-On Spray Drying Session (this session is fully booked!) at the Hovione Site

Image: Hovione

Spray Drying

Solutions for the Pharmaceutical Industry

22-24 May 2012, Lisbon, Portugal

SPEAKERS

DR SUNE KLINT ANDERSEN
Novo Nordisk, Denmark

DR POUL BACH
Novozymes A/S, Denmark

DR FILIPE NEVES
Hovione, Portugal

DR MICHELLE MADSEN
Chr. Hansen A/S, Denmark

DR ULRICH MEIER
Novartis, Switzerland

HENRIK SCHWARTZBACH
GEA Process Engineering A/S, Denmark

DR MÁRCIO TEMTEM
Hovione, Portugal

PROF PETER WALZEL
Technical University Dortmund, Germany

HIGHLIGHTS:

- Fundamentals of Spray Drying
- Development of Spray Drying processes
- Influence of the nozzle design on product parameters
- Quality-by-Design for Spray Drying processes
- Scale up of a pharmaceutical Spray Drying processes
- Validation of Spray Drying processes in an cGMP environment
- Spray Dried Solid Dispersions – Overcoming Solubility Limitations
- Spray Drying of sensitive biological material
- Lyophilisation and Spray Drying – a comparison

This conference is recognised for the ECA GMP Certification Programme „Certified Technical Operations Manager". Please find details at www.gmp-certification.eu

Spray Drying

22-24 May 2012, 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, quality control and assurance 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.

Moderation

Dr Sune Klint Andersen

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 under Quality by Design

- Spray drying & QbD in Pharma (overview)
- Risk assessment (CQA's vs. pCPP's/pCMA's)
- Model development (statistical vs. mechanistic)
- Design Space establishment (uncertainty analysis)
- Normal operating ranges selection (capability analysis)
- Process control strategy (PAT and multi-variate analysis)

A risk based approach is effective in identifying the processes areas and control loops that are most likely to result in product quality deviations. By applying PAT the processes and control loops can be monitored for better process understanding and improved process control, ultimately leading to a better product consistency.

Programme (cont'd)

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, 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.

Influence of spray parameters and nozzle design on product quality

The drying performance of individual slurry droplets depends on the uniformity of the spray particle diameter d as the drying time is proportional to d2. The particle structure formed during solidification as a major quality parameter is linked to the drying time. This statement includes the droplet size as well as the trajectories of the particles, which may lead to very different drying histories of individual drops. Fairly uniform drop size distributions and spray propagation is obtained from swirl nozzles at moderate pressures within a limited flow rate range. Fine particles can be obtained with pneumatic atomizers even so the drop size distribution is fairly broad. Rotary atomizers usually also lead to broad spectra even so recent developments may provide a method to obtain very narrow PSD and very uniform products.

Validation of Spray Drying Processes in Production Scale

- Establishing User Requirement Specifications and Validation Master Plan
- Risk assessment in the context of qualification and validation
- Carrying out Installation Qualification and Operational Qualification
- Performance Qualification and Process Validation
- The Effect of Quality-by-Design on Validation

Comparison of Spray Drying and Lyophilisation

- Comparison of Spray Drying and Lyophilization
- Introduction to heat and /or oxygen labile pharmaceutical products
- Methods and techniques to minimize oxygen and/or heat impact on products
- Formulation strategy for spray dried product compared to lyophilized products
- Formulation/drying case story: Inhalable Deslorelin

Spray drying of sensitive biological materials

- Understanding the I-X diagram
- Drying phases – impact on heat sensitive materials
- Drying kinetics – how to measure?
- Inactivation kinetics – how to measure it using DSC
- Effects of formulation excipients – case study: alpha-amylase
- Conclusion and recommendations

Spray Dried Solid Dispersions – A Platform to overcome Solubility Limitations

- Why Solid Dispersions?
- Methods to manufacture Solid Dispersions
- Development of Spray Dried Solid Dispersions – A Case Study
- From the lab to large scale manufacturing

Site Visit

Hovione cGMP Spray Drying Equipment and Facility (Thursday, 24 May 2012)
Part of the programme on the third day of the conference is a guided tour at the Site Hovione.

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 allows Hovione to offer from just few grams to full scale commercial production and guarantee a straightforward process scale-up throughout all phases of product development. With FDA-inspected plants in Europe, the Far East and the Technology Transfer Center in the United States, Hovione is well prepared 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.

Fully booked

Hands-on Spray Drying Session

Thursday, 24 May 2012

Target group of the Session

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.

Experiments

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.

Process Engineers, Pharmaceutical Technologists, Pharmaceutical Formulation Scientists, Application Chemists, Drug Development Engineers, Particle Design Engineers

- 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 16.30 h.

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

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

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.

DR POUL BACH, Novozymes A/S, Denmark
Poul has a master of science and did his PhD. Study in chemical engineering. He worked for Niro's R&D Department as well as for Novo Nordisk an principal scientist in product development in the enzyme business. Now he is working for Novozymes as Senior Science Manager in the R&D department for Solid Product Development. Poul is also certified censor at Technical University of Denmark. He is author of many publications with regard to spray drying. His scientific work led to more than 10 patents.

FILIPE NEVES, Hovione, Portugal
Filipe is an Engineer in the R&D Particle Design Discipline at Hovione FarmaCiencia SA, Loures, Portugal. Before joining Hovione, he worked several years as a Development Engineer in the continuous process chemical industry, being responsible for the Computer Aided Process Engineering area, i.e., mathematical modelling, simulation and optimization of industrial processes. He received both his degree in Chemical Engineering and his PhD in Applied Mathematics from the University of Coimbra, Portugal. Currently, he concentrates on the development of Quality by Design (QbD) methodologies and CAPE tools for particle design technologies.

DR ULRICH MEIER, Novartis Pharma AG Switzerland
Dr 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. Other fields of interest include handling concepts for highly active substances, as well as contributions to the Novartis 'Process Analytical Technologies' and 'Quality by Design' concepts. Ulrich complements his scientific and technological work with teaching assignments at Novartis workshops and professional networks' seminars, at the University of Applied Sciences in Luzern.

Speakers

DR MICHELLE MADSEN, Senior Research Scientist, Chr. Hansen A/S, Denmark
Michelle M. Madsen studied Mechanical/Chemical Engineering and holds a master in Industrial Drug Development from the University of Copenhagen. For over 20 years she worked for GEA Niro in development and engineering projects and later as principal formulation/process development scientist for Pharma Division of GEA Niro and formulation consultant for GEA Pharma Systems. She also worked for Novozymes in the solid products development department, responsible for the process characterization and production of several biopharmaceutical molecules. She is currently working for the Human Health & Nutrition Division of Chr. Hansen A/S, developing high stability probiotic formulations and up-scaling from laboratory process to full production scale".

HENRIK SCHWARTZBACH, GEA Process Engineering A/S, Denmark
Henrik Schwartzbach has been working for GEA Niro since 1992 with research & development and process optimisation. The focus for the last 12 years has been research & development and process optimisation within pharmaceutical spray drying. Henrik Schwartzbach has detailed and in-depth knowledge about cutting edge pharmaceutical spray drying. As the GEA Niro Pharma Senior Process Technologist he is deeply involved in setting the industry standards for pharmaceutical spray drying.

DR MÁRCIO TEMTEM, Hovione, Portugal
Márcio Temtem has a degree in Chemical Engineering and obtained his Ph.D. from the New University of Lisbon in the area of polymer synthesis and processing using supercritical fluids. He is the co-author of several papers in several international peer reviewed Scientific Journals in topics such as production of "smart" porous structures, synthesis of thermo and pH sensitive polymers as well as controlled release devices. He holds a position of Process Development Engineer in the Particle Design Discipline at Hovione where he is technically involved in the development of Spray drying processes, Solid dispersions and milling technologies.

PROF DR PETER WALZEL, Technical University of Dortmund, Germany
Prof Walzel studied chemical engineering and completed his PhD in Graz. He habilitated in Essen were he also started his work as Professor in 1990. Since 1999 he is professor for mechanical chemical engineering at the technical university in Dortmund. Besides his university career he also worked for Bayer AG for 13 years.

Social Event

On Tuesday, 22 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.

Special offer with Lufthansa – up to 20% discounted travel for all ECA Events Attendees

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We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date
Tuesday, 22 May 2012, 14.00 to approx 18.30 h
(Registration and coffee 13.30 – 14.00 h)
Wednesday, 23 May 2012, 09.00 to approx 18.15 h
Thursday, 24 May 2012, 8.30 - 16.30 (approx. airport arrival)
17.00 h (approx. return to hotel)

There will be a bus transfer after the **hands-on session** to the hotel via the airport.
There will also be a shuttle 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 13.00 h and 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 incl. guided tour at Hovione but without workshop
ECA Members € 1,390.- per delegate plus VAT
APIC Members € 1,490.- (does not include ECA membership)
Non-ECA Members € 1,590.- per delegate plus VAT
EU GMP Inspectorates € 795.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days 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 or be sure to mention "Concept Heidelberg" to receive the specially negotiated rate (single room € 145,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 21 April 2012. Early reservation is recommended.

Conference language
The official conference language will be English.

Organisation and Contact
CONCEPT HEIDELBERG
P.O. Box 10 17 64
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For questions regarding content:
Dr Robert Eicher (Operations Director) at +49-62 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 +49-62 21 / 84 44 51,
or per e-mail at strohwald@concept-heidelberg.de.

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Reservation Form (Please complete in full) +49 6221 84 44 34

Spray Drying with Guided Tour at Hovione
22-24 May 2012, Lisbon, Portugal

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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 %.

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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)!