



■ Full-day hands-on
Spray Drying Course

Image: GEA Pharma Systems

Spray Drying 2010

Solutions for the Pharmaceutical Industry

20 – 22 April 2010, Copenhagen, Denmark

SPEAKERS:

Dr Sune Klint Andersen
Novo Nordisk A/S, Denmark

Dr Filipe Gaspar
Hovione, Portugal

Dr Marco Gil
Hovione, Portugal

Prof Geoffrey Lee
Erlangen University, Germany

Dr Michelle Madsen
Novozymes A/S, Denmark

Henrik Schwartzbach
GEA Process Engineering A/S, Denmark

Dr Harald Stahl
GEA Pharma Systems, Germany

Dr Jody Voorspoels
SEPS Pharma, Belgium

Prof Peter Walzel
Technical University Dortmund, Germany

PROGRAMME:

- 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
- Risk-based approach to Spray Drying
- Stable amorphous solid dispersions for enhanced bioavailability
- Spray-dried powders for direct tablet compression



EUROPEAN COMPLIANCE
ACADEMY

Spray Drying – Solutions for the Pharmaceutical Industry

20-21 April 2010, Copenhagen, Denmark

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 course** 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 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 Group

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.

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

Development of a Spray Drying Process

Practical Aspects on how to develop a spray drying process

- Process limitations
- Equipment limitations
- Feed material characteristics
- Desired product and process characteristics
- Spray drying process evaluating
- Process and equipment optimisation/scale-up

Spray Drying under Quality by Design

- Advantages of QbD
- How and when we conduct Risk-Assessments
- How we develop a Design Space
- How we define the Normal Operating Range
- How we implement a Control Strategy

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.

Spray Drying on Laboratory Scale

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

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 d^2 . 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.

Scale-up of Spray Drying Processes

Spray drying has become a widespread technology applied within the pharmaceutical development. The bench scale units can be found in most of 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

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

Spray-dried Pharmaceutical Powders for Direct Tablet Compression

- Introduction to spray-dried direct compressible powders
- FSD spray agglomeration
- Tall form dryers for large mono particles
- Case story 1 (CS1): Spray dried Paracetamol powders from a Mobile Minor laboratory spray dryer
- Case story 2 (CS2): 16 x Up-scaling from CS1 to a semi-production scale spray dryer (SD-12-N)

Enhanced Bioavailability of Amorphous Spray-dried Dispersions

- Poorly soluble drugs
- Amorphous solid dispersions
- Enhanced bioavailability by spray drying
- Case studies



Hand-On Spray Drying Course

Thursday, 22 April 2010

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



Photo: Niro

You will see how different spray drying equipment, different solvents, products, and variation of process parameters affect the yield, drying progress 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 of aqueous/organic solvent applications under contained conditions and influence of process parameters on drying conditions
- Upscale to pilot-scale spray drying of organic solvent applications and influence of process parameters on particle size
- Labscale nano spray drying of aqueous application and influence of process parameters on particle size
- Labscale spray drying of organic solvent application and influence of process parameters on drying conditions

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

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.

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 Filipe Gaspar, *Hovione, Portugal*

Filipe Gaspar gained profound knowledge in the use of supercritical fluids technologies in both pharmaceutical and nutraceutical industries. In 2003, Dr. Gaspar joined Hovione, first as Production Engineer and later in R&D as a Senior Engineer. He is now the Director of the Discipline of Particle Design and the focus of his work is in the application of particle engineering technologies, such as spray drying, to active ingredients and pre-formulated products.

Prof Dr Geoffrey Lee, *Erlangen University, Germany*

Geoff Lee studied pharmacy in London and also completed his PhD in colloid science there. After 2 years' stay as an Assistant Professor at the University of Illinois, Chicago, he 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.

Dr Marco Gil, *Hovione, Portugal*

Marco Gil studied Chemical Engineering at Technical University of Lisbon, from where he obtained also his PhD. In 2007 he joined Hovione's Particle Design group where he is focused on the application of particle engineering technologies, such as spray drying, in the development of pharmaceutical products with enhanced properties, wherein amorphous solid dispersions have special relevance.

Dr Michelle Madsen, *Novozymes A/S, Denmark*

Michelle studied Mechanical Engineering and holds a master in Industrial Drug Development. She worked for Niro in engineering projects and latter as process development scientist for the spray dryer line and formulation consultant for the Pharma Division of Nir. Since 2009 she works for Novozymes in the sold products development, responsible for the process characterization of several biopharmaceutical molecules.

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 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 Jody Voorspoels, *SEPS Pharma, Belgium*

Jody is a pharmacist and holds a Ph.D. in pharmaceutical technology from Ghent University. In 2000 he joined Tibotec, where he was responsible for early formulation of a number of new HIV compounds. In 2002 he joined Janssen Pharmaceutica and was responsible for the development of solid dosage forms. In 2009 he joined SEPS Pharma as Chief Scientific Officer. He has developed drug delivery systems from immediate release to controlled release, for water soluble to poorly soluble drugs, liquid to solid dosage forms.

Prof Dr Peter Walzel, *Technical University of Dortmund, Germany*

Prof Walzel studied chemical engineering and completed his PhD in Graz. He habilitated in Essen where 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, 20 April 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.

Date

Tuesday, 20 April 2010, 13.00 – 18.00 h
(Registration and coffee 12.30 – 13.00 h h)
Wednesday, 21 April 2010, 08.30 to approx 17.00 h
Thursday, 22 April 2010, 8.30 -16.30¹/17.00² h

Tuesday, 20 April		Conference
Wednesday, 21 April	Conference	
Thursday, 22 April	Workshops: Hands-on Training ^{1,2}	

¹ Approximate Airport Arrival

² Approximate Hotel Arrival

Venue

Radisson SAS Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S
Denmark
Tel +45 339 650 00
Fax +45 381 565 01

Fees

Fees Conference

Non-ECA Members EUR 1,490.- per delegate plus VAT
ECA Members EUR 1,341.- per delegate plus VAT
APIC Members EUR 1,415.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates EUR 745.- 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 the second day and all refreshments. VAT is reclaimable.

Fees Conference and Workshop

Non-ECA Members EUR 1,990.- per delegate plus VAT
ECA Members EUR 1,790.- per delegate plus VAT
APIC Members EUR 1,890.- per delegate plus VAT
(does not include ECA Membership)
EU GMP Inspectorates EUR 995.- 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 the second day and a lunch snack on the third day and all refreshments. VAT is reclaimable.

Fees Workshop on 22 April 2010

Non-ECA Members EUR 990.- per delegate plus VAT
ECA Members EUR 890.- per delegate plus VAT
APIC Members EUR 940.- per delegate plus VAT
(does not include ECA Membership)
(Please ask for registration details)

There will be a bus transfer after the hand-on session to the hotel via the airport.

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 when you have registered for the event. Please use this form for your room reservation or be sure to mention "A200409ECA" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 19 March 2010. 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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

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.:

Jessica Stuermer (Organisation Manager), at
+49-62 21 / 84 44 43, or per e-mail at
stuermer@concept-heidelberg.de

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG.

ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

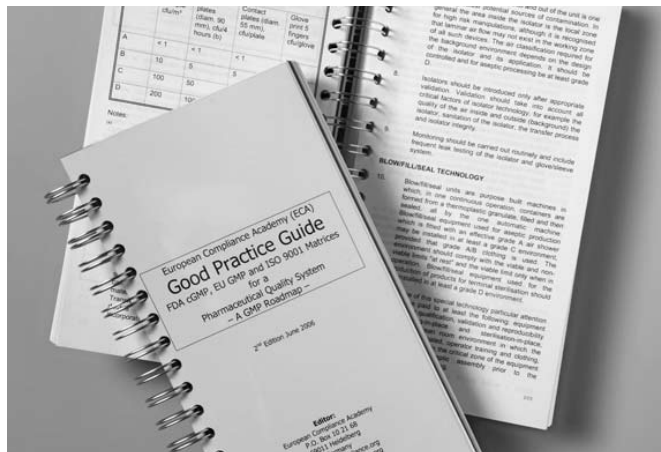
The Three Most Important Guidelines and Comparison Matrix in One Booklet

The European Compliance Academy (ECA) has developed a Good Practice Guide „FDA cGMP, EU / PIC/S GMP and ISO 9001 Matrix for a pharmaceutical Quality System“.

- This Roadmap includes the full-text version of the three Guidelines:
- FDA's cGMP Guide (21 CFR 210/211)
 - PIC/S GMP Guide incl. Annex 18 / ICH Q7A (identical with EU GMP Guide)
 - ISO 9001 on Quality Management Systems

The three Guidelines will be supplemented by a GMP/ISO Matrix that compares the requirements of all three Guidelines. The booklet contains 20 pages of the GMP Matrix and 390 for the three Guidelines.

You can purchase the booklet that is printed in an easy-to-use format at www.gmp-compliance.org. You will be granted the ECA Members price of 99.- € (plus VAT and shipping costs). The regular price is 149.- € (plus VAT and shipping costs).



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

Reservation Form (Please complete in full)

Spray Drying – Solutions for the Pharmaceutical Industry

- Conference on 20-21 April 2010, Copenhagen, Denmark
- Conference and Workshop on 20-22 April 2010, Copenhagen, Denmark
- Workshop on 22 April 2010, Copenhagen, Denmark

- Mr.
- Ms.

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O. Number, if applicable

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

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

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D-69007 Heidelberg
GERMANY

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities.

The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit:

During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:

The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.



How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website <http://www.gmp-compliance.org>

General Terms of Business

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 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT 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 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. **You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!**