

- Guided Tour at Niro A/S in Soeborg
- Full-day Hands-On Spray Drying Course

Spray Drying 2008

Solutions for the Pharmaceutical Industry

3 – 5 December 2008, Copenhagen, Denmark

SPEAKERS:

Dr Sune Klint Andersen

Novo Nordisk A/S, Denmark

Dr Albert W. Brzezczko

International Specialty Products, USA

Dr Filipe Gaspar

Hovione, Portugal

Prof Geoffrey Lee

Erlangen University, Germany

Dr Dan Mohan

Applied Prime Technologies, USA

Henrik Schwartzbach

Niro A/S, Denmark

Dr Harald Stahl

Niro Pharma Systems, Germany

PROGRAMME:

- Fundamentals of Spray Drying
- Development of Spray Drying processes
- Scale up of a pharmaceutical Spray Drying processes
- Validation of Spray Drying processes in an cGMP environment
- Risk based approach to PAT in Spray Drying
- Aseptic Spray Drying: Engineering, Environment and Control
- Stable amorphous solid dispersions for enhanced bioavailability
- Particle design of APIs and intermediates



Spray Drying – Solutions for the Pharmaceutical Industry

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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 you will visit Niro's Pharma Test Station where you will gain insight into managing different technologies of spray drying with different equipment: **Scale up, handling of highly potent compounds, spray drying in a GMP environment** are some of the stations of the guided tour. 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

Dr Harald Stahl, *Niro Pharma Systems*

Spray Drying on Laboratory Scale

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

Prof Geoffrey Lee, *University of Erlangen*

Scale up of spray drying processes

Bench scale spray dryers are inexpensive units which are widely available to the pharmaceutical industry. They can be found in drug discovery teams, material characterisation units, drug development and/or as production units of high-value low-volume drugs. However, it is often not clear, to the users of these bench scale units, what type of the information can be gathered from a lab scale unit, how scale up is done and how can scale up be used to improve the properties of the product. This lecture intends to clarify the above issues and to present a scale up methodology for spray drying processes.

- Usage of lab scale data
- Product improvement during scale up
- Methodology for scale up of SD processes

Dr Filipe Gaspar, *Hovione*

A Risk-based Approach to Product Quality in Spray Drying

- A risk based approach to product quality
- Spray drying impact assessment
- Spray drying product quality risk assessment
- Spray drying PAT implantation

Hendrik Schwartzbach, *Niro A/S*

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.

Validation of Spray Drying Processes in Production Scale

- Validation
- Technology Transfer
- Quality-by-Design

Dr Sune Klint Andersen, *Novo Nordisk A/S*

Aseptic Spray Drying in Pharmaceutical Industry

- Essentials of Aseptic Spray Drying Process
- Aseptic Spray Drying Environment and Control
- Sterile Boundary Considerations and Management
- Challenges in Process Engineering Set-up for sterile processing and system integrity
- Microbiological aspects of sterility assurance in aseptic processing.
- Spray Drying Process Simulation Testing Protocol

Dr Dan Mohan, *Applied Prime Technologies*

Enhanced Bioavailability and Product Performance for Amorphous Pharmaceutical Spray Dried Dispersions

- Poorly soluble drugs
- Amorphous Solid Dispersions
- Enhanced Bioavailability by spray drying
- Predictive stability modeling

Dr Albert W. Brzezko, *ISP*

Guided Tour on 4 December 2008 at Niro A/S in Soeborg

About Niro's Pharma Test Station

The test station, located at Niro A/S in Soeborg, Denmark, is one of the best-equipped and most comprehensive facilities in the world for testing customers' products on spray drying equipment. Plants are available for feasibility studies and pilot scale testing of various processes used in the manufacture of chemical, dairy, food and pharmaceutical products.



The Niro Pharma Test Station is built according to GMP standards for final drug production with a cleanroom for powder collection and process control that is 21 CFR part 11 compliant. It includes two fully equipped spray dryers, a PSD-1 and a PSD-4, both in closed-cycle execution. This allows for realistic full-size testing or generation of data for safe scale-up. The PSD-1 is designed for handling of potent compounds class 3b.

The guided tour on the second day of the conference will be organized in small groups to guarantee deep insight and intensive mentoring.

During the tour you will have the opportunity to see

- GMP and non-GMP spray drying plants
- How scale up is done from small none GMP- to production scale equipment in a GMP environment
- How high potent compounds are handled
- A spray dryer in action and how it looks in the inside
- How operating conditions effect product parameters
- State of the art analytical lab and equipment

You will be brought directly to the airport or back to the hotel after the tour. Arrival at airport planned for 17.30 h

Hand-On Spray Drying Course

(Friday, 5 December 2008)

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.

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 spray drying of aqueous application and influence of process parameters on drying conditions
- Labscale spray drying of organic solvent application and influence of process parameters on particle size

A shuttle bus will bring you back to the hotel with a prior stop at the airport. Airport arrival is scheduled for 17.30 h.

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

Social Event



On Wednesday, 3 December 2008 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 1997-2007 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 Albert W. Brzeczko, *International Specialty Products, USA*

Dr. Brzeczko is currently responsible for ISP Global Pharma R&D groups including excipients, tablet coating and drug solubilization programs. The ISP drug solubilization team has a primary focus to develop novel platform technologies for bioenhancing poorly water soluble drugs. He obtained his PhD in Pharmaceutics from the University of Maryland, School of Pharmacy and has a diverse industrial background with over 20 years experience in formulation development and oral solid dosage R&D/Pilot operations.

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 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 Dan Mohan, *Applied Prime Technologies, USA*

Dan holds a Ph.D in Chemical Engineering from Stevens Institute of Technology, New Jersey. Over the last twenty years, Dan had worked as an Engineering Fellow with Johnson & Johnson Companies in California and as Director of Product Development with Becton Dickinson & Company in New Jersey. His expertise is in the area of medical device development, aseptic process development, barrier isolator systems, scale-up strategies, equipment engineering and validation. He has successfully implemented pilot plant facilities capable of manufacturing drug/device combination products for clinical trials and commercial production. Currently, Dan is an independent consultant to the Pharma / Biotech industry.

Henrik Schwartzbach, *Niro A/S, Denmark*

Henrik Schwartzbach has been working for Niro A/S since 1992 with research & development and process optimisation. The focus for the last 9 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 Niro A/S Pharma Division Senior Process Technologist he is deeply involved in setting the industry standards for pharmaceutical spray drying.

Dr Harald Stahl, *Niro 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 Niro Pharma Systems. He has published more than 20 papers on various aspects of pharmaceutical production.

Date

Wednesday 3 December 2008, 13.00 – 18.00 h
(Registration and coffee 12.30 – 13.00 h Uhr)
Thursday 4 December 2008, 8.30- 17.30¹ / 18.00² h
Friday 5 December 2008, 8.30 – 16.30¹ / 17.00² h

Wed., 3 Dec 2008		Conference, Afternoon
Thurs., 4 Dec 2008	Conference, Morning	Guided Tour ^{1,2}
Friday, 5 Dec 2008	Workshops: Hand-on Training ^{1,2}	

¹Airport Arrival

²Hotel Arrival

Venue

Radisson SAS Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S
Denmark
Tel +45 33 96 50 00, Fax +45 33 96 55 00

Fees

Fees Conference (including the guided tour)

Non-ECA Members EUR 1490.- per delegate plus VAT
ECA Members EUR 1340.- per delegate plus VAT
APIC Members EUR 1415.- 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 snack on the second day and all refreshments. VAT is reclaimable.

Fees Conference, guided tour and Workshop

Non-ECA Members EUR 1990.- per delegate plus VAT
ECA Members EUR 1790.- per delegate plus VAT
APIC Members EUR 1890.- 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 snack on the second and third day and all refreshments. VAT is reclaimable.

Fees Workshop (Friday 5. Dec. 2008)

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)
Registration for Hands on Session (without participation in the conference) is on Thursday, 4. Dec. 2008, 18.00 – 19.00 h)

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

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 "VA A031208CON ECA Course" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 20 October 2008. 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
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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

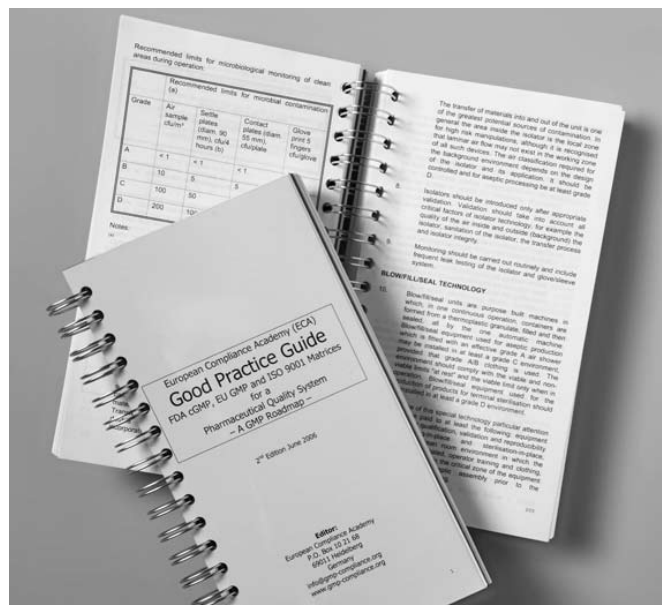
The European Compliance Academy (ECA) has developed a Good Practice Guide „FDA cGMP, EU / PIC/S GMP and ISO 9001 Matrix for a pharmaceutical Quality System“.

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

- 3 – 5 December 2008, Copenhagen, Denmark
- Conference (3 – 4 December 2008)
 - Conference & Workshop (3 – 5 December 2008)
 - Workshop (5 December 2008)
- Mr. Ms.

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

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E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
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)!