

Guided Tour at Niro A/S in Soeborg
on 11 October 2007

Spray Drying – Solutions for the Pharmaceutical Industry

10-11 October 2007, Copenhagen, Denmark

SPEAKERS:

Filipe Gaspar, PhD
Hovione, Portugal

Ulrich Meier, PhD
Novartis Pharma, Switzerland

Henrik Schwartzbach
Niro A/S, Denmark

Howard Smith
CBL, UK

Harald Stahl, PhD
Niro Pharma Systems, Germany

Prof Dr Gerhard Winter
University of Munich, Germany

PROGRAMME:

- Fundamentals of Spray Drying
 - Control of critical process parameters
 - Setting up a Spray Drying Process
- Spray Drying in a GMP Environment
 - Development of the process
 - Routine operation
- Risk-based Approach to PAT in Spray Drying
- Rapid Drying of Sensitive Materials
 - Aseptic and apyrogenic spray drying of vaccines
 - Spray Drying of Liposomes
- Particle Design of APIs and Intermediates
 - Manufacture of direct compressible materials
 - Adjustment of the pharmaceutical properties
- Scale up of a Pharmaceutical Spray Drying Process
- Handling of High Potent Materials



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 during the conference. Further you'll have the chance to **visit Niro's Pharma Test Station** where you will gain deep insight into managing different technologies of spray drying with different equipment. **Scale-up**, handling of **highly potent compounds**, spray drying in a **GMP environment** and spray drying in progress are only some of the stations of the guided tour.

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 to 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
- Improved product 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 in the manufacture of powders and granules, as e.g. in the manufacture of solid dosage forms for oral or pulmonary administration.

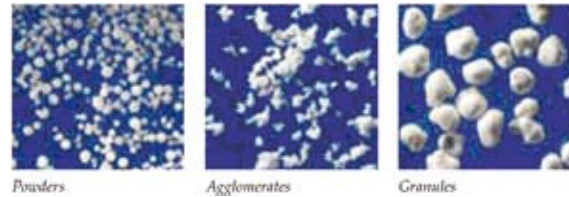
Moderator

Dr Harald Stahl

Programme

Fundamentals of Spray Drying

- 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 offers unique opportunities in particle engineering. Examples are for example particles for sustained release, for inhalation or applications for enhanced bioavailability or superior taste masking. The approval of inhaleable insulin by European and US authorities is a vital proof of this. The process is scientifically well understood. In order to get the desired results it is important to understand the interaction between the materials, the equipment and the process parameters. As a continuous process Spray Drying is additionally suited to fulfil the requirements of the FDA PAT initiative.

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

The increasing interest in Process analytical technology / PAT rises the question what to measure and where. 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 identified processes areas and control loops can be monitored for better process understanding and improved process control, ultimately leading to better product consistency.

Application of Spray Drying Technologies for the Stabilisation of Liposomes

- Novel process development for drying of liposome dispersions
- Continuous production and drying of liposomes
- Spray drying of solvent systems using an "inert loop" setup
- Scale up considerations
- Novel concepts for spray freeze drying

Manufacture of cGMP Stable Suspension Vaccines by Aseptic Apyrogenic Spray Drying

- Review of CBL vaccine stabilization process
- Application of spray drying to vaccine stabilization
- Development of manufacturing scale spray dryer
- Asepsis and apyrogenicity

Production of biopharmaceuticals which do not require controlled storage conditions has huge potential for improving supply to remote areas, leading to enormous benefits in healthcare. Reductions in the costs of mass vaccination programmes would give savings from existing budgets of more than \$200 million per year. Cambridge Biostability has technology to produce such vaccines which uses spray drying. In moving towards performing clinical trials CBL has constructed a cGMP aseptic apyrogenic spray dryer.

Spray drying - particle engineering technology for the pharmaceutical industry

- Applications of the technology in the pharmaceutical industry
- Obtaining amorphous, solid dispersions
- Microcapsules and specific particle properties for direct compressible materials or products for inhalation

Conventional and fluidized bed spray drying for manufacture of pharmaceutical intermediates

- Spray drying and competing methods of particle design and manufacture
- Development of pharma spray-drying processes
- Target properties of spray-dried powders and how to achieve them
- Special requirements for pharma spray driers



Photo: Hovione

Guided Tour on 11 October 2007 at Niro A/S in Soeborg



About Niro's Pharma Test Station

Spray drying 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

After lunch you will be brought directly to the airport and back to the hotel.

Speakers

Filipe Gaspar, PhD

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.

Ulrich Meier, PhD

Ulrich Meier studied Process Engineering at the Swiss Federal Institute of Technology in Zürich, from where he also obtained his PhD. After several years in academia, he works since 1998 as a lab head and currently senior fellow in the process technology department of Novartis Pharma. His main interests and experience are in the development of solids isolation processes for API and pharmaceutical intermediates manufacture, among others by spray drying.

Henrik Schwartzbach

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.

Howard Smith

Howard Smith has worked in the biotechnology vaccine industry since 1991 across a variety of fields including veterinary vaccines against intestinal parasites, vaccine expression systems using plant viruses and vaccines from transgenic food crops. He was head of Biopharmaceutical Analysis at NDA Analytics, providing contract cGLP/cGMP analytical and stability services. Joining CBL in April 2004 he co-ordinated the ongoing research projects and is currently responsible for management of the commercial activities.

Harald Stahl, PhD

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.

Prof Gerhard Winter

In 1999 G.Winter was appointed as a full professor for Pharmaceutical Technology and Biopharmaceutics at the University of Munich, Centre for Drug Research, where he is currently working on protein stabilisation, parenteral dosage form technology, novel drying technologies, drug delivery systems and colloidal drug formulations. Prof. Winter has issued numerous patents and publications in his research field, he is member of many scientific societies and scientific advisory boards.

Social Event



On Wednesday, 10 October you are cordially invited to a social event. This is an excellent opportunity to share your experience with colleagues from other companies in a relaxed atmosphere and to explore the beautiful city of Copenhagen.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

- Certified Quality Assurance Manager – Pharmaceutical Production (ECA)
- Certified Quality Assurance Manager – API Production (ECA)
- Certified Quality Control Manager (ECA)
- Certified Pharmaceutical Engineering Manager (ECA)
- Certified Computer Validation Manager (ECA)
- Certified Regulatory Affairs Manager (ECA)
- Certified Validation Manager (ECA)

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

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.

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)!**

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>

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 together with the conference registration. If you do so, 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)

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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)

CONCEPT HEIDELBERG
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Date

Wednesday, 10 October 2007, 09.00 h – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Thursday, 11 October 2007, 08.30 h – 13.30 h
(There will be transfer to the airport, arriving at approx 14.00 h)

Venue

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

Fees

Non-ECA Members € 1.290,- per delegate plus VAT
ECA Members € 1.161,- per delegate plus VAT
EU GMP Inspectorates € 645,- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner and lunch on the first day, a light lunch on the second day and all refreshments.
VAT is reclaimable.

Accommodation

CONCEPT has reserved a limited number of rooms in the Radisson SAS Scandinavia Hotel. Reservation should be made directly with the hotel not later than 09 September 2007. You will receive a room reservation form when you have registered for the course. Please use this form for your room reservation or be sure to mention ECA/CONCEPT and the password A101007HK to receive the specially negotiated rate for the duration of your stay. 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

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For questions regarding reservation, hotel, organisation, etc.:

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