ECA Academy
Your GMP/GDP Information Source

Quality of Nasal and Inhalation Drug Products

Good Development Practices, Specifications, and Analytical Methods for Inhalation Drug Products (Metered Dose Inhaler (MDI), Dry Powder Inhaler (DPI)) and Nebulized and Nasal Drug Products

SPEAKERS:

Dr Carol Barbour
UK

Dr Manfred Fischer
Skyepharma (member of Vectura group), Switzerland

Dr Armin Hauk
Sartorius Stedim Biotech GmbH, Germany

Dr Rudi Müller-Walz
Skyepharma (member of Vectura group), Switzerland

Mark Parry
Intertek Melbourn, UK

23 – 25 November 2016, Berlin, Germany

HIGHLIGHTS:

- Regulatory Requirements:
  - Pharmacopoeia Requirements
  - Guidance Documents (Europe and U.S.)
  - Specifications and Analytical Methods
- Regulatory Strategy for the Global Respiratory Market
- Good Development Practices for Modern Nasal and Inhalation Drug Products
- Quality by Design in Inhalation Drug Product Development
- Formulation of Biologics for Inhaled and Nasal Drug Products
- Extractables / Leachables Assessment
- Requirements for Starting Materials and Device Components
- Dose Content Uniformity Testing – What is the Future for the DCU Method?
- Aerodynamic Particle Size Distribution – The Key Performance Testing Method for Respiratory Drugs
- Transfer of Inhalation Specific Methods
- Product Characterisation Studies
- Nasal and Nebulizer Testing

This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager“.
Please find details at www.gmp-certification.eu

Quality of Nasal and Inhalation Drug Products

23 – 25 November 2016, Berlin, Germany

Objectives

This GMP Education Course on Nasal and Inhalation Drug Products aims at providing delegates with a sound understanding and best practices in the development and analytical quality control of Metered Dose Inhaler (MDI), Dry Powder Inhaler (DPI) and Nasal Drug Products. The course provides a comprehensive overview of the regulatory requirements in Europe and U.S. (Ph.Eur., USP, FDA, and EM(E)A) and shows how all these requirements can be put into practice.

Background

The market for Oral Inhalation and Nasal Drug Products (OINDPs) has become increasingly important and at the same time the number of requirements from regulatory authorities have increased.

Key guidance documents and relevant pharmacopoeial General Chapters are:

- FDA Draft Guidance for Industry: Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI),
- EM(E)A: Guideline on the Pharmaceutical Quality of Inhalation and Nasal Products,
- Ph.Eur. 2.9.18, Preparations for Inhalation (Inhalanda),
- USP <601> Inhalation and Nasal Drug Products: Aerosols, Sprays and Powders-Performance Quality Tests.

Pharmaceutical development based on Quality by Design (QbD) principles is key to achieve inhalation drug products of high reproducible performance. Extensive characterisation of the drug substance and drug product batches is necessary to qualify an inhalation drug product for its intended use - the delivery of the drug substance into the lungs.

Challenging issues in the development and control of inhalation drug products are:

- Physical characterisation of starting materials
- Control of extractables and leachables
- Reproducibility of the delivered dose
- Constant particle size distribution throughout shelf-life
- Patient friendly performance characteristics of the drug product

The objective of this course is to cover all aspects of development and analytical testing of Inhalation and Nasal Drug Products with focus on practical examples.

Workshops are an essential part of the course in order to encourage the exchange of experience and to allow interactive and in depth discussion of the subject.

Target Audience

This course is dedicated to scientists and managers in the pharmaceutical industry working in

- Quality control
- Quality assurance
- Analytical development
- Formulation and process development
- Regulatory Affairs

The course is also intended for participants from contract laboratories, regulatory authorities, and inspectorates.

Programme

Regulatory Requirements for Respiratory Drugs

- Pharmacopoeia requirements
  - USP <601> Aerosols, Nasal Sprays, Metered Dose Inhalers, and Dry Powder Inhalers
  - Ph.Eur., Preparation of Inhalation (Inhalanda), 2.9.18 Preparation for Inhalations
- Guidance documents
  - EM(E)A: Guideline on the Pharmaceutical Quality of Inhalation and Nasal Products
  - FDA: Draft Guidance for Industry: Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products
- Specifications for raw materials (APIs and excipients) and components for container closure system (valves, canisters, actuators)
- Analytical test methods and specifications for the drug product, U.S. vs. EU
- Product characterization studies
- Finished product stability

Good Development Practices for Inhalation Drug Products

- Evolution of regulatory framework
- Guidelines on combination drug products
- Quality by Design in inhalation drug product development
- Container closure systems for MDIs

Development of Modern Nasal Drug Products

- Formulation and technologies
- Regulatory considerations
- Differences to inhalation products

Dose Content Uniformity Test – a Key Method to Characterize Inhalation Drugs

- Basics of the method according to USP <601> and Ph.Eur. Inhalanda
- Challenges in sample preparation
  - MDIs
  - DPIs
- Testing design and specifications: U.S. vs. EU
- Additional requirements of EM(E)A and FDA guidelines
- What is the future for DCU method: Zero tolerance vs. parametric tolerance interval test

Particle Size Distribution and Determination

- Current test requirements (USP <601> and Ph. Eur. Inhalanda)
- Key aspects of testing (concentrating on ACI and NGI)
- Proposed future developments

Nasal and Nebulizer Testing

- Requirements for product and performance quality tests
- Discussion of the types of testing required from USP <5> and <601>
- Specific requirements for nebulisers (EP 2.9.44)

WORKSHOP I
Transfer of Inhalation Specific Methods – Dose Content Uniformity (DCU) and Aerodynamic Particle Size Distribution (APSD)

- Transfer of these key methods for the characterization and control of respiratory drugs based on the new USP General Chapter <1224> Transfer of Analytical Procedures.
- Overcome issues in method transfer considering the human factor in the predominantly manual based sample preparation of both procedures.

Requirements for Starting Materials for Inhalation and Nasal Drug Products

- Drug substance requirements and characteristics
- Engineered drug particles
- Functional excipients for inhalation drug products
- Excipients for nebulized and nasal formulations

New Testing for Spacer Devices

- Types of spacer device
- Potential challenges with spacers
- Testing required to characterise performance

Requirements for Devices and Delivery Systems

- Inhaler devices and device components
- Nebuliser technologies
- Device development and medical device aspects
- Device functionality and patient usability
- Basics on Human Factor Engineering

Formulation of Biologics for Inhaled and Nasal Drug Products

Regulatory Strategy for the Global Respiratory Market

- The respiratory market – A global view
- Development of OINDPs for the global market in a fragmented regulatory environment
- Aspects for a common world-wide regulatory strategy

Extractables / Leachables Assessment for MDI and DPI Devices

- The relevance of extractables and leachables testing for MDI and DPI
- The strategy for E & L testing for MDI and DPI
- Illustrative examples from E & L investigations on MDI and DPI
- The evaluation and assessment of E & L data

Development of Generic and Line Extension Products

- General requirements for generic OIPs
- In-vitro equivalence of the original and generic products
- Development approaches

Product Characterisation Studies

- Requirements for Drug Product Characterisation Studies:
  - FDA Draft Guidance for Industry for MDIs and DPIs
  - EMEA Guidelines for OINDPs
  - Specific differences for MDIs and DPIs

WORKSHOP II
Product Characterisation

- Discussion of the requirements for drug product characterisation studies, the differences depending on territory and product type.
- Examples of how the guidance documents can be interpreted for particular products, and why these studies are important.

Speakers

Dr Carol Barbour, *UK*

Dr Carol Barbour joined Glaxo in 1985 and worked in pharmaceutical analysis, including inhaler analysis. She joined Melbourn Scientific (now Intertek Melbourn), based near Cambridge in the UK, in 1992 and worked in various analytical roles there before becoming Quality Director. She has been involved in inhaler testing for over 20 years.

Dr Manfred Fischer, *SkyePharma AG (member of Vectura Group), Muttenz, Switzerland*
Dr Manfred Fischer worked for AstraZeneca (former ASTRA Chemicals GmbH), Altana Pharma (former Byk Gulden) and Lilly Forschung GmbH. Since March 2007, Dr Fischer is the Head of the Analytical Department & Quality Control at SkyePharma AG in Muttenz (Switzerland), responsible for development, validation / transfer of analytical methods and quality control of clinical trial material.

Dr Armin Hauk, *Sartorius Stedim Biotech GmbH, Göttingen, Germany*
After his PhD, Armin joined the central analytical department of Ciba in 1995. He was head of the trace analysis group, the GLP testing facility and the GMP laboratory. In his functions he was responsible for organic trace analysis, special analytics for registration, migration studies, extractables and leachables investigations, for GMP QC analytics and stability testing under GMP. In 2010 the Ciba Expert Services® labs were bought by Intertek, where Armin worked as consultant for pharmaceutical customers mainly in the area of E&L and as QP (FvP acc. Swiss Pharma Law). Armin was an active member in the EDQM Pharmacopeia expert group on plastic containers for pharmaceutical use. Since June 2016 Armin has a position at Sartorius Stedim Biotech as Lead Scientist E&L.

Dr Rudi Müller-Walz, *SkyePharma (member of Vectura group), Muttenz, Switzerland*
Dr Müller-Walz is the Head of the Inhalation Formulation and Process Development at SkyePharma AG (now a member of the Vectura group of companies), in Muttenz in Switzerland. The group is responsible at SkyePharma for the galenical development of drugs intended for inhalation use from early feasibility up to site transfer to a commercial manufacturing organization. He started in 1988 with Ciba-Geigy AG (now Novartis) in Basle, Switzerland, where he established a laboratory dedicated to particle size measurements of metered dose inhalers and lead the technical development of several MDI development projects. In 1997, Dr Mueller-Walz joined SkyePharma with the responsibility for development of all inhaled dosage forms of this company.

Mark Perry, *Intertek Melbourn, Melbourn, UK*
Mark Parry has worked with Intertek Melbourn for 14 years after graduating from Cambridge University and currently works as the Technical Director. Mark has worked in a range of pharmaceutical analysis and formulation development areas with a particular focus on inhaled and nasal drug products. Mostly working in the pre-approval stages, Mark's background includes extensive experience with product and formulation development, as well as method development and validation, stability studies, and pharmaceutical development activities for a wide range of clients across the pharmaceutical industry.

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

Wednesday, 23 November 2016, 09:00 – 17:30 h
(Registration and coffee 08:30 – 09:00 h)
Thursday, 24 November 2016, 08.30 – 17.30 h
Friday, 25 November 2016, 08:30 – 13:00 h

Venue

InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Straße 5
10557 Berlin, Germany
Phone +49 (0) 30 288 755 0
Fax +49 (0) 30 288 755 900

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on the first 2 days and all refreshments. VAT is reclaimable.

Would you like to safe money?
If you register for ECA's Education Course Reduced Sampling / Reduced Testing from 21-22 November 2016 at the same time, you will receive a 350 € discount. This is not valid for EU GMP Inspectorates

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. Reservation should be made directly with the hotel. 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

ECA has entrusted Concept Heidelberg with the organisation of this event.

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

For questions regarding content:
Dr Günter Brendelberger (Operations Director)
at +49 (0)62 21 / 84 44 40 or at
brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Mr Rouwen Schopka (Organisation Manager)
at +49(0)62 21/84 44 13 , or per e-mail at
schopka@concept-heidelberg.de.

Social Event

In the evening of the first course day, 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.

ECA Education Course
Reduced Sampling/Reduced Testing
21 – 22 November 2016, Berlin, Germany

Directly before this ECA Education Course on the Quality of Inhalation and Nasal Drug Products on 21-22 November 2016, there will be the ECA Education Course Reduced Sampling/Reduced Testing with these topics:

- Regulatory Requirements for Sampling Procedures
- Design and Qualification of Sampling Areas for Incoming Goods Products
- Supplier Qualification: an important Prerequisite for Reduced Sampling and Reduced Testing
- How to Deal with Divergent Compendial Method Requirements (EP, USP, JP)
- Case Study I: How to Define Inspection Procedures for Packaging Materials (Primary and Secondary) in the Incoming Goods Control
- Case Study II: How to Define and Optimise Sampling and Testing Procedures for APIs and Excipients in the Incoming Goods Control
- Sampling and Documentation to make the Supplier liable for Defect Products

Further details will be discussed in a parallel session with 3 workshops.

Further information about this course can be received at www.gmp-compliance.org.

Participants who register simultaneously for both courses will receive a 350 € discount (not valid for EU GMP Inspectorates).

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

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **Quality of Nasal and Inhalation Drug Products,** 23 – 25 November 2016, Berlin, Germany
☐ **Reduced Sampling / Reduced Testing ,** 21 – 22 November 2016, Berlin, Germany

☐ 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)

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)! (As of January 2012)
Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html).
I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.