



Good Development Practices,  
Specifications, and Analytical Methods  
for Metered Dose Inhaler (MDI) and Dry  
Powder Inhaler (DPI) Respiratory Drugs

# Technology and Quality of Inhalation Drug Products

5 – 6 November 2015, Berlin, Germany

## SPEAKERS:

**Dr Carol Barbour**

*Intertek Melbourn, Melbourn, UK*

**Dr Manfred Fischer**

*SkyePharma, Muttenz, Switzerland*

**Dr Armin Hauk**

*Intertek Life Science, Switzerland*

**Dr Rudi Müller-Walz**

*SkyePharma, Muttenz, Switzerland*

**Derek Solomon**

*Intertek Melbourn, Melbourn, UK*

## HIGHLIGHTS:

- Regulatory Requirements:
  - Pharmacopoeia Requirements
  - Guidance Documents (Europe and U.S.)
  - Specifications and Analytical Methods
- Regulatory Strategy for the Global Respiratory Market
- Quality by Design in Inhalation Drug Product Development
- 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



# Technology and Quality of Inhalation Drug Products

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## Objectives

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This GMP Education Course on 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) and Dry Powder Inhaler (DPI) 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

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The market for inhalation drug products has become increasingly important and at the same time the number of requirements from regulatory authorities has 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- FDA Draft Guidance for Industry: Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI),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> Aerosols, Nasal Sprays, Metered Dose Inhalers, and Dry Powder Inhalers.

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 Products with a 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

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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

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### 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

### 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

### Good Development Practices for Inhalation Drug Products

- Guidelines and evolution of regulatory framework
- Quality by Design in inhalation drug product development
- Container closure systems
- Device development and medical device aspects
- Device functionality and patient usability

### 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

### Requirements for Starting Materials and Device Components

- Drug substance requirements and characteristics
- Engineered drug particles
- Functional excipients for inhalation drug products
- Devices and device components

### 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

#### 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.

### 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)

### Product Characterisation Studies

- Requirements for Drug Product Characterisation Studies:
  - FDA Draft Guidance for Industry for MDIs and DPIs
  - EMA 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

*Intertek Melbourn, Melbourn, UK*

Dr Carol Barbour joined Glaxo in 1985 and worked in pharmaceutical analysis, including inhaler analysis. She joined Melbourn Scientific in 1992 and worked in various analytical roles there before her current role as Quality Director. She is responsible for maintaining the GMP status of the facility, and has been involved in inhaler testing for over 20 years.



#### Dr Manfred Fischer

*SkyePharma AG, 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**

*Intertek Life Science, Switzerland*

Dr Armin Hauk joined the central analytical department of the former Ciba-Geigy Inc. in 1995. Since 2000 he was head of the trace analysis group, the GLP testing facility and the GMP quality control laboratory of the Ciba services laboratories in Basle. He was responsible for organic trace and ultra trace analysis, special analytics for registration, migration studies, extractables and leachables studies. In 2010 the Expert Services® labs of the former Ciba/BASF were bought by Intertek to strengthen their capabilities in the field of E & L studies and other pharma related analytics.



**Dr Rudi Müller-Walz**

*SkyePharma, Muttenz, Switzerland*

Dr Müller-Walz is the Head of the Inhalation Formulation and Process Development at SkyePharma AG, 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. Müller-Walz joined SkyePharma with the responsibility for development of all inhaled dosage forms of this company.



**Derek Solomon**

*Intertek Melbourn, Melbourn, UK*

Mr Derek Solomon is the Operations Director at Intertek Melbourn in Cambridge, England. Intertek Melbourn are a leading provider of product development and analytical services to the pharmaceutical industry and have a long history in developing orally inhaled and nasal drug products. Derek joined Intertek Melbourn in 2005 having previously worked for the The Wellcome Foundation, Abbott Laboratories, Eli Lilly and Colorcon. He is responsible for all formulation development, product development and analytical operations within Intertek Melbourn.

**Social Event**

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On Thursday evening, 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.



## 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

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Thursday, 5 November 2015, 09:00 – 18:00 h  
(Registration and coffee 08:30 – 09:00 h)  
Friday, 6 November 2015, 08:30 – 16:00 h

### Venue

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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)

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ECA Members € 1,490  
APIC Members € 1,590  
Non-ECA Members € 1,690  
EU GMP Inspectorates € 845

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.

### Would you like to save money?

If you register for ECA's Education Course Reduced Sampling / Reduced Testing from 3-4 November 2015 at the same time, you will receive a 350 € discount. This is not valid for EU GMP Inspectorates

### Accommodation

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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

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Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

### Conference Language

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The official conference language will be English.

### Organisation and Contact

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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.:

Ms Nicole Bach (Organisation Manager)  
at +49(0)62 21/84 44 22 , or per e-mail at  
bach@concept-heidelberg.de.

#### ECA Education Course

##### Reduced Sampling/Reduced Testing

3 – 4 November 2015, Berlin, Germany

Directly before the ECA Education Course on the Technology and Quality of Inhalation Drug Products on 5-6 November 2015, 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](http://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:

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P.O. Box 101764  
Fax +49 (0) 62 21/84 44 34  
  
D-69007 Heidelberg  
GERMANY

Reservation Form (Please complete in full)

- Technology and Quality of Inhalation Drug Products, 5 – 6 November 2015, Berlin, Germany**  
 I also want to participate in ECA's Education Course **Reduced Sampling / Reduced Testing, 3 - 4 November 2015, Berlin, Germany**

- Mr  Ms

Title, first name, surname

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**Important: Please indicate your company's VAT ID Number** \_\_\_\_\_ **P.O. Number (if applicable)** \_\_\_\_\_

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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 week prior to the conference 50 %  
- within 1 week prior to the conference 100 %.

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**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.gnnp-compliance.org/eca\\_privacy.html](http://www.gnnp-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.