ECA Academy
Your GMP/GDP Information Source

# Reduced Sampling / Reduced Testing

cGMP compliant Sampling and Testing of Starting and Packaging Materials – how to Meet EU and FDA Requirements and safe Costs in QA/QC

## SPEAKERS:

Emerich Grassinger
*Aenova Group - Haupt Pharma Wülfing GmbH, Germany*

Dr Matthias Heuermann
*NRW Centre for Health (LZG. NRW), Germany*

Dr Gerald Kindermann
*F. Hoffmann-La Roche, Switzerland*

Dr Michael Möhlen
*Valneva Austria GmbH, Austria*

Dr Bernd Renger
*Bernd Renger Consulting, Germany*

Dr Martin Wesch
*Wesch & Buchenroth, Law Office, Germany*

21 - 22 November 2016, Berlin, Germany

## LEARNING GOALS:

- Regulatory Requirements for Sampling
- Design and Qualification of Sampling Areas
- Supplier Qualification as an Important Prerequisite for Reduced Sampling / Reduced Testing:
  - Supplier Audits
  - Quality Agreements
  - Specifications / Monographs / Supplier CoA
- How to Define and Optimise Sampling and Testing Procedures for
  - APIs
  - Excipients
  - Primary Packaging Materials
  - Secondary Packaging Materials
- Options for Reduced Sampling
- Options for Reduced Testing
- How to Deal with Multicompendial Testing?

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

# Reduced Sampling / Reduced Testing

21 - 22 November 2016, Berlin, Germany

## Objectives

The aim of this course is to demonstrate the process of the qualification of starting materials (APIs and excipients) and packaging materials (primary and secondary) and to define the prerequisites for implementing a system for reduced sampling and reduced testing for these products. This system has to be in compliance with the actual GMP requirements in Europe and in the US, though. Case Studies will show how to define and optimise sampling and testing procedures and you will discuss further details in a parallel session with 3 workshops.

## Background

Testing active pharmaceutical ingredients, excipients and packaging materials is one of the main tasks of the quality control units in the pharmaceutical industry. It must be ensured that the necessary tests are conducted on the incoming goods and that the materials are released only after their quality was judged as satisfactory.

According to the revised Chapter 5 – Production – of the EU GMP Guide in operation since 1 March 2015, the selection, qualification, approval and maintenance of suppliers has to be documented and the level of control has to be proportionate to the potential risks posed by the individual materials. Manufacturers of medicinal products are responsible for testing the starting and packaging materials as described in the marketing authorisation dossier. However, it is explicitly accepted to outsource these testing activities, if the following requirements are fulfilled:

a) Distribution controls (transport, wholesaling, storage and delivery) to ensure the maintenance of the quality characteristics of the starting materials

b) Audits performed at appropriate intervals at the sites carrying out the testing

c) A certificate of analysis signed by a designated person with appropriate qualifications and experience

d) Significant experience in dealing with the starting material manufacturer ("history of compliance")

e) Full analyses that are performed regularly by the medicinal product manufacturer to compare the results with the supplier's certificate of analysis.

It is the aim of this GMP Education Course to show how these requirements can be put into practice.

Other focus areas of this course are the regulatory requirements for sampling, the design and qualification of sampling areas and the handling of varying specifications in the different pharmacopoeias for identical APIs and excipients used for finished drug products dedicated for the markets in Europe, in the US, and in Japan.
Must different tests be conducted according to EP, USP, and JP, respectively?

The course programme will be completed by a lawyer's presentation about the legal and contractual liability of suppliers for defect products

## Target Audience

This GMP Education Course is directed at all those employees from quality control units in the pharmaceutical industry (including heads of quality control and laboratory managers) who are competent or responsible for sampling, testing and release of starting materials (APIs and excipients) and packaging materials (primary and secondary). This course is also of interest to personnel from quality assurance and to those employees from API, excipient or packaging material suppliers who want to inform themselves about the requirements of the pharmaceutical industry on the testing of these materials.

## Programme

### Regulatory Requirements for Sampling Procedures

- API and finished goods sampling
- Regulatory requirements
  - EU GMP Part 1, Chapters 4, 5, 6
  - EU GMP Part 2, Chapter 7
  - EU GMP Annex 8
  - EU GMP Annex 19
- Other regulations
  - US / FDA Requirements
  - WHO - PIC/S - ISO (former Military Standard)
- Supplier qualification and audits
  - Reduced testing

### Design and Qualification of Sampling Areas for Incoming Goods Products

- Sampling area for raw materials, APIs and excipients
- Layout and design of premises and equipment
- "Cleanroom"-like classification?
- What are the appropriate environmental requirements for sampling areas?
- How to qualify and maintain sampling areas?
- Is a change of pallets/removal of cart boxes required?
- Are expectations increasing? - Lessons learned during inspections

### Supplier Qualification and Supply Chain Traceability: an important Prerequisite for Reduced Sampling and Reduced Testing

- Prerequisites
- Qualification of packaging materials
- Qualification of APIs and excipients
- Supplier qualification / Supplier audits
- Quality Agreements
- Specifications / Pharmacopoeial monographs / Supplier CoA
- Complaint Handling

### Sampling and Documentation to make the Supplier liable for Defect Products

- Legal and Contractual Liability
- Definition of a Product Defect
- Express Warranty
- Admissible Evidence
- Insurability

### Case Study I: How to Define Inspection Procedures for Packaging Materials (Primary and Secondary) in the Incoming Goods Control

- Sampling Plans for printed packaging materials, glass containers, plastic containers, etc.
- AQL (Acceptable Quality Level)
- Tests required according to Ph.Eur. / USP
- Options for reduced sampling
- Options for reduced testing
- Skip lot testing

### Case Study II: How to Define and Optimise Sampling and Testing Procedures for APIs and Excipients in the Incoming Goods Control

- Sampling Plans for APIs / excipients
- Verification of pharmacopoeial procedures
- Options for reduced sampling
- Options for reducing analytical costs
- Use of / NIR / Raman for an efficient control

### Parallel Sessions: Working on specific Tasks

**1. Strategies/Prerequisites for Reduced Testing / Reduced Sampling**

The aim of this workshop is to evaluate in small discussion groups how the opportunities and requirements of EU GMP Annex 8 and 21 CFR Part 211 should be implemented in QA / QC.
*Moderator: Dr Bernd Renger*

**2. Reduced Testing / Reduced Sampling for APIs / Excipients**

Participants will discuss and calculate benefits of different measures in small groups. Scenarios of different materials / suppliers / qualification status, use of NIR/RAMAN for identity testing and optimization of the order size to reduce testing effort will be evaluated including their impact on the sampling and testing plans for APIs and excipients.
*Moderator: Emerich Grassinger*

**3. Reduced Testing / Reduced Sampling for Primary and Secondary Packaging Materials**

Participants will discuss in small groups scenarios of different materials / suppliers / qualification status / etc. and their impact on the sampling and testing plans with regard to reduced sampling and reduced testing for packaging.
*Moderator: Dr Gerald Kindermann*

**You will be able to attend 2 of these parallel sessions. Please choose the ones you would like to attend when you register for this Course.**

### How to Deal with Divergent Compendial Method Requirements

- ICH QB4 and the Pharmacopoeial Discussion Group
- Divergent and conflicting pharmacopoeial requirements
- CDER's MAPP 5310.7 "Acceptability of Standards from Alternative Compendia"
- How to proceed in case of missing harmonization?
- How to proof equivalence?

## Social Event

On 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.

## Speakers

Emerich Grassinger
*Aenova Group - Haupt Pharma Wülfing GmbH, Germany*
Emerich Grassinger works since 1995 in various positions for the pharmaceutical industry. 2002-2010 he headed several labs within Boehringer Ingelheim and was there also responsible for the Raw Material laboratory in which the testing and release of the APIs and Excipients was carried out. He led several improvement projects throughout the supply chain involving the raw material releasing process. 2010 he joined Haupt Pharma Wülfing, where he is responsible for Quality Control, including the raw material laboratory and the sampling of incoming goods.

Dr Matthias Heuermann
*NRW Centre for Health (LZG.NRW), Münster, Germany*
Since 2004 Dr. Heuermann is employed as head of the Official Medicines Control Laboratory (OMCL), today within the NRW Centre for Health of the federal state North Rhine-Westphalia. He studied pharmacy and gained his PhD thesis at the University of Münster, Germany. Since 1995 Dr Heuermann is involved in national and international GMP inspections with a focus on QC laboratories and QA systems.

### Dr Gerald Kindermann

*F. Hoffmann-La Roche, Basel, Switzerland*

Dr Gerald Kindermann is Product Quality Manager at the Global Quality Group at Roche working on quality systems. Before that he was Group Leader Quality Control and Quality Manager for the Supply Center.

### Dr Michael Möhlen

*Valneva Austria GmbH, Vienna, Austria*

Dr Möhlen is the Head of Technical Operations at Valneva Austria GmbH in Vienna and responsible for industrialisation of Vaccine candidates. This includes oversight as well to Quality Control and Clinical Serology. Until 2009 Dr Möhlen held various management positions in the Quality Control arena with Chiron and later Novartis Vaccines, including responsibility for raw material sampling and testing.

### Dr Bernd Renger

*Bernd Renger Consulting, Germany*

Dr Bernd Renger was a member of the European Compliance Academy (ECA) Advisory Board and Immediate Past Chair of the European QP Association. Since 2011 he is running his own consultancy business. Before that he was VP of Quality Control at Vetter Pharma-Fertigung. He started his career 1977 at Hoechst AG as a research and development chemist. Since then, he has held several quality management positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna.

### Dr Martin Wesch

*Wesch & Buchenroth, Law Office,* Germany

Dr Martin Wesch is a lawyer specialised in medical and industrial law and working for the Stuttgart-based firm of lawyers Wesch & Buchenroth, which he founded in 2001. Since April 2002, he has been teaching industrial law at the University of Stuttgart. He is author of several publications, both in journals and books, to legal demands on quality assurance in manufacturing pharmaceuticals. In 2007 he received the Wallhäusser Prize for publications in that field from Concept Heidelberg.

## 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

Monday 21 November 2016, 09.00 - 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Tuesday,22 November 2016, 08.30 - 15.30 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 € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845

The course 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 safe money?

If you register for ECA's Education Course "Quality of Nasal and Inhalation Drug Products" from 23-25 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
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0, Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de, www.concept-heidelberg.de

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

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

ECA Course
**Quality of Nasal and Inhalation Drug Products**
23 – 25 November 2016, Berlin, Germany

On 23 – 25 November 2016, i.e. from Wednesday to Friday of the same week, the ECA Education Course Quality of Nasal and Inhalation Drug Products will take place in the same hotel in Berlin. Topics to be covered will include:

- Regulatory Requirements for Respiratory and Nasal Drug Products
- Good Development Practices for MDIs, DPIs and Nasal Drug Products
- Dose Content Uniformity Test - a Key Method to Characterize Inhalation Drugs
- Particle Size Distribution and Determination
- Requirements for Starting Materials and Device Components
- Nasal and Nebulizer Testing
- Extractables / Leachables Assessment for MDI and DPI Devices
- Product Characterisation Studies

Interactive Workshops will also be part of this course. Further information about this Education Course can be received at www.gmp-compliance.org.

**Register simultaneously for both courses and receive a 350 € discount (not valid for EU GMP Inspectorates).**

**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 HEIDELBERGwill 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.

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Reservation Form (Please complete in full)

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

+ 49 6221 84 44 34

**Please choose TWO parallel sessions:**
☐ Strategies/Prerequisites for Reduced Testing /Reduced Sampling
☐ Reduced Testing / Reduced Sampling for APIs / Excipients
☐ Reduced Testing / Reduced Sampling for Primary and Secondary Packaging Materials

ECA Academy
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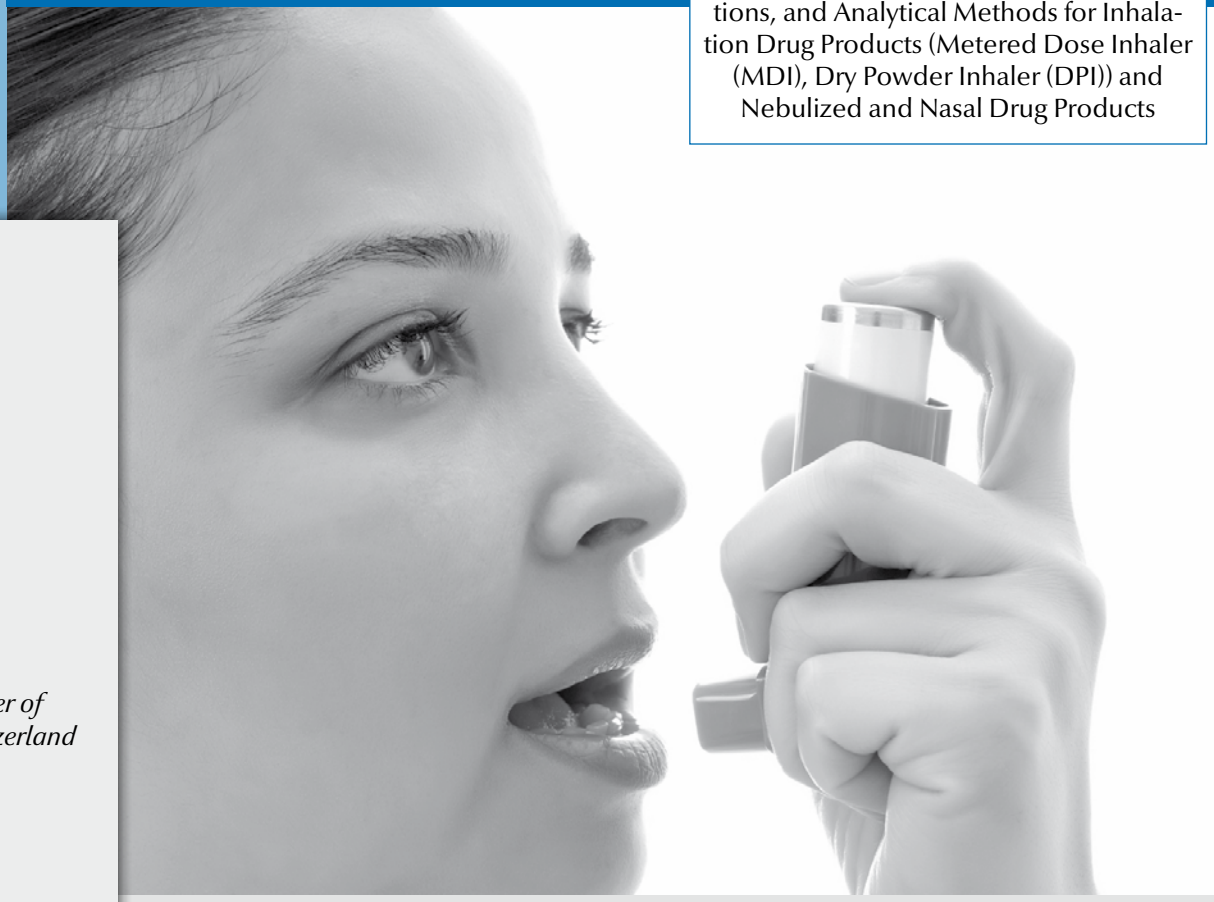
# Quality of Nasal and Inhalation Drug Products

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 Practics 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 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

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 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

## 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?**
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### Accommodation

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### Registration

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### 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).**

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

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