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

Quality of Inhalation Drug Products

10 – 11 November 2014, Prague, Czech Republic

SPEAKERS:

Dr Carol Barbour
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HIGHLIGHTS:

- Regulatory Requirements:
  - Pharmacopoeia Requirements
  - Guidance Documents (Europe and U.S.)
  - Specifications and Analytical Methods
- 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

ECA ACADEMY

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

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Objectives

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

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- FDA Draft Guidance for Industry: Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI),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

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 MDIs and DPIs

- 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

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.

Social Event

On Monday 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.

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.

Easy Registration

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69007 Heidelberg
Germany

Reservation Form:
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e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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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Date

Monday, 10 November 2014, 09:00 – 17:30 h
(Registration and coffee 08:30 – 09:00 h)
Tuesday, 11 November 2014, 08:30 – 15:30 h

Venue

Corinthia Hotel Prague
Kongresova 1
10069 Prague, Czech Republic
Phone: + 420 261 191 111
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Fees*

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.

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

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