Participate in
3 Workshops!

Quality of Herbal Medicinal Products

26 - 27 November 2015, Prague, Czech Republic

SPEAKERS:

Dr Andreas Hofmann
Phytos GmbH & Co. KG, Germany

Dr Bernhard Klier
PhytoLab GmbH & Co. KG, Germany

Dr Sven Oliver Kruse
Diapharm GmbH & Co. KG, Germany

Dr Christian Lottner
Bionorica SE, Germany

Dr René Roth-Ehrang
Amway GmbH

Dr Alexander Schenk
Zeller AG, Switzerland

PROGRAMME:

- The Regulatory Framework of Herbal Medicinal Products (HMPs)
- Herbal Medicinal Products:
  - Well-established Use
  - Traditional Use
  - Food Supplement
- Characteristics of HMPs
- Specifications and Markers for HMPs
- Stability Testing of HMPs today
- Conversion of Analytical Methods HPLC to UHPLC
- Contaminants in Herbal Drugs and Herbal Drug Preparations – Current Review of
  - Pesticides
  - Mycotoxins
  - Heavy Metals
- The European Variations Regulation/ Guideline applied to (Traditional) Herbal Medicinal Products

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 course will provide you with the necessary knowledge to control the quality of Herbal Medicinal Products (HMPs). You will learn about all aspects that are needed to build up the CTD quality module 3 for your registration dossier. This includes legal and regulatory requirements as well as analytical methods and the challenges often encountered in HMPs.

Background

Herbal Medicinal Products are accepted and widely-used remedies. Although several routes exist for HMPs to receive a marketing authorization, e.g. well-established or traditional use - but also as food supplements - they all need to fulfill the same quality standards. However, HMPs have some specific characteristics that must be taken into consideration for quality control measures to produce sound analytical results – especially when these quality control measures have to remain economically viable:

- Due to their high number of constituents HMPs are complex in nature.
- The constituents belong to different chemical classes with different analytical behaviour.
- Constituents have different and sometimes very low concentrations in the finished product.

This two-day course will furnish you with the necessary knowledge to develop intelligent and pragmatic solutions for the analysis of HMPs. You will learn about the

- Legal and regulatory framework
- Characteristics of HMPs
- Quality control methods for HMPs
- Typical obstacles and pitfalls

The combination of lectures and workshops will help you to retain and later apply the newly gained insights to your own products.

Target Group

This course is designed for all people in pharmaceutical and API industry's quality control, regulatory affairs, pharmacovigilance, production and purchasing departments who need to establish, monitor and/or manage the quality of Herbal Medicinal Products.

Social Event

At the end 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.

Programme

The Regulatory Framework of Herbal Medicinal Products

- Definitions
- Marketing authorization and registration
- Particularities of Traditional Herbal Medical Products
- Quality aspects

Dr René Roth-Ehrang

Characteristics of HMPs

- From Herbal Drug to Herbal Medicinal Product
- Definition of the API
- Defining marker substances and forced degradation studies
- Special analytical methods

Dr Andreas Hofmann

Quality of HMPs

- GACP
- Herbal drug sourcing
- Microbiological aspects
- Setting specifications (Herbal Drug, Extracts, Herbal Medicinal Products)

Dr Andreas Hofmann

Stability Testing of HMPs today

- Stability testing - general requirements
- Characteristic of HMPs
- Particular analytical aspects of HMPs:
  - Markers, methods, fingerprints, validation
  - Shelf-life specifications
  - OOS Results

Dr Sven Oliver Kruse

Conversion of Analytical Methods HPLC/UHPLC - The Sticking Points are in the Detail

- Shorter running times and saving of solvents by conversion of analytical methods from HPLC to UHPLC
- Existing methods can be converted easily in a large number of cases with the available translation tools
- Further optimization of separation, particular in the case of complex mixtures of similar secondary components becomes possible with experience and some useful tricks
- UHPLC equipment is often used for running conventional HPLC methods, sometimes with surprisingly different results and unexpected problems to be resolved

Dr Alexander Schenk

Contaminants in Herbal Drugs and Herbal Drug Preparations – Current Review

- Contaminants in Ph.Eur:
  - Pesticides
  - Mycotoxins
  - Heavy metals
- Foodstuff Regulation (EG) No. 1881/2006
- Relevance in practice

Dr Bernhard Klier

The European Variations Regulation/Guideline applied to (Traditional) Herbal Medicinal Products

- Introduction and legal background of the European Variations Regulation
- Supporting information and guidelines
- Classification of variations: in general and specially focused on Herbal Medicinal Products
- Handling of Variations: workflow and submission (e-CTD, CESP)
- Some case studies

Dr Christian Lottner

Workshops

Some of the most important topics of this course will be further discussed in workshops on day 2.

1. Changes and Variations – How to handle for HMPs?
The aim of this workshop is to evaluate in small discussion groups how to come to valid variations step-by-step.
Participants are invited to send **specific questions** regarding the practical handling of changes and variations prior to this course directly to info@concept-heidelberg.de
Moderator: Dr Christian Lottner

2. UHPLC
By the means of examples from analytical development and routine analysis participants will learn and discuss important tools for developing UPLC-methods for secondary natural component analysis. Conversion of HPLC to UHPLC methods are exercised on the basis of real examples.
Moderator: Dr Alexander Schenk

3. Contaminants in Herbal Drugs and Herbal Drug Preparations – Examples from Daily Practice
In this workshop participants will discuss the following topics:

- Sampling of herbal drugs
- Pyrrolizidine Alkaloids (natural sources, analytical options, legal requirements, current situation in practice)
- Pesticide residues (definition, regulation, contamination)

Moderator: Dr Bernhard Klier

Participants will be able to attend all these 3 Workshops on Day 2.

Speakers

Dr Andreas Hofmann
Phytos GmbH & Co. KG, Neu-Ulm, Germany
Dr Andreas Hofmann was partner of the company Phytos GmbH, from 1989 to 2014, an external testing laboratory for the analysis of phytopharmaceuticals. Since 2001 Dr. Hofmann is member of the German Homöopathical Pharmacopoeia commission, since 2009 member of the Expert Group 13B of the EDQM in Straßbourg, France. Since 2014 working for GBA Laboratory Group, Pharma Division.

Dr Bernhard Klier
PhytoLab GmbH & Co. KG, Vestenbergsgreuth, Germany
Dr Bernhard Klier has been working since 1993 at PhytoLab GmbH & Co. KG, responsible for quality control tests and contaminants and is registered Qualified person at MartinBauer and Plantextrakt. He is member of the expert group "Herbal Drugs" (German Pharmacopoeia and European Pharmacopoeia), member of Pesticide Working Group of the Society of German Chemists (GdCh) and the EDQM working party "Pesticides in Herbal Drugs".

Dr Sven Oliver Kruse
Diapharm GmbH & Co. KG, Münster, Germany
Dr Sven Oliver Kruse is a member of the Management-Board at Diapharm GmbH & Co. KG. His responsibilities include the position of Managing Director at Diapharm Analytics GmbH, Diapharms´ service lab (GMP certified, authorization for batch release) and he is also a Qualified Person (Directive 2001/83/EC) for this company.

Dr Christian Lottner
Bionorica SE, Neumarkt, Germany
After his PhD Dr Lottner was Research Group Leader at the Institute of Pathology at the University of Regensburg in collaboration with the Centre of Excellence for Fluorescent Bioanalytics. In 2005 he joined the department of Drug Regulatory Affairs at Bionorica SE. Since 2008 he has been in charge of all Regulatory Processes in (Western) Europe as Senior Drug Regulatory Affairs Manager.

Dr Rene Roth-Ehrang,
Amway, Puchheim, Germany
Dr. René Roth-Ehrang studied Pharmacy at the University of Hamburg. He has many years of experience in the development, production and marketing authorization and registration of herbal medicinal products and plant food supplements. He's been directing the product development, quality assurance and regulatory affairs at Amway Europe since 2011.

Dr Alexander Schenk
Zeller AG, Romanshorn, Switzerland
Pharmacist Dr rer nat Alexander Schenk, is analytical development manager at Max Zeller Söhne AG, in Romanshorn/Switzerland and specialised on secondary natural components in plants. He established numeros methods for determination of active components and contaminants with a focus on UHPLC-HRMS technology.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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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

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Phone/Fax

E-Mail (please fill in)

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

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- until 2 weeks prior to the conference 10 %,
- until 1 week prior to the conference 50 %
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Date

Thursday, 26 November 2015, 9.00 h – 18.00 h
(Registration and coffee 8.30 h – 9.00 h)
Friday, 27 November 2015, 8.30 h – 16.00 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague, Czech Republic
Phone + 420 261 191 111
Fax + 420 261 225 011

Fees (per delegate plus VAT)

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 with all further information when you have registered for the event. 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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For questions regarding content:
Dr Günter Brendelberger (Operations Director) at phone +49 (0) 62 21 / 84 44 40, or per e-mail 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.