ECA Academy
Your GMP/GDP Information Source

Speakers Main Conference


Dr Cornelia Bodinet
Schaper & Brümmer, Germany


Dr René Roth-Ehrang
Finzelberg, Germany


Univ-Doz. Dr Reinhard Länger
Austrian Agency for Health and Food Safety (AGES)


Dr Margit Müller
WALA Heilmittel, Germany


Dr Ulrich Rose
Formerly EDQM, France


Anke Steuber
PhytoLab, Germany


Dr Jonathan Thompson
United Science, USA


Dr Ingrid Walther
Pharma Consulting Walther, Germany, *Leader of the ECA Cannabis Working Group*

Speakers Post-Conference on Qualification & Validation Aspects for Cannabis


Mike Kleinebecker
Siemens, Germany


Dr Ingrid Walther
Pharma Consulting Walther, Germany, *Leader of the ECA Cannabis Working Group*


Sebastian Zeller
Canexis Pharma, Switzerland

GMP for Herbal Medicinal Products (HMPs)

+ Post-Conference Qualification & Validation Aspects for Cannabis

Live Online Conferences on 8-9 November 2022

Post-Conference:
Every participant will receive the printed version of **ECA´s Cannabis Roadmap** - Global GMP Requirements and Regulatory Information on Medicinal Cannabis (and CBD Products)!

Highlights

- GACP vs GMP requirements
- Regulatory Framework
- Requirements for Marketing Authorization Applications
- Contaminants - A Risk-based Approach
- Stability & Microbiological Testing
- GMP Aspects for Extracts
- Experiences from GMP Inspections / Audits

Post-Conference

- Environmental control and monitoring
- Process Validation & Equipment Qualification
- Case study
- Lessons learned

Post-Conference:
Download for participants only

Non-official English translations of the German Pharmacopoeia (DAB) Monographs *Cannabis flower* and *Cannabis Extract*

Objectives

The course will provide you with the necessary GMP/GACP knowledge for Herbal Drugs, Herbal Drug Preparations (e.g. Extracts) and Herbal Medicinal Products (HMPs). This includes regulatory & quality requirements as well as applicable pharmacopoeial monographs and challenges often encountered in HMPs, e.g. during stability studies.

In addition, more and more countries around the world legalize cannabis for medical use. But what qualifies as medical grade cannabis? And which aspects have to be considered in particular during Qualification/Validation? The dedicated Post-conference will provide you with the necessary details for medical cannabis products.

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 – or special cases like medical cannabis as "Formula magistralis / officinalis" without marketing authorization - they all need to fulfill the same pharmaceutical quality standards. However, HMPs have some very specific characteristics that must be taken into consideration for GMP compliant production, quality control, release and stability testing. Questions often raised include the following:

- Which contaminants have to be considered?
- Which microbiological provisions apply?
- Which kind of decontamination procedures can be used?
- Are there different requirements for herbal drugs, herbal drug preparations (like extracts) and the final HMP?

To provide more detailed information on these requirements, the European Medicines Agency (EMA) recently published the final guidelines (Revision 3) on quality and specifications for herbal medicinal products (HMPs). Amongst others, a written GACP confirmation for the herbal substance should be provided either by the herbal drug supplier or the manufacturer of the active substance / the HMP. In addition, EMA´s HMPC is currently working on the revision of the GACP guideline and recently already published a concept paper.

Moreover, Qualification and Validation is an essential GMP requirement. Non-EU suppliers, who currently produce according to GPP, will have to implement EU-GMP standards if they want to supply herbal drugs like medical cannabis to the EU market. But which requirements apply? And what does it mean in practice? The post-conference will specifically answer these questions and provide you with practical examples.

Target Audience

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 Drugs / Herbal Medicinal Products. The Post-conference specifically addresses Qualification/Validation aspects to consider for Growers, Manufacturers, Start-Ups, Suppliers, Importers, Wholesalers, QPs and QA/QC personnel involved in Cannabis production.

Moderator

Dr Andrea Kühn-Hebecker, CONCEPT HEIDELBERG

Programme - 8 November 2022

The Regulatory Framework for HMPs

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

Quality Requirements for Marketing Authorization Applications

- Borderline GACP-GMP
- Types of extracts
- Control strategy for extracts and drug products
- Context with clinical data and regulatory pathway
- Is a complete dossier always required?

Herbal Reference Standards (HRS)

- Pharmacopoeial definition (Ph. Eur.)
- Different types of HRS
- Active and analytical markers

Q&A Session 1

EU GMP Annex 7 / GMP vs GACP

- GACP Guideline
- Herbal drugs: "Special APIs"? - EU GMP Part II
- EU GMP Part I and Annex 7
- Points to consider

Contaminants – A Risk based Approach

- Regulatory basis for risk-based testing for medicinal products with herbal ingredients
- Procedure for the development of test concepts based on risk analyses
- Different scopes of testing for release and re-testing of starting materials
- Current examples of risk-based testing for contaminants:
  - Example 1: Pyrrolizidine alkaloids
  - Example 2: Elemental Impurities (ICH Q3D)
  - Example 3: Aflatoxins

GMP Aspects for Extracts

- Process Design
- Qualification / validation
- Extraction Solvents
- Sampling and Testing Operations

Q&A Session 2

Programme - 9 November 2022

Current Requirements for the Microbiological Testing of HMPs

- Typical microflora of medicinal plants
- Requirements for the microbiological quality of herbal medicinal products
- Microbiological test methods and proof of suitability
- Decontamination methods for herbal starting materials
- Experiences from authority inspections

Challenges in Stability Studies

- Stability testing - general requirements
- Characteristic of HMPs
- Particular aspects of HMPs:
  - Markers, methods, fingerprints, validation
  - Shelf-life / re-test date
  - OOS / OOT Results

Experiences from GMP Inspections / Audits

- Quality management System (QMS)
- Quality Risk Management (QRM)
- Points to consider

Final Discussion

Post-Conference on Qualification & Validation Aspects for Cannabis
(for Growing, Processing, Handling and Storage of Medical Cannabis)

Environmental Control and Monitoring

- Solutions to control and monitor facilities in a safe, efficient and GMP-compliant manner

Process Validation & Equipment Qualification

- Qualification of equipment / rooms / facilities / utilities (systems)
- Qualification / Validation Master Plan (VMP)
- Principles of Quality Risk Management (QRM)
- How to identify critical parameters

Case study:
A New Production Facility for Cannabis

The presentation will provide insight in:

- The main concept to set-up a Cannabis production facility
- The zone concept, general layouts, hygienic aspects
- How to integrate GMP requirements in the project
- How to deal with the authority
- How to qualify suppliers
- Realization of Qualification and Validation in practice

Experiences / Lessons learned

- Changing Rooms – Air-locks - Zoning Concepts
- Room Design and Room Separation
- Drying Process – What needs to be done?
- Points to consider

Final Discussion

Speakers Main Conference

Dr Cornelia Bodinet, Schaper & Brümmer GmbH & Co. KG, Germany

Dr Cornelia Bodinet is Division Manager Pharmaceutical Laboratories at Schaper & Brümmer and is responsible for quality control, hygiene and microbiology. She has also been a member of the management team since 2007.

Dr René Roth-Ehrang, Member of the Management Board Quality / Development, Finzelberg GmbH & Co. KG, Germany

After studying pharmacy in Hamburg and obtaining his doctorate in Bonn, Dr Roth-Ehrang has been with Finzelberg since 1998 in various positions, including Head of Scientific & Regulatory Affairs. In addition, he gained insights in the food supplement industry when serving Amway as Director of Regulatory and Technical Services. Currently Dr Roth-Ehrang is Member of the Management Board Quality & Development at Finzelberg.

Univ-Doz. Dr Reinhard Länger, Head of Department Herbal, Homoeopathic and Veterinary Medicinal Products, Austrian Agency for Health and Food Safety (AGES),

Dr Reinhard Länger started his work at AGES in 2006 as assessor. Currently he is Head of the Department for Herbal, Homoeopathic and Veterinary Medicinal Products at the Institute for Marketing Authorization of Medicinal Products & LCM. He is member of EMA´s Committee on Herbal Medicinal Products.

Dr Margit Müller, WALA Heilmittel GmbH, Germany

Dr Margit Müller has been group leader of "Analytical Development for Intermediates and Finished Products" in the "Analytical Development/Research" department at WALA Heilmittel GmbH in Bad Boll since 2007.

Dr Ulrich Rose, Former Deputy Head of the European Pharmacopoeia Department, EDQM, France

Dr Rose was Deputy Head of the European Pharmacopoeia (Ph. Eur.) Department at the EDQM in Strasbourg and in this context responsible (amongst others) for the preparation of monographs on herbal drugs & preparations. He was also involved in the harmonization of international pharmacopoeias. Previously, he was responsible for the establishment and control of Ph. Eur. Herbal Reference Standards.

Anke Steuber, PhytoLab GmbH & Co. KG, Germany

Anke Steuber has been Head of the Regulatory Affairs Department since 2006 and has headed the Stability Department at PhytoLab since 2020. Further of her topics are demarcation issues between foodstuffs and medicinal products as well as regulatory issues relating to foodstuffs. She is an accredited counter-sample expert for the field of "Examination of herbal foodstuffs and their source materials (plant parts, extracts)".

Dr Jonathan Thompson, United Science LLC, USA

Dr Thompson is highly experienced in separations engineering, facility design, GMP regulations (from plant to final dosage form) and botanical product development. His industry experience includes botanical processing, flavors, active ingredients, and fiber manufacturing and he is an expert in botanical & healthy living markets with emphasis on environmentally sustainable operations.

Dr Ingrid Walther, Pharma Consulting Walther, Germany, Leader of the ECA Cannabis Working Group

Dr Walther joined Fresenius AG in 1986 and was employed in various positions and has many years of experience in research and development, quality assurance/quality control and management of strategic projects. Since July 2009, she runs her own business as GMP compliance consultant, recently including many Cannabis Projects.

Speakers Post-Conference on Qualification & Validation Aspects for Cannabis

Mike Kleinebecker, Siemens AG, Germany

Mike Kleinebecker is a consulting professional for Pharma, Life Science and Critical Environment at Siemens Smart Infrastructure. His expertise is building automation and environmental monitoring in the GMP environment. Prior to that, he gained in-depth knowledge of the manufacture of oral solid dosage forms at a global process equipment company.

Dr Ingrid Walther, Pharma Consulting Walther, Germany, Leader of the ECA Cannabis Working Group

Dr Walther joined Fresenius AG in 1986 and was employed in various positions and has many years of experience in research and development, quality assurance/quality control and management of strategic projects. Since July 2009, she runs her own business as GMP compliance consultant, recently including many Cannabis Projects.

Sebastian Zeller, Canexis Pharma AG, Switzerland

Sebastian Zeller received his Bachelor of Science from the ZHAW (academic award: Dean´s List). Currently he is Chairman of the Board, Managing Director and Founder of Canexis. Before that he worked as laboratory technician (analytics, quality control, research and development) at Zeochem AG.

Your Benefit

Internationally Acknowledged Certificate from ECA Academy
The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

This could be of interest for you as well

Why not online? GMP/GDP seminars, webinars and e-learning
Take advantage of the wide range of „on demand" training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course.

Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/recordings.

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
- APIs (ICH Q7)
- Medicinal Products
- Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

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GERMANY

Reservation Form (Please complete in full)

Live Online Conferences

☐ GMP for Herbal Medicinal Products (HMPs), 8-9 November 2022
☐ Post-Conference on Qualification & Validation Aspects for Cannabis, 9 November 2022

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks 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 July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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 https://www.gmp-compliance.org/privacy-policy). 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.

Date of the Live Online Conferences

GMP for Herbal Medicinal Products (HMPs)
Tuesday, 8 November 2022, 09.00 to approx. 17.30 h CET
Wednesday, 9 November 2022, 09.00 to approx. 12.45 h CET

Post-Conference on Qualification & Validation Aspects for Cannabis
Wednesday, 9 November 2022, 13.45 to approx. 18.00 h CET

Technical Requirements
We use Webex Events for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

GMP for Herbal Medicinal Products (HMPs)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The fee is payable in advance after receipt of invoice.

Post-Conference on Qualification & Validation Aspects for Cannabis
ECA Members € 990
APIC Members € 1,040
Non-ECA Members € 1,090
EU GMP Inspectorates € 545
The fee is payable in advance after receipt of invoice.

Save money and book both courses:
ECA Members € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,440
The fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org

Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

You cannot attend the Live Event?
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Conference language
The official conference language will be English.

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