ECA Academy
Your GMP/GDP Information Source

Conference 2020

Speakers


Jennifer Ayotte
AI Data Grow, USA


Claudia Baumung
CVUA Karlsruhe, Germany


Oliver el-Atma
CVUA Karlsruhe, Germany


Dr Reinhard Kerker
GMP Inspectorate, Germany


Dr Andrea Kühn-Hebecker
Concept Heidelberg, Germany, *ECA Cannabis Working Group*


Silja du Mont
GDP/GCP Inspectorate, Germany


Luis Meirinhos Soares
GMP / GACP Inspector, Infarmed, Portugal


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


Stephanie Wilmott
Consultant, Canada; *ECA Cannabis Working Group*

GMP for Cannabis – what you need to know

09/10 June 2020 | Hamburg, Germany

All relevant GMP/GDP aspects for Medical Cannabis!

Highlights

- GACP/GMP/GDP requirements for Medical Cannabis
- How to get a MA, Import License / How to get a GMP Certificate?
- Experiences from current Inspections
- Requirements of the Narcotics Law
- Overview of Pharmacopoeial Monographs
- How to get a GMP certificate for Export?
- First Experiences - Lessons learned

NEW

- **GPP vs. GMP**
- **Aspects to consider for CBD Products**
- **German Pharmacopoeial Monograph (DAB 2020) for Cannabis Extracts**

Objective

Medical cannabis has been permitted for prescription in Germany since 2017, causing a need for producers supplying pharmacists and physicians with the newly legalized drug. In addition, more and more countries around the world are following Germany by introducing programs in order to legalize cannabis for medical use. But what qualifies as medical grade cannabis? And which aspects have to be considered for CBD-Products? This conference will give you an overview of all relevant regulatory and GACP/GMP/GDP requirements and aspects for medical cannabis and CBD-Products.

Background

In March 2017, the national German legislature expanded the options for prescribing medical cannabis products by passing a law amending provisions under the Narcotics Law and other regulations. These products, however, must comply with the relevant requirements laid down under Medicinal and Narcotics Law, including GACP/ GMP and GDP. Therefore, the BfArM (the Federal Institute for Drugs and Medical Devices) has taken over new responsibilities by establishing the Cannabis Agency. This agency is meant to help in ensuring supplies for medical-quality cannabis.

Unlike AGES in Austria, though, where cultivation of medical cannabis has already been established, cannabis will not be cultivated by BfArM itself, but by commissioned companies. Cannabis is not meant to be stored directly at BfArM during any stage of the purchasing, harvesting or distribution process. These steps will be carried out by relevant producers or other commissioned companies (i.e. suppliers, importers). Hence, the agency will manage and monitor the cultivation, harvest, processing, quality assurance, storage, packaging and distribution of cannabis to wholesalers, chemists or manufacturers.

The GMP inspectorates are responsible for issuing manufacturing and import licenses or GMP Certificates. Thus, they will perform inspections at the sites of manufacturers who apply for these certificates and licenses.

In summary:

- The Cannabis Agency is responsible for ensuring that only medical grade cannabis is supplied,
- The relevant requirements based on the underlying legal framework (including Pharmacopoeias) and the corresponding GMP, GDP and GACP guidelines must be complied with, and finally
- Cannabis for medical purposes is also subject to the provisions of the Narcotics Law.

Non-EU suppliers, who currently produce according to GPP, will have to implement EU-GMP standards if they want to supply medical cannabis to the EU market. However, since there is currently no harmonized EU standard and pharmacopoeial monograph for medical cannabis (and extracts), national legislations, guidelines and pharmacopoeial monographs will have to be followed and applied in addition to EU-GMP.

Target Audience

This conference addresses specific GMP aspects to consider for Growers, Manufacturers, Start-Ups, Suppliers, Importers, QPs and QA/QC personnel involved in Cannabis production and release. The topics provided are also of interest for GACP/GMP/GDP Inspectors responsible for issuing a GMP certificate or manufacturers/import license.

Programme

Welcome and Introduction

- GMP for Cannabis: setting the scene

GMP Certification / Manufacturing and Importation Authorization

- Aspects to consider for applications for Manufacturing and Importation Authorizations
- Aspects to consider for analytical labs
- GMP certification: What you need to know
- Inspections in Europe and beyond: Typical and recurrent compliance issues

GDP for Cannabis

- Requirements for transport to pharmacies, veterinary dispensaries, hospitals
- Requirements for distribution of cannabis through international distribution partners, wholesalers and 3PL partners

Aspects to consider for CBD (and other Hemp) Products

- Requirements due to the German Narcotics Law
- How to differentiate between CBD/Cannabis Products for medical use and other CBD (Hemp) Products?
- Which legal rules apply?
- Practical examples

Overview of Pharmacopoeial Monographs

- Europe (Ph. Eur.)
- Germany (DAB / DAC)
- Denmark
- Netherlands
- Switzerland (Ph. Helv.)
- Israel
- New Zealand (Product Quality Standards Monograph)
- USA (USP)

The Intersection between GACP and GMP - View on the Inspection of Cannabis GACP and its Relation to GMP

- When does GACP end and (EU) GMP start?
- What will be checked during GACP and EU GMP inspections?
- Observations in inspections
- Open questions and issues to be solved

GPP vs. GMP

- Differences and similarities
- Validation as part of the PQS
- Stability testing / stability programme
- QP Batch Release

How to get GMP certified for Export?

- Growing, harvest, packaging, quality control and release: Requirements to fulfil
- Agreements & Responsibilities
- EU GMP Conformity & Export / Import License

Experiences - Lessons learned

- Application of GMP principles to Cannabis
- Quality management System (QMS) including Qualification/Validation
- DAB Monograph "Cannabis Flos": Points to consider

Moderator
Dr Ingrid Walther

Speakers

Jennifer Ayotte, AI Data Grow, USA
Jennifer is certified in Agronomy and Horticulture and brings a deep understanding of producing and processing cannabis on a large scale. Jenn was a co-founder of Midwest Ranch, one of the largest wholesalers of cannabis flowers in the State of Colorado. She has arranged, supported and acquired multiple licenses and certifications including but not limited to: GMP, GPP, GACP, Import/Export licenses. She provides audit services and staffing, and is Quality Assurance Person and Master Grower designee from Health Canada.

Claudia Baumung, CVUA Karlsruhe, Germany
Claudia Baumung holds a Diploma in Food Chemistry. She is currently working as laboratory manager and expert, e.g. for cosmetic products, at the CVUA Karlsruhe (Official Surveillance of Food in Baden-Württemberg). Claudia is a member of the OCCL Network (European Network of Official Cosmetics Control Laboratories) at the EDQM (European Directorate of the Quality of Medicines & Health Care) in Strasbourg.

Oliver el-Atma, CVUA Karlsruhe, Germany
Oliver el-Atma is scientific officer and expert at OMCL Karlsruhe (official medicine control laboratory) since 2005. He is an expert with work scope in phytopharmaceutical and homeopathic products, quality assurance representative and contact person of the OMCL for EDQM. He is a member of the analytical working group of the German Homoeopathic Pharmacopeia at the German Federal Institute for Drugs and Medical Devices (BfArM) and different working groups at EDQM.

Dr Reinhard Kerker, GMP Inspectorate, Germany
Dr Reinhard Kerker studied pharmacy at the University of Tuebingen and economics at the University of Hagen. He received a PhD in Pharmaceutical Technology at the University of Munich and has more than 25 years experience in pharmaceutical industry in various positions (e.g. Quality Control, Manufacturing, Plant Manager and Managing Director). Since 2017 he is GMP Inspector at the Local Authority in Tuebingen.

Dr Andrea Kühn-Hebecker, Concept Heidelberg, Member of the ECA Cannabis Working Group, Germany
Andrea started to work for Concept Heidelberg in 2015. Before that time she gained 10 years experience in the field of herbal drugs at WALA / Dr Hauschka Cosmetics (a herbal medicinal products and natural organic cosmetics company located near Stuttgart/Germany) where she was five years Head of Quality Control according to § 12 of the German AMWHV.

Silja du Mont, GDP/GCP Inspectorate, Germany
Since 2010 Silja du Mont is working as GCP/GDP Inspector for medicinal products / medical devices at the district authority of Freiburg (Regierungspräsidium Freiburg). She is Head of the German GCP Inspectors Expert Group at ZLG (Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices), European Expert GCP IWG EMA and also responsible for Pharmacy Surveillance.

Luis Meirinhos Soares, GMP / GACP Inspector, Infarmed, Portugal
Luis holds a B.Sc. (Hons.) in Biochemistry, and is M.Sc. Biotechnology. Since January 2019 he is GACP, GMP, GDP Inspector, and Project Manager for GACP Inspections of Medicinal Cannabis, at INFARMED, the Portuguese Medicines Agency. He has more than twenty years' experience in the field of Official medicines control, served as Director of the Biology and Microbiology of INFARMED for fifteen years, and has been appointed Expert of Ph. Eur. Working Groups (Microbiology, Blood Products, Biotechnology). He is a Member of the Portuguese Pharmacopoeia Commission.

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

Stephanie Wilmott, Consultant (Gold Leaf Standard), Member of the ECA Cannabis Working Group, Canada
Stephanie Wimott is a Consultant for Regulatory Affairs and License application processes (standard and micro cultivator). Her work includes: Health Canada compliant SOP's and QMS/QA systems, site design and floor plan creation, provision of GMP & GPP documentation for compliance to Health Canada requirements and HR documentation and creation of Site Master Files for compliance reporting under the Cannabis Tracking and Licensing System.

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GERMANY

Reservation Form (Please complete in full)

GMP for Cannabis – what you need to know | 09/10 June 2020, Hamburg, Germany

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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).
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 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.

Date

Tuesday, 9 June 2020, 9.30 to approx. 17.30 h
(Registration and coffee 08.30 – 09.30 h)
Wednesday, 10 June 2020, 08.30 to approx. 13.30 h

Venue

Barceló Hotel Hamburg
Ferdinandstrasse 15
20095 Hamburg, Germany
Phone +49 40 22 63 62 0
Email hamburg@barcelo.com

Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes, lunch and dinner on day 1, business lunch on day 2 and all refreshments. VAT is reclaimable.

Please note

There will not be any print-outs at the conference. Instead you will receive all presentations prior to the conference as downloads. All delegates will also receive the presentations on a USB stick at the registration center.

Social Event

In the evening of the first conference 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.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. 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.
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