ECA Academy
Your GMP/GDP Information Source

2nd Conference 2019

Speakers


Constantine Emmanouilidi
Epsilon Greenhouses, Greece


Dr Reinhard Kerker
GMP Inspectorate, Germany


Silja du Mont
GDP/GCP Inspectorate, Germany


Dirk Ohlenforst
Bonn, Germany


Dr Andreas Schieweck
GMP Inspectorate LAGuS, Germany


Robert Schwanke
GrowIn, Germany


Judith Steffens
Cannamedical, Germany


Dr Mona Tawab
Zentrallaboratorium Deutscher Apotheker, Germany


Dr Ingrid Walther
Pharma Consulting Walther, Germany

GMP for Cannabis – what you need to know

29-30 October 2019 | Heidelberg, Germany

Highlights

- GMP/GDP for Medical Cannabis
- Growing Cannabis according to GACP
- How to get an MA, Import License / How to get a GMP Certificate?
- Experiences from current Inspections
- Requirements of the German Narcotics Law
- Quality of medicinal Cannabis / Testing
- Supplier qualification and handling
- First Experiences - Lessons learned

All relevant GMP/GDP aspects for **Medical Cannabis!**

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. But what qualifies as medical grade cannabis? This conference will give you an overview of all relevant regulatory and GMP/GDP requirements and aspects of medical cannabis.

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 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 German Narcotics Law.

Target Audience

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

Moderator

Dr Ingrid Walther

Programme

Welcome and Introduction

- GMP for Cannabis: setting the scene

Greek law for Pharmaceutical Cannabis - A reliable framework for final medical products with Cannabinoids

- GMP and GACP in Greece
- Possible pitfalls and strategies to avoid them
- Timeframe and steps to acquire a license
- Greek National Organization for Medicines (EOF)
- Future issues to be solved

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

Narcotic drugs – The regulations

- Short overview of the German Narcotics Law („Betäubungsmittelgesetz", BtMG)
- Necessary documents for granting general licenses and import / export authorizations by the Federal Opium Agency (BfArM)
- Surveillance with respect to inspections
- Reasons for refusal

GDP for Cannabis

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

Quality of medicinal Cannabis and Extracts

- What to test
- How to test
- Limits
- Challenges and problems

Steps of Growing Cannabis according to GACP

- Facility plan, design, set up – Hurdles and Solutions
- From Seed to...
- ...Harvest and drying

Supplier qualification and handling (facilities, packaging, release)

- Requirements to fulfil
- Agreements & Responsibilities

- EU GMP Conformity & Import License
- Stability studies, shelf life

Experiences - Lessons learned

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

Speakers

Constantine Emmanouilidi, Epsilon Greenhouses, Greece

Constantine Emmanouilidi is the owner and director of Epsilon Greenhouses based in Thessaloniki Greece, currently consulting foreign investors into preparing their projects for creating and running a Pharmaceutical Cannabis company. His company has designed six projects working with the Greek legislators and have accomplished an equivalent number of licenses for companies that will produce the final medical products with cannabinoids that are going to be distributed both within the Greek pharmacies but also to other countries where the use of such narcotic substances are legal.

Dr Reinhard Kerker, GMP Inspectorate, Germany

GMP Inspector

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.

Silja du Mont, GDP/GCP Inspectorate, Germany

GDP/GCP Inspector

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.

Dirk Ohlenforst, Bonn, Germany

Pharmacist, Qualified Person, Bonn

Dirk Ohlenforst began his pharmaceutical career in the field of formulation development and clinical trials. He finally worked as Qualified Person according to § 14 AMG. He gained more than 10 years of experience in the field of legal trade in narcotic drugs there and in subsequent positions.

Dr Andreas Schieweck, GMP Inspectorate LAGuS, Germany

GMP Inspector

Dr Andreas Schieweck works as GMP Inspector at the State Office of Drug Surveillance and Testing (State Office of Health and Social Welfare, Mecklenburg-Vorpommern). He is specialized in sterile products and biologics, and a member of the German Inspectors Expert Group for sterile and biotech products (EFG 03 & 04)) at the ZLG (Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices).

Robert Schwanke, GrowIn, Germany

Consultant to the Managing Board / Chief Consulting

Robert Schwanke is responsible for international customer relationship (Germany, Switzerland, Austria, Jamaica, Macedonia, Australia, Canada) in regard of GMP aspects for irrigation systems, climate- and control systems, indoor/ outdoor cultivation („closed greenhouses"), extraction and processing (oil/resin), and development/selection of strains.

Judith Steffens, Cannamedical, Germany

Senior QA / QC Manager

Judith Steffens is responsible for the qualification of suppliers, contract manufacturers and service providers at Cannamedical. She assists in signing contracts and quality-assurance-agreements and manages deviations and CAPAs. Furthermore she is responsible person for narcotics ("BTM-Beauftragte" according to §5ff BtMG, "German Narcotic Drugs Act") and responsible person according to §52a AMG ("wholesaler").

Dr Mona Tawab, Zentrallaboratorium Deutscher Apotheker, Germany

Mona Tawab studied pharmacy and did her PhD at the Johann Wolfgang Goethe University in Frankfurt. She is the deputy scientific manager and head of research and development in the Zentrallaboratorium Deutscher Apotheker (ZL). Being an independent laboratory of the German pharmacists founded to test and assure the quality of drugs, the ZL focuses on counterfeit drugs and carries out test purchases.

Dr Ingrid Walther, Pharma Consulting Walther, Germany

Consultant

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.

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.

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P.O. Box 101764
Fax +49(0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

GMP for Cannabis – what you need to know | 29-30 October 2019, Heidelberg, 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, 29 October 2019, 10.00 to approx. 17.30 h
(Registration and coffee 9.30 – 10.00 h)
Wednesday, 30 October 2019, 9.00 to approx. 13.30 h

Venue
Heidelberg Marriott Hotel
Vangerowstraße 16
69115 Heidelberg, Germany
Phone +49 (0)6221 – 908 0
Email Info.heidelberg@marriott.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.

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.

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 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Andrea Kühn-Hebecker (Operations Director) at
+49(0)62 21/84 44 35, or per e-mail at
kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49 (0)62 21/84 44 51, or per e-mail at
strohwald@concept-heidelberg.de.