20 YEARS | ECA Academy
Your GMP/GDP Information Source

Speakers


Mag. Bernhard Föger
AGES, Austria


Dr Reinhard Kerker
GMP-Inspectorate, Germany


Savvas Koulouridas
Fagron, Netherlands


Silja du Mont
GDP/GCP-Inspectorate, Germany


Dirk Ohlenforst
Bonn, Germany


Dr Ingrid Walther
Pharma Consulting Walther, Germany

GMP for Cannabis

What you need to know

5 June 2019 | Heidelberg, Germany

Pre-Conference to the 8th European GMP Conference
6/7 June 2019, Heidelberg, Germany

Highlights

- GMP/GDP/GACP for Medical Cannabis
- How to get a MA-, Import-License / How to get a GMP Certificate?
- Requirements of the German Narcotics Law
- How to launch a cannabis product
- Supplier qualification and handling after import
- First Experiences - Lessons learned

All relevant GMP/GDP aspects for Medical Cannabis

GMP for Cannabis – what you need to know

Objectives

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-qua-lity 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

Production of Cannabis flos for medical purpose

- Good Agricultural and Collection Practice, GACP
- Cannabis Production / Infrastructure / Monitoring
- Security Measures

GMP Certification / Manufacturing and Importation Authorization

- Aspects to consider for applications for Manufacturing and Importation Authorizations
- 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)
- 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

Launch of Cannabis products

- Requirements to fulfil
- Infrastructure, global marketing and distribution agreements
- Medicinal cannabis products like oils and oil derivate products such as capsules, sublingual wafers and topical creams

Supplier qualification and handling after import

- Facilities
- Packaging
- Release

Experiences - Lessons learned

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

Speakers

Mag. Bernhard Föger, AGES (Austrian Agency for Health and Food Safety), Austria

Bernhard Föger is Head of the Institute for Sustainable Plant Production at AGES. The Institute is involved in public and in private activities concerning the sustainable production of plants. Amongst other things, Mr Föger is responsible for the Austrian (Federal) Cannabis production for Medicinal Cannabis.

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 has been GMP Inspector at the Local Authority in Tuebingen.

Savvas Koulouridas, Fagron, Netherlands

Savvas Koulouridas is Global Innovation Director of Fagron. He is leading the innovation and global marketing department of the company. He is a lawyer in profession and has also worked as a consultant on pharmaceutical law (GMP regulations and Pharmaceutical Contracts).

Silja du Mont, GDP/GCP -Inspectorate, Germany

Since 2010 Silja du Mont has been 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, European Expert GCP IWG EMA and also responsible for Pharmacy Surveillance.

Dirk Ohlenforst, Bonn, Germany

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 Ingrid Walther, 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.

Combination with 8th European GMP Conference – 6/7 June 2019

Directly following this conference will be the 8th European GMP Conference. At this unique conference we will focus on key GMP compliance developments. So, join us and get an update on topics like data integrity, trending of data and a new validation approach. Discussions with the leading experts from industry and authority – and various new and revised ECA Guidance Documents you will receive – will also provide you with ideas for solution approaches in your daily practice. To find out more, please visit www.gmp-conference.org.

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

Reservation Form (Please complete in full)

GMP for Cannabis

5 June 2019, Heidelberg, Germany

☐ I would also like to register for the 8th European GMP Conference (6/7 June 2019)

☐ Mr. ☐ Ms.

Title, first name, surname

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P.O. Box 101764
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D-69007 Heidelberg
GERMANY

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 %.

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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.

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Date

Wednesday, 5 June 2019, 10:30 h – approx. 18:00 h
(Registration and coffee from 10:00 h – 10:30 h)

Pre-Conference Venue

Design Offices Heidelberg Colours GmbH
Langer Anger 7/9
69115 Heidelberg

Hotel Accomodation

Star Inn Hotel & Suites Premium Heidelberg
Speyerer Straße 9
Gottlieb- Daimler- Straße
69115 Heidelberg
Phone: +49 6221 36 00 0
Email: heidelberg@starinnhotels.com

8th GMP Conference Venue

Heidelberg Marriott Hotel
Vangerowstrasse 16
69115 Heidelberg
Phone +49 (0)6221 – 908 0 | Fax +49 (0)6221 – 908 660
Email: info.heidelberg@marriott.com

Fees (per delegate plus VAT)

	Pre-Conference	8th GMP Conference
ECA Members	€ 890.-	€ 1,390.-
APIC Members	€ 940.-	€ 1,690.-
Non-ECA Members	€ 990.-	€ 1,790.-
EU GMP Inspectorates	€ 495.-	€ 895.-

The conference fee is payable in advance after receipt of invoice and includes conference documentation per download and on a USB stick, lunch 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/POG 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

ECA has entrusted Concept Heidelberg with the organisation of this event.
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Questions

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