

## 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 (invited)



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-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

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- GMP for Cannabis: setting the scene

### Production of Cannabis flos for medical purpose

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

### GMP Certification / Manufacturing and Importation Authorization

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- 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

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- 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

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- 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

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- 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

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- Facilities
- Packaging
- Release

### Experiences - Lessons learned

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- 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 (invited)**

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](http://www.gmp-conference.org).



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## GMP for Cannabis

5 June 2019, Heidelberg, Germany

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

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Fax +49 (0) 62 21/84 44 34

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.

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- Cancellation until 1 week prior to the conference 50 %

- Cancellation within 1 week prior to the conference 100 %

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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 con-

ference (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](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

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](mailto: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](mailto: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](http://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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