ECA Academy
Your GMP/GDP Information Source

Speakers

Moran Dvora
BOL Pharma, Israel,
ECA Cannabis Working Group

Dr Rainer Gnibl
GMP Inspector, District Government of Upper Bavaria, Germany

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

Rita Prazeres
Clever Leaves, Portugal,
ECA Cannabis Working Group

Luis Meirinhos Soares
former GMP / GACP Inspector, Infarmed, Portugal,
ECA Cannabis Working Group

Giorgia Tossi,
Linnea, Switzerland

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

Dr Christian Werz
Federal Office of Public Health (FOPH), Switzerland

GMP for Cannabis – what you need to know

Live Online Conference on 8-9 June 2022

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

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

Highlights

- GACP/GMP/GDP Requirements for Medical Cannabis
- Medicinal cannabis products that do not require a Marketing Authorization
- How to get a MA-, Import-License (MIA) / How to get a GMP Certificate
- Experiences from Current Inspections
- Aspects to Consider for CBD
- Requirements of the Narcotics Law
- Overview of Pharmacopoeial Monographs
- How to get GMP certified for Export
- Facility Design
- Qualification/Validation

Download for participants only

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

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. 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, wholesalers). 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 no European pharmacopoeial monograph (Ph. Eur.) for medical cannabis and extracts exists, national legislations, guidelines and pharmacopoeial monographs will have to be followed and applied in addition to EU-GMP.

Target Audience

This Live Online Conference addresses specific GMP aspects to consider for Growers, Manufacturers, Start-Ups, Suppliers, Importers, Wholesalers, 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.

Moderator

Dr Ingrid Walther

Programme - 8 June 2022

Provisional timetable, the actual schedule may vary depending on the situation

Welcome 12.00 – 12.15 h

Introduction 12.15 – 12.45 h

- GMP for Cannabis: setting the scene

Time for Discussion – 12.45 – 13.00 h

Break – 13.00 – 13.15 h

GMP Certification / Challenges and Experiences from current Inspections 13.15 – 14.45 h

- Authorization, registration & import
- Which requirements apply?
- Current issues

Break – 14.45 – 15.00 h

Transport and Import/Export Requirements 15.00 – 15.45 h

- Challenges & requirements for transport according to GDP
- Required licenses
- Exports of GACP grade cannabis

Time for additional Questions and Discussion – 15.45 – 16.15 h

Break – 16.15 – 16.30 h

Aspects to Consider for CBD (and other Hemp) Products 16.30 – 17.30 h

- Pharma, food and cosmetic products and requirements
- How to differentiate between CBD/Cannabis Products for medical use and other CBD (Hemp) Products?
- Which legal rules apply?
- Practical examples

Final Discussion Day 1 – 17.30 – 18.00 h

Programme - 9 June 2022

Legal Foundations for Extemporaneous Preparations containing more than 1% THC in Switzerland
🕐10.30 – 11.30 h

- Extemporaneous preparations
- THC & CBD
- Exceptional licence

The Intersection between GACP and GMP - View on the Inspection of Cannabis GACP and its Relation to GMP 🕐11.30 – 12.15 h

- 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

Time for additional Questions and Discussion – 🕐12.15 – 12.45 h

Break – 🕐12.45 – 13.45 h

Overview of Pharmacopoeial Monographs (and other Quality Requirements)
🕐13.45 – 14.45 h

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

Time for additional Questions and Discussion – 🕐14.45 – 15.00 h

Break – 🕐15.00 – 15.15 h

Israel Medical Cannabis Regulation 🕐15.15 – 16.15 h

- The Israeli Medical Cannabis unit and the licensing process
- Major guidelines: IMC-GAP, IMC-GMP, IMC-GDP, IMC-GSP
- Differences and similarities: Israel vs. Europe
- The export process to Europe
- The import process of medical cannabis to Israel

Experiences – Lessons learned 🕐16.15 – 17.15 h

- Application of GMP principles to Cannabis:
  - Quality management System (QMS)
  - Facility Design
  - Qualification / Validation: Points to consider

Final Discussion Day 2 – 🕐17.15 – 18.00 h

Speakers

Moran Dvora, Quality Assurance Manager, BOL Pharma, Israel, Member of ECA's Cannabis Working Group

Moran currently works as QA manager at BOL Pharma, a Medical Cannabis company in Israel. In the last three years, as part of her previous position at a consultancy firm, she has gained a wide experience in quality and regulatory aspects in the medical cannabis industry. She has worked in the pharmaceutical industry since 2006 in several Quality Assurance, Regulatory Compliance and Quality Control roles.

Dr Rainer Gnibl, GMP Inspector, District Government of Upper Bavaria, Germany

District Government and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Dr Andrea Kühn-Hebecker, Concept Heidelberg, Germany, Member of ECA's Cannabis Working Group

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 where she was five years Head of Quality Control according to § 12 of the German AMWHV.

Rita Prazeres, Clever Leaves, Portugal, Member of ECA´s Cannabis Working Group

Rita has more than 20 years of experience in the Pharmaceutical Industry including Regulatory Affairs and Pharmacovigilance. Since June 2019 she is EU Head of Regulatory Affairs & Technical Director at Clever Leaves Portugal, responsible for the cannabis licensing activities of the company and overseeing Quality Compliance (Quality Assurance & Quality Control).

Luis Meirinhos Soares, former GMP Inspector at Infarmed, Portugal, currently Quality Specialist at the EMA

Luis worked as GMP / GDP Inspector and Project Manager for "GACP Inspections" of Medicinal Cannabis, at INFARMED. He has more than twenty years' experience in the field of official medicines control and has been appointed expert of several Ph. Eur. Working Groups. Since September 2021 Luis has joined the Pharmaceutical Quality Office at EMA as Seconded National Expert.

Giorgia Tossi, Linnea, Switzerland

Giorgia studied Organic Chemistry, Business, at the University of California in Berkeley. She was Quality Assurance Coordinator at Sandoz, Italy, before she started her work as Technical Director / Quality Unit Executive Manager at Linnea in Switzerland in 2005. Since October 2019 she is Chief Quality Officer at Linnea

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.

Dr Christian Werz, Federal Office of Public Health (FOPH), Switzerland

Christian joined the Federal Office of Public Health in September 2019. His main focus is on exceptional licenses for cultivation and use of Cannabis with more than 1% THC. He is also involved in the elaboration of past and upcoming law changes related to Cannabis in Switzerland for recreational and medical purposes. Before joining the FOPH, he worked as product manager in the pharmaceutical industry.

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

_____

_____

_____

_____

CONCEPT HEIDELBERG
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
Live Online Conference on 8/9 June 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 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 of the Live Online Conference

Wednesday, 8 June 2022, 12.00 to approx. 18.00 h
Thursday, 9 June 2022, 10.30 to approx. 18.00 h

All times mentioned are CEST.

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 events 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)

ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
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.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Conference language

The official conference language will be English.

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.

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 organisation please contact:
Ms Julia Grimmer (Organisation Manager) at
+49 (0)62 21/84 44 44, or per e-mail at
grimmer@concept-heidelberg.de.