ECA Academy
Your GMP/GDP Information Source

1st Conference 2021

GMP for Cannabis – what you need to know

With Regulatory-Post-Conference on Day 3!

Live Online Conferences on 14-16 June 2021

ECA Cannabis Roadmap: Every participant will receive the printed version of ECA´s Cannabis Working Group 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
- How to get 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
- Lessons learned

NEW

Download for participants only

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

Speakers Main Conference

Claudia Baumung
CVUA Karlsruhe, Germany

Moran Dvora
Gsap, Israel,
ECA Cannabis Working Group

Oliver el-Atma
CVUA Karlsruhe, Germany

Michelle Johnson
Leafcann, Australia
ECA Cannabis Working Group

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

Silja du Mont
GDP/GCP Inspectorate, Germany

Roland Pietz
GMP Inspector, Cologne, Germany

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

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

Speakers Regulatory Post-Conference

Univ-Doz. Dr Reinhard Länger
Austrian Agency for Health and Food Safety (AGES)

Dr Ana Paula Martins
Assessor, Infarmed, Portugal

Angela Müller
Dr. Willmar Schwabe, Germany

Dr Constantin von der Groeben
DEMECAN, Germany

Silvia von Pistor
Tilray, Germany

Programme “Main Conference”

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). 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 (Ph. Eur.) 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 Live Online 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. The regulatory Post-conference is in particular interesting for RA personnel dealing with Marketing Authorizations.

Moderator

Dr Ingrid Walther

Programme - 14 June 2021

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

Welcome 13.00 – 13.15 h

Introduction 13.15 – 13.45 h

- GMP for Cannabis: setting the scene

Time for Discussion – 13.45 – 14.00 h

Break – 14.00 – 14.15 h

Requirements for EU GMP Certifications / Manufacturing and Importation Authorization (MIA) in Germany 14.15 – 15.15 h

- GMP Requirements: What you need to know (EU GMP Guideline Part I)
- Aspects to consider for applications for Manufacturing and Importation Authorizations in Germany
- Aspects to consider for analytical labs
- (Remote) Inspections in Europe and beyond: Typical and recurrent compliance issues

GDP for Cannabis 15.15 – 15.45 h

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

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

- 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

Final Discussion Day 1 – 17.30 – 18.00 h

Programme - 15 June 2021

Australian GMP Requirements for Medicinal Cannabis and the Export of Product to Europe
🕐10.30 – 11.30 h

- Australian Regulations and the Therapeutic Goods Administration
- Disparity between Eudralex 4, PIC/s PE009-14 and country specific requirements for MC
- Bridging the gap for export to Europe

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 & Export to Europe 🕐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

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

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 in Strasbourg.

Moran Dvora, Quality and Laboratory Project Manager, Gsap, Israel, ECA Cannabis Working Group
Moran is a Quality and Laboratory project manager at Gsap. She started in 2006 in the pharmaceutical industry and since joining Gsap in 2018 she is working with Pharmaceutical and Medical Cannabis companies. She has a wide experience in quality assurance, regulatory compliance and analytical quality control.

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 products, quality assurance representative and contact person of the OMCL for EDQM.

Michelle Johnson, General Manager Operations, Leafcann, Australia, ECA Cannabis Working Group
Michelle has over 20 years' experience in pharmaceutical manufacturing and GMP with a focus on Quality Assurance and Compliance. Moreover, she has extensive knowledge in the design, development, implementation and management of TGA licensed manufacturing and distribution facilities.

Dr Andrea Kühn-Hebecker, Concept Heidelberg, Germany, ECA 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.

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. She is Head of the German GCP Inspectors Expert Group at ZLG, European Expert GCP IWG EMA and also responsible for Pharmacy Surveillance.

Roland Pietz, GMDP Inspector, Cologne, Germany
Roland Pietz is currently GMP Inspector for the District Government of Cologne. He performs GMDP inspections (national and worldwide) of pharmaceutical manufacturers and wholesalers. Before that he was working for Dr. August Wolff GmbH & Co. KG, Bielefeld (Germany), most recently as Deputy Head of Quality Control.

Luis Meirinhos Soares, GMP / GACP Inspector, Infarmed, Portugal, ECA Cannabis Working Group
Since January 2019 Luis 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 several Ph. Eur. Working Groups.

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.

Programme - 16 June 2021

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

Welcome and Introduction 13.00 – 13.15 h

Quality Requirements for Applications for Marketing Authorization
13.15 – 14.00 h

- Borderline GACP-GMP
- Types of extracts
- Control strategy for extracts and drug products
- Context with clinical data and regulatory pathway

Time for Discussion – 14.00 – 14.15 h

Break – 14.15 – 14.30 h

GACP – Regulatory Information 14.30 – 15.15 h

- Herbal Drugs
- Framework
- GACP vs. GMP
  - Guidelines
  - Interpretation
- Information in the Dossier
  - Mockup
  - Grower and Supplier
  - Geographical source
  - Herbal substance Manufacturing

Regulatory Requirements for Marketing Authorization
15.15 – 15.45 h

- Is a complete dossier always required?
- Special procedures created by several MS, like Portugal & Denmark

Time for additional Questions and Discussion – 15.45 – 16.00 h

Break – 16.00 – 16.15 h

Regulatory Submission in Portugal
16.15 – 16.45 h

- Challenges
- Practical aspects
- Clinical indications

Regulatory Requirements for Cannabis Production in Germany
16.45 – 17.30 h

- Interaction with the Cannabis Agency
- Security Measures
- Distribution to pharmacies
- Production in Germany vs. Imports

Final Discussion – 17.30 – 18.00 h

Speakers “Regulatory Post-Conference”

Univ-Doz Dr Reinhard Länger, Head of Department Herbal, Homoeopathic and Veterinary Medicinal Products, Austrian Agency for Health and Food Safety (AGES)

Dr Reinhard Länger started his work at AGES in 2006 as assessor. Currently he is Head of the Department for Herbal, Homoeopathic and Veterinary Medicinal Products at the Institute for Marketing Authorization of Medicinal Products & LCM. He is member of EMA´s Committee on Herbal Medicinal Products.

Dr Ana Paula Martins, Assessor, Infarmed, Portugal

Ana Paula Martins is assessing the medicinal Cannabis processes in PT and other herbal medicines. She is also a member of the EMA Committee on Herbal Medicinal Products (HMPC).

Angela Müller, Dr. Willmar Schwabe GmbH & Co. KG, Germany

Angela is a pharmacist and holds currently the position of a Senior Regulatory and Scientific Affairs Manager in the International Division of Schwabe in Karlsruhe.

Dr Constantin von der Groeben, DEMECAN, Germany

Constantin von der Groeben is a co-founder and managing director of DEMECAN. He leads the company’s legal and regulatory affairs department. Dr Groeben’s expertise lies in the regulatory framework of medicinal cannabis including EU-GMP, narcotics, and pharmaceutical law.

Silvia von Pistor, Tilray, Germany

Silvia has been Head of Regulatory and Clinical Affairs EMEA at Tilray since 2019. Before that she was working in different positions (e.g. International Project Leader, Director Portfolio & Project Management, Lead Clinical Project Team) at Grünenthal.

Your Benefit

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.

This could be of interest for you as well

Why not online? GMP/GDP seminars, webinars and e-learning

Take advantage of the wide range of „on demand“ training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course. Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/on-demand-online-training/recorded-online-training-webinars

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)

Live Online Conferences

☐ GMP for Cannabis – what you need to know, 14-15 June 2021

☐ Regulatory-Post-Conference, 16 June 2021

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

GMP for Cannabis - what you need to know
Monday, 14 June 2021, 13.00 to approx. 18.00 h CEST
Tuesday, 15 June 2021, 10.30 to approx. 18.00 h CEST

Regulatory-Post-Conference
Wednesday, 16 June 2021, 13.00 to approx. 18.00 h CEST

Technical Requirements
For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At https://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

GMP for Cannabis - what you need to know
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The fee is payable in advance after receipt of invoice.

Regulatory Post-Conference
ECA Members € 790
APIC Members € 840
Non-ECA Members € 890
EU GMP Inspectorates € 445
The fee is payable in advance after receipt of invoice.

Save money and book both courses:
ECA Members € 2,190
APIC Members € 2,290
Non-ECA Members € 2,390
EU GMP Inspectorates € 1,340
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.

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