ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Viviana Braude
Cronos Israel
ECA Cannabis Working Group

Tina Cacanoska
PharmaRolly

Dr Rainer Gnibl
GMP Inspector, District Government of Upper Bavaria

Dominik Hedderich
Genillard

Luis Meirinhos Soares
CANNAVIGIA, former GMP Inspector at INFARMED
ECA Cannabis Working Group

Dr Giorgia Tossi,
Linnea
ECA Cannabis Working Group

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

Dr Anne Wolf
German Cannabis Agency, BfArM

GMP for Cannabis – what you need to know

Live Online Conference on 5-6 June 2024

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

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

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
- Update from the German Cannabis Agency
- 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*

Programme

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 was already established, cannabis is not 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 manages and monitors the cultivation, harvest, processing, quality assurance, storage, packaging and distribution of cannabis to wholesalers, pharmacists 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 will have to implement EU-GMP standards if they want to supply medical cannabis to the EU market. Meanwhile, European pharmacopoeial monographs (Ph. Eur.) describing the quality requirements for cannabis flower (as API and for direct prescription to patients) and for CBD have been established and will be implemented as of 1 July 2024. However, questions still arise, because:

- There is no harmonized “EU GMP Cannabis Standard” available for medical cannabis (API / Drug Product).
- The Ph. Eur. Cannabis Flower and CBD monographs are currently not harmonized with the corresponding USP (draft) monographs.
- Regarding quality requirements for Cannabis Extracts (and Dronabinol) only national monographs exist so far.

Thus, 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.

Moderation

Dr Ingrid Walther / Dr Andrea Kühn-Hebecker
(ECA Cannabis Working Group)

Programme - 5 June 2024

Welcome

Introduction

- GMP for Cannabis: setting the scene

Discussion

GMP Certification / Challenges and Experiences from current Inspections

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

The Intersection between GACP and GMP - View on the Inspection of Cannabis GACP and its Relation to GMP

- 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

Discussion

Regulatory Status and Quality Standard of Cannabinoids Manufacture

- 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

Programme - 6 June 2024

Cannabis Cultivation under GACP

- Requirements for buildings, facilities and Equipment
- Cultivation / Harvesting
- Drying /Trimming
- Waste management

Drying of Medicinal Cannabis – Challenges for Process Validation

- Post-harvest processes as a preparation for drying of Medical Cannabis
- Drying process - different types of drying
- Sampling and testing during drying- what are the challenges
- Validation of the drying process and determination of the end of drying
- Curing and why it is needed
- Testing after curing and storage of dry cannabis flowers

Discussion

Update from the German Cannabis Agency

- Current Status of Medical Cannabis in Germany
- Development of Cannabis Monographs (DAB / Ph. Eur.)
- Changes in the submission requirements for AmRadV applications
- Current Challenges

Discussion

Israel Medical Cannabis Regulation

- 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

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

Final Discussion Day 2

Speakers

Dr Viviana Braude, Cronos Israel, Member of ECA's Cannabis Working Group
Viviana joined Cronos Israel in May 2019 as VP Quality and Regulations. She escorted the company from initial permits approvals through products commercialization and regulatory updates. Viviana has over 25 years of experience in the pharmaceutical and chemical industry in the areas of quality assurance, compliance, technical customer service, supply chain, process development of active pharmaceuticals as well as chemical compounds. She is also a member of the ASTM Cannabis Committee.

Tina Cacanoska, PharmaRolly, North Macedonia
Tina currently works as a Chief Quality Officer and QP at PharmaRolly, a Medical Cannabis company in North Macedonia. In the last six years she has gained a huge amount of experience in quality and regulatory aspects in the medical cannabis industry. Tina has led PharmaRolly's EU GMP certification process for the past year.

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.

Dominik Hedderich, Genillard, Germany
Dominik studied at the University of Hohenheim (Master of Science - MS, Crop Science). Amongst others, he was working for AltoVerde as a Horticultural Consultant and has extensive experience in the development and operation of crop production systems. Currently, he is Risk Analytics Consultant at Genillard in Munich. His current work focuses on risk analysis and the development of risk mitigation strategies for the agricultural sector.

Luis Meirinhos Soares, CANNAVIGIA, former GMP Inspector at INFARMED, Portugal, Member of ECA´s Cannabis Working Group
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, has been appointed expert of several Ph. Eur. Working Groups and was Seconded National Expert for the Pharmaceutical Quality Office at EMA. Currently he is Head of Compliance and Regulatory Affairs at CANNAVIGIA.

Dr Giorgia Tossi, Linnea, Switzerland, Member of ECA´s Cannabis Working Group
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 Anne Wolf, German Cannabis Agency, BfArM
Dr Anne Wolf has been a scientist at the German Cannabis Agency of the Federal Institute for Drugs and Medical Devices (BfArM) in Bonn since 2019. After studying Biopharmaceutical Technology at the University of Applied Sciences Gießen, she obtained her doctorate in pharmacology from the University Bonn. Before joining the BfArM she has worked at a research facility and in the quality control department in a pharmaceutical company.

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Reservation Form (Please complete in full)

GMP for Cannabis - what you need to know
Live Online Conference on 5/6 June 2024

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
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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 July 2022).
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 https://www.gmp-compliance.org/privacy-policy). 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, 5 June 2024, 12.00 to approx. 18.00 h
Thursday, 6 June 2024, 10.30 to approx. 18.00 h

All times mentioned are CEST.

Technical Requirements
We use Webex 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.

Conference language
The official conference language will be English.

You cannot attend the Live Event?
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

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.

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