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

Alfred Hunt
Hunt Pharma Solutions, Ireland

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

Christina Møller Poulsen
Senior QA Specialist, Denmark

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

Giorgia Tossi,
Linnea, Switzerland,
ECA Cannabis Working Group

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

GMP for Cannabis – what you need to know

Live Online Conference on 6-7 June 2023

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*

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 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 - 6 June 2023

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

Aspects to Consider for CBD (and other Hemp) Products

- 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 - 7 June 2023

The Danish Cannabis Programme & and Some Practical Views

- The Danish medicinal cannabis pilot programme
- Guidelines and executive orders
- GACP vs. GMP in a production unit
- Qualification and validation

Transport and Import/Export Requirements

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

Discussion

Overview of Pharmacopoeial Monographs (and other Quality Requirements)

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

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

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.

Alfred Hunt, Hunt Pharma Solutions, Ireland

Alfred Hunt is a consultant. From 2008 until 2015 he was an Inspector with the Health Products Regulatory Authority (HPRA), formerly the Irish Medicines Board (IMB). He was also key member of the European Medicines Agency (EMA) drafting group which developed the revised EU GDP Guidelines (2013/C 343/01).

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.

Christina Møller Poulsen, Senior QA Specialist, Denmark

Christina started working at Aurora Nordic Cannabis A/S as a QA Specialist in 2018, when the Danish medicinal cannabis pilot programme entered into force. Prior to that she worked with quality assurance and production in the pharmaceutical industry (Novo Nordisk A/S and others) and as a Quality Manager at the Hospital Pharmacy at Hospital Lillebælt.

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.

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.

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Reservation Form (Please complete in full)

GMP for Cannabis - what you need to know
Live Online Conference on 6/7 June 2023

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)

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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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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.

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Date of the Live Online Conference
Tuesday, 6 June 2023, 12.00 to approx. 18.00 h
Wednesday, 7 June 2023, 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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