ECA Academy
Your GMP/GDP Information Source

2nd Conference 2020

Speakers Main Conference


Moran Dvora
Gsap, Israel,
Member of the ECA Cannabis Working Group


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


Dr Reinhard Kerker
GMP Inspectorate,
Germany


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


Silja du Mont
GDP/GCP Inspectorate,
Germany


Giorgia Tossi
Linnea,
Switzerland


Dr Angel Valerio
EnWave,
Canada


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


Dr John Zhang
EnWave, Canada

Speakers GACP Post-Conference


Dr Joachim Erler
Auditor / QP,
Blue Inspection Body,
Germany


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


Sonny Moerenhout
CULTIVATORS,
The Netherlands


Angela Müller
Senior Regulatory &
Scientific Affairs Manager,
Dr. Willmar Schwabe,
Germany

GMP for Cannabis – what you need to know

Live Online Conferences on 23-25 November 2020

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 aspects for Medical Cannabis!

Highlights

- GACP/GMP/GDP Requirements for Medical Cannabis
- How to get a MA-, Import-License / 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

NEW

GACP-Post-Conference on Day 3!

Programme "Main Conference"

Objective

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 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.

Moderator

Dr Ingrid Walther

Programme – 23 November 2020

Welcome 13.30 – 13.45 h

Introduction 13.45 – 14.15 h

- GMP for Cannabis: setting the scene

Time for Discussion – 14.15 – 14.30 h

Break – 14.30 – 14.45 h

GMP Certification / Manufacturing and Importation Authorization 14.45 – 15.30 h

- Aspects to consider for applications for Manufacturing and Importation Authorizations
- Aspects to consider for analytical labs
- GMP certification: What you need to know
- Inspections in Europe and beyond: Typical and recurrent compliance issues

GDP for Cannabis 15.30 – 16.00 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 – 16.00 – 16.15 h

Break – 16.15 – 16.30 h

Israel Medical Cannabis Regulation and Export to Europe 16.30 – 17.30 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

Final Discussion Day 1 – 17.30 – 18.00 h

Programme – 24 November 2020

Aspects to Consider for CBD (and other Hemp) Products 10.30 – 11.30 h

- Swiss Cannabis situation: 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

Classification, Challenges and Experiences from Current Inspections 11.30 – 12.30 h

- Current Issues
- Definitions and Classification of Cannabis flower (e.g. herbal drug, API, finished medicinal product)
- Which requirements apply?
- Authorization, Registration & Import

Time for additional Questions and Discussion – 12.30 – 12.45 h

Break – 12.45 – 13.45 h

Overview of Pharmacopoeial Monographs 13.45 – 14.45 h

- Europe (Ph. Eur.)
- Germany (DAB / DAC)
- Denmark
- Netherlands
- 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

Cannabis Drying Within GMP Compliant Supply Chain 15.15 – 16.15 h

- Drying of flowers utilizing Radiant Energy Vacuum technology
- Utilizing non-ionizing microwave radiation to reduce microbial counts
- Equipment qualification according to GMP

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 – 17.45 h

Speakers

Moran Dvora, Quality and Laboratory Project Manager, Gsap, Israel, Member of the 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.

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

Dr Rainer Gnibl is pharmacist and GMP Inspector for the 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 Reinhard Kerker, GMP Inspectorate, Germany

Dr Reinhard Kerker received his 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 is GMP Inspector at the Local Authority in Tuebingen.

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

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.

Giorgia Tossi, Linnea, Switzerland

Giorgia graduated at the University of Turin (Italy) in Industrial Chemistry, she studied Organic Chemistry at the University of California in Berkeley. She was QA 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 Angel Valerio, EnWave, Canada

Dr Valerio is an Operations professional with over a decade of practical and managerial experience in the manufacturing, engineering and high-tech agri-food and energy industries in North America. In his current role at EnWave, Dr Valerio has been instrumental in the deployment of REV machinery technology on a global scale across 15+ countries, including cGMP machinery.

Dr Ingrid Walther, Leader of the ECA Cannabis Working Group, 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.

Dr John Zhang, EnWave, Canada

Dr Zhang is a seasoned R&D professional and well respected academic with 20 co-authored research papers and patents. His educational qualifications include a Master's Degree in Food Microbiology from the University of Manitoba and a PhD in Food Nutrition and Health (FNH) from the University of British Columbia.

Programme “GACP Post-Conference”

25 November 2020

Welcome and Introduction 13.30 – 13.45 h

The Intersection between GACP and GMP - View on the Inspection of Cannabis GACP and its Relation to GMP 13.45 – 14.45 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 Discussion – 14.45 – 15.00 h

Coffee Break – 15.00 – 15.15 h

GACP – Regulatory Information 15.15 – 16.00 h

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

GACP – Auditor´s View 16.00 – 16.30 h

- Cannabis Cultivation
- SOPs & records
- Expectations of a GACP auditor

Time for additional Questions and Discussion – 16.30 – 16.45 h

Break – 16.45 – 17.00 h

GACP – Grower´s / Supplier´s View 17.00 – 17.30 h

Growing medicinal cannabis is pharma, not food!

- The essence of cultivation under GACP
- Challenges and opportunities for growers within medicinal cannabis cultivation
- Practical implications for growers and suppliers

Final Discussion – 17.30 – 18.00 h

Speakers “GACP Post-Conference”

Dr Joachim Erler, Auditor / QP, Blue Inspection Body GmbH, Germany

Joachim has more than 30 years experience in the Pharmaceutical Industry. Amongst others, he worked as Head of Manufacturing and Qualified Person for Bionorica. His focus during the last 15 years has been on qualification of equipment, validation of manufacturing processes, galenic development, process optimization, quality assurance, audits, etc..

Luis Meirinhos Soares, GMP / GACP Inspector, Infarmed, Portugal

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.

Sonny Moerenhout, CULTIVATORS, The Netherlands

Sonny has been consulting growers for years on cannabis cultivation in countries where medicinal cannabis is legalized. He holds a master’s degree in plant science from Wageningen University with greenhouse horticulture as his specialization. Sonny was “born in a greenhouse” as his parents had an eggplant nursery. He understands the importance of working together with the pharmaceutical & horticultural industry.

Angela Müller, Senior Regulatory & Scientific Affairs Manager, 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.

Your Benefits

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 Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

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

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Reservation Form (Please complete in full)

Live Online Conferences

☐ GMP for Cannabis – what you need to know, 23-24 November 2020

☐ GACP-Post-Conference, 25 November 2020

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

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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 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 %.

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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 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 Conferences

GMP for Cannabis - what you need to know
Monday, 23 November 2020, 13.30 to approx. 18.00 h CET
Tuesday, 24 November 2020, 10.30 to approx. 17.45 h CET

GACP-Post-Conference
Wednesday, 25 November 2020, 13.30 to approx. 18.00 h CET

Technical Requirements

For our 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.

GACP Post-Conference
ECA Members € 590
APIC Members € 640
Non-ECA Members € 690
EU GMP Inspectorates € 345
The fee is payable in advance after receipt of invoice.

Save money and book both courses:
ECA Members € 1,990
APIC Members € 2,090
Non-ECA Members € 2,190
EU GMP Inspectorates € 1,240
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.

Note: There will be no recording of the Live Online Conferences.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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