WEBINAR

Quality, GMP and GACP Requirements for Medicinal Cannabis and Cannabis Products in the European Union and Switzerland

Status Quo

Prof. Dr. Markus Veit

ALPHATOPICS

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SPEAKER

Prof. Dr. Markus Veit
is the managing director of ALPHATOPICS GmbH. He studied pharmacy in Frankfurt, obtained his doctorate at the Julius Maximilians University in Würzburg and was assistant professor there in the Department of Pharmaceutical Biology. He is a member of the German pharmacopeial expert committee at BfArM. In the past 25 years, he has worked as a managing director in companies providing services for the pharmaceutical industry with a focus on pharmaceutical development, testing and regulatory affairs.

At the same time, he designed and led numerous training and continuing education events for employees in the pharmaceutical and medical device industry. He is an expert in herbal medicinal products and has been involved in numerous applications for marketing authorisations of herbal medicines in Europe and in the rest of the world.
In recent years he has been increasingly involved in projects related to medicinal and other cannabis products.

INTRODUCTION

Quality, GMP and GACP Requirements for Medicinal Cannabis and Cannabis Products in the European Union and Switzerland

Medicinal cannabis and respective products have been available in EU member states as single-patient prescriptions without regular marketing authorisations for a couple of years. The Netherlands was the first member state to allow this, and since then other member states have followed.

Today, besides the Netherlands, Germany is the most important market for such products. The regulatory framework for the approval of medicinal cannabis and its distribution to patients in EU member states is, however, not harmonised at all and there are distinct national regulations. Regarding the quality of such products, the general requirements for herbal medicinal products as defined in the European Pharmacopoeia, national pharmacopoeias and the EMA guidance documents in place alongside GMP requirements in the EU are applicable. However, for a couple of aspects, every EU member state follows its own interpretation of these requirements.

Non-medicinal borderline products with low THC or based on CBD are marketed with health or well-being promoting claims in a regulatory grey zone. For these products as well there are quality requirements, or those requirements should at least be requested.

The webinars aim to provide an overview of the current requirements regarding CMC and GMP in EU member states and Switzerland for medicinal cannabis and borderline products. Aspects regarding regulations for narcotics will not be covered by the webinars.

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WEBINAR

WEBINAR 1

24.3.2022 / 10:00 – 12:00 CET (live, available later as recording)

QA, GACP and GMP requirements

- Concepts followed by EU member states for demarcation between GACP, EU GMP Part II and EU GMP Part I
- HACCP for borderline products
- Quality requirements for medical devices
- Consequences of different concepts for importation in and distribution within the EU and related licences needed
- Overview of GACP requirements
- Overview of GMP requirements | Differences between EU GMP Part I and II
- Audits and inspections – Challenges and experiences
- GMP considerations for products used in clinical trials

WEBINAR 2

24.3.2022 / 14:00 – 16:00 CET (live, available later as recording)

CMC requirements for flowers, extracts and products, respectively

- Phytochemistry of cannabis
- Quality requirements for CBD and borderline products
- CMC requirements for herbal medicinal products and respective starting materials in the EU
- Detailed requirements for cannabis flowers, extracts and (magistral) products
- Pharmacopeia monographs (DAB, Ph. Helv.) and other monographs issued by authorities
- Requirements for contaminants
- Control strategies for manufacture, release and stability testing
- Irradiation of cannabis flowers
- CMC considerations for products to be used in clinical trials
- Recent developments and outlook for the future

REGISTRATION

Prices & conditions of participation

€790.00 per person plus VAT for both webinars
€450.00 per person plus VAT for single booking

The fee includes, for a single booking:

- one-time viewing of the booked webinar or webinar series by the person or persons named to us in advance;
- receipt of the slides shown as a printable PDF file.

The training is personal and, in the case of an individual booking, is for personal training purposes only – not for an entire team.

Duration:

Approx. 2 hours each part / in total approx. 4 hours
Lecture language and slides: English

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Team discount

Team bookings:

If the training is of interest to a group of colleagues, please contact us. We will offer an attractive special group price, even for large groups. In the latter case, the number of participants is not limited.
The recording of the webinars is also available for unlimited use for internal company training purposes.

Note on bookings as part of our 10-webinar package:

When booking these two webinars as part of our 10-webinar package, they will count as a total of four webinars to be deducted from the total of 10 webinars purchased.

CONTACT

Katrin Kurtz and Daniela Müller will be happy to assist you with your booking and are available to answer any further questions.

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Monday to Thursday
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