ECA Academy
Your GMP/GDP Information Source

Speakers

Isabel Cordeiro
Clever Leaves, Portugal

Dr Henrik Harms
BfArM, Germany

Dr Timo Krebsbach
HHAC Labor Dr. Heusler, Germany

Dr Nandakumara D Sarma
USP, USA

Stability Testing for Cannabis

Requirements, Challenges & Solutions

Live Online Training on 11 November 2021

Highlights

- Introduction to ICH & EMA Guidelines
- Specific Regulatory Stability Aspects for Herbals
- Bracketing and Matrixing
- Test Parameters during Stability Studies for Cannabis Flower and Extracts
- Practical Stability Experiences
- Interpreting Data and making sure Regulatory Requirements are met
- Challenges & Solutions due to the Narcotics Law

For participants only

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)!

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

Objectives

This Live Online Training is intended to provide information on the different aspects of stability testing for medical cannabis. The conference will provide an overview of regulatory requirements with a special focus on the ICH and EMA Guidelines. In the subsequent presentations, important aspects of stability testing for cannabis flower and cannabis extracts are discussed.

The specific requirements for stability testing of herbal drugs which are narcotics are challenging. E.g. storage needs to be done in climate chambers in specifically designed and secured facilities. In addition, specific rules have to be followed concerning transport, waste and documentation. These aspects will also be covered.

Background

More and more countries around the world are introducing programs in order to legalize cannabis for medical use. These products, however, must comply with the relevant requirements laid down under Medicinal and Narcotics Law, including Pharmacopoeias and GACP/ GMP / GDP Guidelines.

In some countries, like for example Canada and New Zealand, cannabis production is usually performed under GPP, where stability testing is not required. Under EU GMP, however, an ongoing stability programme is mandatory. Medicinal Products have to be labelled with an expiry date.
Therefore some of the frequently asked questions are:

- Which specific parameters have to be tested during stability studies?
- Which specification limits apply?
- How to establish a re-test period for APIs or a shelf life for drug products?
- How to deal with OOS and OOT results?

This online course will address how to set up a stability programme for cannabis related products. Specific aspects like bracketing and matrixing according to the ICH Q1 Guidelines will be covered. In addition, the specific rules for herbal medicinal products (HMPs) and narcotics will be discussed.

Target Audience

This Live Online Training addresses specific aspects related to stability testing to consider for Growers, Manufacturers, Start-Ups, Suppliers, Importers, QPs and QA/QC/Regulatory Affairs personnel involved in Cannabis production. The topics provided are also of interest for GMP Inspectors responsible for issuing a GMP- certificate or manufacturers-/ import license.

Moderator

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

Programme

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

Welcome and Introduction 10.00 – 10.15 h

General ICH & EMA Principles and Requirements / Specific Aspects for HMPs 10.15 – 11.15 h

- Stability testing, in-use stability
- Re-test period, Shelf life and storage conditions
- Focus on herbal substances / preparations / medicinal products
- Bracketing and Matrixing

Time for Discussion – 11.15 – 11.30 h

Break – 11.30 – 11.45 h

Challenges & Solutions due to the Narcotics Law 11.45 – 12.45 h

- Regulatory and technical requirements before / during / after stability testing
- Import / export, delivery, acquisition
- Documentation
- Destruction of narcotics
- How does a compliant outsourcing of stability testing succeed?

Time for Discussion – 12.45 – 13.00 h

Break – 13.00 – 14.00 h

USP General Notices section 3.10 Applicability of Standards: The standards in the relevant monograph, general chapter(s), and General Notices apply at **all times in the life of the article from production to expiration**. It is also noted that the manufacturer's specifications, and manufacturing practices, generally are followed to ensure that the article will **comply with compendial standards until its expiration date**, when stored as directed. Every article in commerce shall be so constituted that when examined in accordance with these assays and test procedures, **it meets all applicable pharmacopeial requirements** (General Notices, monographs, and general chapters).

Recommended Quality Attributes for Cannabis Inflorescence from the USP Cannabis Expert Panel as a potential Objective for Stability Testing 14.00 – 15.00 h

- Specifications for cannabinoids and limits for contaminants
- Test for stability-indicating degradant: CBN
- Recommended storage conditions

Time for Discussion – 15.00 – 15.15 h

Break – 15.15 – 15.30 h

Practical Stability Experiences for Cannabis Flower and Extracts 15.30 – 16.30 h

- The challenges setting up stability studies for medicinal cannabis and complying with ICH Q1
- From the set up of the study, finding the right lab to perform the study, import /export licenses for the material and standards up to the final results - logistics is a nightmare compared with regular APIs and finished products
- Interpreting data and making sure regulatory requirements are met

Final Discussion – 16.30 – 17.00 h

Speakers

Isabel Cordeiro
Clever Leaves, Portugal
Isabel is a Chemical Engineer with +18 years' experience on the pharmaceutical industry. Her experience includes, among others, analytical method development and validation; designing and setting up stress studies and stability studies to support NDA fillings, for finished products in the liquid form, lyophilized, and others; and Quality Control activities for the Pharma industry. In 2020, she has joined the world of Medicinal Cannabis as QC manager for Clever Leaves Portugal. Her new journey includes oversight of all analytical activities, designing and planning stability for cannabis medicinal product as well as the design and set up of a new QC Lab to support the GACP and GMP activities for CLP.

Dr Henrik Harms
BfArM, Germany
Since 2018 Henrik has been working as Quality Assessor at the German Federal Institute for Drugs and Medical Devices (BfArM). He is responsible for registration and marketing authorization of pharmaceutical drugs including evaluation of herbal and traditional medicinal products.

Dr Timo Krebsbach
HHAC Labor Dr. Heusler, Germany
Timo has 20 years of professional experience, both in a variety of contract laboratories and in a variety of positions. He was employed in microbiological quality control in a medium-sized contract laboratory in Germany for 10 years. Here, as Division Manager of the Sterility Testing Department, his responsibilities included the sterility tests performed in a cleanroom and in isolators. In 2015, Timo moved to HHAC Labor Dr. Heusler, a medium-sized GMP contract laboratory. He has been Managing Director since October 2015.

Dr Nandakumara D Sarma
USP, USA
Nandakumara Sarma is Director for Dietary Supplements and Herbal Medicines at the US Pharmacopeia (USP). He is working with global stakeholders and expert volunteers on the development of quality standards (monographs and general chapters) for dietary supplements and herbal medicines that are published in the USP Dietary Supplements Compendium and the Herbal Medicine Compendium.

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

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings.

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/recordings.

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)

Stability Testing for Cannabis - Requirements, Challenges & Solutions
Live Online Training on 11 November 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 Training

Thursday, 11 November 2021, 10.00 to approx. 17.00 h
All times mentioned are CET.

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://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 e-mail 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)

ECA Members € 1,090
APIC Members € 1,140
Non-ECA Members € 1,190
EU GMP Inspectorates € 595
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.