ECA Academy
Your GMP/GDP Information Source

Speakers


Joaquín Dell'Acqua
Agronomist, Spain


Dr Henrik Harms
BfArM, Germany


Philip Junker Andersen
IntuBio, Denmark


Dr Gerlinde Kugler
Austrian Agency for Health and Food Safety (AGES)


Dr Ulrich Rose
Formerly EDQM, France


Dr René Roth-Ehrang
Finzelberg, Germany


Dr Evelyn Wolfram
Zurich University of Applied Sciences, Switzerland


Dr Nikos Xynos
Nomad Labs Scientific, Greece

GMP for Herbal Medicinal Products (HMPs)

Live Online Conference on 8-9 October 2025

Highlights

- GACP vs GMP requirements
- Regulatory Framework
- Requirements for Marketing Authorization Applications
- Stability & Microbiological Testing
- GMP Aspects for Extracts
- Experiences from GMP Inspections / Audits

Objectives

The course will provide you with the necessary GMP/GACP knowledge for Herbal Drugs, Herbal Drug Preparations (e.g. Extracts) and Herbal Medicinal Products (HMPs). This includes regulatory & quality requirements as well as applicable pharmacopoeial monographs and challenges often encountered in HMPs, e.g. during stability studies.

Background

Herbal Medicinal Products are accepted and widely-used remedies. Although several routes exist for HMPs to receive a marketing authorization, e.g. well-established or traditional use – or special cases like medical cannabis as "Formula magistralis / officinalis" without marketing authorization - they all need to fulfill the same pharmaceutical quality standards. However, HMPs have some very specific characteristics that must be taken into consideration for GMP compliant production, quality control, release and stability testing. Questions often raised include the following:

- Which contaminants have to be considered?
- Which microbiological provisions apply?
- Which kind of decontamination procedures can be used?
- Are there different requirements for herbal drugs, herbal drug preparations (like extracts) and the final HMP?

To provide more detailed information on these requirements, the European Medicines Agency (EMA) recently published the final guidelines (Revision 3) on quality and specifications for herbal medicinal products (HMPs). Amongst others, a written GACP confirmation for the herbal substance should be provided either by the herbal drug supplier or the manufacturer of the active substance / the HMP. In addition, EMA´s HMPC is currently working on the revision of the GACP guideline and recently already published a draft paper.

Target Audience

This course is designed for all people in pharmaceutical and API industry's quality control, regulatory affairs, pharmacovigilance, production and purchasing departments who need to establish, monitor and/or manage the quality of Herbal Drugs / Herbal Medicinal Products.

Moderator

Dr Andrea Kühn-Hebecker, CONCEPT HEIDELBERG

Programme - 8 October 2025

Do Phytopharmaceuticals have a Future?

- Regulatory hurdles and growing competition with dietary supplements
- Challenges in the Lifecycle management of herbal medicines
- How a modernization of EU regulations could help
- Health claims Issues

Quality Requirements for Marketing Authorization Applications

- Borderline GACP-GMP
- Types of extracts
- Control strategy for extracts and drug products
- Context with clinical data and regulatory pathway
- Is a complete dossier always required?

Quality Control and Stability Testing: Specific Aspects for HMPs

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

Q&A Session 1

Herbal Drugs & Herbal Drug Preparations in the European Pharmacopoeia (Ph. Eur.)

- General / Individual Monographs & General Texts
- Pyrrolizidine Alkaloids (PAs)
- Alternatives for Assays
- Outlook

Herbal Reference Standards (HRS)

- Pharmacopoeial definition (Ph. Eur.)
- Different types of HRS
- Active and analytical markers

GMP and Technology Considerations for Extraction and Purification of Herbal Active Compounds

- Processes and methods
- Different extraction, refining and purification technologies
- Key considerations for GMP compliance in integrated processes and technologies
- Environmental impact, cost efficiency, and operational aspects

Q&A Session 2

Programme - 9 October 2025

From Field to Facility: Lessons from Annex 7 vs GACP and Inspections

- Regulatory Aspects
- Quality management System (QMS)
- Quality Risk Management (QRM)
- Points to consider

Cultivation under GACP

- Cultivation and the implementation of GACP standards
- Practical insights
- Case studies

Requirements & Challenges for the Microbiological Testing of HMPs

- Typical microflora of medicinal plants
- Requirements for the microbiological quality of herbal medicinal products
- Microbiological test methods and proof of suitability
- Decontamination methods for herbal starting materials
- Experiences from authority inspections

Final Discussion

Speakers

Joaquín Dell'Acqua, Agronomist, Spain

Joaquín is an agronomist with over seven years of hands-on experience in the cultivation and management of medicinal cannabis crops across Uruguay and Spain. He has led the implementation of GACP and EU-GMP practices in both indoor and greenhouse environments, focusing on production optimization, traceability, and quality assurance. His work includes the development of SOPs, staff training, and overcoming practical challenges in large-scale cannabis operations.

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.

Philip Junker Andersen, IntuBio, Denmark

Philip is currently Chief Scientific Officer at IntuBio.

Dr Gerlinde Kugler, Quality Assessor in the Department of Herbal, Homoeopathic and Veterinary Medicinal Products, Austrian Agency for Health and Food Safety (AGES)

Dr Gerlinde Kugleris a Biochemist and currently working as a quality assessor at the Austrian Agency for Health and Food Safety / Federal Office for Safety in Health Care (AGES / BASG). She performs quality assessments of Herbal Medicinal Products/Traditional Herbal Medicinal Products and Homoeopathics

Dr Ulrich Rose, Former Deputy Head of the European Pharmacopoeia Department, EDQM, France

Dr Rose was Deputy Head of the European Pharmacopoeia (Ph. Eur.) Department at the EDQM in Strasbourg and in this context responsible (amongst others) for the preparation of monographs on herbal drugs & preparations. He was also involved in the harmonization of international pharmacopoeias. Previously, he was responsible for the establishment and control of Ph. Eur. Herbal Reference Standards.

Dr René Roth-Ehrang, Member of the Management Board Quality / Development, Finzelberg GmbH & Co. KG, Germany

After studying pharmacy in Hamburg and obtaining his doctorate in Bonn, Dr Roth-Ehrang has been with Finzelberg since 1998 in various positions, including Head of Scientific & Regulatory Affairs. In addition, he gained insights in the food supplement industry when serving Amway as Director of Regulatory and Technical Services. Currently Dr Roth-Ehrang is Member of the Management Board Quality & Development at Finzelberg.

Dr Nikos Xynos, Nomad Labs Scientific, Founder and Managing Director, Greece

Nikos is a pharmaceutical scientist with a PhD in Natural Products Chemistry. His core scientific & technological advisory and technology transfer services include process design for extraction, refining and purification of natural products and health ingredients from various botanicals for food and/or pharma grade products.

Dr Evelyn Wolfram, Natural Product and Phytopharmacy Research Group, Department of Life Sciences and Facility Management, Zurich University of Applied Sciences, Switzerland

Evelyn served in several R&D and Quality Management positions in the pharmaceutical, food and cosmetic supplement industry before she became senior researcher and lecturer at ZHAW for phytopharmacy and natural products and especially Quality Management and Pharma GMP. She is currently working in applied science in academic as well as commercial projects within the herbal health product industry. She is a senior scientific advisor of the global non-for-profit Empowered by Evidence initiative and member of the board and scientific committee of ESCOP.

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GERMANY

Reservation Form (Please complete in full)

GMP for Herbal Medicinal Products (HMPs)
Live Online Conference on 8/9 October 2025

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.
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- 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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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 course in detail and with which you document your training.

For questions regarding organisation please contact:
Ms Nicole Bach (Organisation Manager) at
+49 (0)62 21/84 44 22, or per e-mail at
nicole.bach@concept-heidelberg.de.

Organisation and Contact

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

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.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the numbers 21366.

Fees (per delegate, plus VAT)

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The fee is payable in advance after receipt of invoice.

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.

Date of the Live Online Conference

Wednesday, 8 October 2025, 9.00 to approx. 17.30 h (CEST)
Thursday, 9 October 2025, 9.00 to approx. 13.00 h (CEST)

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