

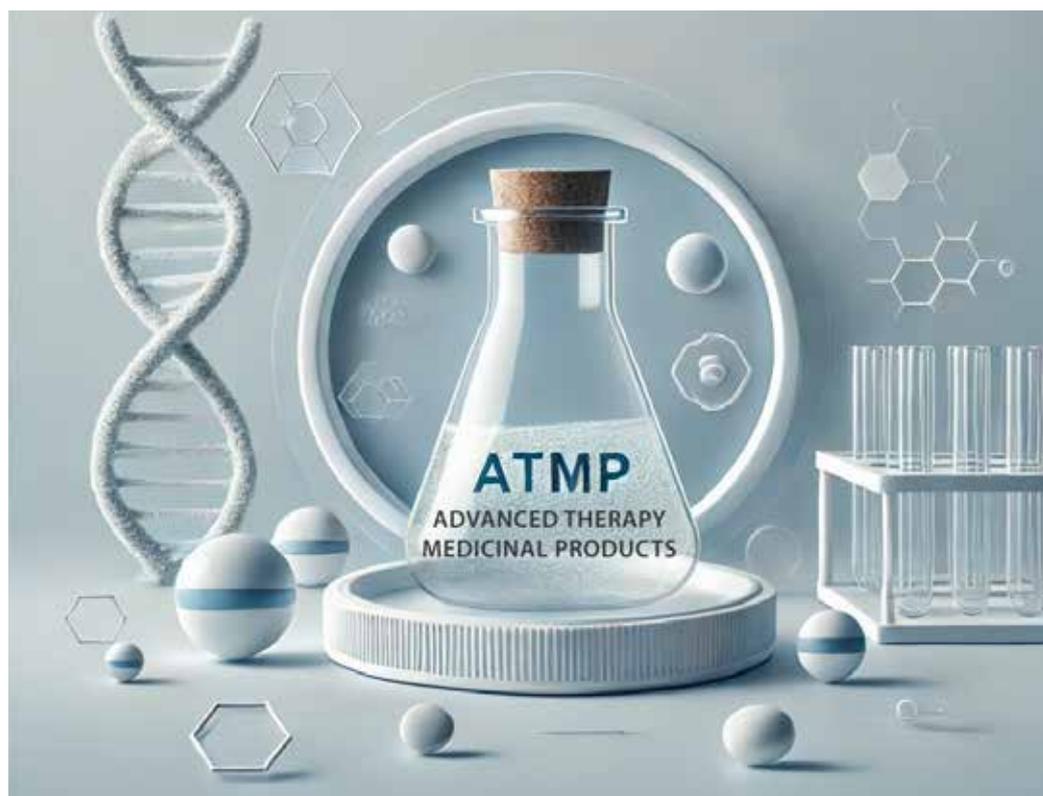


GMP Webinar

ATMP – Short & Simple

Date:
Thursday, 03 July 2025, 14.00 – 16.00 h CEST

Speaker:
Dr Sabine Hauck



ECA has entrusted
CONCEPT HEIDELBERG with the
organisation of this webinar.

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Background

Advanced Therapy Medicinal Products (ATMPs) are an important component of innovative and personalized medicine. They offer ground-breaking treatment options for serious and often incurable diseases. These therapies include for example CAR-T cells, viral vectors (such as AAV, lentiviruses and adenoviruses), plasmid DNA and tissue engineering. To ensure that these products are of consistent quality, safe and effective, they must be manufactured in accordance with GMP (Good Manufacturing Practice) rules. These rules ensure that the manufacture and control of products is safe, standardized and traceable. To comply with these standards, it is important to understand the basics in the first place - and this is often a challenge.

In this training course, you will learn the basic GMP rules for ATMPs. We start with the fundamentals and cover the following topics:

Basic terms: What does GMP mean, how does it look like to ATMPs, and what are ATMPs actually?

Overview of the regulations: From EU regulations and EMA guidelines to GMP guidelines and important pharmacopoeia chapters for ATMPs.

Special features of ATMPs: How do they differ from traditional medicinal products?

This course offers you the opportunity to develop a solid basic understanding of GMP and ATMPs - the first step on the way to the safe manufacture of these innovative therapies.

Educational Objectives

The training will give a brief and concise overview of ATMP and GMP so that participants will hear the following presentations:

GMP – A first Approach

- Definition, context and history
- What makes GMP so special?
- GMP for ATMPs in the EU and outside Europe

ATMP - To be or not to be

- Which products are ATMPs?
- Overview of regulations
- Special features of ATMPs

Target Audience

This webinar addresses itself to all, which are involved in Quality Assurance, Research and Development, Regulatory, Quality Control and Manufacturing of ATMP. This course creates a basic understanding of GMP and ATMP.

Speaker



Dr Sabine Hauck

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Sabine Hauck has 20+ years of experience in the biotech industry, in which she held various positions in pharmaceutical development, quality assurance, regulatory affairs and corporate development. Her product experience spans from small molecules to cell therapies and includes a variety of dosage forms. After gaining experience in several biotech companies she is now providing freelance consulting and trainings for biotech and biopharma companies in the field of pharmaceutical development, quality assurance, and regulatory affairs. Sabine is also active as the chair of the ECA ATMP interest group.

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Fees (plus VAT)

Single participation: € 349,- for ECA Members

Single participation: € 399,- for non-ECA Members

(This fee does not include the ECA Membership. You will find more about the ECA Membership at www.gmp-compliance.org/about-the-academy).

Participation of a Group

You have colleagues who also want to participate in the webinar? Then register yourself and your colleagues as a GROUP! You can view the webinar either together (e.g. in a conference room, etc.) or also each individually on your own PC.

Group Participation (fee per person):

3-10 Persons € 359,10

11-20 Persons € 319,20

more than 20 Persons € 279,30

Registration

By e-mail – or **search and register directly at www.gmp-compliance.org under the number 22108**. In order to avoid misunderstandings, please indicate the exact address and the full name of the participant. You will receive your access data by e-mail in due time prior to the event.

Technical Requirements

We use Webex for our live online training courses and webinars. At 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.

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.

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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 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 %

- Cancellation within 2 weeks 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 HEIDELBERG will 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 July 2022). 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 www.gmp-compliance.org/ecca_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.