Speakers

Dr Rüdiger Alt
Novartis

Dr Rainer Gnibl
Local Government of Upper Bavaria

Dr Sabine Hauck
Chair of ECA ATMP Interest Group

Dr Ulrich Kissel
Chair of ECA ATMP Interest Group

GMP for ATMPs

Made simple

14/15 October 2025 | Heidelberg, Germany

Highlights

- Definitions and Key Regulations of ATMP and GMP
- Risk-based Approach
- Environmental Monitoring and (Cross) Contamination
- Raw/Starting Materials
- Handling of Quality Defects

Basic Training for Beginners & Newcomers

Objective

In this basic GMP course for ATMPs (Advanced Therapy Medicinal Products), experts from authorities, industry and consultancy will explain the basic GMP requirements for working with ATMPs. In addition, you will gain an understanding of the most important regulatory requirements in this area.

Background

Advanced therapy medicinal products (ATMPs) play a key role in innovative, personalized medicine. They are leading biomedical research and providing breakthrough treatments for serious and often incurable diseases. These therapies include CAR-T cells, viral vectors (AAV, lentiviruses, adenoviruses), plasmid DNA and tissue engineering, all driven by advances in genetics, molecular biology and cell biology.

GMP compliance is essential for the consistent, traceable manufacture and control of medicines. To achieve this, employees must understand the basic rules. In practice, this understanding is often incomplete. This training gives you an insight in the GMP rules for ATMPs starting from the basics.

Target Audience

This basic course is aimed at Quality Assurance, Quality Control and Production personnel who work with ATMPs on a daily basis. This course will refresh or create a basic understanding of GMP with a focus on ATMPs.

This course provides new employees and employees in their first years of employment with an initial insight into GMP regulations, as well as the day-to-day characteristics and GMP-compliant handling when working with ATMPs.

Moderator

Clemens Mundo, Concept Heidelberg

Programme

GMP – A first Approach
Dr Sabine Hauck

- Definition, context and history
- What makes GMP so special?
- GMP outside Europe

ATMPs – Modern Medicines between Cells and Genes
Dr Sabine Hauck

- To be or not to be - which products belong to ATMPs?
- A decision tree to help you
- Regulation 1394/2007

Risk-based Approach
Dr Sabine Hauck

- Flexibility and responsibility
- Understanding of processes and products as a prerequisite
- Application and examples

Outsourced Activities
Dr Ulrich Kissel

- Scope and importance
- Supplier management
- Specification management
- Change control

Personnel & Rooms
Dr Rainer Gnibl

- Requirements for ATMP personnel
- „Shared“ or “dedicated” facilities?
- EU-GMP compliant design

Equipment - Single Use and more
Dr Ulrich Kissel

- Scope and importance
- Sterility management
- Handling SUS in storage and operation
- Special features, Teflon

Aseptic Environment, Environmental Monitoring and (Cross-)Contamination
Dr Rainer Gnibl

- Principles of particulate and microbiological monitoring
- Avoidance of (cross) contamination
- Basics of aseptic production

Handling of Raw/Starting Materials, Cell Bank System and more
Dr Rainer Gnibl

- Requirements for various materials
- Incoming goods
- Traceability

Quality Control
Dr Ulrich Kissel

- Scope and importance
- Pharmacopoeia Europaea
- Samples and their handling
- Method validation and method transfer

Qualification & Validation
Dr Rainer Gnibl

- Cleanroom qualification
- Basics of process and cleaning validation
- Aseptic validation (media fill)
- Validation life cycle

Batch Release
Dr Rüdiger Alt

- Batch certification and release by the EU QP
- Batch certification before fully completed testing
- Decentralized production

Handling of unplanned Deviations
Dr Rüdiger Alt

- Recording and documentation
- Initial evaluation and classification
- Root Cause Investigation & CAPA

Handling of OOS Results
Dr Rüdiger Alt

- OOS investigation and risk assessment
- Exceptional provision request
- Exceptional batch supply and notification to authorities

Often forgotten GMP Areas
Dr Ulrich Kissel

- Reconstitution after batch release
- Data with regards to ATMPs and GMP Annex 11
- Temperature management - Is it really necessary?
- Purchasing and Supply Chain Management and GMP

Specific Guidelines for selected Product Types
Dr Sabine Hauck

- Supplementary requirements for manufacture and control
- Requirements for product properties and characterization
- Examples for product-related guidelines

Speakers

Dr Rüdiger Alt
Novartis
Qualified Person for AT(I)MPs

Dr Rüdiger Alt joined Cytonet in 2013 as Deputy Head of QC/QA and QP. Since 2015, he has been responsible for cell- and vector-based AT(I)MPs as QP at Novartis.

Dr Rainer Gnibl
Local Government of Upper Bavaria
GMP Inspector for EMA and local Government

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria 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 Sabine Hauck
dequra pharma consult hauck

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.

Dr Ulrich Kissel
KisselPharmaConsulting GmbH

Ulrich Kissel is Qualified Person and Chairman of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Social Event

On Tuesday evening, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

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GERMANY

Reservation Form (Please complete in full)

GMP for ATMPs
14/15 October 2025, Heidelberg, Germany

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 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 %.

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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
Tuesday, 14 October 2025, 09.00 h – 17.00 h
(Registration and Coffee 8.30. h – 09.00 h)
Wednesday, 15 October 2025, 08.30 h – 17.00 h
All times mentioned are CEST

Venue
Intercity Hotel Heidelberg
Kurfürsten-Anlage 81
69115 Heidelberg, Germany
Phone: +49/6221/1881 0
Email: heidelberg@intercityhotel.com

Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
EU GMP Inspectorates € 945
Non-ECA Members € 1,890
The conference fee is payable in advance after receipt of invoice and includes dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21967.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. 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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