ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Katja Aschermann
Astator

Dr Rainer Gnibl
Local Government of Upper Bavaria

Dr Sabine Hauck
Chair of ECA ATMP Interest Group

Dr Roland Pach
Roche

Prof Dr Sven Stegemann
DWI – Leibniz-Institut für Interaktive Materialien e.V.

Navigating ATMP Development

- From Bench to Bedside -

Live Online Training on 07/08 October 2025

Highlights

- Current regulatory requirements (EMA, ICH, GMP) along the ATMP development process
- Strategies for CMC, validation, QbD and scale-up
- Understanding the roles of QP, development teams and clinical units
- Practical case studies

Objectives

The aim of the training is to provide participants with fundamental, practical knowledge along the entire ATMP development process - from preclinical research to clinical application and GMP-compliant manufacturing. The content covers regulatory requirements (EMA, ICH, GMP), CMC strategies, process development, analytics, validation and quality assurance. Participants will learn how to overcome typical challenges, avoid typical mistakes and efficiently integrate regulatory and scientific requirements into everyday development work.

Background

The development of advanced therapy medicinal products (ATMPs), including gene therapies, cell therapies, and tissue-engineered products, is characterized by a high level of scientific, technical, and regulatory complexity. These innovative medicinal products must comply with stringent and ever-changing regulatory requirements, as set out in various European and international guidance documents. Examples include the EMA Guideline on "Quality, non-clinical and clinical aspects of gene therapy medicinal products" (EMA/CAT/80183/2014), The guideline on "Human cell-based medicinal products" (EMEA/CHMP/410869/2006), EudraLex Volume 4 Part IV for ATMPs and cross-cutting ICH guidelines, such as ICH Q8–Q10 (quality by design and pharmaceutical quality systems) and ICH Q14 (analytical procedure development).

The transition from preclinical research to first-in-human trials and later market authorization – often referred to as the "bench to bedside" process – requires a development strategy that integrates regulatory foresight, robust CMC (Chemistry, Manufacturing and Control) planning, and comprehensive quality oversight from the earliest stages. Particular challenges in ATMP development include raw material qualification, platform-independent process validation, aseptic processing strategies, and the implementation of analytical approaches in accordance with ICH Q14 principles. Upscaling and tech transfer into GMP-compliant manufacturing environments require strategic foresight and alignment with GMP for ATMPs (EudraLex Vol. 4 Part IV).

This training course provides participants with a practice-oriented understanding of the end-to-end ATMP development process. It offers in-depth insights into regulatory expectations, process and analytical development, validation strategies, and the specific responsibilities of the Qualified Person (QP) under EU legislation. Participants will develop confidence in applying risk-based approaches (as outlined in ICH Q9) and addressing critical regulatory interfaces during development and scale-up. The course provides professionals with the strategies and regulatory expertise needed to successfully implement, ensure GMP compliance and ultimately authorize ATMPs in a dynamic and highly regulated environment.

Moderator

Clemens Mundo, Concept Heidelberg

Target Audience

This training is aimed at specialists and managers from development, production, quality assurance, regulatory affairs and project management, especially pharmaceutical companies focusing on ATMPs, as well as qualified persons and representatives of authorities.

Programme

From Phase 1 to Scale-up: GMP Requirements for ATMPs

Sabine Hauck

- Regulatory landscape: EMA guidance, ICH and GMP
- Stability program
- Challenges of IMPs and IMPD

Raw Material Selection in ATMP Development

Katja Aschermann

- Why it matters
- Regulatory requirements
- Selection criteria

CMC Strategies for ATMPs: Process Development and Quality Oversight

Roland Pach

- Quality oversight & regulatory
- Addressing specific challenges in ATMP CMC
- AAV case study

Qualification & Validation Challenges in ATMP Manufacturing Systems

Rainer Gnibl

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

Analytical Development for ATMPs - Implementing ICH Q14 in Practice

Katja Aschermann

- Approaches for analytical procedure development
- Enhanced approach in theory
- Practical examples

Applying QbD principles in ATMP development – Challenges and Opportunities

Sven Stegemann

- QbD (ICH Q8) in pharmaceutical product development to assure reproducibility by product and process understanding
- Differences and communalities of small molecules, biologics and ATMP products
- Potential of QbD to improve ATMP processing and control for point-of-care manufacturing

The QP's Role in ATMP Development and Lot Release Under EU Law
Sabine Hauck

- GMP requirements for the QP role
- Managing special cases specific to ATMPs
- Communication between QP, manufacturing, and clinical teams

Towards "First-in-Human" – Considerations for early Clinical Trial Design of ATMP
Sven Stegemann

- Preclinical studies and data to support the appropriate design for the "first-in-human" clinical trial
- Traditional and evolving clinical study designs to proof safety and efficacy
- Prerequisites and considerations to enter into a "first-in-human" trial

Scaling Up ATMP Manufacturing
Roland Pach

- Key aspects of scaling up ATMP
- Examples & challenges of scaling up strategies
- AAV case study

How to handle Deviations
Katja Aschermann

- What is a deviation and how to evaluate criticality
- Core characteristics of an efficient deviation handling system
- Root cause investigations

Change Control in agile ATMP Development Environments
Katja Aschermann

- Managing change control throughout the product lifecycle
- The change control process in an agile environment

Risk-based approaches: How to do it right
Sabine Hauck

- Understanding the Risk-Based Approach in development of ATMPs
- Risk assessment tools and the link to ICH Q9
- Examples for implementation of risk-based approach

Bridging Development and GMP
Sabine Hauck

- Common pitfalls in ATMP tech transfer between R&D and GMP
- Establishing robust documentation and traceability early on
- Role of development reports, knowledge management, and comparability data

Speakers

Dr Katja Aschermann
Astator, Consultant

Dr Katja Aschermann is an accomplished leader in the biopharmaceutical industry with over 20 years of experience in various senior positions. Her extensive experience spans from transforming academic spin-offs into GMP companies to submitting regulatory dossiers to the EMA. She is a member of the ECA ATMP-Interest Group Board and has participated in the development of the "National Strategy for Gene and Cell-Based Therapies". In Nov 2024 she started working as a freelance consultant.

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.

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. After gaining experience in several biotech companies she is now providing freelance consulting and trainings for biotech and biopharma companies. Sabine is also active as the chair of the ECA ATMP interest group.

Dr Roland Pach
Roche
Global Analytical Expert CMC Cell- & Gene Therapy & alternative formats

Prior Roche, he was leading the Analytical Development department at Berna Biotech and the QC department of Bio-Process Development at Merck Serono. Roland is the global CMC Analytical Technical Lead in the cancer vaccines and cell- & gene therapy (CGT) area of Roche more than 10 years. In his assigned area, he represents Roche in external development projects, industrial consortiums like CGT BioPhorum and numerous due diligences of in-licensing candidates or companies in the CGT fields. In his second role at Roche as global technical development leader, he had led successfully new formats like immunotoxins from pre-clinics into entry to human (EiH).

Prof Dr Sven Stegemann
DWI – Leibniz-Institut für Interaktive Materialien e.V.
CEO

Sven Stegemann is a pharmacyst by education and has a PhD in pharmacology. He has a 30 years experience in the pharmaceutical industry, has been Professor for Patient-Centric Drug Product Design and Manufacturing at the University of Technology in Graz, before he became the head of the new Leibniz Jointlab "First-in-Translation", dedicated to translational research and clinical manufacturing in Aachen (Germany).

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Reservation Form (Please complete in full)

Navigating ATMP Development
Live Online Training on 07/08 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)

General terms and conditions
If you cannot attend the conference you have two options:
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- Cancellation until 3 weeks prior to the conference 25 %,
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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 January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Tuesday, 07 October 2025, 09.00 h – 17.30 h
Wednesday, 08 October 2025, 09.00 h – 16.30 h
All times mentioned are CEST

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 trainings 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.

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.

Registration

Via the attached reservation form, by e-mail or by fax message – or search and register directly at www.gmp-compliance.org under the number 22170.

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.

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.

Organisation and Contact

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