ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Katja Aschermann
Astator

Dr Thomas Becker
Dr Thomas Becker Pharma & Biotech Consulting

Dr Rainer Gnibl
Local Government of Upper Bavaria

Dr Sabine Hauck
Chair of ECA ATMP Interest Group

Kati Kebbel
Fraunhofer Institute for Cell Therapy und Immunology

Dr Wolfgang Schumacher
ECA Advisory Board

Advanced GMP for ATMPs

Perfect your skills in the ATMP world of GMP and Annex 1

11/12 June 2025 | Vienna, Austria

Highlights

- Regulatory Overview Part IV
- Lyophilization According to Annex 1
- Impact of Annex 1 in the Aseptic Manufacturing of HCGTP
- Creation of a CCS
- Case Study for a Clinical Phase I/II CAR T Cell Product

Objective

As part of this GMP course for ATMPs (Advanced Therapy Medicinal Products), you will learn about the existing regulatory requirements for aseptic manufacturing, CCS, data integrity, lyophilisation according to the new Annex 1 and much more from various experts from authorities, industry and consulting. In addition to the GMP requirements, you will also learn about the impact and implementation of the new Annex 1.

Background

The new Annex 1 is in effect and must now be implemented. The correct interpretation and implementation in daily business is often difficult and raises many questions. Compliance with the GMP regulations is essential for the continuous, traceable and high-quality manufacture, testing and control of pharmaceutical products.
Advanced Therapy Medicinal Products (ATMPs) are a group of innovative and sophisticated medical treatments that use advanced technologies to modify or use living cells, tissues or genes for therapeutic purposes. These therapies focus on targeting the underlying causes of disease at the cellular and genetic level, with the aim of treating, preventing or diagnosing diseases. ATMPs include gene therapies, cell therapies and tissue engineered products and represent a significant step in medical treatments.
New ATMPs with innovative properties are constantly being developed. It does not matter whether it is a personalized product, production or even transport. The ultimate goal always remains a safe and effective product that provides the patient with healing or relief without harming them. To ensure this, employees must comply with the current regulations. This course offers deeper insights into the regulations and advice on implementing the new and existing requirements of ATMPs.

Target Audience

This training is aimed at employees from quality assurance, quality control and production who have daily contact with ATMPs and have to work according to the existing GMP requirements. Experienced staff will have the opportunity to extend and deepen their existing knowledge in core aspects of GMP and Annex 1 areas.

Moderator

Clemens Mundo, Concept Heidelberg

Programme

EU-GMP Guideline Part IV: Overview
Dr Rainer Gnibl

- Positioning within EudraLex Vol. 4
- Definition of ATMPs
- Document structure & technical content
- Key messages

Quality Risk Management for ATMPs
Dr Rainer Gnibl

- What does QRM mean?
- ICH Q9 Quality Risk Management (Overview)
- Bounderies & limitations
- Examples from Guideline

Freeze-drying of Vectors in the Light of Update Annex 1
Dr Sabine Hauck

- Annex 1 requirements for lyophilization
- Further regulatory requirements for (non-)viral vectors
- Benefits of freeze-dried viral vector formulations

Aseptic Manufacturing of Cell-based ATMPs (HCGTP)
Dr Katja Aschermann

- Challenges
- Impact of new Annex 1
- Cross Contamination Control Strategy

Environmental Monitoring
Dr Rainer Gnibl

- Segregation between Classification, Qualification & Monitoring
- Clean room lifecycle
- Monitoring elements
- Personell & clean room monitoring

Data Integrity of Automated, Decentralised Cell Therapy Production
Dr Wolfgang Schumacher

- DI concept in research-oriented smaller companies
- Computer-assisted manufacturing of therapeutics
- DI issues in testing, release and logistics
- DI questions in the context of inspections

Contamination Control Strategy
Dr Katja Aschermann

- Definition
- Creation of a CCS
- Selected items

Qualification and Validation – a Versatile and Efficient Quality Tool in the ATMP Manufacturing
Kati Kebbel

- Clarification of types of qualification and validation applied in ATMP manufacturing
  - supplier qualification
  - device qualification
  - software validation
- (Aseptic) process qualification / validation
  - method validation
  - operator qualification
- Regulatory basis
- How are these types used in the ATMP manufacturing - described in a case study for a clinical phase I/II ATMP

ATMPs a Challenge for Quality Control
Dr Katja Aschermann

- From product to control strategy via CQAs
- Measurement of quality attributes
- Specifications
- Stability
- Validation

Regulatory Landscape - Opportunities and Challenges
Dr Sabine Hauck

- Overview for ATMPs
- Specific requirements for ATMPs - opportunities and challenges
- Examples on points to consider in CMC

If the Guidelines become a Challenge
Kati Kebbel

- Media Growth Promotion Test according to EP 2.6.1 vs. 2.6.27 and impact to sterility method validation
- APS challenges
- Change of standard APS strategy - a future vision?

Batch Release- What to Consider for AT(I)MPs
Gabriela Schallmeiner

- EU Regulatory framework
- GMP for AT(I)MPs
- QP batch certifcation

Social Event

On Wednesday 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.

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 Thomas Becker
Dr Thomas Becker Pharma & BiotechConsulting

Thomas Becker has more than 25 years of experience in the pharmaceutical industry mainly collected in senior positions with Quality Assurance, Compliance and Quality Control. Thomas´ focus is on aseptic manufacturing of mainly biological drug products and on production of biological active substances, including vaccines and mRNA. Since June 2024 Thomas is working as a freelance GMP consultant. Thomas is registered as Qualified Person according § 15.3 and 3a AMG for vaccines and ATMPs.

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.

Kati Kebbel
Fraunhofer Institute for Cell Therapy und Immunology, Head of Department GMP Cell and Gene Therapy, Qualified Person

Kati Kebbel has been working in the field of ATMP Manufacturing, Quality Control and Quality Assurance for more than 17 years. She is heading the department GMP Cell and Gene Therapy and in addition, she is Qualified Person. In her current position she supported several process transfers from US to Germany, established new manufacturing processes / methods, drove process and method qualifications and supports regulatory submissions.

Dr Wolfgang Schumacher
Principal Consultant

After entering Asta Medica, Dr Schumacher headed different positions. From 2001 to 2016 he was Head of the department of Quality Computer Systems at F. Hoffmann-La Roche, Basle. He is a member of the ECA Advisory Board. Currently he works as a consultant.

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GERMANY

Reservation Form (Please complete in full)

Advanced GMP for ATMPs
11/12 June 2025, Vienna, Austria

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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German law shall apply. Court of jurisdiction is Heidelberg.

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Date
Wednesday, 11 June 2025, 09.00 h – 16.30 h
(Registration and Coffee 08.30 h – 09.00 h)
Thursday, 12 June 2025, 09.00 h – 15.30 h
All times mentioned are CEST

Venue
Doubletree by Hilton Vienna Schönbrunn
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110
Email info@doubletree-schonbrunn.at

Fees (per delegate, plus VAT)
ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
Academic Scientists/ Students € 1,045
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 21883.

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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