ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Katja Aschermann
Tetec

Dr Rainer Gnibl
Local Government of Upper Bavaria

Dr Sabine Hauck
Chair of ECA ATMP Interest Group

Dr Ulrike Herbrand
Charles River Laboratories

Kati Kebbel
Fraunhofer Institute for Cell Therapy und Immunology

Mag. Gabriela Schallmeiner
Austrian Qualified Person Association (aqpa)

Dr Wolfgang Schumacher
ECA Advisory Board

Advanced GMP for ATMPs

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

Live Online Training on 02/03 July 2024

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

Learn how to tackle the hot topic of potency testing in a GMP environment

Programme

Objective

As part of this GMP course for ATMPs (Advance 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.

New ATMPs with new special features are constantly being created. Whether this is a personalized product, the production or even the transport is irrelevant. The ultimate goal should be a safe, effective preparation that offers the patient a cure or relief without harming them. To achieve this, employees must adhere to basic rules. 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

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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 seminar in detail and with which you document your training.

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

Bioassay Challenges
Dr Ulrike Herbrand

- Principles and regulatory environment of bioassays
- Matrix approach
- Case studies for various types of ATMPs

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

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

Speakers

Dr Katja Aschermann
Tetec, Vice President Quality

Over the last 20 years Katja Aschermann held various executive positions in the biological life science industry. During this time, she worked as Head of Quality Assurance, Head of Business Development, Director of Quality Control, Founder and Chief Operating Officer. Selected tasks of her professional career were transforming academical spin offs to GMP certified life science SMEs, merging of business units after acquisition and obtaining GMP manufacturing authorization for allogenic iPSC production in Germany.

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 Ulrike Herbrand
Charles River Laboratories
Scientific Director Global *in vitro* Bioassays

Ulrike Herbrand joined Charles River Laboratories in 2007. She is Scientific Director Global *in vitro* Bioassays and Head of the Bioassay Research & Development team at Charles River Laboratories' site in Erkrath, Germany. She gained a PhD in biological sciences during her time at the Max-Planck-Institute for Molecular Physiology in Dortmund (Germany) and worked five years at post-doctoral positions at medical research centers in the field of cancer research. She is an expert in mechanism of action-reflecting bioassays for protein therapeutics as well as for advanced therapy medicinal products.

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

Kati Kebbel is engineer for Biotechnology. She 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 at the Fraunhofer Institute for Cell Therapy and Immunology in Leipzig which is performing work as CDMO. In addition, she is Qualified Person. At the Fraunhofer Institute, she supported several process transfers from US to Germany, established new manufacturing processes/methods, drove process and method qualifications and supports regulatory submissions.

Mag. Gabriela Schallmeiner
Inspection-Ready Consulting, Owner

Gabriela Schallmeiner is an independent consultant and Qualified Person with special focus on ATMP and vaccines. She has many years of experience in leading quality and QC functions and as a QP in companies such as Roche, Boehringer Ingelheim, AfFFiRiS, Pfizer and more. She is also deputy chairwoman and founding member of Austrian Qualified Person Association (aqpa).

Dr Wolfgang Schumacher
Principal Consultant

Dr Schumacher studied chemistry and pharmacy. After entering Asta Medica, he 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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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Advanced GMP for ATMPs, Live Online Training on 02/03 July 2024

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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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 %,
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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 of the Live Online Training

Tuesday, 02 July 2024, 09.00 h – 15.30 h CEST
Wednesday, 03 July 2024, 09.00 h – 15.00 h 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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

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.
CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Clemens Mundo (Operations Director) at
+49(0)62 21/84 44 42, or at
mundo@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Sonja Nemec (Organisation Manager) at
+49(0)62 21/84 44 24 or at
nemec@concept-heidelberg.de.