ECA Academy
Your GMP/GDP Information Source

Speakers


Dr Rüdiger Alt
Novartis


Dr Katja Aschermann
TETEC


Dr Rainer Gnibl
Local Government Upper Bavaria


Stephane Gumy
PMS


Dr Sabine Hauck
Leukocare


Dr Armin Hauk
Sartorius Stedim Biotech


Ohad Karnieli, PhD
Adva Biotechnology


Kati Kebbel
Fraunhofer IZI


Didier Meyer
DMCompliance


Lisa Meyer
Minaris Regenerative Medicine


Erik Steffensen
Novo Nordisk


Dr Mohamad Toutounji
Molgenium


Dr Joaquin Urdinez
Cutiss

ATMP – Manufacturing, Quality and Safety

Part of PharmaCongress 2023

28/29 March 2023 | Wiesbaden, Germany

Highlights

- GMP for ATMP
- Process, QC and Realease Strategies for ATMPs
  - Cellular Starting Materials
- Vectors for ATMP
- Mini Isolators for Cell Therapies
- Release in spite of OOS? – Exceptional Provision of AT(I)MPs
- The Assessment of Process Equipment Related Leachables in Cell and Gene Therapies

GMP–PHARMA CONGRESS

This conference is part of PharmaCongress 2023

Objectives

This conference track is aimed at all those who develop and manufacture cells, tissues, cell- and tissue-based products and ATMPs. The conference will address manufacturing challenges, e.g. GMP regulations, but also quality control issues, appropriate ways to maintain, assure and control the expected quality. Experienced speakers from the field of ATMP will explain the current requirements and report on their experiences during inspections and the implementation in the company.

Background

Modern systems of regenerative medicines, such as cells and tissues or ATMPs (gene therapeutics, somatic cell-based products and tissue-based products) represent an innovative group of drugs that is becoming increasingly important. With the entry into force several regulatory guidelines e.g. of the European Directive EC 1394/2007 for ATMPs, such products were classified as medicinal products and must therefore comply as such with the EU requirements for medicinal products. Although the biopharmaceutical industry has considerably intensified its activities in this field, many of these products are developed and manufactured at universities, hospitals and in small and medium-sized enterprises. These university or medical roots lead to special challenges for the respective institutions as well as for the regulatory authorities in fulfilling the compliance requirements for quality, safety and GMP aspects and approval. This is also forced by frequently given manufacturing conditions, e.g. the open manipulation of cells and tissues, which are necessary for obtaining such products on a medical/surgical level or by the short shelf life of the obtained final product.
Challenges for small batch manufacturing, rapid testing and analysis and storage are only some of the challenges for such short shelf life products in terms of:

- Comparability with Compendial Methods
- Sensitivity and Robustness
- Suitability Testing and Validation
- Variability

Target Audience

This conference is aimed at all persons who

- are involved in the extraction and manufacture of Cells, Tissues and ATMPs
- are responsible persons from quality assurance and control of Cells, Tissues and ATMPs
- are responsible for microbiological or analytical testing
- perform inspections or audits of ATMPs facilities
- deal with the authorisation

Moderator

Dr Sabine Hauck, Leukocare

Programme 28 March 2023

Vectors for ATMPs – Stabilization by Formulation Development

Dr Sabine Hauck, Leukocare

- Algorithm based formulation development and in silico long-term prediction
- Stabilization of viral vectors beyond the expected
- The next generation: LNPs as vectors

Cellular Starting Material for ATMP

Lisa Meyer, Minaris Regenerative Medicine

- Starting material source
- Starting material challenges for manufacturing
- Starting material qualification & regulatory requirement

ATMP: Market, Manufacturing and Challenges

Dr Mohamad Toutounji, Molgenium

- Global market overview of ATMP
- ATMP Clinical trials
- Advanced manufacturing processes and scalability
- Development of new methods for quality control of ATMP
- Regulatory pathways and challenges

GMP for ATMP

Dr Rainer Gnibl, Government of Upper Bavaria

- How far can risk-based approach be stressed?
- NEW Annex 1 and now?
- ATMP clean room qualification & monitoring vs. NEW Annex 1

From Process Transfer to clinical / commercial Manufacturing of Cell and Gene Therapy Products - Experiences of a CDMO

Kati Kebbel, Fraunhofer Institute for Cell Therapy und Immunology

- Execution of Process transfer / process setup from CDMO point of view
- Interaction in a pharmaceutical system
- Process documentation and Manufacturing license
- Exemplary challenges of a CDMO like raw materials, ramp up, phase out

Cell based ATMPs: A Success Story

Dr Katja Aschermann, TETEC

- Tissue engineered products
- Regulatory Landscape
- Challenges of autogenous cell-based ATMPs
- Case study: Novocart® Inject

Programme 29 March 2023

Individual stringent Mini Isolators for autologous Cell Therapy

Didier Meyer, DMCompliance

- Common Strategy to avoid Cross Contamination
- A decentralised scale-out concept to be implemented in hospitals
- How a dual temperature Class C or D decentralised platform of a maximum of 10 mini-isolators from donor/patient leukapheresis allows within one to three weeks to take care of more than 100 patients a year using CAR- T techniques and making it affordable

Case Study: QC Test Profile and Release Strategies for ATMP

Dr Joaquin Urdinez, Cutiss
Stephane Gumy, PMS

- The QC profile of ATMPs
- The challenges of releasing extemporaneous ATMPs
- Different release startegies for ATMPs (extemporaneous finished products, reconstitued vaccine, ...)
- The use of potential contaminated ATMPs or OOS products in the frame of clinical trials

Exceptional Provision of AT(I)MPs affected by OOS Results

Dr Rüdiger Alt, Novartis

- Introduction & regulatory framework
- Process and workflow for exceptional provisions
- Health Authority interactions
- Opportunities and limitations of chapter 11.5

Metabolic Sensing and AI Control to improve Quality of Cell Therapy Manufacturing and potentially enable Release by Exception

Dr Ohad Karnieli, ADVA Biotechnology

- How can online Metabolic sensing allow better quality control on the process
- Adoptive culturing via sensing and AI to ensure the quality of autologous manufacturing - Case studies
- Release by exception – automation of the quality assurance process

Establishment of Quality Management System (QMS) for Cell Therapies

Erik Steffensen, Novo Nordisk

- Cell therapies - When living human cells are the pharmaceutical product
- Similarities and differences between conventional medicines and cell therapies from a scientific and regulatory point of view
- To what extent considerations from the development and manufacture of conventional medicines and biologics can be used in the design of the QMS for cell therapies
- Design principles and the implementation of a QMS for cell therapies

The Assessment of Process Equipment Related Leachables in Cell and Gene Therapies

Dr Armin Hauk, Sartorius Stedim Biotech

- The specialties with extractables and process equipment related leachables (PERLs) in cell and gene therapy
- Exposure estimations for therapeutic cells and patients established with PERL-model calculations and digital twins
- The use of a high throughput cell painting assay to screen for toxic and/or detrimental effects of PERLs on therapeutic cells

Speakers

Dr Rüdiger Alt, Novartis

Dr Alt studied Biology in Stuttgart and Leipzig. He first became acquainted with GMP in cell therapy at the University Hospital Leipzig, Department of Haematology. After positions at the Translational Centre for Regenerative Medicine and at Vita 34 AG, where he worked in R&D of ATMPs, he joined Cytonet in 2013 as Deputy Head QC/QA and QP. Since 2015 he is QP at Novartis overseeing investigational and authorized AT(I)MPs of cell and vector based nature.

Dr Katja Aschermann, Tetec

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

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.

Stephane Gumy, PMS

>25 years experience in pharma, biopharmaceutical & medical device industry with managerial positions in QA, QC, manufacturing and process development in international companies as well as in small and medium-sized companies. Since 2007 independent consultant and founder of the consulting company "PMS Process Management System GmbH", located in Freiburg (Switzerland). Specialized in cell therapies. Since 2013 contracted Qualified Person for ATMP IMP.

Dr Sabine Hauck, Leukocare AG

Sabine Hauck has 20+ years of experience in the biotech industry, in which she held various positions in pharmaceutical development, quality assurance and regulatory affairs. Her experience spans from small molecules to cell therapies and includes a variety of dosage forms. She is responsible for digitalization activities at Leukocare AG as well as for Business Process and Quality Management. In this role, she supports the ongoing digital transformation of the organization related to the algorithm-based formulation development approach at Leukocare.

Dr Armin Hauk, Sartorius Stedim Biotech

Armin started his career at Ciba in 1995. After 2010 Armin worked as consultant and Qualified Person (QP) for Intertek C&P in Basel. Since 2016 Armin has a position at Sartorius as Principal Scientist. Armin is a member of ELSIE- and the BPOG-supplier group and the German delegate in the Pharmacopoeia expert group 16 of the EDQM.

Ohad Karnieli, PhD, Adva Biotechnology, Israel

Ohad studied at the Universities of Haifa and Tel Aviv. After working in different positions at High-Tech Lipids and RF Dynamics he became VP Technology and Manufacturing at Pluristem Therapeutics. Today he is Founder and CEO of ADVA Biotechnology and Process & Product Committee International Society for Cell Therapy (ISCT).

Kati Kebbel, Fraunhofer Institute for Cell Therapy und Immunology

Kati Kebbel studied Biotechnology. In 2006 she joined the Fraunhofer Institute and became Head QC in 2008. From 2009 to 2013 she was working with Innovastem GmbH. Following, she was QP at Northwest Biotherapeutics. Since 2016 she is Head of Department GMP Cell and Gene Therapy at Fraunhofer Institute for Cell Therapy und Immunology.

Didier Meyer, DMCompliance

Expert in isolator technology for various applications in biopharma industry. Participation in the writing of PDA TRs and ISO standards regarding isolator technology. 40 years of experience.

Lisa Meyer, Minaris Regenerative Medicine, Germany

Lisa Meyer studied Molecular Biology and Biomedicine at the Johannes Gutenberg University Mainz. From 2015 to 2022, she worked as an Assoc. Scientist and Scientist Research and Development at Exosome. In 2022, she joined Minaris as Manager Process Development & Innovation.

Erik Steffensen
Novo Nordisk

Erik Steffensen has 25 years of industry experience. He has been working in Manufacturing, Product & Process Development, and Quality and has in-depth experience with drug substance, drug product, medical devices and combination products. Throughout his career Erik has been involved in numerous development projects – including Advanced Therapy Medicinal Products (ATMPs) – thus having domain expertise within drug and device development covering Target Product Profile, lead candidate selection, clinical trials, product & process development, manufacturing process design, process validation and regulatory submission.

Dr Mohamad Toutounji
Molgenium

Molecular biologist with industrial expertise regarding CAR-T and CAR-NK cell therapy, Gene therapy product development scientist.

Dr Joaquin Urdinez , Cutiss AG

Joaquin did his MSc at St John's University and PhD doctorate at UZH/ETH Zürich. He worked at mAbxience in the GMP production and process development of biosimilars. In 2014 he joined the start-up Symbiotic Health as a Scientist. In 2019 he joined CUTISS AG, a company specialized in tissue engineered products (ATMPs) to treat various skin defects. Since 2020 he leads the analytical QC program, specialized in cell-based assays and rapid microbiological methods.

PharmaCongress 2023

GMP–PHARMA CONGRESS

The guiding theme of the PharmaCongress 2023 on 28/29 March will be „users sharing challenges and solutions in practice". Therefore, benefit from your colleagues' experience and from the direct information exchange at PharmaCongress & PharmaTechnica 2023.

The Tracks

As a participant you can switch between any of the tracks any time and also visit the PharmaTechnica Expo with more than 100 international exhibitors.

Conference Tracks	28 Mar	29 Mar
European Aseptic Conference	✓	✓
New Developments in Barrier Systems & Robotics	✓	✓
PUPSIT: Complying with the Main Annex 1 Changes	✓	✓
GMP for Pre-Filled Syringes (PFS)	✓	✓
Pharma 4.0 & Digitalisation	✓	✓
Handling of Highly Active Products	✓	✓
ATMP – Manufacturing, Quality & Safety	✓	✓
PharmaTechnica Expo	✓	✓

Find out more about the other conference tracks on our website www.pharma-congress.com.

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

ATMP – Manufacturing, Quality and Safety - Part of PharmaCongress 2023,
28/29 March 2023, Wiesbaden, Germany

☐ **Day 1 & 2 (28/29 March 2023)**
☐ **Day 1 (28 March 2023)**
☐ **Day 2 (29 March 2023)**

☐ **Yes, I would also like to take part in the Social Event on the evening of 28 March 2023.**

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 %.

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 HEIDELBERGwill 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 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 Conference
Tuesday, 28 March 2023, 09.00 - 18.00 h
Wednesday, 29 March 2023, 09.00 - 17.00 h
Registration: 28/29 March 2023, 08.00 - 09.00 h

Venue
RheinMain CongressCenter (rmcc)
Friedrich-Ebert-Allee 1
65189 Wiesbaden
Phone: +49 (0) 611 / 1729-444
veranstaltungsservice-rmcc@wicm.de

Fees (per delegate, plus VAT)
The one day ticket is available for € 690,- plus VAT (until 31 January 2023 only € 590,- plus VAT), both days for € 1,380 plus VAT (until 31 January 2023 only € 1,180 plus VAT). It includes participation in any conference track of PharmaCongress 2023 on that day(s) and the visit of the PharmaTechnica Expo. In addition, lunch and beverages during the tracks and in breaks as well as the social event on the evening of the first congress day, 28 March is included; please mark if you would like to attend the Social Event.

The fee is payable in advance after receipt of invoice.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms close to the CongressCenter. You will receive a room reservation form when you have registered for the conference. Reservation should be made directly with the hotel. Early reservation is recommended.

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 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.
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:
Axel H Schroeder (Operations Director) at
+49 (0) 62 21 / 84 44 10, or at
schroeder@concept-heidelberg.de

For questions regarding organisation please contact:
Mr Ronny Strohwald (Organisation Manager) at
+49 (0) 62 21 / 84 44 51, or at
strohwald@concept-heidelberg.de