ATMPs – Hurdles & Achievements in Quality and Safety

Part of PharmaCongress 2024

19/20 March 2024
Wiesbaden, Germany

Highlights

- Quality and Regulatory Strategies
- New Isolator Technology
- Viral Vectors and LNPs for ATMP
- Contamination Control Strategies (CCS)
- Viral Clearance
- Definition of CQA

Speakers

Yogesh K. Davé | Cypress Quality Consultancy, UK

Dr Sabine Hauck | Leukocare, Germany

Dr Juliane Heilig | CMT Cellex Manufacturing Transports and Logistics, Germany

Dr Ulrike Herbrand | Charles River Laboratories, Germany

Christian Klinger | Roche, Germany

Sandra Meier | Charles River Laboratories, Germany

Dr Veronika Nindl | VTU Engineering, Austria

Dr Nicole Paland | Minerva Biolabs, Germany

Marsha Steed | Resilience, USA

Erik Steffensen | Spot-on Pharma Consulting, Denmark

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

Dr Gülbengü Yüksel | Tigen, Switzerland

Only until 31 December 2023: Save up to € 200 Early Bird Discount

GMP-PHARMA CONGRESS

This conference is part of PharmaCongress 2024

ECA Academy
Your GMP/GDP Information Source

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

PROGRAMME 19 March 2024

Quality and Regulatory Strategies for the successfull Registration of an ATMP

Yogesh K. Davé, *Cypress Quality Consultancy*

- Understanding of Cell and Gene Therapy Products
- Autologous vs. Allogenic
- Is CAR-T the same as stem cell transplant?
- Pros and Cons of each therapy

Challenges in the Bench-to-Bedside Translation of Gene and Cell Therapeutics (GCT)

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

- GCTs continue to emerge into personalized first line treatments especially in oncology and immunology
- Major challenges in clinical and commercial manufacturing remain to be solved
- Multidisciplinary collaboration will be crucial to assure the bench-to-bedside translation of innovative GCTs

Distributed Manufacturing for T-Cell Therapies

Dr Gülbengü Yüksel, *Tigen*

- Difficulties with centralized production
- Development of distributed manufacturing for clinical and commercial supply
- Regulatory hurdles with distributed manufacturing

Biopharma Use Cases applying Process Analytical Technology (PAT)

Dr Veronika Nindl, *VTU Engineering*

- Implementation of biomass sensors for an accurate in-line analyses and an on time process control
- Establishment of DLS as an in-line impurity check to increase the clearance of hcDNA and HCPs prior protein A chromatography and thereby enhance purification
- Total protein determination of an inhomogeneous precipitation flow through for and automated protein concentration adjustment

Design Considerations for allogeneic Cell Therapies

Erik Steffensen, *Spot-on Pharma Consulting*

- How does a typical allogeneic manufacturing process look?
- What is critical to control during manufacturing of allogenic cell therapies?
- Considerations regarding upscaling and process transfer

Challenges in allogeneic CAR-T Manufacturing using Viral Vectors and LNPs

Dr Juliane Heilig, *CMT Cellex Manufacturing Transports and Logistics*

- Comparison of autologous & allogeneic concept
- Viral vector transduction & LNP knock out rates
- Challenges in manufacturing and product characterization
- Storage of off the shelf products

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
- 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

PROGRAMME 20 March 2024

Contamination Control Strategy (CCS) for ATMPs

Marsha Steed, *Resilience*

- Developing a CCS for ATMP manufacturing products & processes
- Microbial contamination risks and challenges for cell therapy products
- Human intervention risk relation to environmental monitoring program design
- Design of Aseptic Processing Simulation (APS) for cell therapy products

Viral Clearance ATMPs – What if the Product is a Virus?

Sandra Meier, *Charles River Laboratories*

- Challenges for viral clearance strategies during downstream manufacturing
- What are the possible problems and limitations?
- Potential virus safety strategies

Effective Cell Culture Operations by accurate, non-invasive Determination of the critical Process Parameter pH in Roche`s Drug Substance Network

Christian Klinger, *Roche*

- Opportunity statement: Limitations of current industry standard
- Proposed technical solution
- Manufacturability and Implementation in commercial manufacturing
- Results and value proposition

Digital PCR for In-Process Control and Lot Release Testing of Gene Therapy Applications

Dr. Nicole Paland, *Minerva Biolabs*

- Determination of vector copy number (VCN) in CAR T-cells for cancer therapy by duplex dPCR
- Standard for accurate calculation of the VCN
- Determination of the titer of adeno-associated viral (AAV) vectors for In-process control and lot release testing
- Parallel detection of residual DNA by duplex dPCR

Definition of CQA – What and When – and is PAT an Option?

Dr Sabine Hauck, *Leukocare*
Dr Ulrike Herbrand, *Charles River Laboratories*
Chairs of ECA's ATMP Interest Group

- How to define CQAs for ATMPs?
- Best time to validate the assays
- The challenge of Bioassay development

SPEAKERS

Yogesh K. Davé
Cypress Quality Consultancy Ltd, UK
A dedicated quality professional and registered EU Qualified Person under the permanent provisions. Extensive experience (more than 30 years) of working in the biopharmaceutical and allied industries, primarily in the Good Clinical Practice (GCP), the Good Manufacturing (GMP), and the Good Distribution Practice (GDP) regulated areas of these industries.

Dr Sabine Hauck
Leukocare AG, Germany
Sabine Hauck is Executive Vice President Corporate Development at Munich-based biotech company Leukocare AG. She 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. In the current position, Sabine is responsible for digitalization activities at Leukocare AG as well as for Business Process Management and Quality Management.

Dr Juliane Heilig
CMT Cellex Manufacturing Transports and Logistics GmbH, Germany
Pharmacist, engaged in cell therapy science since 10 years, since three years CAR T specialist at CMT.

Dr Ulrike Herbrand
Charles River Laboratories, Germany
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). She is an expert in mechanism of action-reflecting bioassays for protein therapeutics as well as for advanced therapy medicinal products.

Christian Klinger
Roche, Germany
Christian Klinger studied biotechnology and chemistry. After over 17 years of professional experience at Roche in the field of cell culture development and manufacturing, he is currently focussed on technology development and deployment in Roche`s Drug Substance network as a Senior Expert for Process Science within the Manufacturing Science and Technology Organisation.

Sandra Meier
Charles River Laboratories, Germany
Sandra joined Charles River, Germany in March 2017. Overseeing more than 50 viral clearance studies as a Study Director she has profound knowledge of viral clearance study design, planning and regulatory requirements. Before joining Charles River Sandra completed her master's degree in Microbiology at the University of Bonn where she researched on bat-borne viruses during her master thesis.

Dr Veronika Nindl
VTU Engineering GmbH, Austria
Veronika Nindl holds a Dr.sc. in Immunology from the ETH Zurich (Switzerland), has 3 years of postdoctoral experience in different areas of immunology and molecular biology (basic research) and more than eight years of experience in pharmaceutical and biotech industries. During her career in pharmaceutical industry she gained profound knowledge in the late stages of process development and in the transition to commercial manufacturing, especially in the drug substance field. Her knowledge in the biotech field is covering drug substance development of Biosimilars, process characterization and process validation, technology transfers, registration and dossier preparations, cell culture cultivation systems and online probes, qualification and validation of devices and systems, implementations of standards and SOPs and quality and project management.

Dr Nicole Paland
Minerva Biolabs GmbH, Germany
After dissertation at the Max Planck Institute for Infection biology in Berlin, Postdoc at the Weizmann Institute of Science and the Technion in Israel with focus on researching the influence of immunological messengers on the initiation and progression of certain diseases. Since 2021 at the Minerva Biolabs in Berlin in the department product development, first as a project manager and since September 2022 as the Head of Product Development. Focus is the development of kits for the detection of microbial contaminations in pharmacological products.

Marsha Steed
Resilience, USA
Marsha Steed studied Biology and now has more than 30 years of experience as a microbiologist in the pharmaceutical, biotechnology and medical device sectors. Marsha Steed is the Director of Corporate Microbial Control & Sterility Assurance at Resilience. She is also a member of the USP Microbiology Expert Committee and Chair of the USP Microbial Control and Sterility Assurance Subcommittee.

Erik Steffensen
Spot-on Pharma Consulting, Denmark
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, 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.

Prof Dr Sven Stegemann
DWI – Leibniz-Institut für Interaktive Materialien e.V. , Germany
Sven Stegemann is a pharmacyst by education and has a PhD in pharmacology. He has a 30year 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).

Dr Gülbengü Yüksel
Tigen, Switzerland
Gülbengü Kuzgun Yüksel is Head of Quality of Tigen. With a background in small molecules, biologics, and cell & gene therapy manufacturing and quality procedures, she has more than 20 years of experience as an operations and quality professional. Prior to joining Tigen Pharma, she was instrumental in constructing state-of-the-art manufacturing facilities and developing thriving businesses across various organisations. Her experience also includes managing cross-functional teams, implementing innovative strategies, and effectively collaborating with international health authorities to ensure compliance with global regulations.

The guiding theme of the GMP PharmaCongress 2024 on 19/20 March will be „users sharing challenges and solutions in practice". Therefore, benefit from your colleagues' experience and from the direct information exchange at the GMP PharmaCongress & GMP PharmaTechnica 2024.

The Conference Tracks

As a participant you can switch between any of the **11 conference tracks** any time and also visit the PharmaTechnica Expo with more than 110 international exhibitors.

The GMP PharmaCongress Conference Tracks	19 March 2024	20 March 2024
Non-Sterile Products – Challenges in Manufacturing & Quality	✓	n.a.
GMP – Green or Good Manufacturing Practice?	✓	n.a.
Packaging/Packaging Materials – Challenges & Solutions	n.a.	✓
European Aseptic Conference – Technology	✓	✓
Trends in Barrier Systems & Robotics	✓	✓
Modern Cleanroom Technology	✓	✓
Digitalisation & Artificial Intelligence	✓	✓
GMP for Pre-Filled Syringes (PFS)	✓	✓
Lyophilization – Modern Techniques & New Requirements	✓	✓
ATMPs – Hurdles & Achievements in Quality and Safety	✓	✓
Vaccines – Advantages & Challenges in Manufacturing	✓	✓
GMP PharmaTechnica Expo	✓	✓

Keynote on 19 March 2024

The CEPI Project – 40 Countries – 1 Billion Euros for Vaccines

Dr Guido Dietrich, *CEPI*

Do you know the worldwide importance of CEPI? And why is this so important for everyone working in pharmaceutical production?
Our first keynote will address a very important new development. More than 40 countries, several non-governmental organizations and the European Commission are involved in the **Coalition for Epidemic Preparedness Innovations (CEPI)**.

What is the goal?
The goal of CEPI is to develop, produce and distribute a vaccine as quickly as possible in the event of the next global pandemic, i.e. within 100 days.

What is the current budget?
For the first 5 years alone, a budget of one billion euros has been made available.

In the Live Demo Area in the PharmaTechnica Expo hall you will benefit from the exhibitors' demonstrations – presenting their latest technology, products and services. Take advantage of these live performances – and get to feel and experience their products. For a list of all companies exhibiting at PharmaTechnica, please see the exhibitor list and plan on the website at **www.pharma-congress.com**.

Exhibitor	Stand	Live Demo
boTec	A 7	TBN
MKVersuchsanlagen	A 12	TBN
Ellab	A 16	TBN
Bausch & Ströbel	A 33	OMNIA - Boost your processes and step closer to your pharmaceutical plant of the future.
PHARMAPLAN	A 37	Accelerated Design Decisions enabled by Digital Twins
Quascenta Pte	B 6	Using an Intelligent Lifecycle-Based Solution for Streamlined Product Tracking, Design Optimization, Collaboration, and Reporting
ZETA	B 12	TBN
IWT / Tecniplast	B 15	High pressure cleaning in pharmaceutical production. Advantages, challenges, sustainability and savings
MBV	B 20	TBN
Emerson Automation Solutions	B 22	TBN
Atec Steritec	B 28	Safe & Sterile Transfer with Minimal Operator Intervention
REA Elektronik	B 29	Experts in Printing and Code Verification of pharmaceutical and medical-device packaging (f.e.UDI/MDR)
Friedrich Sailer	B 31	Shining Solutions: Live Demo of Cutting-Edge Stainless Stell Cleanroom Equipment
Merck	B 32	Annex 1's "Specific Risks Associated with Single-Use Systems"
Particle Measuring Systems	C 7	Facility Monitoring Systems
Yokogawa	C 9	Flow Imaging using FlowCam for High Performance Products to warrant constant excellent Quality

Easy Registration

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg

Registration Form:
(06221) 84 44 34

E-Mail:
info@concept-heidelberg.de

Internet:
www.pharma-congress.com

Congress Dates

Tuesday, 19 March 2024, 09.00 - 18.00 h
Wednesday 20 March 2024, 09.00 - 17.00 h
Registration
Tuesday & Wednesday, 19/20 March 2024, 08.00 - 09.00 h

Fees

Only until 31 December 2023: Save up to € 200 Early Bird Discount

The one day ticket is available for € 690,- plus VAT, both days for € 1,380.- plus VAT. It includes participation in any track on that day 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, 19 March is included; please mark if you would like to attend the Social Event. The fee is payable in advance after receipt of invoice.

Venue

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

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.
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

ATMPs – Hurdles & Achievements in Quality and Safety

Part of PharmaCongress 2024

19/20 March 2024, Wiesbaden, Germany

☐ Day 1 & 2 (19/20 March 2024)
☐ Day 1 (19 March 2024)
☐ Day 2 (20 March 2024)

☐ Yes, I would also like to take part in the Social Event on the evening of 19 March 2024.

☐ Mr ☐ Ms ☐ Mx ☐ Dr

First name, Surname

Company

Department

Important: Please indicate your company's VAT ID Number | P.O. Number (if applicable)

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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.
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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.

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