ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers


Dr Johannes Blümel
Paul-Ehrlich-Institut


Dr Sven M. Deutschmann
Roche


Dr Oleg Krut
Paul-Ehrlich-Institut


Dr Solène Le Maux
EDQM


Dr Roland Pach
Roche


Joseph Pierquin
Redberry


Dr David Roesti
Novartis


Dr Michael Ruffing
Boehringer Ingelheim


Laura Sands
Lonza


Dr Friedrich von Wintzingerode
Roche/Genetech

Microbiological Control of Cell- and Gene-Based Products/ATMPs

A Part of the European Microbiology Conference 2022

Live Online Training on 03 May 2022

Highlights

- Current Pharmacopoeial Thinking
- Bacterial Safety Aspects
- Viral Safety Aspects
- Strategy for a mRNA Product
- Alternative Sterility Testing
- Strategy for Gene Therapy Products

Complete Conference (03-05 May 2022) 3 Tracks: Control of Cell- and Gene-Based Products/ATMP, Trend in Endotoxin and Pyrogen Testing, Robotic Isolators

Objectives

The number of cell-, tissue- or gene-based advanced therapy medicinal products (ATMPs) in research, development and production is steadily increasing. Due to the very different characteristics of the biological materials, the often small batches, the limited shelf life or the bio-safety requirements of the manufacturing environment, conventional control methods can often only be used to a limited extent. Alternative approaches for microbiological control, independent whether we are talking about sterility testing, endotoxin detection or others, are often necessary for such products.

The following conference will provide insight into how pharmacopoeias deal with this, the experiences and expectations of regulatory authorities and how microbiological control and testing strategies and methods are implemented in industry and laboratories. During the Q&A-session you will also have the opportunity to ask the speakers your individual questions.

Background

In the current era, where conferences and seminars are mainly held online and virtually, new approaches and structures are needed to offer participants optimal value and expert input. Therefore, the ECA Academy has decided to offer the European Microbiology Conference 2022, which has been an integral part of the European conference landscape since 2008, in a special topic-focused format. During 2.5 days, 3 topics will be offered, which can be booked individually or in combination.

Target Audience

This track provides information for all industry, authority or laboratory personnel involved in the microbiological control of cell and tissue products or gene therapeutics.

Moderators

Dr Sven M. Deutschmann
Roche, Chair of the ECA Pharmaceutical Microbiology Working Group

Axel Schroeder
Concept Heidelberg

Programme

Welcome and and Organisationals
Axel H. Schroeder

Introduction - Overview ATMP's -MTS / MTO-Products
Dr Sven M. Deutschmann, Roche

- ATMP Product Classes impacting the microbial control concept
- Shelf-life of the different products classes
- Volumes of products available for testing purposes

E2E perspective to the identification of pre-cQAs of GT products
Dr Roland Pach, Roche

- QbD approach and cQA identification in Biologis
- Challenges of GT based therapeutics
- A potential path for the identification of pre-cQAs of GT products
- Snapshot of current microbial control strategy & its needs for innovative solution

European Pharamcopoeia Perspective
Dr Solène Le Maux, EDQM, Council of Europe

- Presentation of the microbiological testing approaches for cell and tissue-based preparations available in the Ph. Eur.
- Focus on the new general chapter Microbiological examination of human tissues (2.6.39.)
- Update on the activities of the Ph. Eur. in the ATMP field

Introduction to the new USP chapter on microbial control strategies for cell and gene therapy products
Dr David Rösti, Novartis

- General outline of the chapter will be presented
- Risk considerations and categories
- Considerations for manufacturing facilities, operations and materials

Bacterial Safety of ATMP
Dr Oleg Krut, Paul-Ehrlich-Institut

An Alternative Sterility Testing Approach
Joseph Pierquin, RedBerry

- Autogene cevumeran introduction
- Turnaround Time (TAT) requirements
- The autogene cevumeran microbial control strategy
- Conclusion

Viral safety concepts for ATMPs
Dr Johannes Blümel, Paul-Ehrlich-Institut

- Control of raw materials
- Testing of cell cultures
- Viral vectors

Contamination Control of Therapeutic Virus Production
Dr Michael Ruffing, Boehringer Ingelheim

- Safety strategy elements
- Control of adventitious agents throughout the manufacturing process
- Testing strategy for raw and starting materials, intermediates and DS/DP

Microbial control strategy for autogene cevumeran a cell-free, individualized, mRNA based ATMP
Dr Friedrich von Wintzingerode, Genentech

- Autogene cevumeran introduction
- Turnaround Time (TAT) requirements
- The autogene cevumeran microbial control strategy
- Conclusion

Aseptic Process Validation in the Cocoon® Platform
Laura Sands, Lonza

- Strict adherence to aseptic processing guidelines is essential for ATMPs, such as cellular products or large viral vectors, that are unable to be terminally sterilized. Conducting Aseptic Process Validation for traditional ATMP manufacturing processes is complex due to the high number of manual manipulations and overall process complexity.
- Improvements in process robustness, efficiency, and contamination control can be realized by utilizing closed, automated, cell therapy manufacturing systems such as the Cocoon® Platform.
- The use of closed, automated manufacturing technologies is gaining traction and recognition by industry and regulatory agencies.
- Lonza will share data from in-house Aseptic Process Validation studies that demonstrate the ability of such systems to effectively produce sterile product and streamline Aseptic Process Validation.

Speakers

Dr Johannes Blümel
Paul-Ehrlich-Institut

Dr. Johannes Blümel is leading the virus safety section at the Paul-Ehrlich-Institut, Langen. He is dealing with assessment of virus safety and TSE safety of blood products and recombinant DNA products such as monoclonal antibodies for clinical trials and marketing authorization. He participates as expert in EMA-Biologics Working Party (BWP) and EDQM TSE-certification procedure. Further, he is working in several research projects on virus inactivation and virus removal. Prior to joining the Paul-Ehrlich-Institut in 1998, Dr. Blümel worked at the University Hospital, University of Bonn (1993-1998) He performed basic research on virus replication and received a five years training in medical virology and virus diagnostics. Dr Blümel completed his Diploma Study in Biology (molecular genetics, microbiology, biophysics and physical chemistry) in 1991 at the University of Freiburg, Germany. He received his Ph. D. degree at the Department of Virology, University of Freiburg, Germany (1993). In 2010 he received teaching graduation (Habilitation) in Medical Virology from the University Frankfurt.

Dr Sven Deutschmann
Roche

Head of Global ASAT Adventitious Agents Testing & Alternative Microbiological Methods, Global Analytical Science & Technology. Sven M. Deutschmann studied biology at the University of Brunswick. In 1995 he joined Roche Diagnostics GmbH. Currently, Sven Deutschmann is Head of Global ASAT Adventitious Agents Testing & Alternative Microbiological Methods, Global Analytical Science & Technology. Besides his local and global responsibilities he is a member of several microbiological expert groups, ,e.g at the German Pharmacopeia Commission, in the Working Parties “Bacterial Endotoxins”, and Expert Group 1 “Biological Methods and Statistical Analysis” of the European Pharmacopeia Commissions. In addition, he is chairman of the Advisory Board of the ECA “Pharmaceutical Microbiology Working Group”.

Dr Oleg Krut
Paul-Ehrlich-Institut

In March 2017, Dr. Oleg Krut became head of the “Microbiological Safety” section in the Microbiology division. The main focus of his work is on developing concepts for ensuring the microbiological safety of biomedicines. In his research projects, Oleg Krut develops and establishes novel methods for detecting microorganisms in blood components, as well as cell and gene therapies. With a doctorate in medicine, he previously worked as a researcher at the Institute for Medical Microbiology, Immunology & Hygiene of the University Hospital of Cologne.

Dr Solène Le Maux
EDQM

Solène holds a PhD in biochemistry from the Institut Agro Rennes, France, which was conducted in association with the Teagasc Research Centre, Ireland. Following post-doctoral research and research officer positions in a consortium of industrial research for functional food and health in-

novation, she joined the pharmaceutical industry as an analytical expert. Here she was principally responsible for the life cycle management of analytical methods. In 2020, she joined the EDQM as a Scientific Programme Manager in the European Pharmacopoeia Department, with responsibilities for a number of Expert Groups including Cell Therapy Products and Gene Therapy Products Working Parties.

Dr Roland Pach
Roche

Dr Roland Pach holds a PhD in molecular parasitology at the University Fribourg analysing the intracellular trafficking of transgenic RNA in human pathogens. Prior Roche, he was leading the Analytical Development department at Berna Biotech (former Swiss Vaccine and Serum Institute) 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, industrialconsortiums like CGT BioPhorum andnumerous due diligences of in-licensingcandidates or companies in the CGT fields. In his second role at Roche as globaltechnical development leader, he had led successfully new formats like immunotoxinsfrom pre-clinics into entry to human (EiH).

Joseph Pierquin
Redberry

Joseph Pierquin started his career as an R&D engineer before joining Air Liquide in 2004 where he served as R&D program director, in charge of the group project portfolio in process control and instrumentation. He joined Merck Millipore in 2008 where he led the product development activities (Quantum, Milliflex Rapid for Sterility Testing) of the Biomonitoring Business Unit. In 2012, he founded Advencis, a company which developed an innovative growth-based method in rapid microbiology (acquired by bioMérieux in 2014). In 2017, he co-founded Redberry which commercializes a new generation of solid-phase cytometry technology providing very fast and quantitative results in a fully automated way. Joseph is a former student of Ecole Normale Supérieure in Cachan and holds a PhD from the University of Lille, France.

Dr David Roesti
Novartis

Dr. David Roesti holds a PhD in microbial ecology from the University of Neuchâtel, Switzerland and has 20 years of experience in the field of microbiology within various domains (drug product manufacturing, food microbiology, biogas production, microbial interactions in the rhizosphere). Currently he works at Novartis Pharma AG in Stein Switzerland in the Manufacturing Science & Technology department and is responsible to define the microbial control strategy at the asite and is a global subject matter expert in microbiology for the Novartis group. Prior to this assignment, he led the Rapid Microbiological Methods team at Novartis Pharma AG and was the laboratory supervisor for the microbiological testing of non-sterile drug products at Novartis Pharma Stein AG. Dr. Roesti is an elected member of the General Chapters Microbiology Expert Committee of the United

States Pharmacopoeia 2020-2025 revision cycle and is a member of the advisory board of the European Compliance Academy Microbiology Group. Finally, Dr. Roesti is main author or co-author of many different publications in either peer-reviewed journals or book chapters and has regularly held presentations in scientific congresses or expert groups.

Dr Michael Ruffing
Boehringer Ingelheim

Michael is a biologist and was trained as a post-doc in virology at the German Cancer Research Centre Heidelberg and at Hoffmann-La Roche prior to working for regulatory authorities in Switzerland and Germany. He then joined the devision Biopharmaceuticals of Boehringer Ingelheim in Biberach. After heading of the group Virology & Contamination Detection, Michael is now in the Analytical Development Biologicals Department of BI`s Innovation Unit responsible for adventitious agents topics of Biologicals including Virus Therapeutics.

Laura Sands
Lonza

Laura Sands is the Head of Regulatory Affairs for Lonza's Personalized Medicine business unit. She has over 20 years of experience in Quality and Regulatory within the Biotech industry, including 10 years supporting manufacture of Cell and Gene Therapy products. Laura has a degree in Biochemistry and Molecular Biology from the University of Maryland, Baltimore County and a Masters in Biotechnology from Johns Hopkins University.

Dr Friedrich von Wintzingerode
Roche/Genetech

Friedrich joined Roche-Genentech after earning his PhD in Microbiology and has over 20 years of experience in Quality Control and Quality Assurance in the biopharmaceutical industry, working on various topics including microbiological testing, material specifications, environmental monitoring, cleaning analytics, and analytics for release. Friedrich has led several global technical teams (e.g. microbial identification, microbiological testing, endotoxin testing, and Low Endotoxin Recovery/LER) at Roche-Genentech. He co-chaired the PDA Low Endotoxin Recovery Task Force, which authored PDA Technical Report No 82 on LER. He is also a member of the PDA ATMP advisory board.

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)

European Microbiology Conference, Live Online Conference on 03-05 May 2022

- ☐ **Day 1 (03 May 2022): Microbiological Control of Cell- and Gene-Based Products/ATMPs**
- ☐ **Day 2 (04 May 2022): Endotoxin and Pyrogen Testing – Current Trends**
- ☐ **Day 3 (05 May 2022, Half Day): Robotic Isolators – Challenges and Modern Monitoring Systems**

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week 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 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, 03 May 2022, 09.00 h - 17.30 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

1 Day Ticket
ECA Members EUR 890.- | APIC Members EUR 940.-
Non-ECA Members EUR 990.- | EU GMP Inspectorates EUR 495.-

2 Day Ticket
ECA Members EUR 1590.- | APIC Members EUR 1690.-
Non-ECA Members EUR 1790.- | EU GMP Inspectorates EUR 895.-

Half Day Ticket (Day 3)
ECA Members EUR 640.- | APIC Members EUR 665.-
Non-ECA Members EUR 690.- | EU GMP Inspectorates EUR 345.-

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.

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 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:
Ms Nicole Bach (Organisation Manager) at
+49(0)62 21/84 44 22, or at
bach@concept-heidelberg.de