

Speakers



Dr Hans-Georg Eckert
Valicare



Dr Anette Jork
BioNTech



Dr Ilona Kalaszczyńska
Medical University of
Warsaw



Dr Thomas Meindl
Labor LS



Dr Christoph Peter
BioNTech



Dr Christoph Prinz
Apceth



Dr Christianne Reijnders
The Dutch Health and
Youth Care Inspectorate



Dr Ralf Sanzenbacher
PEI, German Federal
Agency for Vaccines and
Biomedicines



Mag. Gabriela
Schallmeiner
Inspection Ready



Prof. Michael Schmitt
University Hospital
Heidelberg



Dr Jan Schrooten
Antleron



Dr Astrid Schwantes
PEI, German Federal
Agency for Vaccines and
Biomedicines

Quality, Safety and GMP for Advanced Therapy Medicinal Products (ATMPs)

10/11 November 2020 | Neuss/Düsseldorf, Germany



Regulatory Requirements and Practical Implementation

Highlights

- European and US Guidelines and Regulatory Requirements and Inspections
- Quality and Manufacturing of CAR-T-Cells
- GMP Implementation in University and Industry – Large Scale and Small Scale
- How to Handle Out-of-Specification Batches
- Microbiological Safety and Testing
- Approaches for Small Batches and Optimising Manufacturing

Regulatory, Academic and
Industrial Challenges

Objective

This workshop provides a comprehensive overview of the current regulatory requirements for the development, manufacture and approval of Advanced Therapy Medicinal Products (ATMP). Representatives of regulatory authorities, experts from small-scale and large-scale production, QC laboratories and consultants will report on their practical experiences. From the construction of a new production facility to the introduction of a quality system and the final sterility test, all relevant topics directly related to ATMPs will be covered.

Background

Modern systems of regenerative medicines, especially ATMPs (gene therapeutics, somatic cell-based products and tissue-based products) represent an innovative group of drugs that is becoming increasingly important. With the introduction of several regulatory guidelines e.g. of the European Directive EC 1394/2007 for ATMP, 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 companies. These university or medical origins result in 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 underlined by commonly occurring operating 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.

This results in a whole range of extraordinary requirements:

- the consideration of later requirements during development and in clinical phases
- the implementation of quality assurance requirements during aseptic production
- the use of alternative methods for analysis and microbiological control and the demonstration of comparability with conventional methods
- the handling of out of specification (OOS) / and out of limit (OOL) results during product testing and the possibility of batch release

Target Audience

This seminar is aimed at all persons who

- Are involved in basic or translational research on cell-based therapy concepts with the perspective of clinical application
- Are involved in the extraction and manufacture of cells, tissues and ATMPs
- Are responsible for quality assurance and control of cells, tissues and ATMPs
- Are responsible for microbiological or analytical testing
- Perform inspections or audits of ATMP facilities
- Are responsible for GMP requirements during pre-approval phases
- Deal with authorisation

Programme

Regulatory Development

- New and revised guidelines
- Other relevant documents
- Current experiences and expectations

Challenges for Cell-Based Medicinal Products

- How to increase stability of cell-based medicinal products
- Can growth medium influence properties of cell-based medicinal product

Risk-based Approach and Evaluation is the Leading Tool towards Manufacturing Authorization for iATMPs

- European GMP guideline Part IV: GMP for ATMPs
- Gaining flexibility by professional risk reduction
- Time to manufacturing authorization

Cell by Design®, a Quality-Focused Process Development Roadmap for ATMPs

- Software for risk-based ATMP process development and data driven decision making
- Quality by design principles coupled to ATMP legislations, standards and guidelines
- Master quality, manufacturability and scalability of ATMP product and process
- Enable QC cost-effectiveness by parametric release

A Case Study - Optimizing Manufacturing

- Patient individualized cancer treatment using targeted RNAs
- The challenges of patient individualized medicines
- The challenge of small batches in combination with large batch numbers
- How to establish high throughput manufacturing - dos and don'ts

In-house Production of CAR-T Cells

ATMP Challenges for a QP

- A glimpse on the legal framework
- The complexity
- ATMP specific challenges
- What you should know about working with a QP

ATMP GMP Inspection Experiences

- Findings
- Pitfalls
- Hospital exemption

Strategies for Validating Nucleic Acid-based Techniques for Testing for the Absence of Mycoplasma

- NAT Techniques
- Strategies for validation/suitability tests
- Pitfalls and practical examples

Virus Safety Concepts for ATMPs

- Safety of raw and starting materials
- Serum and serum replacement(s) for cell-based products
- Testing methodologies (NGS)
- Virus inactivation and removal

Process Optimization for Individualized ATMPs - a Modern Approach

- Aseptic filling for small batches
- Hygiene monitoring in closed Isolators required?
- Regulatory challenges

Treating Patients with OOS Batches - when Physicians Request Non-Conforming ATMPs

- Regulatory framework
- Perspective and expectations from patients, physicians, sponsors, manufacturers, QPs, authorities - EU vs. US
- Batch control, review and release process

Moderator

Dr Andrea Hauser, Vice Chair ECA ATMP Interest Group, University Hospital Regensburg

Speakers

Dr Hans-Georg Eckert, Valicare GmbH, Germany

Dr Eckert is biologist by education and has more than 20 years of professional experience in accompanying and managing compliance tasks. After positions as Project Manager and Head of Quality, he has led Valicare since 2016 as Site Manager with special focus on ATP-GMP projects.

Dr Anette Jork, BioNTech, Germany

Dr Jork works as a Qualified Person for BioNTech since 2018. From 2001 to 2017 she worked for BTG International GmbH/CellMed AG in different functions e.g. Head of QC, QP and Director of Quality. She gained additional international experience in QM as part of her secondments from 2014 to 2017 in the UK and the US.

Dr Ilona Kalaszczyńska, Medical University of Warsaw

Ilona Kalaszczyńska is a graduate of the Faculty of Biology at the University of Warsaw. Since 2010, she is an associate professor at the Medical University of Warsaw. Since 2014, participated in or directed the process of accreditation of several cell/tissue banks - cord blood, bone allografts, and stem cell-based ATMPs. In 2016 she became a Quality Control Manager at the Laboratory for Cell Research and Application of the Medical University of Warsaw.

Dr Thomas Meindl, Labor LS, Germany

Dr Meindl has been head of the Labor L+S AG division since 2005. From 2003 to 2005 he worked in oncological research at SKM Oncology GmbH. Prior to that, Dr Meindl was project manager at Sympore where he was responsible for the development of new and modified drugs.

Dr Christoph Peter, BioNTech, Germany

Dr. Peter studied at the University of Heidelberg and gained his PhD at the Max-Planck Institute for Medical Research. After a postdoc fellowship at Stanford University, he joined Apceth, a CMO for cell based ATMPs in 2008 as Head of Production. 2011 he became Deputy QP and later Head of Quality Assurance. 2016 he came to BioNTech as Head of Quality and Deputy Qualified Person.

Dr Christoph Prinz, Apceth, Germany

Dr Prinz is pharmacist and joined Novartis as Critical Deviation Investigator in 2011 before he changed to apceth Biopharma. Parallel to his work in the pharmaceutical development of new stem-cell based ATMPs, he increasingly took over responsibility in Quality Management. In 2018, he became Head of Quality Management and Qualified Person responsible for investigational and commercial ATMPs.

Dr Christianne Reijnders, The Dutch Health and Youth Care Inspectorate

Christianne studied at the University of Utrecht Medical Biology and gained her PhD at the VU University Medical Centre (The Netherlands). Following she worked at the Leids University Medical Centre and at A-Skin Nederland B.V. In 2017 she became Senior Inspector at the Dutch Health and Youth Care Inspectorate (Netherlands) for GMP inspections.

Dr Ralf Sanzenbacher, Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines

Dr Sanzenbacher works at the Section of Somatic Cell Therapy and Tissue Engineering at the Paul-Ehrlich-Institut. He is an expert for regulatory aspects, as well as quality and preclinical issues aspects within the scope of manufacturing license, clinical trials and marketing authorisation. He is also member of several expert panels on cell therapies.

Mag. Gabriela Schallmeiner, INSPECTION-READY Consulting, Austria

Gabriela is a Founding Member and the Deputy Chair of the Austrian Qualified Person Association (www.austria-qp.at). Since 2007 she is running her own GxP Consultancy Services Company. She works as a QP in Austria and in Germany for ATMPs, vaccines and immunological products.

Prof Dr Michael Schmitt, University Clinic and University of Heidelberg, Germany

Michael Schmitt obtained his MD from the University of the Saarland, Homburg, Germany. He is currently Siebeneicher-Endowment Professor of Cellular Immunotherapy and Head of the Good Manufacturing Practice (GMP) Facility at the University Clinic Heidelberg, Germany.

Dr.ir. Jan Schrooten, Antleron, Belgium

Antleron is a young R&D company on a mission to enable personalized manufacturing 4.0 in the domain of advanced therapies. Previously Jan Schrooten was senior research manager at KU Leuven (Belgium), responsible for the long-term management and technology transfer of biomaterials and tissue engineering research.

Dr Astrid Schwantes, Paul Ehrlich Institut, German Federal Agency for Vaccines and Biomedicines

Astrid Schwantes studied Biology at the University Mainz. 2003 she joined the Division of Virology at the Paul-Ehrlich Institut. Since 2013 she is regulatory assessor at the section virus safety at the PEI.

Reservation Form (Please complete in full)

Quality, Safety and GMP for Advanced Therapy Medicinal Products (ATMPs) 10/11 November, Neuss/Düsseldorf, Germany

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)

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

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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 2 weeks prior to the conference 10 %
 - Cancellation until 1 week prior to the conference 50 %
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- Important: This is a binding registration and above fees are due in case of cancellation.

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- 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.

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In the evening of the first course day, 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.

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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Date

Tuesday, 10 November 2020, 09.00 – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Wednesday 11 November 2020, 08.30 – 17.30 h

Venue

Crowne Plaza Düsseldorf / Neuss
Rheinallee 1
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Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
Academic Scientists/ Students € 895

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. 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.

Social Event