ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Rüdiger Alt
Novartis

Dr Hans-Georg Eckert
Valicare

Dr Elena Ferber
Labor LS

Dr Jessica Horbelt
Fraunhofer Institute for Manufacturing, Engineering and Automation

Dr Anette Jork
BioNTech

Dr Christoph Peter
BioNTech

Dr Christoph Prinz
BioNTech

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)

Live Online Conference on 10/11 November 2020

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

Programme

Objective

This Live Online Conference 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 Live Online Conference 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 Day 1

Provisional timetable, the actual schedule may vary depending on the situation.

09.00 - 09.15 h Welcome and Organisationals

09.15 – 10.15 h
Regulatory Developments

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

10.15 – 11.15 h
Development of an adaptable, modular strategy for quality control of cell-based therapies

- Evaluation of existing technologies for quality control of ATMP
- Development of new technologies and diagnostics for the quality control of various cell therapeutics
- Automation and modular integration of the different methods/products/processes and their adaptation for high throughput

11.15 – 11.30 h Break

11.30 – 12.30 h
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

12.30 – 13.00 h
Questions and Answers

13.00 – 14. 00 h Break

14.00 15.00 h
Cell by Design®, a Quality-Focused Process Development Roadmap for ATMP

- 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

15.00- 16.00 h
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

16.00 – 16.15 h Break

16.15 - 17.15 h
In-house Production of CAR-T Cells

- Requirements for hardware and procedures,
- Regulatory affairs (with local/federal authorities

17.15 – 18.00 h
Questions and Answers

Programme Day 2

08.30 – 09.15 h
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

09.15 – 10.00 h
ATMP GMP Inspection Experiences

- Findings
- Pitfalls
- Hospital Exemption

10.00 – 10.15 h Break

10.15 – 11.00 h
Process Optimization for individualized ATMPs - a Modern Aseptic filling for small batches

- Hygiene monitoring in closed Isolators required?
- Regulatory challenges

11.00 – 11.45 h
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

11.45 – 12.15 h
Questions and Answers

12.15 – 13.15 h Break

13.15 – 14.00 h
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

14. 00 – 15.00 h

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

15.00 – 15.15 h Break

15.15 – 16.15 h
Exceptional Provision of ATMPs affected by OOS Results

- Regulatory Framework
- OOS investigation and risk assessment
- Risk / benefit evaluation and exceptional provision request
- Exceptional batch supply and Health Authority notifications

16.15 – 17.00 h
Questions and Answers

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

Speakers

Dr Rüdiger Alt, Qualified Person for ATMPs, Novartis Pharma GmbH, Nürnberg
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 ATMPs of cell and vector based nature.

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 Elena Ferber, Labor LS, Bad Bocklet

Elena studied Biology with the focus on biotechnology and pharmaceutical biology at the University of Würzburg. She worked on her dissertation at the department of Pharmaceutical Biology with a focus on molecular techniques. In 2018 she joined Labor LS, where she is the specialist manager in the department of molecular biology. There she is responsible for molecular biological analysis with the focus on microbiological identification and mycoplasma testing.

Dr Jessica Horbelt, Fraunhofer Institute for Manufacturing, Engineering and Automation

Doctorate in biochemistry in the field of regenerative medicine, research work at the FU Berlin and the Charite since 2014 at Fraunhofer IPA in the field of laboratory automation and bioproduction technology.

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 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, Head of Quality Assurance GMP, BioNTech

Dr Christoph 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.Since 2020 he is with BioNTech.

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 is-

sues 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 Immu-notherapy 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.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

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.

This Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

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Reservation Form (Please complete in full)

Quality, Safety and GMP for Advanced Therapy Medicinal Products (ATMPs)
Live Online Conference on 10/11 November 2020

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 %.

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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.

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Date of the Live Online Conference
Tuesday, 10 November 2020, 09.00 – 18.00 h CET
Wednesday 11 November 2020, 08.30 – 17.00 h CET

Technical Requirements
For our 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 e-mail 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)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
Academic Scientists/ Students € 895
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.

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