

GMP for Advanced Therapy Medicinal Products

Regulatory Requirements and Practical Implementation

SPEAKERS:

Dr Iris Bürger
Miltenyi Biotec



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Dr Markus Fido
VelaLabs



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*Gouvernement
Upper Bavaria*



Dr Hiltrud Horn
*Horn Pharmaceuti-
cal Consulting*



Dr Thomas Meindl
Labor LS



Dr Christoph Prinz
Apceth



**Dr Antonio
Rodríguez Acosta**
*Andalusian Initiative
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**Dr Ralf
Sanzenbacher**
*Paul-Ehrlich-Institut,
German Federal
Agency for Vaccines and
Biomedicines*



26/27 June 2019, Vienna, Austria

PROGRAMME:

- European and US Guidelines and Regulatory Requirements and Inspections
- Quality and Manufacturing of CAR-T-Cells
- Quality Aspects – CMO Experiences
- GMP Implementation in Industry – large scale
- Analytical Characterisation
- Microbiological Safety and Sterility Testing



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Objectives

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, the relevant topics directly related to ATMP will be covered.

Background

Advanced therapy medicinal products (ATMP) are an emerging class of innovative biopharmaceutical medicines, summarizing gene therapy, somatic cell therapy and tissue-engineered products. With the adoption of the ATMP regulation EC 1394/2007, ATMPs are regarded as medicinal products and must consequently comply with current EU drug legislation including GMP. Although pharma industry recently increased their activities to this new area, but the development of these complex products is still focused at universities, hospitals and spin off companies derived thereof (small medium enterprises, SME). This implicates special challenges for compliance these SME with regulatory requirements on marketing authorization and GMP. With the publishing of the new stand-alone guidance document on the GMP requirements in November 2017, EMA tried to define the expected standards for this special kind of medicinal products.

Target Audience

This course is advisable to people who

- Are involved in basic or translational research on cell-based therapy concepts with the perspective of clinical application
- Are responsible for quality aspects on ATMP
- Implement GMP in ATMP manufacturing
- Are involved in regulatory inspections of ATMP
- Are responsible for GMP requirements during pre-approval phases

Moderator

Dr. Andrea Hauser,
Jose-Carreras Center, University Hospital Regensburg

Programme

Regulatory Expectations on Tissues, Tissue Preparations and ATMPs – an Introduction

- Overview on Products and Therapies: Reality and Future
- Legal Framework in EU and Germany
- CTA, Hospital Exemption and Marketing Authorisation: Steps to Consider in the Development of ATMPs

Quality Aspects of ATMP – Practical Experiences from a CMO's point of view

- Complexity of ATMPs and good Technology Transfer
- Quality Assessment on Cell Products after Non-Conformances
- The role of the QP

Requirements on Manufacturing of Cell-based products and Inspection Experiences

- Important Aspects for Characterisation and Control
- Quality of Reagents and Materials
- Relevant guidance documents
- Inspection Experiences and Findings
- Common Deficiencies in Clinical Trial Applications

Quality and manufacturing aspects of CAR-T-Cells

Microbiological Safety of Advanced Therapy Medicinal Products

- Aseptic manufacturing of ATMPs according new Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products.
- How to apply the Ph. Eur. 2.6.27 Microbial examination of cell-based preparations using Automated Growth-Based Methods, Method suitability studies and results.
- Microbiological security of ATMPs. A review of the main sources of microbial contamination: from starting and raw materials to finished products.
- The big challenge of the future: Viral security of allogeneic ATMPs. The immunosuppressed hosts factor and viral reactivation.

Sterility Testing of ATMP

- Challenges of sterility testing of ATMPs
- Matrix-specific selection of a rapid method for sterility testing
- Time to result / negative-to-date results

Analytical characterization of ATMPs according to EMA expectations

- Requirements and categorization for ATMPs
- Examples and analytical designs for selected drugs
- Developing and control under GL(C)P & GMP
- Products on the market – description and characterization

The New EU-GMP Guideline for ATMP (Part I)

- Guideline Overview
- ATMPs & Quality Risk Management
- Zone Concept for ATMP-Facility
- Focus: Qualification & Monitoring

The New EU-GMP Guideline for ATMP (Part II)

- Focus: Process-Validation & Media Fill
- Focus: Documentation
- How to certify/release an ATMP Batch
- Specific Products/Processes

GMP for ATMP – Considerations to European and US Requirements from industrial point of view

- Essential Effects of the New Guideline
- Challenges in Practice
- US Requirements

Development and implementation of a large scale GMP production plant for EMA – approved ATMP cartilage substitute

- Scaling-up ATMP production does not involve only dimensional considerations
- A correct management of production complexity reflects on the overall process quality
- Hardware and Software innovative approaches are fundamental for a successful and cGMP compliant outcome

Speakers

Dr Iris Bürger,

Management Cell Factory, Miltenyi Biotec GmbH



Dr Rainer Gnihl,

GMP Inspector, District Government of Upper Bavaria, Germany

Dr Rainer Gnihl is pharmacist and GMP Inspector for the District Government and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnihl also holds a lectureship at the University Erlangen-Nürnberg.



Marco Fadda,

R&D and Regenerative Medicine Solution Specialist, Comecer, Italy

Long Term Technical Engineer with medical experience, dedicated to identification of key solutions for automation of the Lifescience and Medical Industry. Expert in aseptic manufacturing and regulatory issues of Advanced Therapies applications.



Dr Markus Fido,

CEO, Vela Laboratories, Austria

Markus Fido is CEO and Founder of Vela Laboratories. Before that he was Head Quality Control at Igeneon / Aphton Biopharma AG and as a Group Leader of Immunology and Product Development at Biomin GmbH, Head Biochemical Control at Baxter AG and Head Quality Operations at Octapharma GmbH.



Dr Hiltrud Horn,

Horn Pharmaceutical Consulting, Germany

After working approx. 15 years in pharmaceutical companies like Hoffmann-La Roche, Knoll and Cap Gemini, Dr Hiltrud Horn is today managing director of Horn Pharmaceutical Consulting providing consulting services for the pharmaceutical and biotech industry in EU and US.



Dr. Thomas Meindl

Labor LS SE & Co KG, Bad Bocklet, 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 Prinz,

Head Quality, Apceth

Dr Prinz gained professional experience in QM at Novartis after his pharmaceutical studies before joining apceth in 2012. Parallel to his research activities at Apceth, Mr. Prinz increasingly took over responsibility in QM and was Deputy Head of Quality Management since 2016.



Dr Antonio Rodriguez Acosta,

Andalusian Initiative for Advanced Therapies, Malaga

Antonio Rodríguez received his Bachelor of Science in Biology from the University of Granada (Spain). He started his career as a clinical analyst and microbiological responsible in clinical laboratories, exerting as Technical Director for over 10 years. He joined the Andalusian Initiative for Advanced Therapies in 2012, in the Cell Manufacturing Unit at Regional University Hospital of Málaga, where he currently holds a position as Quality Manager and deputy QP.



Dr Ralf Sanzenbacher,

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

Dr Ralf 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.

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GMP for Advanced Therapy Medicinal Products

26/27 June 2019, Vienna, Austria

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Date

Wednesday 26 June 2019, 09.00 – 18.00 h
(Registration and coffee 08.30 h – 09.00 h)
Thursday, 27 June 2019, 09.00 – 13.30 h

Venue

Radisson Blu Park Royal Palace Hotel Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43 (1) 891 10 - 0
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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
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and dinner on the first day 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 event. 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.

Conference language

The official conference language will be English.

Organisation and Contact

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