GMP for Advanced Therapy Medicinal Products

Regulatory, industrial and scientific view of the current guidance documents

SPEAKERS:

Jacqueline Barry
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Paul-Ehrlich-Institut, German Federal Agency for Vaccines and Biomedicines

Dr Gabriele Wanninger
GMP Inspectorate of the Local Government Upper Bavaria

28 March 2017, Frankfurt/Mörfelden, Germany

PROGRAMME:

- Regulatory and Non Regulatory View on the Current Guidelines
- Inspection Experiences
- Practical Experiences with the Implementation of GMP in Clinical Trials
- GMP Aspects for Manufacturing of Cells and Cell-based Products

This education course is recognised for the ECA GMP Certification Programme „Certified Biotech Manager“. Please find details at www.gmp-certification.eu
Objectives

Considering the ongoing development of the new GMP related guideline documents for Advanced Therapy Medicinal Products, this workshop aims to provide an insight view in the discussion and the proposed regulatory adaptations on ATMP with a focus on GMP aspects important for development and manufacturing of Advanced Therapy Medicinal Products. Representatives from authorities, consulting as well as from academia and manufacturers will share their experiences with you and give you the possibility to discuss intensively the challenges for ATMPs.

Background

Advanced therapy medicinal products (ATMP) represent an emerging class of innovative biopharmaceutical medicines, summarizing gene therapy, somatic cell therapy and tissue-engineered products. With adoption of the ATMP regulation EC 1394/2007, all ATMPs are regarded as medicinal products and must consequently comply with current EU drug legislation including GMP requirements. Pharma industry recently increased their activities to this new area, nevertheless 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 of the different stakeholders with regulatory requirements on GMP.

Target Audience

This course is advisable to people who

- are involved in basic or translational research on cell- or gene-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 Ralf Sanzenbacher, PEI and
Axel H. Schroeder, Concept Heidelberg

Programme

GMP for ATMP – A Regulatory View
- Development of the current Guidance Documents
- GMP Aspects and Trends
- Regulatory Considerations

Jürgen Scherer, Paul-Ehrlich-Institut

GMP for ATMP - Practical Considerations for Developers
- Comparison of new Guidance with Volume 4
- Considerations for Developers
- Next Steps and Recommendations

Jacqueline Barry, Cell and Gene Therapy Catapult

Case Study – Manufacture of an ATMP for a Phase I/II Clinical Trial in an Academic Setting
- Installation of a Clean room Facility for Manufacture of ATMPs in an Academic Setting
- Establishment and Validation of the Manufacturing process with Special Focus on GMP Compliant FACS Sorting
- Application for a Phase I/II Investigator Initiated Clinical Trial

Dr. Andrea Hauser, José Carreras Center for Somatic Cell Therapy

Specific Quality Issues of Cell-based Products and Inspection Experiences
- Process development
- Quality of Reagents and Materials
- Important Aspects for Characterisation and Control of Cells
- Relevant Guidance Documents
- Inspection Experiences and Findings
- Common Quality Deficiencies in Clinical Trial Applications

Dr Ralf Sanzenbacher, Paul-Ehrlich-Institut

GMP Implementation for advanced cell and cell based products at a CDMO
- Peculiarities of ATMPs
- Challenges of Manufacturing and QC throughout the different clinical stages
- GMP Implementation in a CDMO company with multiple customers

Ulrike Verzetnitsch, Apceth Biopharma GmbH

GMP Inspection Experiences
- GMP for Clinical Phases
- Inspection Expectations and Experiences

Dr Gabriele Wanninger, Local Government Upper Bavaria
Speakers

Jacqueline Barry, Catapult, UK
Jacqueline Barry is Director of Regulatory Affairs for Cell and Gene Therapy Catapult, the UK’s centre for the acceleration of the translation of cell therapies towards commercialisation. Prior to this Jacqueline worked at the Scottish National Blood Transfusion Service in a number of senior regulatory and quality positions, the responsibility for which included designing the regulatory strategy for the Cellular Therapies developed by the Blood Transfusion Service, acting as Responsible Person for Blood and Qualified Person for medicinal product release. Before that she held a number of post-Doctoral academic posts at the University of Edinburgh studying neuromuscular regeneration. She has considerable experience in the development, translation, clinical trial and approval of cell based medicinal products and therapies.

Dr. med. vet. Georg Belke-Louis, Head of GMP Manufacturing and Process, apceth Biopharma GmbH, Ottobrunn
Georg Belke-Louis studied Veterinary Medicine in Munich. After his degree, he worked at the institute for Pharmacology, Toxicology and Pharmaceutics. After that he worked in different positions for Munich Biotech, and MediGene. 2011 he joined apceth as Head of Manufacturing and Process of ATMP.

Andrea Hauser is Head of Operations, Head of Production and Head of Quality Assurance at the José-Carreras-Centre for Somatic Cell Therapy, a department of the University Hospital Regensburg. She studied Pharmacy at the University of Regensburg. After that she was working as a GMP inspector at the Government of Upper Bavaria in Munich, where she conducted numerous GMP and GCP inspections mainly in the field of blood, tissue and (stem) cell therapy. Dr Hauser holds the qualification to act as Qualified Person.

Dr. med. vet. Georg Belke-Louis, Head of GMP Manufacturing and Process, apceth Biopharma GmbH, Ottobrunn

Ralf Sanzenbacher, PhD, graduated in biology with a focus on immunology at the Technical University of Darmstadt, Germany. Following a postdoctoral research fellowship at the Institute of Immunology of the University Clinics Schleswig-Holstein, Kiel, he joined the Paul-Ehrlich-Institut (PEI), where he continued his scientific studies on cellular signaling and virus-host cell interactions. Currently, Ralf Sanzenbacher serves as Deputy Head of the Section “Tissue Engineering and Somatic Cell Therapy Medicinal Products” at the PEI. Since 2006 he has been involved in the scientific evaluation of tissue preparations and cell-/tissue-based medicinal products within national and European regulatory procedures, with a strong focus on quality. He is also engaged in the development of regulatory guidance for these products. In addition, he is member or adviser to several cell therapy expert panels.

Dr Jürgen Scherer, Paul-Ehrlich-Institut, German Federal Institute for Vaccines and Biomedicines
Jürgen Scherer studied Biology at the Johannes-Gutenberg-University Mainz (Germany). After his PhD graduation at the Max-Planck-Institut for Brain Research (Germany) and a postdoctoral fellowship at the Max-Delbrück Centre, he joined 1993 the Paul-Ehrlich-Institut. His current position is Head of Section of the unit Advanced Therapy Medicinal Products, Tissue Preparations.

Dr Gabriele Wanninger, Head of the Department Pharmacy, Inspectorate Southern Bavaria, Government of Upper Bavaria, München, Germany
Gabriele Wanninger studied Pharmacy at the University Munich and received her PhD in 1985 in pharmaceutical chemistry. Until 1995 she was analyst at the Bavarian OMCL. From 1995 – 2002 Gabriele Wanninger was GMP Inspector and deputy head of the Department Pharmacy, Government of Upper Bavaria and after that Head of the Department Pharmacy and authorised person for quality assurance of Bavarian inspectorates, Bavarian Health and Food Safety. Since September 2013 she is Head of the Department Pharmacy, inspectorate Southern Bavaria, Government of Upper Bavaria.

Get-together on 27 March 2017

On 27 March 2017, the evening before the Workshop, you are cordially invited to a social event at the nh Hotel. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere. Starting time is 18.30 h.
If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 101764
D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

GMP for Advanced Therapy Medicinal Products,
28 March 2017 Frankfurt/Mörfelden, Germany

- Yes, I will take part in the Get-together on 27 March 2017

Mr. / Ms.
Title, first name, surname
Company
Department

Important: Please indicate your company’s VAT ID Number
P.O. Number (if applicable)
Street, P.O. Box
City
Zip Code
Country
Phone / Fax
E-Mail (please fill in)

Date

Get Together
27 March 2017, 19.00 - 22.00 h
Workshop GMP for ATMP
Tuesday, 28 March 2017, 09.30 – 17.30 h
(Registration and coffee 09.00 - 09.30 Uhr)

Venue
NH Frankfurt Mörfelden
Hessenring 9
64546 Mörfelden-Walldorf
Phone +49(0)6105-204 0
Email nhfrankfurtmoerfelden@nh-hotels.com

 Fees (per delegate plus VAT)
Non-ECA Members € 890
ECA Members € 790
APIC Members € 845
EU GMP Inspectorates € 445

The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation. A special rate for the conference has been arranged 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.

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 %, - until 1 week prior to the conference 50 %, - within 1 week prior to the conference 100 %.

We reserve the right to change the materials, instructors, or speakers if not possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable without deduction 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.

Reservations 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.

Contact
For questions regarding reservation hotel, 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 HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

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