

# GMP for Advanced Therapy Medicinal Products (ATMP)

Regulatory Requirements and Practical Implementation

## SPEAKERS:



**Dr Rainer Gnibl**  
*Government of Upper Bavaria*



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



**Dr Hiltrud Horn**  
*Horn Pharmaceutical Consulting*



**Jan-Oliver Karo**  
*PEI, German Federal Institute for Vaccines and Biomedicines*



**Dr Matthias Renner**  
*Paul-Ehrlich-Institut; German Federal Institute for Vaccines and Biomedicines*



**Niina Taylor**  
*Pfizer*



Discussing the new  
GMP Guide

21-22 June 2018, Berlin, Germany

## HIGHLIGHTS:

- New European Guideline – Development, Background and Impact
- US Regulation
- Inspection Experiences
- GMP Implementation in Clinical Trial Applications and Manufacturing
- GMP Implementation in Industry
- Microbiological Safety



# GMP for Advanced Therapy Medicinal Products (ATMP)

21-22 June 2018, Berlin, Germany

## Objectives

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Relating to the fact of the new GMP Guidelines on GMP requirements for ATMP and the ongoing scientific developments, this Workshop aims to provide an insight view in the regulatory requirements on ATMP with a focus on GMP aspects. During development as well as during manufacturing of Advanced Therapy Medicinal Products for clinical trials and on industrial level. Representatives from authority, consulting as well as from science and manufacturers will share their experiences with you and give you the possibility to discuss intensively the special challenges for ATMPs.

## Background

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Advanced therapy medicinal products (ATMP) are a 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 academic/medical roots of these SME implicates generally special challenges to stay in compliance with regulatory requirements on marketing authorization and GMP. Especially open manipulations of cells and tissues on medical level necessitate adapted procedures. 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

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This course is advisable to people who

- are involved in basic or translational research on cell-based therapy concepts with the perspective of clinical applicationm,
- are responsible on quality aspects on ATMPs,
- implement GMP in ATMP manufacturing,
- are involved in regulatory inspections of ATMP,
- are responsible for GMP requirements during pre-approval phases.

## Moderator

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Axel. H. Schroeder, Concept Heidelberg

## Programme

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### Tissues, Tissue Preparations and ATMPs: 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

### 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

### Regulatory and Practical Aspects for ATMPs - requirements for QPs

- Starting materials for ATMPs
- Raw/ancillary materials for production
- Specifics for process validation and quality control of ATMPs
- Responsibilities of the QP - what is different for ATMPs

### Requirements on Manufacturing of Cell-based products under GMP

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

### 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

## GMP Implementation - Practical Industrial Experiences

- Challenges in aseptic manufacturing
- Dealing with research grade raw materials in a cGMP environment
- Dealing with Contract Manufacturing organisations
- Specific cGMP challenges and possible solutions

## Microbiological Safety of ATMPs

- Challenges and Critical Aspects
- Relevant Guidance Documents
- Modern Microbiological Safety Concepts
- Case Studies from Microbiological Assessment

## Speakers

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### Dr Rainer Gnibl

*Government of Upper Franconia, Germany*

Dr Rainer Gnibl is EU-GMP inspector in Germany and performs GMP inspections worldwide also on behalf of the European Medicines Agency (EMA).



### Dr Andrea Hauser

*Jose-Carreras-Centrum, University Hospital Regensburg*

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 Hiltrud Horn

*Horn Pharmaceutical Consulting, Germany*

Dr Hiltrud Horn is managing director of Horn Pharmaceutical Consulting providing consulting services for the pharmaceutical and biotech industry in EU and US. From 1990 to 1999, she worked at Hoffmann-La Roche, Basel in QC/QA and in Regulatory Affairs. In 1999, she joined Knoll AG as Head of "Regulatory Compliance and CMC Documentation". In 2002, she was working as consultant at Cap Gemini Ernst & Young (biotechnology and life sciences) prior to starting her own business.



### Jan-Oliver Karo

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

Oliver studied biology at the Technical University in Darmstadt with focus on microbiology. Since 2009 he is at the Paul-Ehrlich-Institut, in the Division Microbial Safety. He is quality assessor and national expert advisor for the microbial safety of advanced therapy medicinal products (ATMPs) and member of the "Cell Therapy Products" Working Party of the German Pharmacopoeia Commission.

### Dr Matthias Renner

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

Matthias Renner studied Biology at the University of Regensburg, got his PhD at MPI for Biochemistry and his habilitation at the University of Vet Med in Vienna. After different positions at Bavarian Nordic and Austrianova Biotechnology he joined PEI in 2009 and is currently Acting Head Non-viral Gene Transfer Medicinal Products.



### Niina Taylor

*Qualified Person, Pfizer, UK*

In 1992, Niina entered commercial APS/Berk Pharmaceuticals progressing from the role of a microbiologist to Qualified Person. In 1999, Niina joined Pharmaceutical Sciences, Pfizer Global Research and Development, Quality Assurance in the UK. She has since held various positions within Pfizer QA; supporting sterile, biologics, solid dose and pharmacy operations. She is currently working in the QA group in Sandwich, UK acting as a Qualified Person for Investigational Medicinal Products (IMPs) for use in Pfizer-sponsored and Investigator initiated clinical trials. She provides QP support for Gene and Cell therapy portfolio.


## Social Event


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On 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.



# Easy Registration

 **Reservation Form:**  
**CONCEPT HEIDELBERG**  
P.O. Box 10 17 64  
69007 Heidelberg, Germany

 **Reservation Form:**  
**+ 49 6221 84 44 34**

 **e-mail:**  
**info@concept-heidelberg.de**

 **Internet:**  
**www.gmp-compliance.org**



+ 49 6221 84 44 34

Reservation Form (Please complete in full)

- GMP for Advanced Therapy Medicinal Products (ATMP), 21-22 June, Berlin, Germany**
- GMP Compliance for Biopharmaceuticals, 19-20 June 2018, Berlin, Germany**

Mr.     Ms.

\_\_\_\_\_  
Title, first name, surname

\_\_\_\_\_  
Company

\_\_\_\_\_  
Department

\_\_\_\_\_  
**Important: Please indicate your company's VAT ID Number**

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**P.O. No if applicable**

\_\_\_\_\_  
Street/P.O. Box

**CONCEPT HEIDELBERG**  
P.O. Box 101764  
Fax +49 (0) 62 21/84 44 34

\_\_\_\_\_  
Zip Code

**D-69007 Heidelberg**  
**GERMANY**

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Phone/Fax

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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 %
  - until 1 weeks prior to the conference 50 %
  - 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 HEIDELBERG will 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.

German law shall apply. Court of jurisdiction is Heidelberg.

**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)

**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](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

Thursday 21 June 2018, 09.00 h - 17.30 h  
(Registration and coffee 08.30 h - 09.00 h)  
Friday, 22 June 2018, 09.00 h - 13.00 h

### Venue

Steigenberger Hotel Berlin  
Los-Angeles-Platz 1  
10789 Berlin, Germany  
Phone +49 (0)30 212 7 - 0  
berlin@steigenberger.de

### 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.

### Fees (per delegate plus VAT)

ECA Members € 1,490  
 APIC Members € 1,590  
 Non-ECA Members € 1,690  
 EU GMP Inspectorates € 845  
 Academic Scientists/ Students € 845

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.

**Would you like to save money?**  
 You can save up to € 500 if you book "GMP for ATMPs" AND "GMP Compliance for Biopharmaceuticals" simultaneously:  
 Fees (per delegate plus VAT):  
 ECA Members € 2,780  
 APIC Members € 2,880  
 Non-ECA Members € 2,980  
 EU GMP Inspectorates € 1,680  
 Academic Scientists/ Students € 1,680

### Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

### 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  
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**For questions regarding content:**  
 Mr Axel H Schroeder (Operations Director) at  
 +49-62 21 / 84 44 10, [schroeder@concept-heidelberg.de](mailto:schroeder@concept-heidelberg.de)

**For questions regarding reservation, hotel, organisation etc.:**  
 Ms Katja Kramer (Organisation Manager) at +49-62 21/84 44 16 or per e-mail at [kramer@concept-heidelberg.de](mailto:kramer@concept-heidelberg.de).