INTERNATIONAL

Fleming

TRAINING COURSE

CELL & GENE THERAPY PRODUCTS – CMC & QUALITY REQUIREMENTS

26 – 28 NOVEMBER 2025
BARCELONA, SPAIN

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ONLINE LIVE **STREAM!**

- ✓ All sessions of this unique course online
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In the light of the current outbreak of COVID 19 across Europe, we have prepared an option to accommodate those delegates who will not be allowed to travel. The situation might fully be under control by the time when the training is planned to run, however we want to make sure everyone will get the same chance to take part in this unique training course.

Are you going to be able to attend the course in-person? Fantastic! We are looking forward to meeting you. Will you not be allowed to travel or do you feel it is safer to enjoy this unique course from the luxury of your office or home via your laptop, tablet or mobile? We obviously understand the situation and offer you the opportunity to join us via the online live stream enabling the mutual interaction between you and the trainer.

Click Here & REGISTER ONLINE

COURSE **OBJECTIVES:**

With the increasing complexity of new cell & gene therapies, as well as a rapid growth of these products in development, unique challenges have emerged especially in manufacturing and control. Leading biotech players are utilizing available regulatory pathways to accelerate the approval of ATMPs. However, the pathways to meeting CMC requirements are not as clearly defined. Novel approaches must be taken to ensure the identity, strength, quality, purity or potency of the product.

This unique course provides a practical & in-depth understanding of CMC & quality requirements and brings clarifications on global regulation, requirements, compliance & quality concerns.

Join us & achieve CMC readiness for your cell & gene therapy medicinal products.

SPECIAL **FEATURES:**

- Interactive learning approaches
- Tailored case studies
- Group exercise on Comparability principles
- Individual case-by-case consultancy with the trainer
- Comprehensive course documentation
- Certificate of completion issued by the trainer

KEY **TAKEAWAYS:**

GET
critical insights into ATMP classification

FAMILIARIZE
yourself with specific EMA & FDA guidelines for cell & gene therapy medicinal products

UNDERSTAND
the interpretation of new guidelines & guidance documents

LEARN
how to establish comparability for complex cell & gene products

GAIN
clarifications on when to qualify and validate critical assays for ATMPs

UNDERSTAND
the principles for establishing CQA, CPP and KPP for cell & gene products

EXPLORE
the quality requirements for raw & starting materials

GAIN
insights into leveraging viral vector manufacturing platforms

UNDERSTAND
aseptic process validation

EXPLORE
data requirements for manufacture & control

LEARN
how to manage change control

UNDERSTAND
microbiological control

ASK
any specific question

KEY **TOPICS:**

- ✓ The ATMP regulatory framework
- ✓ Quality of raw materials & starting materials criteria
- ✓ Process development & manufacturing strategy
- ✓ Process validation requirements
- ✓ Method validation/qualification strategies
- ✓ Release specifications for ATMPs
- ✓ Analytical characterization & comparability
- ✓ Data requirements for manufacture and control
- ✓ Gene therapy product class specificities
- ✓ Manufacturing process changes/ Change control

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MEET THE **TRAINING LEADERS:**

MATTHIAS RENNER

Paul-Ehrlich-Institut (PEI), Germany

Head of Section Quality of Coagulation Products and Gene Therapy

Senior Scientific Assessor for quality aspects of ATMPs

Matthias Renner is Head of Section "Assessment Quality of Coagulation Products and Gene Therapy" - in the Department of Hematology, Cell and Gene Therapy and Senior Scientific Assessor for quality of ATMPs at the Paul-Ehrlich-Institut (PEI), the German Federal Institute for the regulation of Vaccines and Biomedicines. In his work Matthias is involved in the evaluation of clinical trial applications and national scientific advice procedures for ATMPs and serves as scientific consultant in GMP-inspections of Gene Therapy Medicinal Products.

Since 2009 he is expert to the European Medicines Agency (EMA) for the assessment of marketing authorisation applications, for scientific advices and other EMA procedures. He is Member of the EDQM Gene Therapy Working Group and of the Cell and Gene Therapy Committee of the International Alliance for Biological Standardization. From 2016 to 2023, Matthias was German Alternate to the CHMP Biologics Working Party and serves Member of this group since 2023.

Before he joined the PEI, he worked in several positions in biotech industry on the development of cell and gene therapies. Matthias holds a Ph.D. and a lecturer´s degree in Virology.

DR. ROBERT E. ZOUBEK

Granzer Regulatory Consulting & Services, Germany

Executive Consultant

Robert has 20 years of experience in development of biologics and gene and cell therapies. His expertise comprises the regulatory requirements for analytical methods, method validation, cell bank establishment, product and process development and actual manufacture. Robert is Executive Consultant at Granzer Regulatory Consulting & Services and supports clients worldwide on CMC from early development up to marketing authorization for Europe and USA. Until he joined Granzer, Robert worked in several positions at the Formycon/Germany, a leading developer of Biosimilars for regulated markets. As Director Scientific Affairs he led Formycon´s drug product development and analytical services. Before that, Robert was Head of Protein Characterisation & Preformulation and Manager Quality Operations. In those positions he supervised Formycon´s GMP-Quality Control and analytical labs, the core of Quality-Biosimilar development.

Robert earned the PhD from the University of Erlangen-Nuremberg for his research on therapeutic peptides and he was awarded Master of Business Administration from the University of Manchester. He also holds a MSc from the University of Munich.

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TRAINING **AUDIENCE:**

The Training Course is of particular interest to:

- ✓ CMC Heads, Managers
- ✓ QA & QC Heads, Managers
- ✓ Product Stability
- ✓ Process Development
- ✓ Bioproduction
- ✓ Cell Manufacturing
- ✓ Regulatory Affairs
- ✓ Analytical Science & Development
- ✓ R&D Scientists

ATMPs exemplified covered by genetically modified cells and viral vectors, additional discussion on the individual ATMP product classes will be covered as well.

DAY 1

26 November 2025

8:45 REGISTRATION & MORNING COFFEE

9:00 WELCOME NOTE

9:10 INTRODUCTION & SPEED NETWORKING

Meet & greet the trainers and participants. Share your experience & expectations on this course.

9:30 **Introduction of ATMPs and EU-regulations**

- Overview of the regulatory landscape
- Proposal for new pharma legislation
- ATMP Product Classes and their classification
- Routes to clinical use
- Authorization of CTA via the clinical trial regulation
- Scientific Advice procedures
- PRIME and Accelerated Assessment Schemes
- Incentives for ATMP development

Matthias Renner

11:00 BREAK

11:30 **Starting materials, manufacture and control**

- Exemplified on CAR-T cells and principle applicable for other products
- Overview about classification of raw materials, starting materials and active substance
- Bacterial cell banks and plasmids
- Cell lines and vector producer cells (e.g. for AAV production)
- Viral vectors and gene editing components
- Primary cells (e.g. for CAR-T cells)

Matthias Renner

13:30 LUNCHEON

14:30 **Manufacture of ATMPs (DS and DP)**

- Discrimination drug substance vs. drug product
- Control strategy
- CPPs and IPCs rational and setting
- Process validation (including for autologous cellular products)
- Adaptive approaches to manufacturing

Robert E. Zoubek

16:00 BREAK

16:30 **DISCUSSION**

- EU Regulations
- Starting materials, manufacturing and control
- Manufacturing of ATMPs

17:30 END OF DAY 1

DAY 2

27 November 2025

8:45 REGISTRATION & MORNING COFFEE

9:00 **GMP for ATMPs**

- Risk-based approach for ATMPs
- Specifics for ATMP, e.g. multiproduct facilities, traceability, batch release prior full QC or from decentralized manufacturing, administration of OOS products

Robert E. Zoubek

10:40 BREAK

11:10 **Analytical characterization and quality control of ATMPs**

- QTPP, CQAs and specifications
- Analytical method spectrum
- Cell & gene therapy medicinal product characterization
- Stability & self-life

Matthias Renner

13:30 LUNCH

14:30 **Process and product improvements, scale up and comparability**

- Principles of comparability
- Introduction of hand-on case studies: AAV, autologous cell product
- Group exercise
- Group presentations on comparability case study
- Summary: Key aspects to a successful comparability exercise

Robert E. Zoubek
Matthias Renner

16:00 BREAK

16:30 **DISCUSSION**

- GMP for ATMPs
- Analytical characterization and quality control
- Process and product improvements, scale up and comparability

17:30 END OF DAY 2

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DAY 3

28 November 2025

8:45 REGISTRATION & MORNING COFFEE

9:00 **Global context of ATMPs**

- Regulations and guidelines in the US
- Global regulatory strategy
- Which agencies to approach for scientific advice

Robert E. Zoubek

10:40 BREAK

11:10 **DISCUSSION, CASE STUDIES & OPEN ISSUES**

- Navigating the global regulatory challenges
- Quality challenges – common issues, failures and success stories
- Comparability best practices
- Other open issues from the audience

Matthias Renner

Robert E. Zoubek

12:40 KEY TAKEAWAYS & CLOSING REMARKS

13:00 END OF TRAINING

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"Knowledge is important, but implementation is crucial."

THE TEAM BEHIND:

We are delighted to bring you the

CELL & GENE THERAPY PRODUCTS – CMC & QUALITY REQUIREMENTS

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Or write to
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to get in touch with a member of our team

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Production Manager - Life Sciences

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Marketing manager

BARCELONA

The famous Basilica of the Sagrada Familia has taken longer to complete than the Egyptian Pyramids. Speaking of architecture, construction of Catalan architect Antoni Gaudí's magnum opus Sagrada Familia began in 1882. To this day, the basilica remains unfinished, but there has been a completion date set that coincides with the hundredth anniversary of its architect's death (who is, surprisingly, buried inside!). Conversely, Egyptologists estimate that the Great Pyramids of Giza were constructed with ancient tools in the span of 10-20 years.

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