3rd APV Interactive Workshop on Cell & Gene Therapy Products

"Bridging standard pharma concepts and ATMP"

APV basics

14 July 2025
Berlin, Germany

Course no. 7057

Biotechnology

Target group

Stakeholders in the field of Advanced Therapy Medical Products (ATMP), management of small and medium sized enterprises and experts engaged in pharmaceutical development, production and quality control of Cell & Gene Therapy Products, masters & PhDs having a strong topic relation or being involved in the relevant pharmaceutical business area.

APV
MAKING SCIENCE WORK

Biotechnology

A workshop organised by the APV focus groups Pharmaceutical Biotechnology and Drug Delivery

Goal of the seminar

The workshop will highlight Advanced Therapy Medicinal Products (ATMP) as products in development for market supply. Speakers will share background knowledge gained during strategic planning and pharmaceutical development of designated orphan and non-orphan drugs.

We will make a lot of room for open discussions. Time slots for these discussions are planned after the talks and before each break. In addition to the speakers, the members of the APV focus group for "Pharmaceutical Biotechnology" will join the course physically and provide additional critical mass for intensive expert exchange. Participants are highly welcome to ask questions verbally during the seminar or by writing them simultaneously to the moderator.

Questions may also be sent to the APV in advance to the course, they will be answered onsite by the speaker´s panel.

The workshop will provide a combination of acquiring/ sharing background knowledge to support market access of ATMP and to discuss about/ get answers regarding questions on specific product portfolios.

For interested participants, the APV offers insights into their organization after the end of the seminar. Board members of the APV will provide an overview of mission, organization, expertise and activities.

Course leaders

Hans-Georg Eckert, PhD
Valicare GmbH

Hans-Georg Eckert is General Manager & Senior GMP Consultant of Valicare GmbH Frankfurt, a Syntegon company providing GMP consultancy and compliance services. By education, he is biologist and has nearly 30 years of professional experience in accompanying and managing GMP compliance.

During different occupations he fulfilled functions as head of production acc. to § 15 of German Drug Law, as project manager acc. to § 14 of German Gene Technology Law and handled a permission to work with biological pathogens acc. to § 44 of German Infection Protection Act.

In the last 20 years, Dr. Eckert accomplished GMP consultancy work in more than onehundred pharmaceutical and biotechnological projects. He successfully managed complex GMP-compliance projects and was responsible for the execution of several hundred different quality projects and customized services. Since 2016, he is the manager behind the strategic focus on ATMP-GMP projects at Valicare.

Ralf Sanzenbacher, PhD
Paul-Ehrlich-Institute (PEI)

Ralf Sanzenbacher, PhD, graduated in biology with a focus on immunology at the Technical University of Darmstadt, Germany. Following 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. At present, Ralf Sanzenbacher serves as Senior Scientific Assessor in the Division Hematology, Cell and Gene Therapy. 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 and regulatory issues. He is also engaged in the development of regulatory guidance for these products. In addition, he is member or advisor to several international and national cell therapy expert panels and lecturer for several organisations.

Regulatory Experience and Expertise
Since 2006, he has participated in GFP/GMP inspections of manufacturing sites, supporting the regulatory oversight of compliance and quality standards. His work has included quality assessment in Clinical Trial Applications (CTA), Scientific Advice (SA) procedures, and national centralized Marketing Authorization Application (MAA) procedures. In 2008, he became a member of the expert group "Biotechnology and Tissues" at the German Central Authority of the Laender for Health Protection with regard to Medicinal Products and Medical Devices (ZLG). He has also served as a lecturer at the Danube University Krems since 2012. From 2013 onward, he has been a member of the International Pharmaceutical Regulators Forum (IPRF) Cell Therapy Group, and from 2013 to 2023, he contributed as a member of the WHO Cell Therapy Advisory Group. As of 2023, he serves as the National Focal Point (NFP) for the European Centre for Disease Prevention and Control (ECDC) on Substances of Human Origin (SoHO) for tissues and cells.

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Programme

Monday, 14 July 2025 08:00-18:00 h

Welcome and Introduction to the Course
Hans-Georg Eckert & Ralf Sanzenbacher

"ATMPs – Current Update on Basic Regulation in Europe"
Ralf Sanzenbacher, Paul-Ehrlich-Institute

"Manufacturing Products for Academia – Challenges"
Annemarie Seyfarth, Stem Cell Facility, Charité

"Funding for GMP Manufacturing of Clinical Trial Material by ForTra"
Martin Zörnig, ForTra (online presentation)

Moderated Discussion & Coffee Break

"Basic ATMP-GMP Requirements – Not Only Facility Counts"
Hans-Georg Eckert, Valicare

"Professional Facility Concepts for ATMPs – Product Determines Design"
Peter Rehm, Syntegon Technologies

"Scalable Automated Manufacturing of ATMPs – A Fraunhofer Perspective"
Andrea Gaißler, Fraunhofer IPA

„Technical Solutions for Fill&Finish of ATMPs – Outlook to Future Technologies"
Svenja Jorga & Sven Filler, Bayer

Moderated Discussion & Lunch Break

"Developing Innovative Ecosystems for Biomedicine"
Christopher Baum, Berlin Institute of Health at Charité (BIH)

„Market Access Strategies for CAR-T Cell Therapies"
Angela Vollstedt, Novartis (online presentation)

"Manufacturing Marketed Gene Therapy Products"
N.N., tbc

Moderated Discussion & Coffee Break

„DNA Vectors for Cell- and Gene Therapy: Quality Aspects for Plasmids and Minicircles Used e.g. as Starting Material"
Martin Schleef, PlasmidFactory

"GMP and Regulatory Requirements for Pharmaceutical Manufacturing of Oligonucleotides for Cell- and Gene Therapy"
Thomas Rupp, Axolabs

"Case Study: GMP Manufacturing of VSV-GP as Oncolytic Virus"
Thomas Kriehuber, Boehringer Ingelheim

Moderated Discussion & Farewell

APV Roadshow 18:30-20:00 h

The APV Roadshow is open for students and younger professionals and is free of charge.

Introduction to International Association for Pharmaceutical Technology / Arbeitsgemeinschaft Pharmazeutische Verfahrenstechnik (APV), Mainz

"Mission, Vision and Activities"
From the APV Board: Karoline Bechthold-Peters, Novartis, Florian Unger, Bayer & Hermann Allgaier, former Teva Biotech

"FG Experiences"
The Members of the APV FG Pharmaceutical Biotechnology

Come together

Programme is subject to change

Registration online on our homepage or by email to info@apv-mainz.de

MAKING SCIENCE WORK

Location

BHT Berliner Hochschule für Technik
Haus Grashof C16
Luxemburgerstr. 10
13353 Berlin
Germany
phone +49 030 4504 296

Date

Course no.: 7057
from 14 July 2025 08:00 h
to 14 July 2025 18:00 h

Registration fee

Industry	790 EUR
Authority/University	395 EUR
Students*	50 EUR

(free of VAT according to § 4,22 UStG)
Coffee breaks, luncheons and electronic proceedings included.

* Limited places for full time students available; written evidence must be submitted.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: 0049 6131 97 69 0
E-mail: info@apv-mainz.de
Web: www.apv-mainz.de

You will receive a confirmation of your registration with the invoice.

Hotelreservation

Participants should make their own hotel reservation.

We recommend booking via a hotel platform such as booking.com or hrs.com.

3rd APV Interactive Workshop on Cell & Gene Therapy Products, 14 July 2025, Berlin, DE, Course no.: 7057

Registration
As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

Registration confirmation
After your registration was successfully processed, you will receive a confirmation.

Before the event
A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

After the event
You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

Follow-up
After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

Declaration of consent in respect of data protection

☐ By registering for this seminar, I agree that the APV uses my data for the purpose of processing the order and provides me with all relevant information.

☐ I also agree that APV may contact me for the purpose of exchanging similar information by email or post.

Your data will not be shared with third parties. You have a right of withdrawal at any time without giving reasons.

All other information can be found in our privacy policy (www.apv-mainz.de/en/imprint/data-protection-statement/).

Title, first name, last name *

Company name *

Street/no. or P.O. box *

Location

Zip-code and city *

Phone

E-mail-address participant *

Order no. and/or billing address

☐ Pay via invoice

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(You will receive further payment information with the invoice)

Date * Signature *

* Mandatory

Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.
Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology and Industrial Pharmacy

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