

# APV Basics ATMP

“Advanced Therapy Medicinal Products”



28-29 April 2021  
Online Seminar

Course no. 6859



## Biotechnology

### Target group

Employees from development, production, quality control and storage/logistics in the pharmaceutical and biopharmaceutical industry.



### Goals of the seminar

A correspondingly oriented transfer of knowledge is currently not offered on the market. The pharmaceutical industry falls back on expert events that overwhelm many employees due to their scientific demands.

This course provides an introduction to the topic of "Advanced Therapy Medicinal Products", or ATMPs for short, from the perspective of the pharmaceutical and biopharmaceutical industry.

Basic knowledge is offered about the nature (what are ATMPs? how do they differ from other drugs?), the special features (how is the current state of the art in production, quality control/specification, storage and transport defined?) and the regulatory requirements of ATMPs (how do the ATMP-GMP rules introduced in Europe in 2017 and binding since 2018 differ from those for active ingredients and medicinal products?). The course has a special focus on the requirements for GMP-compliant manufacturing and quality control.

The virtual classroom sessions are a substantial part of the course. Questions can be asked upfront, during and after the lectures and will be collected and discussed/answered by the experts afterwards in this sessions.

### Course leader



**Hans Georg Eckert, PhD, Valicare GmbH**

Hans-Georg Eckert is Site Manager, Senior GMP Project Manager & Senior GMP Consultant of Valicare GmbH Frankfurt, a daughter company of Syntegon Technology GmbH providing GMP compliance services. By education, he is biologist and has more than 20 years of professional experience in accompanying and managing compliance tasks.

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, 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 100 pharmaceutical and biotechnological projects. He successfully managed complex GMP-compliance-projects and was responsible for execution of more than 600 different quality projects and customized services. Since 2016, he leads Valicare GmbH towards a strategic focus on ATMP-GMP projects.

### Programme

**Wednesday, 28 April 2021**

**13:00-18:00 h**

#### Opening remarks

Hans-Georg Eckert, Valicare  
Ralf Sanzenbacher, Paul-Ehrlich-Institut

#### ATMPs – Basic Regulation in Europe

Ralf Sanzenbacher, PEI

#### Advanced Therapy Medicinal Products – Basics, Specialities, "Game Changer" Characteristics

Claudia Papewalis, Valicare

#### ATMP-GMP-Requirements Based on Part V EU-GMP-Guideline

Hans-Georg Eckert, Valicare

#### Risk Based Approach in ATMP Process Development

Hans-Georg Eckert, Valicare

#### Gene Therapy Manufacture

Magdalena Obarzanek-Fojt, Novartis

#### Virtual Discussion Room

**Thursday, 29 April 2021**

**08:30-15:00 h**

#### ATMP – QC, Specifications, Method Development and Validation

Claudia Papewalis, Valicare

#### ATMP – QC, Flow Cytometry Method Development and Validation

Sabine Hünecke, Labor für Stammzelltransplantation und Immunologie, Klinik für Kinder- und Jugendmedizin

#### ATMP – Specific QC Testing: Matrix specific development of rapid testing strategies for Mycoplasma

Thomas Meindl, L&S

#### ATMP – Specific QC Testing: Rapid Sterility Testing for Short-Life Products - Test Methods and Risk-Based Approaches

Stefan Gärtner; L&S

#### Virtual Discussion Room

#### ATMP – Specific QC Testing: Pyrogen Detection on Cellular Preparations and other Short Shelf Life Pharmaceuticals

Stefan Gärtner, L&S

#### ATMP-Logistics

Bengt-Simon Feth, Marken

#### Virtual Discussion Room

# Registration by fax +49 6131 97 69 69 or by email [apv@apv-mainz.de](mailto:apv@apv-mainz.de)



## Date

Course no.: 6859  
from 28 April 2021 13:00 h  
to 29 April 2021 15:00 h

## Registration fee

Industry	1090 EUR
Authority/University	545 EUR
Students*	178 EUR

(free of VAT according to § 4,22 UStG)

\* 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  
Fax: 0049 6131 97 69 69  
E-mail: [apv@apv-mainz.de](mailto:apv@apv-mainz.de)  
Web: [www.apv-mainz.de](http://www.apv-mainz.de)

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

## APV Basics ATMP, 28-29 April 2021, Online Seminar, Course no.: 6859

### 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.

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\* Mandatory

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APV-Geschäftsstelle  
Kurfürstenstraße 59  
55118 Mainz/Germany

Phone: 0049 6131 97 69 0  
Fax: 0049 6131 97 69 69  
E-mail [apv@apv-mainz.de](mailto:apv@apv-mainz.de)