

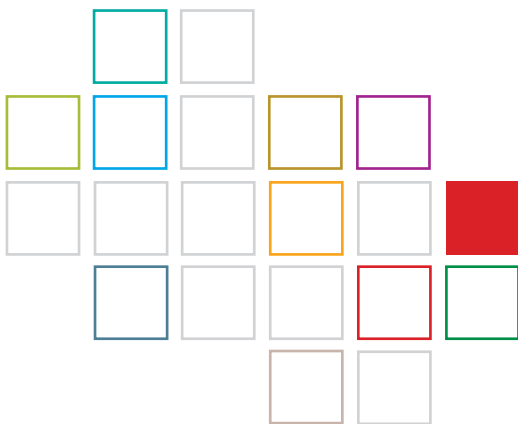
2nd APV Interactive Workshop on ATMP

“Bridging standard pharma concepts and ATMP”



19 - 20 November 2020
Frankfurt am Main, Germany

Course no. 6828



Biotechnology

Target group

Management of small and medium sized enterprises and experts from development, manufacturing and quality control in pharmaceutical industry involved in the process development and strategic planning necessary for market access of an Advanced Therapy Medical Products (ATMP).



Goals of the seminar

The workshop will focus on Advanced Therapy Medical Products (ATMP) as products in development for market supply. Speakers will share background knowledge gained during strategic planning and pharmaceutical development of designated orphan drugs. In the afternoon session of the first workshop day round table discussions will provide a platform for the participants to discuss their own topics, issues and strategy in an interactive manner.

Share background knowledge for pharmaceutical and strategic development of Advanced Therapy Medical Products (ATMP).

The workshop will exclusively provide the combination to share background knowledge supportive for market access of ATMP and to discuss questions about own product portfolio.

Programme

Thursday, 19 November 2020 9:00-17:30 h

Opening remarks

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

News and views on CAR-T-cells

Michael Hudecek, University Würzburg

Not your typical academic GMP-facility: ATMP manufacturing at German Red Cross Blood Service BaWüHe

Halvard Bönig, DRK-Blutspendedienst

CAR T cell therapy product understanding and control strategy evolution

Margit Jeschke, Novartis

Open issues from CAR-T and gene therapy commercial experience

Sergio Fracchia, Novartis

CAR-T-cells in daily routine – first impressions

Peter Bader, Universitätsklinikum Frankfurt

Current regulation and future perspectives

Ralf Sanzenbacher, Paul-Ehrlich-Institut

Round table – discussion with all available speakers

CAR-T-cells - where do we stand

- Market supply
- Centralized vs decentralized production
- New developments

Minicircle DNA as raw material for gmp manufacturing in CAR-T cell therapy

Martin Schleef, PlasmidFactory

Concepts and challenges for DP development of viruses

Thomas Kriehuber, Boehringer

Process development for an ATMP Manufacturing Process

Klaus Kühlcke, BioNTech

Round table – Discussion with all available speakers

Vector's used to manufacture genetically modified cells - starting material and/or API

- Definition of pharmaceutical quality
- Risk based discussion of critical quality attributes
- Safety aspects and characterization

Networking dinner

APV Interactive Workshop on ATMP

Programme

Friday, 20 November 2020

09:00-13:30 h

EU regulation 536/14: update and implications for clinical trials with ATMPs

Heiko von der Leyen, Orgenesis

Microbiological release analysis on ATMPs with focus on sterile testing

Thomas Meindl, L&S

Rapid detection of bacteria and fungi in ATMPs prior treatment – validation of a real time PCR-based test

Kai Neseemann, Sartorius

One round table – discussion with all available speakers

- Release testing of ATMPs - Real-time analysis
- Acceptance of novel methods e.g. rapid sterility testing
- Method verification/validation
- Comparability tool and demonstration

Arm-to-Arm: Global cell journeys from clinical to commercial – Autologous Supply Chain

Bengt-Simon Feth, Marken

Import and Pharmaceutical Release of ATMPs to the EU

N.N.

Closing Remarks

Hans-Georg Eckert, Valicare

Ralf Sanzenbacher, Paul-Ehrlich-Institut

Programme is subject to change

Course leaders

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.

Ralf Sanzenbacher, Paul-Ehrlich-Institute



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), the German Federal Institute for Vaccines and Biomedicines.

At present, 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 focus on regulatory, quality and non-clinical aspects. He is also engaged in the development of regulatory guidance for these products. He is member of the WHO Cell Therapy Advisory Group, 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, adviser to several ATMP therapy expert boards and lecturer at the Donau-University Krems as well as other organisations.

Registration by fax +49 6131 97 69 69 or by email apv@apv-mainz.de



Location

Fraser Hospitality Frankfurt GmbH
Capri by Fraser
Europa-Allee 42
60327 Frankfurt am Main
Germany
phone 0069 13388775102

Registration fee

Industry 1490 EUR
Authority/University 745 EUR
Students* 178 EUR
(free of VAT according to § 4,22 UStG)

Coffee breaks, luncheons, dinner 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
Fax: 0049 6131 97 69 69
E-mail: apv@apv-mainz.de
Web: www.apv-mainz.de

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

Hotelreservation

Fraser Hospitality Frankfurt GmbH
Capri by Fraser
Europa-Allee 42
60327 Frankfurt am Main
Germany
phone 0069 13388775102
mail reservations.frankfurt@capribyfraser.com

Participants should make their own hotel reservation referring to the APV seminar. Deadline for special conference rate: 20. October 2020. Special rate: Single room incl. breakfast from 120,00 € per night.

Mainz, August 2020

Date

Course no.: 6828
from 19 November 2020 09:00 h
to 20 November 2020 13:30 h

APV Interactive Workshop on ATMP, 19 - 20 November 2020, Frankfurt a.M., Germany, Course no.: 6828

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/).

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Street/no. or P.O. box *

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Phone

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Order no. and/or billing address

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(You will receive further payment information with the invoice)

Date *

Signature *

* Mandatory

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International Association for Pharmaceutical Technology

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