

Cell & Gene Therapy

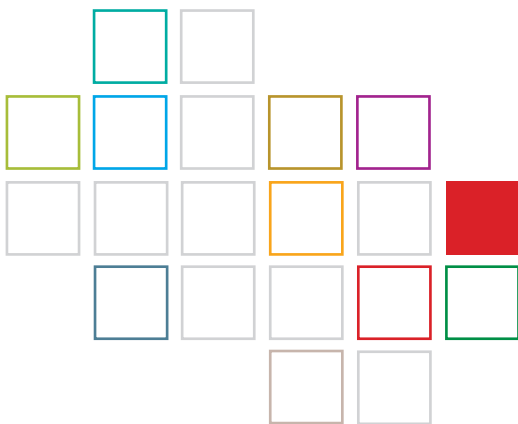
From Pharmaceutical Development to Delivery



08 - 10 May 2023

Frankfurt am Main, Germany

Course no. 6916



Biotechnology

Target group

Scientists, managers and other professionals involved or interested in the development of Cell & Gene Therapy products, such as CAR-T, LVV- and AAV-based products. The event will be particularly relevant for professionals involved in the technical product and process development, including formulation development, product characterisation, analytical development, process development, scale-up, supply management and quality assurance, as well as for project or programme managers.



Biotechnology

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

Objectives of the workshop

The three day interactive workshop will focus on cell & gene delivery and each day is dedicated to special topic sessions. Each session comprises several lectures followed by round table discussions.

The first day gives an overview on the status quo of cell & gene therapy and perspectives for the future and the related potential and challenges. The following session deals with all aspects of product design, formulation development and storage of viral vectors, e.g. AAV, and a comparison to non-viral based gene therapy.

The second day comprises sessions on delivery and administration incl. delivery systems, characterisation methods incl. MS, AUC and flow imaging microscopy, regulatory issues and CAR T cells incl. open issues and news from daily routine.

The third day focuses on GMP process development, scale-up & manufacturing and release testing.

Be part of this interactive workshop and get up to date content and connect and network with the scientific community.

Course leaders



Magdalena Obarzanek-Fojt, PhD
Novartis Pharma AG

Cell and Gene Technical Development,
Novartis Pharma AG

Magdalena Obarzanek-Fojt, PhD, works at Novartis in Cell and Gene Therapy group where she is responsible for External Partner Management in scope of Alliance Management Team in Technical Research and Development (TRD).

Magdalena has joined Novartis in 2015 as a pharmaceutical development expert focusing on drug product development for Cell-based therapies and Viral Vector products. During her professional career she was exposed to different modalities and aspects of the project life cycle from basic research, through technical development including drug product manufacturing. Magdalena has contributed to multiple CGT IND/IMPd filing, as well as BLA filing for Kymriah, the first approved ATMPs in the US.

Magdalena has a strong passion to innovative approaches in medicine such as Cell and Gene Therapies and tissue engineering. She strives her work by implementation of harmonized approaches and strategic solutions. Prior her work in CGT field, she worked on 3D in vitro models for drug development.

Magdalena is a member of APV Drug Delivery Focus Group,



Karsten Cremer, PhD
Pharma Patents International AG

Karsten Cremer, PhD, has a broad interest in all aspects of drug product development, with a particular focus on drug delivery.

Karsten is a pharmaceutical scientist and a European patent attorney with more than 25 years of professional experience. As a technology and IP consultant, he builds on his intimate knowledge of drug product design and development, formulation techniques and manufacturing methods.

Karsten is the founder and managing partner of Pharma Patents International AG, an IP consultancy located in Basel (Switzerland). In previous appointments, he was CEO of Capsulation Nano Science AG, Director of Oral Drug Delivery at LTS Lohmann Therapy Systems, and Lecturer of Pharmaceutics at the University of Marburg. As a pharmaceutical IP expert, Karsten works with large pharmaceutical companies as well as small and medium-size technology and product development companies. His specialities include IP issues relating to pharmaceutical formulations and drug delivery technologies.

Within the APV and other professional organisations, Karsten is an experienced workshop organiser, speaker and tutor, and has contributed to the success of many seminars, workshops and conferences. He is also co-founder and member of the APV Drug Delivery Focus Group.



Hans-Georg Eckert, PhD
Valicare GmbH

Hans-Georg Eckert, PhD is Site Manager and Senior GMP Consultant at Valicare in Frankfurt, a daughter company of Syntegon Technologies. By education, he is biologist and has more than 20 years of professional experience in accompanying and managing GMP and GxP 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 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 more than 100 consultancy tasks for customers in the GMP regulated Industry. He successfully managed complex GMP compliance projects and was responsible for execution of more than 700 different quality projects and customized services. Since 2016, he leads Valicare towards a strategic focus on ATMP-GMP projects.

Cell & Gene Therapy – From Pharmaceutical Development to Delivery

Programme

Monday, 08 May 2023

10:30-18:00h

Welcome address

Magdalena Obarzanek-Fojt, Novartis
Karsten Cremer, Pharma Patents
Hans-Georg Eckert, Valicare

Keynote Session

Cell & Gene Therapy: Huge Potential, Huge Challenges?

Dr. Erik Rutjens, Cell Therapy Operations, Enara Bio

Panel: Product Design, Formulation Development and Storage

Challenges and opportunities for formulation and drug dev for gene therapies (Viral Vector)

Rafi Mohamad, Bayer US LLC

AAV formulation development – a case study

Chunlin Tang, Associate Director, Process Development, Novartis (tbc)

AAV-based gene therapy delivery to inner ear

Otmane Boussif, Chief Technical Officer, Sensorion Pharma

Algorithm-Based Liquid Formulation Development using a DoE Concept

Dr. Andreas Seidl, Chief Scientific Officer at Formycon AG, Scientific Advisor, Leukocare

Nucleic acid therapeutics and vaccines utilizing lipid nanoparticle technology – recent development, challenges and prospects

Dr. Dominik Witzigmann, Chief Executive Officer & Co-Founder NanoVation Therapeutics

Roundtable discussion on Vector Development

Tuesday, 09 May 2023

08:00-18:30h

Panel: Delivery and Administration

Challenges in Delivering CAR T-Cell Therapy to Children: A clinical perspective

Prof. Joerg Krueger, The Hospital for Sick Children

Cell & Gene Therapy Delivery System: Challenges and Opportunities

Hicham Majd, Novel Solutions and Technologies, Novartis

Panel: Advanced Characterisation Methods

Structure and size distribution analysis of AAV by MS and AUC

Prof. Susumu Uchiyama, Osaka University

AAV characterisation with focus on full vs empty determination

Klaus Richter, Coriolis Pharma Research GmbH

The visible particle challenges in cell and gene therapies from detection to identification

Pascal Chalus, Lonza

Machine learning-enabled flow imaging microscopy for characterization of cell-based medicinal products

Alexandra Rösch, Coriolis Pharma Research GmbH

Roundtable discussion on Delivery, Administration and Characterisation

Panel: Regulation and Market Entry

Regulation of Cell and Gene Therapy in Europe

Ralf Sanzenbacher, Paul Ehrlich Institut

Pricing and Reimbursement of CT/GT Medicinal Products in the EU Countries

Dr. Thomas Grub, Medac GmbH

Panel: CAR-T Cells

News and views on CAR T cells

Prof. Dr. Michael Hudecek, University of Würzburg

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

Dr. Martin Schleef, PlasmidFactory

Open issues from CAR T and gene therapy commercial experience

Dr. Sergio Fracchia, Novartis

CAR T cells in daily routine – first impressions

Prof. Dr. Peter Bader, University Hospital Frankfurt

Roundtable discussion on CAR-T-Cells

Networking dinner



Wednesday, 10 May 2023

08:15-15:30h

Panel: GMP Process Development

Not your typical academic GMP-facility: GT product manufacturing at German Red Cross Blood Service Centers

Prof. Dr. Halvard Bönig, German Red Cross Blood Service Center

Concepts and challenges for DP development of viruses

Dr. Thomas Kriehuber, Boehringer Ingelheim

Process development for GMP manufacturing of viral vectors

Dr. Klaus Kühlcke, BioNTech

Roundtable discussion on GMP Aspects

Panel: Release Testing

Microbiological release analytics on CT/GT products with focus on sterile testing

Dr. Thomas Meindl, L&S

Rapid detection of bacteria and fungi in CT/GT products prior treatment – validation of a real time PCR-based test

N.N.

Roundtable discussion on Release Testing

Panel: GMP Scale Up & Manufacturing

Catalent CDMO capabilities focus on industrialization in viral vector manufacturing

Peter Jaehn, Catalent

Establishing of a clinical grade manufacturing process for ROR1 CAR T-cells using a novel virus-free protocol

Gerno Schmiedeknecht, Unit Head, Fraunhofer Institute

Supply chain oversight, temp. conditions, implication for shipment under low temp

N.N.

Closing remarks

Magdalena Obarzanek-Fojt, Novartis

Karsten Cremer, Pharma Patents

Hans-Georg Eckert, Valicare

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



Location

Essentials by Dorint Frankfurt-Niederrad
Hahnstraße 9
60528 Frankfurt am Main
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phone +49 69 66306 0
mail reservierung.frankfurt-niederrad@dorint.com

Date

Course no.: 6916
from 08 May 2023
to 10 May 2023

10:30 h
15:30 h

Registration fee

All-day-ticket
Industry 1890 EUR
Authority/University 945 EUR
Students* 300 EUR

One-day ticket (each Mon/Tue/Wed)
Industry 790 EUR
Authority/University 395 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

Essentials by Dorint Frankfurt-Niederrad
Hahnstraße 9
60528 Frankfurt am Main
Germany
phone +49 69 66306 0
mail reservierung.frankfurt-niederrad@dorint.com
Participants should make their own
hotel reservation referring to the APV
seminar.
Deadline for special conference rate:
09 April 2023. Special rate: Single
room incl. breakfast: 125,00 €/night.

Cell&Gene Therapy, 08-10 May 2023, Frankfurt a.M., DE, Course no.: 6916

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

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the APV uses my data for the purpose of
processing the order and provides me with all
relevant information.

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Your data will not be shared with third parties. You
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(www.apv-mainz.de/en/imprint/data-protection-statement/).

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☐ Thursday only

☐ Wednesday only

☐ Friday only

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