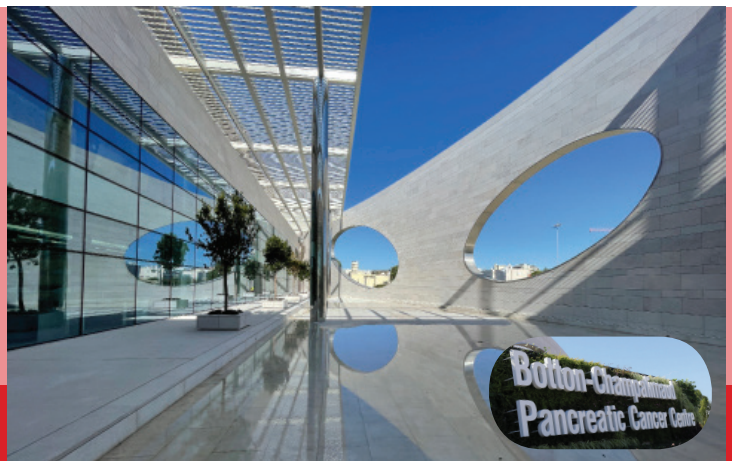
Advanced Therapy Medicinal Products (ATMPs): Regulation and GMP Manufacturing Basics

(including GMP facility tour at Champalimaud Foundation)



25 - 26 April 2024
Lisbon, Portugal

Course no. 6990

Biotechnology

Target group

ATMP Regulation & Manufacturing Basics Workshop:

The course is especially designed for people who are either in the first 10 years of their professional career, dealing with pharmaceutical manufacturing of cell therapy, gene therapy, tissue engineering products, or are from related business areas - or fulfill distinct tasks for which a profound and broad background knowledge is required in regard to regulation, manufacturing and testing of living, personalized drugs (ATMPs).

Personalized T-cell therapy has now reached the solid tumor field as a first-of-its-kind immunotherapy for patients with melanoma with an approval granted by the FDA on February 17th 2024!

In cooperation with

Champalimaud Foundation

APV MAKING SCIENCE WORK

Objectives of the workshop

To present and discuss scientific expertise in the development, manufacturing, analysis, quality assurance, distribution and clinical use of advanced therapy medicinal products (ATMPs), knowledge sharing and to support interested stakeholders in cell therapy and regulatory processes.

We offer a discussion platform for:

- Active participation in an interdisciplinary workshop,
- individual networking with enthusiastic, like-minded colleagues,
- workshop and training of the highest quality.

Goals of the "ATMP Regulation & Manufacturing Basics Workshop":

The event will transfer background knowledge for ATMPs and ATMP-GMP-regulation and state of the art manufacturing . This information is hard to find and only available in a very limited manner.

This workshop provides an introduction to the topic of "Advanced Therapy Medicinal Products" (ATMPs), with a special focus on the requirements for GMP-compliant manufacturing and quality control. This comprises basic and expert knowledge followed up by interactive, moderated discussions and Q&A sessions.

Lectures will include:

- ATMP Regulatory Requirements
- ATMP GMP Manufacturing and Quality Control
- ATMP Specification Setting
- Development and validation of complex analytical methods, e.g. Flow Cytometry
- Possibilities to interact with the speakers and attendees on specific topics in moderated discussions

Basic knowledge is offered regarding:

- the specific nature of Advanced Therapy Medicinal/ Drug Products (what are ATMPs? how do they differ from other drugs? how is manufacturing realized?),
- special features (how is the current state of the art in production and quality control/specification, defined?)
- and the regulatory requirements of ATMPs (how do the ATMP-GMP rules in part VI of the EU-GMP guidelines differ from the requirements of medicinal products (part I) and active ingredients (part II).

The Q&As, moderated discussions and an attendees topic session are a substantial part of the course. Attendees` will be asked up-front for specific short topics which will then be incorporated in the program. Questions can be asked up-front, during and after the lectures and will be collected and discussed/answered by the experts afterwards in a moderated discussion.

Including onsite facility tours:

All participants of both workshops will have the possibility of joining two separate facility tours through the new clinical building of the Champalimaud Centre of the Unknown and the newly installed GMP manufacturing facility, which is currently in the qualification phase.

Course leaders

Magdalena Obarzanek-Fojt, PhD
Novartis Pharma AG

Dr. Obarzanek-Fojt works at Novartis in the 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 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 has been 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 filling, as well as BLA filing for Kymriah, the first approved ATMPs in the US.

Magdalena has a strong passion for innovative approaches in medicine such as Cell and Gene Therapies and tissue engineering. She strives to implement harmonized approaches and strategic solutions..

Magdalena is a member of APV Drug Delivery Focus Group, as an expert for ATMPs.

Hans-Georg Eckert, PhD
Valicare GmbH

Dr. Hans-Georg Eckert is General 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 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, Hans-Georg accomplished 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.

Hans-Georg is head of APV Focus Group Pharmaceutical Biotechnology and an ATMP-GMP expert.

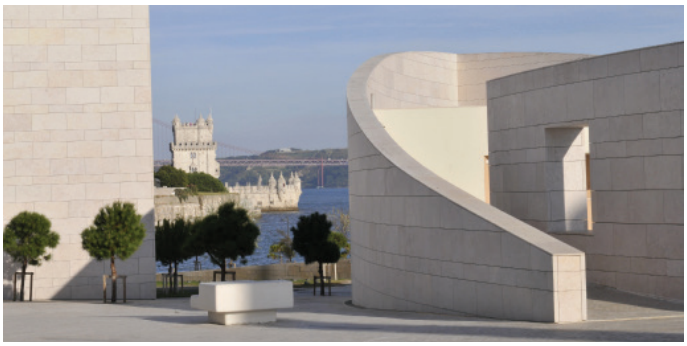
TIL regulatory talks: Open for participants of the ATMP Regulation & Manufacturing Basics Workshop

13:30 - 15:30 h TIL for the treatment of patients with solid cancer – experts on future perspectives

Regulation of `Tumor Infiltratong Lymphocytes´ in Europe
N.N., CAT/INFARMED speaker to be named

Cell therapies come of age – balance of efficacy and safety
Michael Bachmann, Helmholtz-Zentrum Dresden-Rossendorf (HZDR) and German Cancer Consortium (DKTK), Dresden and German Cancer Research Center (DKFZ), Heidelberg

Moderated panel discussion



Program

Thursday, 25 April 2024 15:30-18:30 h

Common Facility Introduction both courses 15:30 - 16:30 h

Opening ceremony and welcome address
Markus Maeurer, Cristina Afonso, Joaquim Teixeira, Magdalena Obarzanek-Fojt, Hans-Georg Eckert

From Vision to reality: installation of GMP manufacturing facility at Champalimaud Foundation – concept, construction, manufacturing start-up
Cristina Afonso, Nuno Pareira, Joaquim Texeira, Champalimaud Foundation & Peter Christian Rehm, Hans-Georg Eckert, Syntegon/Valicare

The Champalimaud Center of the unknown – history of a modern hospital facility
speaker tbd, Champalimaud Foundation

Facility/Hospital Tours 16:30 - 18:30 h
GMP Manufacturing Facility tour Botton Champ. Pancreatic Center Champalimaud Centre for the Unknown Hospital Round Tour

Social Program ATMP Regulation & Manufacturing Basics Workshop 18:45 h
Tejo sightseeing walk to places of interest, e.g. Hieronymites Monastery (Mosterio dos Jeronimos) and Tower of Belem. Networking dinner at Darwin's Cafe, Drinks & Food

Friday, 26 April 2024 09:00 - 17:00 h

Welcome reception and introductory session
Magdalena Obarzanek-Fojt, Hans-Georg Eckert

Basic regulation of ATMPs in Europe
Ralf Sanzenbacher, Paul-Ehrlich-Institute

EMA, US-FDA and PIC/S – guideline comparison global view
Wassila Cherief, Roche

Moderated discussion

Coffee break

Cell & gene therapy product development challenges and considerations
Magdalena Obarzanek-Fojt, Novartis

ATMP process risk analysis and validation
Hans-Georg Eckert, Valicare

ATMPs – QC, specifications, method development and validation
Claudia Papewalis, Valicare

Moderated discussion

Industrial sponsored lunch break 13:00 - 14:30 h

Decentralized autologous cell therapy manufacturing at the point of care - advantages of harmonized tils manufacturing in an OMPUL™ (Orgenesis Mobile Processing Units and Labs™)
Moran Meiron, Orgenesis

TIL characterization by flow cytometry
Michael Kapinsky, Beckman Coulter

Gene therapy manufacturing: end-to-end process steps and key pain points
Magdalena Obarzanek-Fojt, Novartis

Coffee break

How to tackle regional differences in CMC requirements for a global clinical / commercial development
Robert Zoubek, Granzer

Pre-Selected Attendees` Topics & Questions
Selected speakers

Farewell address and closing remarks
Markus Maeurer, Cristina Afonso, Joaquim Teixeira, Magdalena Obarzanek-Fojt, Hans-Georg Eckert

Program is subject to change

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

Location

Champalimaud Foundation and Botton-Champalimaud Pancreatic Cancer Centre, Lisbon Portugal
Avenida Brasília
1400-038 Lisboa
Portugal
phone + 351 210 480 200
mail info@fundacaochampalimaud.pt
web www.fchampalimaud.org

Registration fee

Separated tickets: 6990 ATMP (25-26.4.)

Industry	1390 EUR
Authority/University	695 EUR
Students*	150 EUR

Combined ticket TIL and ATMP (24-26.04.) (6991)

Industry	2490 EUR
Authority/University	1245 EUR
Students*	250 EUR

Registration

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

(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.

Hotel reservation

Please book your hotel yourself. We recommend using offical hotel booking platforms such as booking.com or hrs.com.

Date

Course no.: 6990 (ATMP)
from 25 April 2024 15:30 h
to 26 April 2024 17:00 h

ATMP Regulation & Manufacturing Basics Workshop, 25 - 26 April 2024, Lisbon, Portugal, Course no.: 6990

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 has been 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 *

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Street/no. or P.O. box *

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Zip-code and city *

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E-mail-address participant *

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☐ Pay via invoice

☐ pay via credit card (Visa, MasterCard, Amex)

(You will receive further payment information with the invoice)

Select ticket*:

☐ ATMP Regulation & Manufacturing Basics Workshop (6990)

Participants ATMP attendance of TIL regulatory talks on 25.04.23:

☐ I will join the TIL regulatory talks

☐ I will not join earlier

☐ Combi 6991: TIL Expert Workshop (6989) + ATMP Basics Workshop (6990)

Date * Signature *

** Mandatory*

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Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology

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