

Champalimaud's "TIL (Tumor Infiltrating Lymphocytes) for the Treatment of Patients with Solid Cancer – Experts on Future Perspectives"

combined with

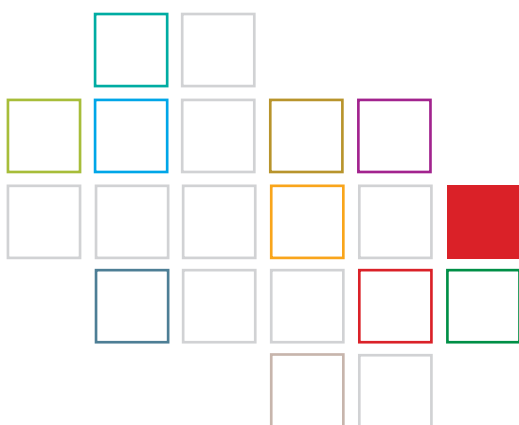
Advanced Therapy Medicinal Products (ATMPs): Regulation and GMP Manufacturing Basics



24 - 26 April 2024

Lisbon, Portugal

Course no. 6991 (6989 and 6990)



Biotechnology

Target group

TIL for the Treatment of Patients with Solid Cancer – Experts Future Perspectives workshop:

Experts from science, industry and authorities involved in development, regulation and marketing of TIL or other T-cell based (transgenic) therapeutic products; Physicians involved in cell-based immunotherapy and immunotherapy in general; Individuals involved in TIL manufacturing and other transgenic immune cell products. Scientists engaged in the development of new cell therapeutic platforms.;Interested individuals who may profit from concept and process oriented inclusive discussions addressing immune cell biology and regulatory hurdles.

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!

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).

In cooperation with



**Champalimaud
Foundation**



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 “TIL for the Treatment of Patients with Solid Cancer – Experts Future Perspectives” workshop:

The 1,5-day workshop includes a public overview presentation provided by internationally renowned experts and key opinion leaders in the field of cell therapy for patients with cancer: Michael T Lotze, UPMC, USA and Markus Maeurer, University of Mainz, Germany and Champalimaud Foundation, Portugal.

The remaining closed part of the workshop will provide an expert view on TIL as a therapeutic treatment option for patients with different tumor entities. Speakers will share state of the art background knowledge from the research & development of biologically and clinically relevant therapeutics, including updates on current TIL protocols and trials, the increased recognition of “non-conventional” T-cells in cell therapy, the biological significance of molecular mapping of the raw product, high-content immuno-monitoring, personalized vaccine trials and transgenic immune cell products. The seminar will focus on regulatory (GMP) and quality aspects of the starting cell material, isolation, expansion of T-cells from different cancer types, ex-vivo T-cell education with defined tumor-antigens, manufacturing of clinical trial material and the specification of the final release cell product. Round table discussions will provide discussions about regulatory and scientific topics in an interactive, open and inclusive manner.

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.

Both courses include 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.

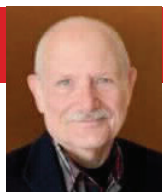


Course leaders



Prof. Markus Maeurer, MD, PhD, FRCP (London) Champalimaud Foundation

Markus J Maeurer received his Medical degree from the Johannes Gutenberg University of Mainz, Germany in 1989. He has been a Research Fellow at the Department of Surgical Oncology, University of Pittsburgh, USA, Assist. Prof of Surgical Oncology and Immunotherapy at UPMC, Pittsburgh, PA, USA. (1999) full Professor of Microbiology and Infectious Diseases at the University of Mainz and Head of the diagnostic Laboratory at the Department of Medical Microbiology (2005) Professor of Infectious Diseases, particularly Clinical Immunology, at the MTC (Microbiology, Tumor Biology Center) of the Karolinska Institute. He then served as head of the division of Therapeutic Immunology at the Karolinska Institute and as Senior Physician of the Center for allogeneic stem cell transplantation, CAST, Karolinska Hospital from 2012 to 2017. Dr. Maeurer is head of immunotherapy / ImmunoSurgery at the Champalimaud Foundation, Lisbon, and Full Professor at the I Medical Clinic of the University of Mainz, Germany. He has published more than 310 scientific articles (28 of which are in the LANCET series) he created 9 patents, and he serves as a reviewer for several international grant agencies, governments and at several high impact journals as editor or reviewer. He is an advisor for the Bill and Melinda Gates Foundation, for the UK Parliament and the Italian Government. He is a Fellow of the Royal Chamber of Physicians, London, and initiated with Sir Alimuddin Zumla (UCL, UK) the consortium against cancer and infectious diseases with a particular focus on COVID-19 (<https://www.fchampalimaud.org/covid19>). He is responsible for governing the newly established GMP facility (for GMP and non-GMOs) at the Champalimaud Foundation.



Michael T. Lotze, MD UPMC

Michael T. Lotze, M.D. served as Chief Cellular Therapy Officer of Nurix and previously as Chief Scientific Officer at Iovance. He is a leading clinician scientist with more than 40 years of experience in immunology and clinical medicine, dedicating his efforts to the advancement of translational research, particularly in immunotherapy for cancer including dendritic cell, T cell, and cytokine therapies. Dr. Lotze is the co-inventor of multiple patents in dendritic cell vaccines and antigen discovery, and tumor infiltrating lymphocyte therapy. He previously held leadership roles in the biopharmaceutical industry as vice president of research at GlaxoSmithKline. Currently, Dr. Lotze serves as professor of surgery, immunology, and bioengineering, and director for Damage Associated Molecular Pattern Molecule (DAMP) Laboratories at the University of Pittsburgh Medical Center Hillman Cancer Center. He is also senior advisor for the Immune Transplant and Therapy Center within the University of Pittsburgh Medical Center Enterprises and serves as associate editor of the Journal of Immunotherapy. Over

the course of his career, he has authored more than 500 publications and several books. Dr. Lotze holds an M.D. from Northwestern University and completed his postdoctoral training as a scientist at the National Cancer Institute under Dr. Steven Rosenberg.



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 a biologist and has more than 20 years of professional experience in accompanying and managing GMP compliance tasks.

During different occupations he has 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 has accomplished more than 100 consultancy tasks for customers in the GMP regulated Industry. He has successfully managed complex GMP compliance projects and has been responsible for the execution of more than 700 different quality projects and customized services. He has led Valicare since 2016 with a strategic focus on ATMP-GMP projects.

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



TIL FOR THE TREATMENT OF PATIENTS WITH SOLID CANCER – EXPERTS ON FUTURE PERSPECTIVES

Program

Wednesday, 24 April 2024 09:00 - 17:30 h

09:00 - 11:15 h

Welcome address

Leonor Belez, João Silveira Botelho, Markus Maeurer
Champalimaud Foundation, Lisbon, Portugal

The Champalimaud TIL program

Markus Maeurer, Champalimaud Foundation, Lisbon, Portugal

Cellular immunotherapy and TIL – history of development and a future foretold

Michael T. Lotze, Departments of Surgery, Immunology, and Bioengineering, University of Pittsburgh Medical Center, Pittsburgh, USA

Moderated discussion

Farewell for public participants and coffee break

Closed Expert Workshop 11:15 - 17:30 h

Welcome address to the participants of the workshop

Markus Maeurer, Champalimaud Foundation, Lisbon, PT

Losing it all – the case for functional MHC expression testing: prerequisites for cell therapy

Barbara Seliger, Translational Immunology MHB Fontane Brandenburg, Brandenburg, Germany

TCR gamma-delta – T-cells for immunotherapy of epithelial cancers

Dieter Kabelitz, UKSH Institute Immunology, University of Kiel, Kiel, Germany

Moderated discussion

Lunch break kindly sponsored by Lonza

13:00 - 14:30 h

Presentation of the Lonza Cocoon System

Clonal neoantigens as key targets for TIL therapy in non-small cell lung cancer

Sergio Quezada, University College London and Achilles London, UK

Clonotypes dynamic and specificity as correlates of efficacy of TIL therapy

Alexandre Harari, Ludwig Institute for Cancer Research, Lausanne, Switzerland

Moderated discussion

Coffee break

The other side of T-cell therapy: private mutations - peptide cancer vaccination
Saskia Biskup, CeGaT & University of Tuebingen, Tuebingen, Germany

Interaction of TIL with the TME – good or bad?
Elfriede Noessner, Helmholtz Center, Munich, Germany

Moderated discussion

Social Program TIL Expert Workshop 18:00 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

Thursday, 25 April 2024

Closed Expert Workshop 08:45 - 18:30 h

Introduction

Markus Maeurer and Carlos Carvalho
Champalimaud Foundation, Lisbon, Portugal

TIL expansion for the treatment of patients with epithelial cancer

Markus Maeurer, Champalimaud Foundation, Lisbon, PT

TIL – treatment for patients with melanoma. Clinical experience and future directions

Guy Ben-Betzalel, Ella Lemelbaum Institute for Immunology, Sheba Clinic, Tel HaShomer, Israel

Moderated discussion

Coffee break

Managing Exhaustion and T-cell fitness: Lessons from CAR-T-cell therapies

Orit Itzhaki, Sheba-Clinical Center, Tel HaShomer, Israel

A tale of tribulations and trials: developing a cell therapy program in Europe

Lana Kandalaft, Chief of Service of the Center of Experimental Therapeutics Dept of Oncology, CHUV-UNIL Assoc. Dir of clinical translation/Ludwig Institute for Cancer Research, Lausanne, CH

Moderated discussion

Lunch break kindly sponsored by Wilson Wolf Corporation

12:00 - 13:30h

Presentation of G-Rex, Cell Ready System, Wilson Wolf Corp.

Regulation of 'Tumor Infiltrating Lymphocytes' in Europe

N.N., CAT/INFARMED speaker to be named

Cell therapies come of age – balance of efficacy and safety: lessons from CAR-T-cell trials

Michael Bachmann, Helmholtz-Zentrum Dresden-Rossendorf (HZDR) and German Cancer Consortium (DKTK), Dresden and German Cancer Research Center (DKFZ), Heidelberg, Germany

Moderated panel discussion

Coffee break and farewell Address to Participants of Champalimaud's Closed Expert Workshop

Common part of both courses 15:30 - 18:30 h

Program is subject to change

BOTH COURSES: TIL and ATMP

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

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 Pereira, Joaquim Texeira,
Champalimaud Foundation & Peter Christian Rehm, Hans-
Georg Eckert, Syntegon/Valicare

The Champalimaud Centre for the Unknown – history
of a modern hospital facility
Joaquim Teixeira and Carlos Carvalho, Champalimaud
Foundation

Facility/Hospital Tours 16:30 - 18:30 h
GMP Manufacturing Facility tour and Champalimaud Centre for
the Unknown Hospital Round Tour

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

Program

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

Welcome reception

Opening ceremony and welcome address
Magdalena Obarzanek-Fojt, Novartis and Hans-Georg
Eckert, Valicare

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

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

6991 Combined ticket TIL & ATMP
Industry 2490 EUR
Authority/University 1245 EUR
Students* 250 EUR
Separated tickets: 6989 TIL (24-25.4.)
Industry 1590 EUR
Authority/University 795 EUR
Students* 150 EUR
Separated tickets: 6990 ATMP (25-26.4.)
Industry 1390 EUR
Authority/University 695 EUR
Students* 150 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 official hotel
booking platforms such as
booking.com or hrs.com.

Date

Course no.: 6991 (6989(TIL),6990(ATMP))
from 24 April 2024 09:00 h
to 26 April 2024 17:00 h

TIL Expert Workshop & ATMP Regulation & Manufacturing Basics Workshop, 24 - 26 April 2024, Lisbon, Portugal, Course no.: 6991 (6989 + 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 protec- tion

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
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email or post.

Your data will not be shared with third parties. You
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E-mail-address participant *

Order no. and/or billing address

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pay via credit card (Visa, MasterCard, Amex)

(You will receive further payment information with the invoice)

Select ticket*: Combi: TIL Expert Workshop + ATMP Reg. & Manuf. Basics Workshop (6991)

TIL Expert Workshop (6989) ATMP 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

Date *

Signature *

* Mandatory

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