

Champalimaud's "Tumor Infiltrating Lymphocytes (TIL) – Experts on Future Perspectives"

combined with

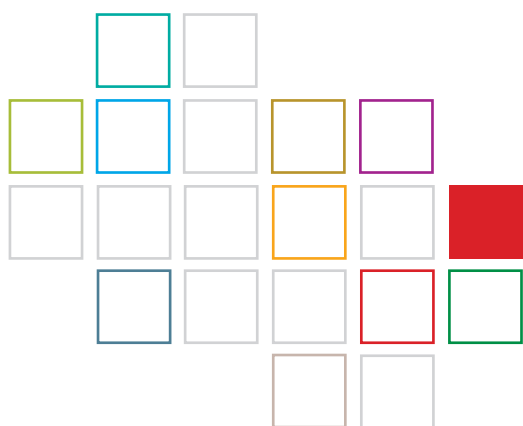
APV's "ATMP Manufacturing Basics Summer School" for advanced students and interested industrial stakeholders



26 - 28 June 2023

Lisbon, Portugal

Course no. 6958 and 6959



Biotechnology

Target group

Tumor Infiltrating Lymphocytes – Experts Future Perspectives workshop:
Experts from science, industry and authorities being involved in development, regulation and marketing of TILs as a cell therapeutic product. Physicians involved in patient's treatment. Most of the conditions of TIL manufacturing are comparable also to other cell therapeutics, scientists engaged in the development of other new cell therapies will also profit from expert discussions.

ATMP Manufacturing Basics Summer School 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 or tissue engineering products or are from related business areas or fulfill distinct tasks for which it is necessary to have a profound and broad background knowledge on the regulation, manufacturing and testing of living, personalized drugs (ATMPs).

In cooperation with



**Champalimaud
Foundation**





Objectives of the workshop

Our purpose is to expand scientific expertise in development, manufacture, analysis, quality assurance, distribution and usage of pharmaceuticals, to impart this knowledge to professionals and to support young scientists.

We offer an independent, non-profit platform for:

- Active participation in interdisciplinary working groups,
- individual networking with enthusiastic, like-minded colleagues,
- workshops, conferences and trainings of highest quality.

Goals of the “Tumor Infiltrating Lymphocytes – Experts Future Perspectives” workshop:

The 2-day workshop includes one public overview presentation provided by internationally well-known experts and key opinion leaders in the field of cell therapy for patients with cancer, Dr. Jason Bock, MD Anderson and CTMC, USA, George Coukos, Ludwig Institute for Cancer Research, CH, Michael T Lotze, UPMC, USA, Stefan Rose-John, University of Kiel, DE, Julie Fleshman, USA, chair of the steering committee of the world pancreatic cancer coalition, shares her worldwide disruptive view concerning current and future treatment options from the patient's perspective.

The remaining closed part of the workshop will provide an expert view on TILs as a therapeutic treatment option for different tumor entities. Speakers will share state of the art background knowledge from research & development of these 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 and personalized vaccine trials. The seminar will additionally focus on regulatory (GMP) and quality aspects of the sourcing of the starting materials (tumor resection), isolation and expansion of tumor cells from different histologies and anatomical localizations,, the manufacturing of clinical trial material and the specification of the T-cell product. Round table discussions will provide a platform for the participants to discuss their regulatory and scientific topics in an interactive manner.

Goals of the “ATMP Manufacturing Basics Summer School”:

Events transferring background knowledge for ATMPs and ATMP-GMP-manufacturing are very limited in the market. The pharmaceutical industry falls back on expert events that overwhelm even advanced students and also many industrial employees due to their scientific and procedural demands.

This part of the workshop provides an introduction to the topic of “Advanced Therapy Medicinal Products” (ATMPs), with special focus on CAR-T Therapy, from the perspective of the pharmaceutical and biopharmaceutical industry. It has a special focus on the requirements for GMP-compliant

manufacturing and quality control. This includes basics followed up by interactive Q&A sessions in:

- ATMP Regulatory Affairs
- ATMP Manufacturing and Quality Control
- ATMP Specification Setting
- Qualification/Validation
- Attendees specific topics sessions

Basic knowledge is offered regarding:

- 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 Q&As and attendees topic sessions are a substantial part of the course. Attendees may also be asked upfront for specific short topics which will then be included into the program in specific sessions. Questions can be asked upfront, during and after the lectures and will be collected and discussed/answered by the experts afterwards in the Q&A sessions.

Both courses include onsite facility tours:

All participants of the both workshops will have the possibility to join two separate facility tours through the new hospital building of the Champalimaud Centre of the Unknown and the newly installed GMP manufacturing facility, which is in the qualification phase at that time.

Course leaders



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

Markus J Maeurer received 1989 his Medical degree at the Johannes Gutenberg University of Mainz, Germany; 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 and Head of the diagnostic Laboratory at the Department of Medical Microbiology 2005 Professor of Infectious Diseases, particularly Clinical Immunology, at the Karolinska Institute, at the MTC (Microbiology, Tumor Biology Center). He served then as head of the division Therapeutic Immunology at Karolinska Institute and Senior Physician of the Center for allogeneic stem cell transplantation, CAST, Karolinska Hospital 2012-2017.

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, published more than 310 scientific articles, 28 among them in the LANCET series, he created 9 patents, he serves as a reviewer for several international grant agencies, governments and at several high impact journals as editor or reviewer.

Advisor for the Bill and Melinda Gates Foundation, for the UK Parliament and the Italian Government, Fellow of the Royal Chamber of Physicians, London; 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 Botton-Champalimaud Cancer.



**Michael T. Lotze, MD
UPMC**

Michael T. Lotze, M.D. has served as Chief Cellular Therapy Officer of Nurix since June 2020. He is a leading clinician scientist with more than 30 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 the chief scientific officer of Iovance Biotherapeutics and vice president of research at GlaxoSmithKline. Prior to joining Nurix, Dr. Lotze served as professor of surgery, immunology, and bioengineering, vice chair of research within the Department of Surgery and director for Damage Associated Molecular Pattern Molecule (DAMP) Laboratories at the University of Pittsburgh Medical Center Hillman Cancer Center. He was 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 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.

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.





TUMOR INFILTRATING LYMPHOCYTES (TIL) – EXPERTS FUTURE PERSPECTIVES

Programme

Monday, 26 June 2023

08:45 - 18:00 h

8:45 - 14:00 h

Welcome address

Leonor Belez, João Silveira Botelho, Markus Maeurer
Champalimaud Foundation

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

The Champalimaud Pancreatic Cancer and TIL Program

Markus Maeurer, Champalimaud Foundation

Minding and Mastering IL-6 in the Treatment of Patients with Pancreatic Cancer

Stefan Rose-John, University of Kiel

Moderated discussion

Coffee break

PanCan and its Precision Promises- The Patient's Perspective - European and American

Julie Fleshman, CEO and President PanCAN, Chair of the Steering Committee of the World Pancreatic Cancer Coalition

The Future of T-cell Therapy for Patients with Cancer

George Coukos, Director of Hi-TiDe - Human integrated tumor immunology discovery engine, Head of the Department of oncology UNIL CHUV, Director of Ludwig Institute for Cancer Research Lausanne

Enhanced TIL: Gene-modified TIL for the Treatment of Patients with Epithelial Cancer

Jason Bock, MD Anderson and CTMC

Moderated discussion

Closed Expert Workshop

14:00 - 18:00 h

Lunch break kindly sponsored by Lonza 14:00 - 15:15 h

Presentation of the Lonza Cocoon System

TIL Expansion for the Treatment of Patients with Pancreatic Cancer

Markus Maeurer, Champalimaud Foundation

Unconventional T-cells in PDAC

Pranav Murthy, University of Pittsburgh and Adicet Bio

Perspectives of Gamma-Delta T cells for immunotherapy of Epithelial Cancers

Dieter Kabelitz, UKSH Institute Immunology, University of Kiel

Moderated discussion

Coffee break

Clinical Pathology - Tissue as the Starting Material for ATMPs: Developing Organoids and TIL from Pancreatic Cancer

Renee Anderko, University of Pittsburgh

Clonotypes Dynamic and Specificity as Correlates of Efficacy of TIL Therapy

Alexandre Harari, Human integrated tumor immunology discovery engine (Hi-TiDe) -T cell discovery, Department of Oncology UNIL & CHUV, Ludwig Institute for Cancer Research Lausanne

Moderated discussion

Social Program on Monday

18:00 h

Tejo sightseeing walk to places of interest, e.g. Hieronymites Monastery (Mosteiro de Jeronimus and Tower of Belem)
Networking dinner at Darwin's Cafe, Drinks & Food

Tuesday, 27 June 2023

Closed Expert Workshop

08:45 - 19:30 h

Introduction

Markus Maeurer and Carlos Carvalho
Champalimaud Foundation

The future of Pancreatic Cancer Surgery

Markus Buechler, Champalimaud Foundation

Diagnostic Pathology: The Role of Pathology in Precision Medicine and Therapeutic Development

Peter Schirrmacher, University of Heidelberg

Moderated discussion

Coffee break

Neoadjuvant Therapy for Pancreatic Cancer: Window of Opportunity Studies for Immunotherapy

Michael T. Lotze, Nurix Therapeutics & University of Pittsburgh Medical Center

Clinical Precision Medicine: Clonal Neoantigens as Key Targets for TIL Therapy Update from the Achilles trial from Patients with Lung Cancer

Sergio Quezada, University College London

Moderated discussion

Lunch break kindly sponsored by Wilson Wolf Corporation

12:15 - 13:30h

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

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

EMA Regulation of TIL

N.N., EMA representative

FDA-approved TIL Products – Current and Future Personalized Therapies

Raj Puri, Executive Vice President, Regulatory Strategy and Translational Medicine, Iovance Biotherapeutics, former FDA

From Basic Understanding of Tumor Immune Escape Mechanisms to Clinical Reality

Barbara Seliger, Institute for Translational Immunology Brandenburg, Martin Luther University Halle-Wittenberg, Institute for Medical Immunology, Halle and Fraunhofer Institute for Cell Therapy and Immunology, Leipzig

Moderated discussion

Coffee break

T-cell Therapy and Dendritic Cell Vaccination

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

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

Moderated discussion

Farewell Address to Participants of Champalimaud's Closed Expert Workshop

Facility/Hospital Tours

18:15 - 19:30 h

GMP Manufacturing Facility tour Botton Champ. Pancreatic Center
Champalimaud Center of the Unknown Hospital Round Tour

Programme is subject to change



ATMP MANUFACTURING BASICS SUMMER SCHOOL

Programme

Tuesday, 27 June 2023

17:45-19:30 h

Welcome reception

Opening ceremony and welcome address

Markus Maeurer, Cristina Afonso, Joaquim Teixeira, Magdalena Obarzanek-Fojt, Hans-Georg Eckert

Facility/Hospital Tours

18:15 - 19:30 h

GMP Manufacturing Facility tour Botton Champ. Pancreatic Center
Champalimaud Center of the Unknown Hospital Round Tour

Social Program

20:00 h

Networking dinner at Darwin's Cafe, Drinks & Teajoview

Wednesday, 28 June 2023

08:45 - 17:00 h

Welcome reception and introductory session

From Vision to Reality: GMP facility at the Champalimaud Foundation

Cristina Afonso, Nuno Pareira, Joaquim Teixeira, Champalimaud and Peter-Christian Rehm, Syntegon

Basic Regulation of ATMPs in Europe

Ralf Sanzenbacher, Paul-Ehrlich-Institute

EMA, US-FDA and PIC/S – Guideline Comparison Global View

Jasna Curak, Roche

Cell & Gene Therapy Product Development Challenges and Considerations

Magdalena Obarzanek-Fojt, Novartis

Coffee break

ATMP Development and Manufacturing License Setup

ATMP-Specific GMP-Requirements Based on Part IV EU-GMP-Guideline

Hans-Georg Eckert, Valicare

ATMP Process Validation

Sergio Fracchia, Novartis

Q&A Session

All speakers

Lunch break

12:45 - 14:15 h

ATMP Development and Manufacturing License Setup

Gene Therapy Manufacturing: End-to-End Process Steps and Key Pain Points

Magdalena Obarzanek-Fojt, Novartis

Pre-Selected Attendees Topics & Questions

Selected speakers

Coffee break

ATMP QC, Specification and Validation

ATMPs – QC, Specifications, Method Development and Validation

Claudia Papewalis, Valicare

Q&A Session

All speakers

Farewell address and closing remarks

Markus Maeurer, Cristina Afonso, Joaquim Teixeira, Magdalena Obarzanek-Fojt, Hans-Georg Eckert

Programme 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
Center, Lisboa Portugal
Avenida Brasília
1400-038 Lisboa
Portugal
phone + 351 210 480 200
mail info@fundacaochampalimaud.pt
web www.fchampalimaud.org

Registration fee

Combined ticket TIL and ATMP

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

Seperate tickets: 6958 TIL (26-27.6.)

Industry	1590 EUR
Authority/University	795 EUR
Students*	150 EUR

Seperate tickets: 6959 ATMP (27-28.6.)

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.

Date

Course no.: 6958 (TIL) + 6959 (ATMP)
from 26 June 2023 08:45 h
to 28 June 2023 17:00 h

Registration only for Champalimaud's open public session only (26.6. 08:45-14:00 h):
please use this link to register: <https://bit.ly/442kOwa>

TIL Expert Workshop and ATMP Summer School, 26 - 28 June 2023, Lisbon, Portugal, Course no.: 6958 + 6959

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 protec- tion

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the APV uses my data for the purpose of
processing the order and provides me with all
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☐ TIL Expert Workshop (6958) ☐ ATMP Summer School (6959)

Select attendance*: ☐ in person/on site ☐ remote/online

Date *

Signature *

* *Mandatory*

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