



CERTIFICATE OF ADVANCED STUDIES (CAS)

# Advanced Therapy Medicinal Products

Product manufacturing and clinical use of ATMPs

## TARGET AUDIENCE

Healthcare professionals and scientists interested in the emerging field of advanced therapies, including pharmacists, physicians, medical researchers, biologists, healthcare engineers, biostatisticians

## ORGANISATION

- Faculty of Biology and Medicine (FBM), University of Lausanne (UNIL), Switzerland
- Faculty of Science, University of Geneva (UNIGE), Switzerland

## INTRODUCTION

Advanced therapy medicinal products (ATMPs) such as cell therapy, tissue-engineered medicine or immunotherapy, as well as innovative medicines like phage therapy or nanomedicine, are pushing the boundaries of currently available treatments. Oncology, reconstructive surgery, orthopaedic surgery, neurosurgery, blood transfusion, infectious diseases – clinical applications are numerous.

Providing healthcare professionals with a thorough understanding of these therapeutic breakthroughs is essential to ensure the effective transition of these innovative treatments and care techniques from the bench to the bedside.

## OBJECTIVES

- Discover therapeutic advances in standardized transplants, cell-based products, blood products, complex and personalized medicines and innovative drug combinations
- Acquire specialized knowledge of the different innovative therapies and their interaction with biological tissues
- Understand the good manufacturing practices (GMP) required for these new types of medicines
- Develop skills in quality control, quality assurance, and regulatory affairs
- Understand the determinants of clinical applications of ATMPs and combinatorial therapies



## Module 1

### CELLULAR THERAPY – FROM BENCH TO BEDSIDE

- 7h face-to-face teaching + 14h online teaching + ~45h individual work
- Thur November 16, 2023 / Fri November 17, 2023 / Fri February 9, 2024
- **Principles of translational science**  
Cell biology / Preclinical relevance and evaluation / Biological products specificities
- **Types of cellular therapy**  
Sources of cells / Clinical targets / Clinical strategies / Histocompatibility
- **Clinical trials of cellular therapy**  
Examples of human applications : burn patients, orthopedics, neuroscience
- **Regulatory aspects of cellular therapy**  
Basis in EU and Switzerland for Good Manufacturing Practices (GMP), Good Clinical Practices (GCP) & ATMPs specificities
- **Production of cellular therapy**  
GMP / Clean room / Manufacturing technologies / T cells
- **Visit of a GMP cellular manufacturing facility**

**Module leaders :** Prof. Lana Kandalaf and Dr Jean-François Brunet

## Module 2

### IMMUNOLOGY

- 7h online teaching + ~15h individual work
- Fri December 15, 2023
- **Introduction to immunology**  
Organs, tissues, functions of the immune system / Innate & adaptive immunity
- **Analytical immunology**  
Overview / Biomarkers / Immune correlates
- **Limitations of immunotherapies**  
Tolerance and autoimmunity / Toxicity / Side effects

**Module leader :** Prof. Alexandre Harari

## Module 3

### TRANSFUSION MEDICINE – SCIENCE AND TECHNOLOGY FROM DONOR TO PATIENT

- 7h face-to-face teaching + 14h online teaching + ~45h individual work
- Thur January 11, 2024 / Fri January 12, 2024 / Thur February 8, 2024
- **Introduction to transfusion medicine**  
Historical developments / Transfusion chain / Blood groups / Immunohematology / Transfusion-related risks
- **Biology and biochemistry of blood products**  
Red blood cells and platelets / Fresh frozen Plasma
- **Medical aspects**  
Needs and use of blood products / Apheresis / Hematopoietic stem cells / Clinical cases and practices
- **Production and regulatory aspects**  
Blood & special products preparation and manufacturing / Regulations and GMP
- **Visits of production site and diagnostic labs**

**Module leader :** Prof. Michel Prudent

## Module 4

### COMBINATORIAL STRATEGIES IN CANCER TREATMENT

- 7h face-to-face teaching + 21h online teaching + ~60h individual work
- Thur March 14, 2024 / Fri March 15, 2024 / Fri March 22, 2024 / Wed June 12, 2024
- **Combination therapy**  
Advantages vs. monotherapy / Combinations strategies in various cancer types / Anti-angiogenic immunotherapy / Pharmacokinetics and pharmacodynamics / Drug resistance principles / Cell death in cancer therapy
- **Preclinical development**  
Drug repurposing / Drug interactions and synergies / Immunotargeting / Cell mitosis
- **Clinical development**  
Clinical trial development / Successful clinical trials examples / New combination strategies for cancer treatment design
- **Visit of research laboratories of cell biology and pharmacology**

**Module leader :** Prof. Patrycja Nowak-Sliwinska

## Module 5

### ONCOLOGY : INNOVATIVE THERAPIES

- 7h face-to-face teaching + 14h online teaching + ~45h individual work
- Thur April 11, 2024 / Fri April 12, 2024 / Fri June 14, 2024
- **Immunotherapy**  
Cellular and drug immunotherapies / Checkpoint inhibitors / Monoclonal antibodies
- **Personalized cellular immunotherapy**  
Chimeric Antigen Receptor (CAR) T cell / Vaccines / HSCT / Personalized medicine

**Module leader :** Dr Francesco Ceppi

## Module 6

### PHAGE THERAPY

- 10h face-to-face teaching + 7h online teaching + ~45h individual work
- Fri April 19, 2024 / Wed June 12, 2024 / Thur June 13, 2024
- **Introduction to phage therapy**  
Antibiotic resistance / Bacteriophages / History of phage discovery & phage therapy
- **Phage banks and production**  
Personalized phage therapy / Phages production processes
- **Phage-based pharmaceutical products regulations**  
Regulation challenges / GMP Basics
- **Modern translational studies and clinical studies**  
Phage-antibiotic synergism / Human applications
- **Practical course**  
Bacteriophage isolation from the environment

**Module leader :** Dr Grégory Resch

## Module 7

### NANOMEDICINES

- 7h online teaching + ~15h individual work
- Fri May 17, 2024
- **Introduction to nanomedicines**  
Nanomedicines types / Nanotechnology applications to drug therapies and vaccines / Pharmacokinetics & pharmacodynamics
- **Nanomedicines technology**  
Physicochemical properties biocompatibility / Nanoformulations / Critical Quality Attributes (CQAs)
- **Production and regulatory aspects**  
FDA and EMA regulations / The many challenges of nanomedicines development, production and clinical practices

**Module leader :** Prof. Gerrit Borchard

## CURSUS

The *Certificate of Advanced Studies (CAS)* in **Advanced Therapy Medicinal Products** is combining face-to-face and synchronous online teaching. It totals 392 hours of training, divided into 7 modules.

- **Face-to-face teaching (38h)**  
Plenary sessions, panel discussions, practical laboratory activities, visits of labs and manufacturing facilities.
- **Online teaching (84h)**  
Synchronous online teaching, video conferencing, panel discussions
- **Individual work (270h)**  
Readings, work on case studies, report writing.

Title obtained : **Certificate of Advanced Studies (CAS)** in **Advanced Therapy Medicinal Products** delivered by the universities of Lausanne and Geneva, 16 ECTS credits



From November 2023 to June 2024



- Programme spread over 8 months
- Blended learning combining face-to-face and synchronous online education



- Online and onsite
- Lausanne University Hospital
- Blood transfusion center, Bern



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6 000.– Swiss francs \*  
\*Payment in instalments possible



Online registration  
Registration deadline : August 21, 2023  
Number of participants is limited

LEARN MORE



## STEERING COMMITTEE

**Co-presidents :** **Prof. Chantal Csajka**, Full professor, Director of the Centre for Research and Innovation in Clinical Pharmaceutical Sciences, Lausanne University Hospital and UNIL ; School of Pharmaceutical Sciences, UNIGE / **Prof. Lana Kandalaft**, Chief of Service - Center of Experimental Therapeutics, Lausanne University Hospital and UNIL ; Associate Director for Clinical Translation – Ludwig Institute for Cancer Research / **Members :** **Prof. Patrycja Nowak-Sliwinska**, Associate Professor, Head of the Molecular Pharmacology Group, School of Pharmaceutical Sciences, UNIGE / **Prof. Michel Prudent**, Associate Professor, Head of Innovation and Therapeutic Products, Transfusion Interrégionale CRS SA ; Centre for Research and Innovation in Clinical Pharmaceutical Sciences, Lausanne University Hospital and UNIL / **Dr Grégory Resch**, Senior Lecturer, Head of the Bacteriophage and Phage Therapy Laboratory, Centre for Research and Innovation in Clinical Pharmaceutical Sciences, Lausanne University Hospital and UNIL

## SCIENTIFIC COMMITTEE

**President :** **Dr Grégory Resch**, Senior Lecturer, Head of the Bacteriophage and Phage Therapy Laboratory, Centre for Research and Innovation in Clinical Pharmaceutical Sciences, Lausanne University Hospital and UNIL / **Members :** **Dr Jean-François Brunet**, Head of the Cell Manufacturing Center, Service of Pharmacy, Lausanne University Hospital and UNIL / **Prof. Lana Kandalaft**, Chief of Service - Center of Experimental Therapeutics, Lausanne University Hospital and UNIL ; Associate Director for Clinical Translation – Ludwig Institute for Cancer Research / **Prof. Alexandre Harari**, Associate Professor, Head of the Tumor Immunology laboratory, Department of Oncology, Lausanne University Hospital and UNIL / **Dr Francesco Ceppi**, Lecturer and Medical Oncologist, Unit of Pediatric Oncology Hematology, Lausanne University Hospital and UNIL / **Prof. Patrycja Nowak-Sliwinska**, Associate Professor, Head of the Molecular Pharmacology Group, School of Pharmaceutical Sciences, UNIGE / **Prof. Michel Prudent**, Associate Professor, Head of Innovation and Therapeutic Products, Transfusion Interrégionale CRS SA ; Centre for Research and Innovation in Clinical Pharmaceutical Sciences, Lausanne University Hospital and UNIL / **Prof. Gerrit Borchard**, Full Professor, Head of the Biopharmaceutics laboratory, School of Pharmaceutical Sciences, UNIGE

## ADMISSION REQUIREMENTS

- Hold a bachelor's or master's degree from a Swiss or foreign university (HEU), from a University of Applied Sciences (HES), or hold another title deemed equivalent by the Steering Committee, and
- Have a minimum of 1 year of professional experience in the health care field

## REGISTRATION

- Admission on file to submit to Formation Continue UNIL-EPFL. Please join to the registration form, letter of motivation, CV, copies of diplomas obtained

## CONTACT

For academic questions :

**Dr Michele Graciotti**, Programme coordinator ; Project Manager, Center of Experimental Therapeutics, Department of Oncology, Lausanne University Hospital and UNIL

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