„FROM TARGET TO MARKET“

THE GLA BIOTECH PHARMA SUMMER SCHOOL

Date: 30 August – 02 September 2023

Time: 09.00 a.m. – 06.30 p.m. (plus evening events)
Location: Gläsernes Labor, Building 13, Rooms 202, 203
Robert-Rössle-Str. 10, 13125 Berlin-Buch

Lecturers: Our trainers are experts in medicine, pharmaceutical industry, biotech companies, leaders of contract research institutes and consultants for clinical development.

Content: The modular course concept combines lectures with case-oriented, practical exercises on each level of the clinical development. Attendees get a comprehensive overview on the process of drug development in biotechnology as well as in the pharmaceutical industry – from the idea to market release.

Agenda

Day 1: Wednesday, 30 Aug 2023
8.30 a.m.
REGISTRATION & BREAKFAST SNACKS

9.00 a.m.
WELCOME & INTRODUCTION
Dr. Uwe Lohmeier, Gläsernes Labor Akademie (GLA), Campus Berlin-Buch GmbH
- Gläsernes Labor (GL), GLA & history of the Campus Berlin-Buch,
- Course concept and objectives
- Organizational information

Module 1: Overview of the Drug Development Process: Phases, challenges and trends
PD Dr. Wolf S. Richter, Pharmtrace klinische Entwicklung GmbH
9.30 a.m.
DRUG DEVELOPMENT: SPECIAL REQUIREMENTS AND CURRENT TRENDS
- A brief overview of the drug development process chain: Drug discovery, preclinical development, exploratory phase I and II clinical trials, phase III – IV trials, approval, definitions

11.15 a.m.
Coffee break

<u>Module 2:</u> Another paradigm in drug development? How to develop Biologics versus Small molecule Drugs (SMDs)
Prof. Dr. Andreas Baumann, Strategic Biotech Consulting & Lecturing

<u>11.30 p.m.</u>
- Differences between Biologics and SMDs
- Connecting the dots: How far away are we from bridging the gap between non-clinical and clinical studies?
- Non-clinical development of Biologics – The case by case approach
- Drug Targeting and Delivery
- Review of New Modalities and why do we need them?

<u>1.30 p.m.</u>
Lunch

<u>Module 3:</u> From Target to Clinical Trial
Dr. Jens Hoffmann, Experimentelle Pharmakologie & Onkologie Berlin-Buch, EPO-GmbH
<u>2.15 p.m.</u>
OVERVIEW ON DRUG DISCOVERY PROCESS
- Targets
- Target Identification
- Target Validation
- Assay Development
- Lead Discovery
- Lead Optimization
- Development Candidates

<u>2.45 p.m.</u>
FROM TARGET TO LEAD
- Target Definition
- Criteria for Targets
- Methods for Target Validation
- Target versus Phenotypic Drug Screening
- Assay Development
- Drug and Antibody Libraries
- Decision Criteria for Lead Molecules
- Development of Biologicals: Antibodies, Proteins, RNA, Cell Therapies, Gene Therapies, Therapeutic Viruses

<u>3.30 p.m.</u>
Coffee break

3.45 p.m.
FROM LEAD TO CANDIDATE
- Lead Optimization
- Pharmacodynamics
- Translational Research and Biomarker Identification
- Safety Pharmacology
- Pharmacokinetics and Bioanalysis
- Toxicology
- Drug Product
- Decision Criteria for Drug Candidates

4.30 p.m.
STRATEGIES TO HANDLE COMMON RISKS
- Adverse Drug Reactions, Target Selectivity
- Translation of Animal Pharmacology Data to Humans
- Pharmacokinetics and Drug Metabolism – Extrapolation of Data to Humans
- Drug Drug/Food Interactions

5.00 p.m.
PRACTICAL EXERCISE: DEVELOPMENT OF A "MASTERPLAN" FOR A DRUG DEVELOPMENT PROJECT
- Selection of Targets
- Medical Need & Market Evaluation (NPV)
- Assessment of Assay Technologies
- Budget, Time Lines & Costs
- Interpretation of Pharmacodynamics Data
- Translational Research Plan
- Biomarker Strategy
- Regulatory Studies in PK and Toxicology

6.00 p.m.
End day 1

Day 2: Thursday, 31 Aug 2023
Module 4: Requirements to get regulatory authorization, to conduct clinical trials and to get Drug Marketing Approval
Prof. Dr. Michael Hildebrand, Hildebrand Pharma Consulting
9.00 a.m.
REGULATORY PROCESSES AND AUTHORIZATION FOR CLINICAL TRIALS PHASES I-IV IN THE EU AND IN THE US
- Global regulatory strategies to obtain approval,
- Active dialogue with authorities as a contribution to successful development,
- Scientific & Regulatory Advice

12.30 p.m.
Lunch

1.30 p.m.
Application in the EU and in the US
- The application procedures will be discussed and differences in application procedures and application types in the EU and the US will be highlighted

3.30 p.m.
Coffee break

4.00 p.m.
FROM DRUG DISCOVERY TO CLINICAL DEVELOPMENT – THE BIOTECH START-UP PANEL DISCUSSION
Dr. Karen Uhlmann, Dr. Robert Fischer, OMEICOS Therapeutics GmbH; Dr. Wolf-Hagen Schunck, MDC; Dr. Christian Regenbrecht, CELLphenomics GmbH & ASC Oncology
- Biotech Teams from the Campus share their founding experiences

6.00 p.m.
Come together

Day 3: Friday, 01 Sep 2023
Module 5: Production of Medicinal Products – Requirements, Resources, Processes
Dr. Michael Buchholz, Matterhorn Biosciences GmbH
9.00 a.m.
GMP HISTORY & LEGAL BASIS & QUALITY MANAGEMENT
- History and Evolution of GMP
- Regulations, Good Manufacturing Practice (GMP) guidance,
- Requirements on documentation for manufacturing and quality control

9.30 a.m.
Coffee break

9.45 a.m.
PLANNING MANUFACTURING
The participants plan together with the trainer the manufacturing of a clinical trial drug according to the principles of GMP

11.15 a.m.
PRACTICAL EXERCISE: GMP DOCUMENTS
Participants develop specific GMP documents required for manufacturing and quality control and present their results

12.45 p.m.
Lunch

Module 6: Clinical Drug Testing Prior to Approval
Michael Firgens, MF Biotech
1.30 p.m
FROM INITIAL APPLICATION TO THE PROOF OF CONCEPT: PRINCIPLES, CONTENT AND REQUIREMENTS OF PHASES I – II

- Safety and tolerability
- Pharmacokinetics characterization and its importance for further development

3.30 p.m.
Coffee break

4.00 p.m.
PHARMACODYNAMICS OR CLINICAL BENEFIT?

- Questions, content and requirements from proof of concept up to approval,
- Tools to avoid bias and chance findings

6:00 p.m. – 8.00 p.m.
DINNER LECTURE: THE GEOGRAPHY OF DRUG APPROVALS IN ONCOLOGY
Prof. Dr. med. Wolf-Dieter Ludwig, Chairman of the Drug Commission of the German Medical Association

- Regulatory review of new therapeutic agents for cancer with special consideration of accelerated pathways introduced by the FDA and the EMA and its implications for drug development as well as certainty about the presented evidence for clinical efficacy, safety and benefit-risk evaluation of novel therapeutics
- EMA guideline on the evaluation of anticancer medicinal products
- Guidelines relevant for advanced therapy medicinal products (ATMP) of the EMA
- German Drug market 2022: Recent data regarding indications, added therapeutic benefit and prices

Day 4: Saturday, 02 Sep 2023
Module 7: Intellectual Property
9.00 a.m.
Dr. Oliver Ladendorf, Kraus & Weisert European Patent and Trademark Attorneys
BASIC PRINICPLES OF INTELLECTUAL PROPERTY RIGHTS

- Overview of essential IP rights in the biotech/pharma sector
- Life cycle of a patent from drafting to infringement

10.45 a.m.
Coffee break

11.00 a.m.
INTRODUCTION IN IP STRATEGIES USING A CONCRETE PATENT CASE EXAMPLE IN THE BIOTECH/PHARMA SECTOR

11.30 a.m.
PRACTICAL EXERCISE: ANALYSIS OF OPPOSITION PROCEEDINGS BEFORE THE EUROPEAN PATENT OFFICE
- Review of prior art documents,
- Development of a line of reasoning (Opponent vs. Patentee) regarding patentability of claims
- Oral presentation of arguments in a mock trial

Module 8: Business Development and Licensing Business
12.00 a.m.
BASICS OF LICENSE AND COOPERATION CONTRACTS
- Introduction of exemplary contracts
- Discussion of problematic sections

12.30 a.m.
PRACTICAL EXERCISE
- Continuation of the case discussed in MODULE 7
- Development of negotiating positions in license negotiations between a Patentee and an Opponent/Competitor
- Exchange of arguments in working groups with subsequent presentation and discussion of results

1.15 p.m.
Lunch

Module 9: Project Planning and Management in Drug Development
Dr. Mathias Schroedter, Bayer AG
2.00 p.m.
INTRODUCTION TO PROJECT PLANNING AND MANAGEMENT
- Project structure / process organization,
- Milestone planning, risk and portfolio management

3.30 p.m.
Coffee break

3.45 p.m.
PROJECT PLANNING WITH PRACTICAL EXAMPLES

5.15 p.m.
PRACTICAL EXERCISE
- Development and set-up of a project plan for drug development and drug approval,
- Presentation of results and discussion

6.00 p.m.
CLOSE-OUT
Dr. Uwe Lohmeier, Head of Gläsernes Labor Akademie (GLA), Campus Berlin-Buch GmbH
- Wrap-up,
- Feedback,
- Issuing the certificates

6.30 p.m.
END OF THE COURSE

The trainers of the GLA Biotech Pharma Summer School 2022

Prof. Andreas Baumann
Prof. Dr. Baumann is Professor of Pharmacology & Toxicology, and has been lecturing for 20 years at Universities in Greifswald, Berlin and Beijing. He has working experience in academia (Pharmacology & Toxicology) and for the last 30 years in R&D in the pharmaceutical industry. He is an internationally recognized expert in the non-clinical development of biologics (including but no limited to pegylated proteins, monoclonal and bispecific antibodies, fusion proteins, ADCs) and has been leading the non-clinical/PK activities in development projects at Schering AG and at Bayer AG, 5 of them successfully developed into marketed products. He has published more than 50 peer-reviewed scientific and textbook articles (see researchgate.net), is editor of a Pharmacokinetic textbook and has been invited regularly to present at international scientific conferences. Andreas has been elected member of the BioSafe Leadership Team of the Biotechnology Industry Organization (BIO, Washington, DC) for more than 10 years. He runs since 2021 his own Biotech Consulting and acts as well as biotech start up mentor.

Dr. Michael Buchholz
studied biochemistry at the Free University in Berlin, Germany. After completion of his PhD at the University of Bath, UK, he started his career in ATMP manufacturing on the contract manufacturing organization (CMO) site at the Fraunhofer Institute for Immunology and Cell Therapy (IZI), Leipzig. 2012 he joined Prima BioMed with focus on ATMP manufacturing at CMOs in the US, Australia and Germany as well as manufacturing of a recombinant therapeutic protein at a CMO in China. In 2016, he joined Cell Medica as Site Head for Cell Medica's GMP manufacturing facility in Berlin, Germany, with focus on cell therapy manufacturing. In his role as Senior Director Manufacturing at T-knife, Berlin, Germany from 2019 Michael was responsible for development of T-knife's genetically engineered T-cell products including process development, selection of contract manufacturer, transfer of T-knifes manufacturing process to the contract manufacturer as well as regulatory filing required to start clinical development of T-knife´s TK-8001 TCR-T cell product in Europe.
Since 2022 Michael is Senior Vice President at Matterhorn Biosciences, Basel, Switzerland responsible for development and GMP compliant manufacturing of Matterhorn´s MR1 T cell products.

Michael Firgens

studied biochemistry at Freie Universität, Berlin and started his career in the area of clinical research as Clinical Project Manager and Clinical Research Associate at Sanofi-Aventis and Dr. Kade. He then worked in different global program management positions related to drug development and manufacturing within Fresenius Healthcare Group in Europe, the US and Asia, where he led a biosimilar development program, international tech transfer programs, biopharmaceutical portfolio strategies, and due diligence processes for in-licensing opportunities.

Since 2017 Michael has been working as a consultant with a focus on program management and regulatory affairs for biopharmaceuticals. In 2019 he founded MF Biotech with the vision to provide best-in-class development support for innovative medicines. He has worked on a broad range of biopharmaceuticals, such as first-in-class therapies, biosimilars and orphan drugs as well as monoclonal antibodies, ATMPs, cell and gene therapies, genetically modified organisms and viruses, bacteriophages, and small molecules.

Michael also holds an MBA degree in General Management and is a certified Project Management Professional.

Prof. Michael Hildebrand

Pharmacist and Expert Pharmacologist DPhG, with more than 25 years experience in pharmaceutical industry (non-clinical, clinical and CMC development). Former head of Global Pharmaceutical Development at Schering AG, since 2008 working as consultant with focus on CMC, R&D, quality topics and QP-services. Professor for Industrial Pharmacy at the Friedrich-Schiller-University, Jena.

Dr. Jens Hoffmann

From 1984 to 1989 Dr. Hoffmann studied pharmacy at the University of Greifswald and obtained diploma in Pharmacy and Experimental Pharmacology and Toxicology. He started working in Oncology Research in 1989 in the Department of Clinical Pharmacology at the Central Institute for Cancer Research in Berlin-Buch. In 1991 he worked as a guest scientist at the German Cancer Research Center in Heidelberg. From 1992 to 1994 he worked on his PhD thesis at the Max-Delbrück-Centrum for Molecular Medicine Berlin. In 1995 he obtained his PhD degree from the Humboldt University Berlin on “Investigations on the phenomenon of multidrug resistance, markers of resistance, and correlation with clinical outcome”.

He took his first postdoc position at Schering AG in the Experimental Oncology working on tumor angiogenesis. During a second postdoctoral training he worked at the University of Pittsburgh, School of Medicine, Department of Pharmacology on “Redox regulation and cell death”

In 1997 he joined Schering AG as group leader in Oncology Research. His main research field was the development of novel steroid hormone receptor antagonists and mechanisms of antihormone resistance. He worked on the preclinical development of new cancer drugs, translational research, and small animal imaging. For that purpose, he developed several new in vivo models, especially for tumor angiogenesis, sarcomas, and hormone dependent cancers.

In 2009 he joined EPO as managing director. Dr. Hoffmann has special expertise for pharmacological investigations concerning endocrine tumors. Biomarker and translational research is another focus of his scientific work. He has published more than 50 original articles in peer reviewed journals and filed more than 30 patents.

Dr. Hoffmann is member of the German Cancer Foundation and the Board of the Experimental Cancer Research Division (AEK) and the American Association for Cancer Research (AACR). He is guest scientist at the Comprehensive Cancer Center of the Charite Berlin.

Dr. Oliver Ladendorf
studied biology at the Ludwig-Maximilians University in Munich and the Universidad de Concepción, Chile, obtaining his degree in 1998. He received his doctorate in 2003 at the University of Marburg and the Max Planck Institute for Terrestrial Microbiology for a thesis in the field of fungal molecular biology. Between 2003 and 2008, Dr. Ladendorf was trained in the field of intellectual property with Vossius & Partner in Munich and subsequently joined Maiwald Patentanwalts GmbH. He qualified as a European Patent Attorney in 2008 and as a German patent attorney and European Trademark and Design Attorney in 2012. He received a Bachelor of Laws (LL.B.) degree in 2015. Dr. Ladendorf joined Kraus and Weisert in May 2014 and became a partner in 2015.

Dr. Uwe Lohmeier
Studied biology at the Freie Universität Berlin. PhD (Dr. rer. nat) in Plant Pathology at the Technische Universtität München. From 2001 – 2015 he worked as a Quality Manager in Clinical Development at Schering Pharma and Bayer AG. Since 2016 he has been at the Gläsernes Labor (GL) Buch at the GL Akademie (GLA) Management and lecturer at the Learning Lab. Since 2017 he is Head of GLA.

Prof. Dr. med. Wolf-Dieter Ludwig
M.D. and Ph.D., with degrees specializing in Internal Medicine, Transfusion Medicine and Hematology/Oncology. From 2001 until August 2017 he has been Medical Director and Head of the Department for Hematology, Oncology, Tumor Immunology and Palliative Care at the HELIOS Clinic Berlin-Buch (formerly: Charité). Since 2006, he is Co-editor of “DER ARZNEIMITTELBRIEF” (ISDB) and Chairman of the Drug Commission of the German Medical Association and since 2013 Member of the Management Board of the European Medicines Agency as representative of the European Doctor’s Association.

Dr. Christian Regenbrecht
mainly focusses on systems-oriented tumor research using three-dimensional organoid tumor models. After studying biology and philosophy at the Rheinische Friedrich-Wilhelms-Universität in Bonn, he was awarded his doctorate in natural sciences under the supervision of Otmar Wiestler at the University Hospital in Bonn in 2005. He then worked at the Max Planck Institute for Molecular Genetics in Berlin as a research assistant to Hans Lehrach.
Together with his research group, he moved to the Charité in Berlin in 2010, where he not only headed the “Tumor Stem Cells” research group at the Institute of Pathology until 2016, but also the central laboratory for functional genome research from 2012 to 2014. Having also been involved in excellent peer reviewed international research projects since 2010, he founded the companies CELLphenomics GmbH in June 2014 and ASC Oncology in 2019. At CELLphenomics, 3D cell culture models (PD3D® models) developed from tumor samples are used in research to further develop cancer drugs.

PD Dr. Wolf S. Richter
Physician, specialized in Nuclear Medicine with more than 12 years clinical experience in Charité Berlin, and more than 15 years in pharmaceutical industry and contract research. Wolf has been head of clinical development radiopharmeuticals at Schering AG. Since 2006, he is the president and owner of pharmtrace, a clinical research organization (CRO) specialized in medical imaging.

Dr. Mathias Schroedter

During his PhD, Mathias founded a biopharmaceutical service company in 1996 which he grew to a full-fledged cGMP contract manufacturing organization for mammalian cell culture products. After the sale of the company he worked with IDT Biologika in Dessau for two years as Director of Strategic Technology Development. From 2011 until 2016 he was responsible for the virtual drug development of an antibody drug candidate for sepsis from early identification until clinical phase I. Since 2018, Mathias is working at the Bayer AG as QA Product Manager External Manufacturing.

Dr. Karen Uhlmann

holds a Master in Biology and a PhD in Molecular Biology from Freie Universität zu Berlin and Humboldt-Universität zu Berlin, respectively. Karen earned a business degree from the Chamber of Commerce Berlin and is a Recognized Technology Transfer Professional. She has been working in the field of life science IP asset and innovation management since 2002, successfully set the contractual and business frame for innovative technologies, leading to multiple license agreements, funding grants, and collaborations between industry and academia. With the scientific founder team, Karen spun-off OMEICOS Therapeutics in 2013 from the Max-Delbrück-Center for Molecular Medicine.

Version: 04 July 2023
Subject to modifications
Dr. Uwe Lohmeier, Head of GLA