„FROM TARGET TO MARKET“

THE BBA BIOTECH PHARMA SUMMER SCHOOL

Date: 09 – 12 September 2025

Time: Daily 09.00 a.m. – 06.00 p.m.
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: Tuesday, 09 September 2025
8.30 a.m.
REGISTRATION & BREAKFAST SNACKS

9.00 a.m.
WELCOME & INTRODUCTION
Dr. Uwe Lohmeier, Berlin BioScience Academy (BBA), Campus Berlin-Buch GmbH
- BBA & 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

Module 2: Challenges in developing biologics and new modalities
Prof. Dr. Andreas Baumann, Strategic Biotech Consulting & Lecturing

11.30 p.m.
- Differences between Biologics and Small molecules Drugs
- Review of new modalities and why do we need them ?
- The multidisciplinary approach for translation of innovative research ideas into development results
- How to be successful with a Biotech Start-up in the competitive Biotech Landscape ?

1.30 p.m.
Lunch

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

2.45 p.m.
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

3.30 p.m.
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: Wednesday, 10 September 2025
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. – 6.00 p.m
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

6.00 p.m.
End day 2

Day 3: Thursday, 11 Sep 2025
Module 5: Production of Medicinal Products – Requirements, Resources, Processes
Dr. Michael Buchholz, CMC Advisor, Immutep 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 PROOF OF CONCEPT: CLINICAL PHASES I – II
- Study objectives and study designs
- Principles for pharmacokinetics and pharmacodynamics
- Case Study

3.30 p.m.
Coffee break

4.00 p.m.
FROM PROOF OF CONCEPT TO APPROVAL AND BEYOND: CLINICAL PHASES III – IV
- Study objectives and study designs
- Case Study
- Key Success Criteria for Clinical Development

GROUP EXERCISE: CLINICAL DEVELOPMENT PLAN

6.00 p.m.
End day 3

Day 4: Friday, 12 Sep 2025
Module 7: Intellectual Property
9.00 a.m.
Dr. Oliver Ladendorf, Kraus & Lederer PartGmbB
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, SCENION 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

5.00 p.m.

PRACTICAL EXERCISE

- Development and set-up of a project plan for drug development and drug approval,
- Presentation of results and discussion

5.45 p.m.

CLOSE-OUT

Dr. Uwe Lohmeier, Head of Berlin BioScience Academy (BBA), Campus Berlin-Buch GmbH

- Wrap-up,
- Feedback,
- Issuing the certificates

6.00 p.m.

END OF THE COURSE

The trainers of the GLA Biotech Pharma Summer School 2025

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 and is Board Member and President elect of Conelis e.V., the expert Network in Life Sciences. He runs since 2021 his own Biotech Consulting and acts as well as biotech start up mentor.

Dr. Michael Buchholz

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.

In 2022 Michael joined Matterhorn Biosciences, Basel, Switzerland as Senior Vice President, in his role he was responsible for development and GMP compliant manufacturing of Matterhorn´s MR1 T cell products.

Since 2024 Michael is with Immutep GmbH focusing on the manufacturing of recombinant therapeutic proteins for Immutep`s late stage clinical development program and preparation of process characterization/ validation studies to enable biologics license application.

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 global development strategy 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 monoclonal antibodies, protein drugs, cell and gene therapies, genetically modified organisms, mRNA-based drugs, bacteriophages, and small molecules.
Michael also holds an MBA degree in General Management and is a certified Project Management Professional. He supports Science4Life as an assessor for early-stage development programs.

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

Dr. Hoffmann studied Pharmacy and Experimental Pharmacology and Toxicology. He started working in Oncology Research in 1989 in Berlin-Buch, the German Cancer Research Center in Heidelberg, and the Max-Delbrück-Centrum for Molecular Medicine Berlin. In 1995 he obtained his PhD degree from the Humboldt University Berlin. After two postdoc position at Schering AG and the University of Pittsburgh, Department of Pharmacology he joined in 1997 Schering AG as group leader in Oncology Research. He worked on the preclinical development of new cancer drugs, translational research, and small animal imaging. In 2009 he joined EPO Berlin-Buch as managing director and the Conelis Expert Network. He has contributed to more than 80 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).

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 & Lederer PartGmbB 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, now Berlin BioScience Academy (BBA) and lecturer at the Learning Lab. Since 2017 he is Head of GLA / BBA.

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.

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. From 2018 till 2024 Mathias worked at the Bayer AG as QA Product Manager External Manufacturing. Since 2024 until today Mathias is VP Technology & Development at Scenion, Berlin.

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Subject to modifications
Dr. Uwe Lohmeier, Head of BBA

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FMP LEIBNIZ FORSCHUNGSINSTITUT FÜR MOLEKULARE PHARMAKOLOGIE
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MDC MAX-DELBRÜCK-CENTRUM FÜR MOLEKULARE MEDIZIN IN DER HELMHOLTZ-GEMEINSCHAFT