# Biotech & Pharma Business Summer School

## September 3 – 6, 2014 Campus Berlin-Buch

German Life Sciences Association (VBIO e. V.) and the Life Science Learning Lab are offering a practice-oriented training course entitled:

**„Biotech & Pharma Business Summer School – from Target to Market"**

### Target Group

20 participants with an academic degree from the fields of basic research, biotechnology and research-oriented pharmaceutical companies

### Objectives

The course will provide participants with a comprehensive overview of the entire drug development process in biotechnology and in the pharmaceutical industry – starting with the initial idea, extending to development and even including marketing.
The team of lecturers is comprised of renowned experts from the pharmaceutical industry, biotech companies, CROs and leading research institutes. The course consists of lectures introducing each topic and case-related practical exercises appropriate for each level of drug development.

### Highlights & Advantages

- Interactive and case-related practical exercises make learning easier
- Course provides a basic understanding of how the pharmaceutical industry „ticks"
- A unique chance to gain insight into the drug development process and to establish contacts
- Opportunity to discuss individual questions with the experts

### Documentation

At the beginning of the course, all participants will receive comprehensive seminar materials. These include all PowerPoint slides, work sheets for the group exercises, a glossary with a list of abbreviations as well as useful links and lists of further reading for each module.

### Cost

The course fee is EUR 1,395 plus German VAT and includes participation in the seminar, course materials and meals indicated in the program. For participants from academic institutions, the course fee is EUR 1,095 plus German VAT.
Individual members of VBIO and members of associations affiliated with VBIO receive a 10% discount on the relevant fee.
Inexpensive accommodation is available in Hotel Bel Air and Hotel Alt-Karow and in the Campus guest houses.

### Certificate of Participation

The participants will receive a certificate of participation in the seminar highlighting the content, main topics and objectives of the course. The certificate is issued by the VBIO and the participating institutions that contributed to the development of the course.

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Gläsernes Labor

# 1st Day: September 3, 2014

Life Science Learning Lab, Campus Berlin-Buch

**08:30 a.m.**

Registration and breakfast snack

**09:00 a.m.**

WELCOME AND INTRODUCTORY PRESENTATIONS: OBJECTIVE AND STRUCTURE OF THE COURSE

*Dr. Kerstin Elbing, VBIO e. V.*

*Dr. Ulrich Scheller, BBB Management GmbH*

**09:30 a.m.**

GUIDED TOUR THROUGH THE TARGET SCREENING UNIT AT THE FMP

*Dr. Jens Peter von Kries, FMP*

## Module 1

### Overview of the Drug Development Process Chain – Phases, Challenges, Trends

**10:45 a.m.**

SPECIAL REQUIREMENTS OF DRUG DEVELOPMENT AND CURRENT TRENDS

- Brief overview of the drug development process chain; drug discovery, preclinical development, exploratory phase I and II clinical trials, phase III trials, clinical phase IV, approval ( concise definitions)

*PD Dr. Wolf-Stefan Richter, Pharmtrace GmbH*

**12:00 noon**

Coffee break

## Module 2

### Drug Delivery and Drug Targeting

**12:15 p.m.**

- Traditional forms of pharmaceutical development
- The role of drug delivery technologies in the R&D process

*Hildebrand Pharma Consulting*

**01:30 p.m.**

Lunch break

## Module 3

### From Active Agent to Preclinical Trial

**02:15 p.m.**

- The role of preclinical drug testing
- Conditions and laws: risk-benefit analysis prior to the start of the clinical trial
- Assessment of the required pharmacokinetics – expected pharmacokinetics in humans
- Safety analysis during clinical development
- Definition of the therapeutic goal
- Selection of pharmacological models
- Relevance of animal studies and transferability of findings
- Determination of type and site of action, mechanism of action, potency

*Dr. Johannes Nagelschmitz, Bayer HealthCare AG*

**03:30 p.m.**

Coffee break

**03:45 p.m.**

- Impact of human metabolism on drug tolerability
- "Risk" toxicology: mechanism-related (possible side effects), compound-related
- Consideration of toxicokinetics: exposure analysis, distribution, accumulation
- Safety pharmacology: study of the organ systems

*Dr. Johannes Nagelschmitz, Bayer HealthCare AG*

**05:00 p.m.**

**PRACTICAL EXERCISE**: interpretation of toxicological data

In small groups, the participants will evaluate the toxicological data of an exemplary case. The aim is to develop an understanding of the measures taken in practice to determine the risk of occurrence of adverse drug reactions prior to administration in humans. Subsequent presentation of the group work and discussion.

*Dr. Johannes Nagelschmitz, Bayer HealthCare AG*

**07:00 p.m.**

Buffet dinner

# 2nd day: September 4, 2014
Life Science Learning Lab, Campus Berlin-Buch

## Module 3

### From Active Agent to Preclinical Trial

**09:00 a.m.**
PRINCIPLES & EXAMPLES FOR THE DEVELOPMENT OF CANCER DRUGS
*Dr. Michael Becker, epo GmbH*

**11:00 a.m.**
Coffee break

## Module 4

### Requirements for Authorization to Conduct a Clinical Trial and for Approval as a Drug

**11:15 a.m.**
- Requirements in phases I-IV of clinical development; regulatory processes and authorization for clinical trials in the EU and the US
- Global regulatory strategies to obtain approval

*Dr. H. Günter Hennings, Hgh regulatory sciences Ltd.*

**12:15 p.m.**
- Active dialog with authorities as contribution to successful development of scientific and regulatory advice

*Dr. H. Günter Hennings, Hgh regulatory sciences Ltd.*

**01:30 p.m.**
Lunch break

**02:15 p.m.**
Based on a specific drug as example, the application procedure will be discussed, whereas the differences in application procedures and application types in the EU and the US will be highlighted.
*Dr. H. Günter Hennings, Hgh regulatory sciences Ltd.*

**06:00 p.m.**
Dinner

**07:00 – 09:00 p.m.**
Dinner lecture: Clinical trials in oncology – a critical evaluation of the clinical significance of phase II/III/IV trials and the need for „post-marketing surveillance"
*Prof. Dr. Wolf-Dieter Ludwig, HELIOS Klinikum Berlin-Buch*

# 3rd day: September 5, 2014
Life Science Learning Lab, Campus Berlin-Buch

## Module 5

### Drug Manufacturing: Requirements, Resources, Processes

**08:00 a.m.**
- Legal basis
- GMP guide
- EU-GMP-Guide requirements for documentation in manufacturing and quality control

*Uwe Werner, IDT Biologika GmbH*

**09:30 a.m.**
Coffee break

**09:45 a.m.**
Together with the lecturer, the participants shall plan the manufacture of a clinical trial drug according to GMP principles.
*Uwe Werner, IDT Biologika GmbH*

**11:15 a.m.**
**PRACTICAL EXERCISE**: GMP documents
In small groups, the participants shall practice creating specific GMP documents for manufacturing and quality control. Subsequent presentation of results u
*Uwe Werner, IDT Biologika GmbH*

**12:45 p.m.**
Lunch break

## Module 6

### Clinical Drug Testing Prior to Approval

**01:30 p.m.**
FROM THE 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

*PD Dr. med. habil. Matthias Grossmann, PAREXEL International GmbH*

**04:00 p.m.**
Coffee break

**04:30 p.m.**
PHARMACODYNAMICS OR CLINICAL BENEFIT?
Questions, content and requirements from proof of concept up to approval
Instruments to avoid bias and chance findings
*PD Dr. med. habil. Matthias Grossmann, PAREXEL International GmbH*

**06:00 p.m.**
GUIDED TOUR OF THE CAMPUS AND BARBECUE

# 4rd day: September 6, 2014

Life Science Learning Lab, Campus Berlin-Buch

## Module 7

### Intellectual Property

**09:00 a.m.**

GENERAL PRINCIPLES & OVERVIEW OF PROPERTY RIGHTS
The patent process – application, examination, granting
Relevance of patent rights in the biotech & pharma sector
*Rafaela Kunz, Patent2Ip*

**10:45 a.m.**

Coffee break

**11:00 a.m.**

FIRST STEPS TO PATENT RESEARCH
Overview of national & international databases

**11:30 a.m.**

**PRACTICAL EXERCISE** with all participants: patent research
*Rafaela Kunz, Patent2Ip*

## Module 8

### Business Development – and the Licensing Business

**12:00 noon**

BUSINESS DEVELOPMENT THROUGH PATENTS & LICENSES
The licensing business
*Rafaela Kunz, Patent2Ip*

**12:30 p.m.**

**PRACTICAL EXERCISE**: Successful negotiation

**01:30 p.m.**

Lunch break

## Module 9

### Project Planning and Management in Drug Development

**02:00 p.m.**

- Project planning guidelines for the development, production and approval of biological classes
- Project structure/process organization
- Milestone planning, risk and portfolio management

*Dr. Mathias Schroedter, Adrenomed AG*

**03:30 p.m.**

Coffee break

**03:45 p.m.**

PROJECT PLANNING WITH PRACTICAL EXAMPLES
*Dr. Mathias Schroedter, Adrenomed AG*

**05:15 p.m.**

**PRACTICAL EXERCISE** with all participants: development of a project plan for the development and approval of a drug; presentation of results and discussion.
*Dr. Mathias Schroedter, Adrenomed AG*

**06:00 p.m.**

Final discussion and presentation of the certificates

**06:30 p.m.**

Conclusion