



# Study Abroad Certificate in Pharmaceutical Engineering

30 ECTS credit program

## Program modules:

Module	ECTS
Sterile Technology	5
Advanced Biotechnology	5
Galenics of Biopharmaceuticals	5
Modern Pharmaceutical Analysis	2,5
Pharmaceutical Technology 2	2,5
Research project	5
Hygiene and Environmental Health	2,5
Sustainable Packaging Technology	2,5

### Further Information / Contact:

#### International Office

Albstadt- Sigmaringen University  
Dr. Conny Bast  
bast@hs-albsig.de

#### International relations

Study Abroad Certificate in  
Pharmaceutical Engineering  
Prof. Dr. Karsten Köhler  
koehler@hs-albsig.de

# Study Abroad Certificate in Pharmaceutical Engineering Sterile Technology

Key facts:

<b>Workload</b>		<b>ECTS</b>
150 h		5
<b>Parts of the module</b>	<b>Contact time</b>	<b>Self-study time</b>
4 contact hour lecture including exercises and 2 practical training sessions	60 h	90 h
<b>Module leader</b>	<b>Assessment</b>	
Prof. Dr. A. Schmid	Written exam, presentation and practical training	

## Curriculum Outline

The module is focussing on the manufacture of sterile pharmaceuticals. The participants gain broad practical knowledge about sterilization processes (including validation), aseptic processing conditions and the associated technologies, aseptic transfer and filling, and hygienic design of facilities and machinery. Additional exercises and practical training (focussing on validation of aseptic processes and visual inspection) prepare the participants for future tasks in sterile manufacturing.

## Key content

Sterilization:

- Sterility testing
- Basic concepts, e. g. SAL, D value, z value,  $F_0$  value
- Technical aspects of sterilization procedures: steam, heat, radiation, chemical, plasma sterilization, sterile filtration
- Validation of sterilization processes

Aseptic Processing:

- Environmental requirements / cleanrooms, class A technologies (isolators, RABS etc.)
- Preparation / washing, CIP / SIP, transfer processes
- Sterile filling and packaging (fill & finish)
- Validation / media fill, quality control / inspection

Hygienic design / sterile design:

- Materials, surfaces, components
- Sterile design using the bioreactor as an example

# Study Abroad Certificate in Pharmaceutical Engineering Advanced Biotechnology

Key facts:

<b>Workload</b>		<b>ECTS</b>
150 h		5
<b>Parts of the module</b>	<b>Contact time</b>	<b>Self-study time</b>
2 contact hour lecture 2 contact hour seminar	60 h	90 h
<b>Module leader</b>	<b>Assessment</b>	
Prof. Dr. D. Stoll	Written exam, term paper and oral presentation	

## Curriculum Outline

The module covers the workflow in state-of-the-art production of biologics. Concepts of the upstream process, knowledge in kinetics and process management are important parts of the course. Furthermore the isolation of biologics API in the downstream process is the second main focus of the course.

## Key content

- Upstream Processing (USP):
  - Biopharmaceuticals / the biopharmaceutical process based on antibody production
  - Expression Systems, Process Control, Equipment, Calculation Basics, Case Studies
- Downstream processing (DSP):
  - Common DSP Technologies: cell disruption, filtration, chromatography (ion exchange, size exclusion, hydrophobic interaction, affinity).
- E-poster with presentation - creation, presentation and reflection of an e-poster on a biopharmaceutical / biotechnological product and its manufacture
- Journal Club: short oral presentation of major outcomes described in scientific papers on biotechnology topics.

# Study Abroad Certificate in Pharmaceutical Engineering Galenics of Biopharmaceuticals

Key facts:

<b>Workload</b>	<b>ECTS</b>	
150 h	5	
<b>Parts of the module</b>	<b>Contact time</b>	<b>Self-study time</b>
2 contact hour lecture 2 contact hour practical training	60 h	90 h
<b>Module leader</b>	<b>Assessment</b>	
Prof. Dr. I. Müller	Presentation and practical training	

## Curriculum Outline

Students know galenic principles of biopharmaceuticals. They know the specific characteristics of biopharmaceuticals as well as the main principles of research and development. They are informed how biopharmaceuticals are being processed.

## Key content

- Characteristics and groups of biopharmaceuticals
- Characteristics, manufacturing processes and quality control of lyophilized products, micro- and nanoparticles, liposomes and special semis-solids, therapeutic systems, vaccines, inhalers
- Stability studies

# Study Abroad Certificate in Pharmaceutical Engineering Modern Pharmaceutical Analytics

Key facts:

<b>Workload</b>	<b>ECTS</b>	
75 h	2,5	
<b>Parts of the module</b>	<b>Contact time</b>	<b>Self-study time</b>
1,5 contact hour lecture 0,5 contact hour exercise	30 h	45 h
<b>Module leader</b>	<b>Assessment</b>	
Prof. Dr. D. Stoll	Oral exam	

## Curriculum Outline

The module covers aspects of modern analytics in pharmaceutical research and industry. Mainly techniques applied in biomarker identification and bioanalytics are presented. Furthermore exercises in GxP compliant analytical validation of simple assays and data sets are performed.

## Key content

- HPLC-ESI-mass spectrometry of small drug molecules and metabolites in pharmacokinetics
- ESI-MS mass spectrometry of biologics (antibodies, QC) and peptides (QC, proteomics)
- Multiplex Immunoassays in biomarker research
- ICH and EMA guidelines. Exercises: Definition of simple validation plans + data statistics and interpretation

# Study Abroad Certificate in Pharmaceutical Engineering Pharmaceutical Technology 2

Key facts:

<b>Workload</b>	<b>ECTS</b>	
75 h	2,5	
<b>Parts of the module</b>	<b>Contact time</b>	<b>Self-study time</b>
2 contact hour seminar	30 h	45 h
<b>Module leader</b>	<b>Assessment</b>	
Prof. Dr. K. Köhler	Presentation	

## Curriculum Outline

The module covers various fields of pharmaceutical technology research as well as manufacturing topics, always in respect to pharmaceutical industrial processes.

## Key content

Current topics in GMP-compliant pharmaceutical production and related areas

# Study Abroad Certificate in Pharmaceutical Engineering

## Research project

Key facts:

<b>Workload</b>	<b>ECTS</b>	
150 h	5	
<b>Parts of the module</b>	<b>Contact time</b>	<b>Self-study time</b>
0.5 contact hour project	7.5 h	142.5 h
<b>Module leader</b>	<b>Assessment</b>	
Professors Pharmaceutical Engineering	Team paper and oral presentation	

## Curriculum Outline

The research project is an in-depth study of an issue or topic from all fields related to the pharmaceutical development and production including packaging, process control, quality management,...). It may be in the form of a small-scale research study, a case study, a program evaluation or a report on a field placement.

## Key content

may cover...

- an analysis of an existing data set in order to test a hypothesis or answer a research question;
- a critical systematic review of a question such as the effectiveness of a policy or intervention;
- an evaluation of the implementation of a new technology in pharmaceutical related industry;
- a small research study, in which data is collected and analyzed. The report and presentation shows the abilities of
  - systematically collecting relevant, up-to-date information about the research task;
  - analyzing, interpretation and discussion of the information;
  - drawing conclusions and making recommendations;
  - writing a report in accordance with academic standards.

# Study Abroad Certificate in Pharmaceutical Engineering

## Module: Hygiene and Environmental Health

### Key facts

<b>Workload</b>	<b>ECTS</b>	
75 h	2,5	
<b>Parts of the module</b>	<b>Contact time</b>	<b>Self-study time</b>
1 contact hour lecture 0.5 contact hour seminar 0.5 contact hour workshop	30 h	45 h
<b>Module leader</b>	<b>Assessment</b>	
Prof. Dr. Benjamin Eilts	Presentation & term paper	

### Curriculum outline

Since hygiene as a science considers all factors that influence human health, the interrelationships between humans and their environment are also in focus. Microorganisms (bacteria, viruses, fungi and parasites) exist naturally in the environment and on or within the bodies of animals and people. There are other sources of microorganisms that may cause infection and these include a person's own normal microbial flora and environmental sources such as air, water, or equipment that may have become contaminated.

### Key Content

- Based on selected areas, the influence of microorganisms and suitable countermeasures are discussed with the help of current specialist literature. The aim is to gain comprehensive knowledge of the literature on the selected topic and to interpret the literature data in terms of their application and to discuss interfaces to other, subject-related aspects (e.g. regulatory framework conditions, market requirements, occupational safety).
- The requirements and measures in the areas of monitoring, hygienic design and decontamination are deepened through additional lab exercises.



# Study Abroad Certificate in Pharmaceutical Engineering

## Sustainable Packaging Technology

### Key facts

<b>Workload</b>	<b>ECTS</b>	
75 h	2,5	
<b>Parts of the module</b>	<b>Contact time</b>	<b>Self-study time</b>
1 contact hours lectures 0,5 contact hour seminars 0,5 contact hour workshops	30 h	45 h
<b>Module leader</b>	<b>Assessment</b>	
Prof. Dr. Markus Schmid	Oral exam	

### Curriculum Outline

This seminar presents a basic overview of food packaging technology with emphasis on packaging sustainability.

### Key Content

- Food packaging as a scientific discipline that applies the principles of materials science, food technology, information science, and socioeconomics to develop useful and packaging concepts for the food industry will be introduced.
- In addition to that, a holistic approach for considering sustainability aspects in food packaging technology will be introduced.
- The students will learn to apply the theoretical basics of packaging production and functionality in several workshops.

