



Advanced Biomedical Expertise
BioMex certificate programme

Module Guide

**BioMex Certificate Programme
Advanced Biomedical Expertise**

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Koblenz University of Applied Sciences
RheinAhrCampus
Faculty of Mathematics, Informatics and Technology

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BioMex Certificate Programme

BioMex is an **upskilling** programme in **blended learning** format currently consisting of **27 modules**, organised across six Competence Clusters. Each module carries 3 ECTS credits, a standardised European measure of learning effort, equivalent to approximately 90 hours of study per module.

Upon successful completion of each module, participants receive a certificate issued by the **University of Applied Sciences Koblenz (Germany)**. Depending on the level of competence achieved, the following certificates will be awarded:

- **Certificate of Microcredential** with 3 ECTS
- **Certificate of Microdegree** with 6 - 9 ECTS
- **Certificate of Advanced Studies (CAS)** with at least 10 ECTS
- **Diploma of Advanced Studies (DAS)** with at least 30 ECTS

Module Guide

In this module guide you will find module descriptions for each Competence Cluster within the BioMex Advanced Biomedical Expertise Certificate Programme. The summaries comprise a concise overview of the module contents, learning outcomes and key information on teaching mode and assessment form. Modules within the BioMex Certificate Programme are principally designed as blended learning offer and facilitate maximum flexibility and custom-made module selection. Modules can be studied independently of one another and in any order, learners can thus tailor the programme to their professional needs and schedule. There are no fixed prerequisites and no set sequence to follow.

Please note that the **offer of modules is constantly being developed** and thus new modules are added on a regular basis; it is important to ensure the most recent version of the guide is consulted for selection purposes.

Note on Semester Times

The semester times are principally aligned with those of the University of Applied Sciences Koblenz, Germany and the academic year is organised into two semesters (Semester 1 and Semester 2). Modules* are thus offered as follows:

Semester 1: Beginning March – Ending August (each year)

Semester 2: Beginning September – Ending February (each year)

**Individual modules may not be offered in a given semester due to lecturer availability, this will be communicated before module enrolment.*

BioMex Competence Clusters Overview

Cluster: Biotechnology and Biomedicine (BT)

Module BT1	Molecular Biology and Molecular Biotechnology
Module BT2	Biostatistics and Data Literacy
Module BT3	Physiology and Anatomy
Module BT5	Molecular Cell Biology
Module BT6	Immunobiology
Module BT7	Medical Microbiology
Module BT8	Genetic Engineering
Module BT9	Immunotherapy
Module BT10	Bioelectrical Signals and Sensors

Cluster: Pharmaceutical Chemistry and Pharmaceutical Technology (PT)

Module PT1	Pharmaceutical Chemistry and Pharmacology
Module PT2	Basic Concepts in Pharmaceutical Industry
Module PT3	Good Manufacturing Practice (GMP) and Quality Controls
Module PT4	Fundamentals in Epidemiology and Clinical Trials
Module PT5	Hygiene in Pharmaceutical Manufacturing Processes
Module PT6	Herbal Production Biotechnology

Cluster: Innovation Management and Intercultural Cooperation (IM)

Module IM1	Innovation Management
Module IM2	Entrepreneurship
Module IM3	Intercultural Communication and Mediation
Module IM4	Scientific Communication

Cluster: Facility, Energy and Environmental Management (EM)

Module EM1	Facility Management
Module EM2	Environmental Management
Module EM3	Energy Management

Cluster: Health Care and Smart Medical Technologies (HC)

Module HC1	Sustainable Operations Management in Healthcare
Module HC2	Standards in Ghana's Healthcare System
Module HC3	Coaching and Leadership Development in Healthcare Contexts

Cluster: GxP – Compliance and Risk Assessment (GR)

Module GR1	Good Manufacturing Practices and Quality Management Systems
Module GR3	Specific Requirements for Manufacturing and Quality Control



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Biotechnology and Biomedicine (BT)



Module BT1: **Molecular Biology and Molecular Biotechnology**

Lecturer: Dr. Thierry Habyarimana (INES Ruhengeri, Rwanda)

This module reviews and examines the major components of molecular biology. The aim of this module is to provide extensive knowledge of biology at a molecular level. It will cover a range of topics including genome structure, replication and repair; the transcription, RNA processing and translation; regulation of gene expression as well as discuss the methods and laboratory techniques of molecular biology and molecular biotechnology.

Having successfully completed the module, students should be able to:

- Demonstrate knowledge and understanding of genome organization and packaging in prokaryotes and eukaryotes
- Demonstrate knowledge and understanding of the process of DNA replication and repair mechanisms, RNA transcription and translation of proteins.
- Explain the processes involved in gene expression in prokaryotes and eukaryotes
- Explain the basic genetic mechanisms
- Accurately perform the basic and advanced molecular biology techniques
- Correlate results of molecular biology techniques in research and in diagnosis of specific diseases.

The module will be delivered online. Learning materials are provided on E-learning platform and students can interact among them as well as the lecturer through the platform. Practical skills are acquired and practiced in the state-of-the-art laboratories. Student are expected to participate proactively during the course delivery through learning activities.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module BT2: **Biostatistics and Data Literacy**

Lecturer: Prof. Dr. Markus Neuhäuser (University of Applied Sciences Koblenz, Germany)

This module introduces biostatistics and data literacy – the discipline of collecting, displaying, analyzing, and interpreting data to draw valid conclusions. As biomedical research relies on observed data, statistical analysis and the ability to read, write, and communicate data are essential for evidence-based medicine. Biostatistics focuses on applying these methods to life sciences and medicine.

The course begins with an introduction to the open-source software R, a key tool for conducting statistical analyses in professional practice. It then covers descriptive statistics and exploratory data analysis, followed by inferential (inductive) statistics, including random sampling, randomization, estimation, confidence intervals, and hypothesis testing across categorical, continuous, and time-to-event data.

Special emphasis is placed on methods suited for small sample sizes, such as permutation tests and the bootstrap. Additional topics include correlation, regression models, analysis of variance, multiple testing, and an overview of clinical trials with interim analyses and a case study.

Throughout, methods are illustrated using example datasets and R code. The final chapter revisits data literacy, highlighting issues such as misleading graphical representations. Bayesian methods are excluded due to the introductory level, but further reading is suggested.

The main objective is for students to understand commonly used statistical methods, select appropriate techniques for specific problems, and perform analyses using R.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Project work (online submission)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module BT3: **Physiology and Anatomy**

Lecturer: Prof. Dr. Lukas Scheef (University of Applied Sciences Koblenz, Germany)

Our body is truly an incredible miracle! It's made up of many amazing organs, systems, and structures that work together like a well-oiled machine! They're built to last, and they're built to be better than any machine we've ever made! It can adapt to different environments and situations, which is one of the reasons why we're such a successful species on Earth. But your body is much more than a perfectly built, adaptable, multi-functional machine. It's also a miracle worker that can repair itself when things are broken. And after repair, they are often even better than before! And there are so many more amazing things about our incredible human body: for example, it can replace whole parts! And it does so every minute, day by day, year by year! Isn't that amazing? Did you know it only takes six weeks for your liver to regenerate completely? And every seven years, your skeleton is wholly rebuilt from the ground up, every single bone!

This module is here to help students understand the human body's different organs and functions better. It is divided into fifteen chapters, each covering a different topic. Students will learn about cells and tissues, the skin, the skeletal system, the muscular system, the nervous system, the endocrine system, the blood, the cardiovascular system, the immune system, the respiratory system, the digestive system, the urinary system, and the reproductive system. Each chapter contains information on histology, gross anatomy, and key physiological concepts. It also dives into some essential pathophysiological concepts, such as inflammation, cancer, and some of the most common diseases, like heart attacks, strokes, diabetes, and infectious diseases like malaria and others.

This module is about building that bridge between what students will learn in the textbook, virtual experiments and online meetings and how it applies to our everyday lives. Together students will explore how the human body works and how to use that knowledge to live healthier, happier lives.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module BT5: **Molecular Cell Biology**

Lecturer: Prof. Dr. Maik Lehmann (Bingen University of Applied Sciences, Germany)

In the depths of a seemingly hidden world lies a small universe that holds the key to understanding life. Welcome to the "Molecular Cell Biology" module, where science and wonder meet and cells become the true heroes of life.

Step by step, we delve into the complexity of cells, the tiny factories of life. But beware! Behind an unassuming membrane lies a labyrinth of molecular machinery and chemical reactions that control the essence of life itself. In this module we will see how DNA, the blueprint of life, reveals its secrets. We will follow the dynamic dance of proteins, how they are modified and receive information for their functions in a network of membranes. We will understand how the intracellular transport of nutrients is organized via tiny molecular motors and how cells can move as if by magic. On our journey, we will learn about cutting-edge technologies, from genome editing to live cell imaging, to unlock the secrets of the cell. In molecular cell biology, we find not only the understanding of life, but also hope for cure and medical progress.

Are you ready to explore the frontiers of life? Then open the gates to the world of molecular cell biology with us and make the invisible visible. The greatest magic lies in the smallest units of life - in the cells.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module BT6: Immunobiology

Lecturer: currently supervised by Prof. Dr. Maik Lehmann (Bingen University of Applied Sciences, Germany); The module was originally conceptualised, created and taught by Dr. Sebastian Newrzela (BioNTech, Germany)

Studying the immune system is of major importance because it protects our bodies from diseases and infections. By understanding how the immune system works, we can develop better treatments and vaccines for various diseases. Additionally, studying the immune system can teach us why certain diseases affect particular people differently and how we can personalize modern medicine based on individual immune responses.

Therefore, this module teaches the key players in immunology and aims to transmit a fundamental understanding on how the immune system works. The module will be built-up in three major learning blocks. At first, an introduction to the immune system will be provided. Starting with scientific milestones, the major immunological components (innate and adaptive) and their functions will be presented. In the second part the central cellular elements (T and B cells) and essential basics of adaptive immunity will be introduced. Finally, in the third part the role of the immune system in health and disease will be outlined and an outlook with basic ideas of how to use the acquired immunological knowledge in order to develop treatment options will be delivered. This outlook will give a preparative connection to the upcoming module of immunotherapies.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module BT7: **Medical Microbiology**

Lecturers: Uta Küsters (Bioscientia, Germany); Prof. Dr. Maik Lehmann (Bingen University of Applied Sciences, Germany)

Discover the intriguing world of Medical Microbiology, where the smallest organisms have the most profound impact on human health. This module provides an in-depth look at key pathogens (viruses, bacteria, fungi, parasites and prions) offering essential knowledge on how they function, cause disease and can be detected in clinical settings.

Through this course, students will explore the mechanics behind infectious diseases and learn to recognize the signs and symptoms associated with various pathogens. Students will dive into state-of-the-art diagnostic techniques, from traditional culture methods to advanced molecular and serological tests. Imagine diagnosing infections accurately in a lab setting - an invaluable skill in today's medical and biotechnological fields.

The module will also tackle one of the biggest challenges in healthcare today: antimicrobial resistance. Students will learn why certain pathogens are harder to treat and the role of microbiologists in combating this global issue. And finally, the module introduces foundational principles in epidemiology and infection control, giving you the tools to understand disease spread and contribute to health safety in clinical environments.

Engage with a curriculum designed to not only teach but also inspire. By the end, students will be equipped with the expertise to identify pathogens, understand disease processes and utilize diagnostic tools in theory - knowledge that's crucial in healthcare, research, and beyond. Take the leap into this essential module and start building the foundation for a rewarding career in the biomedical sciences.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module BT8: **Genetic Engineering**

Lecturer: currently supervised by Prof. Dr. Maik Lehmann (Bingen University of Applied Sciences, Germany); The module was originally conceptualised, created and taught by Dr. Benjamin Manirakiza (University of Rwanda, Rwanda)

This module introduces genetic engineering, a transformative field at the core of modern biotechnology that explores how DNA can be read, edited, and redesigned. It covers technologies such as recombinant DNA, gene cloning, and gene editing, which enable modification of genetic material and gene transfer across species to create improved or novel organisms. Applications span medicine, agriculture, industry, and environmental protection, while also addressing potential risks and the need for careful assessment to ensure safe outcomes.

Students will learn the fundamentals of DNA, RNA, protein synthesis, gene structure and function, and recombinant DNA technology. The module includes techniques for gene isolation, cloning, vector design, and transformation in various organisms, as well as genetic modification in bacteria, plants, and animals. Genome editing technologies such as CRISPR-Cas9 are examined in terms of mechanisms, precision, and ethical considerations. The course also provides an overview of applications in healthcare, agriculture, and industry, including gene therapy and personalized medicine, alongside discussions of ethical issues and biosafety protocols.

Learning materials are provided via an e-learning platform to support interaction with peers and the lecturer. The module includes illustrated slides, a concise digital textbook, instructional videos, and self-assessment questions to promote independent learning. Interactive Zoom sessions are conducted in a seminar-style format focused on Q&A rather than traditional lectures.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module BT9: Immunotherapy

Lecturer: currently supervised by Prof. Dr. Maik Lehmann (Bingen University of Applied Sciences, Germany); The module was originally conceptualised, created and taught by Dr. Sebastian Newrzela (BioNTech, Germany)

Immunotherapy is a rapidly evolving field that has transformed the treatment of cancer and other diseases by harnessing the body's immune system to stimulate or suppress immune responses. Several immunotherapies are now used clinically, including immune checkpoint inhibitors, cytokine therapies, antibody therapies, and adoptive cell transfer.

Immune checkpoint inhibitors block proteins that prevent immune cells from attacking cancer and are effective against cancers such as melanoma, lung, and bladder cancer. Cytokine therapies, such as interferon-alpha and interleukin-2, stimulate immune responses to fight disease. Antibody therapies use monoclonal antibodies (e.g., rituximab, trastuzumab) to target specific cells or proteins. Adoptive cell transfer involves modifying a patient's immune cells in the lab and reinfusing them to attack cancer, showing promise in diseases like melanoma and leukemia.

Challenges include identifying which patients will respond to treatment—driving research into predictive biomarkers—and managing side effects that can range from mild to severe across different organs.

Despite these challenges, immunotherapy continues to expand rapidly, with ongoing research focused on developing more effective treatments and understanding immune-disease interactions. By the end of the course, participants will understand key principles, clinical applications, and recent advances, and will gain the foundational knowledge and skills to contribute to future immunotherapy research and development.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module BT10: **Bioelectrical Signals and Sensors**

Lecturer: Prof. Dr. Jens Bongartz (University of Applied Sciences Koblenz, Germany)

Have you ever wondered how an electrocardiogram (ECG) works and how cardiac activity can be visualized? This course provides a comprehensive introduction to the technology used to measure the body's bioelectrical signals, covering the underlying physiology, electrochemistry, electronics, and signal processing. No prior knowledge is required, as all essential fundamentals are introduced throughout the course.

Alongside the theory, the module emphasizes practical application. Students will build their own ECG using simple electronic components and develop the corresponding software, with the option to work hands-on with their own hardware. By the end, students will have gained a versatile technical skill set that can be applied to a wide range of biomedical engineering topics.

The module begins with fundamental concepts of information, sensors, and signals, followed by the basics of electronics and microcontrollers and an introduction to programming for data and signal processing. It then explores bioelectrical signals in the body, including their sources and transmission, and examines electrodes as the interface between biological systems and electronic devices. Further topics include signal amplification, potential shifting, and the conversion of analog signals into digital data. The course also covers serial communication, data storage using buffers and ring buffers, digital filtering to reduce noise, and methods for visualizing and plotting signals. Finally, it addresses data processing for extracting meaningful information and concludes with a bonus topic on wireless devices.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Pharmaceutical Chemistry and Pharmaceutical Technology (PT)



Module PT1: **Pharmaceutical Chemistry and Pharmacology**

Lecturer: Prof. Dr. Gabriele Costantino (University of Parma, Italy)

This module is intended to provide students with the conceptual and methodological basis needed to understand the mechanism of action of drugs, their therapeutic value and their potential toxicity. The students will be introduced to the current definitions of 'drug' and 'medicine' and how these definitions have evolved over the centuries. The students will be introduced to the notion that the biological effect of a drug is due to its chemical structure and its capacity to interact with 'receptor' macromolecules expressed by cells. Pharmaceutical chemistry is the discipline which studies the structural basis of the action of drugs and the way in which drug can be modified to produce new, better, and safer medicines. Pharmacology is the discipline that studies the mechanism of action of drugs in terms of their ability to perturb basilar cellular processes. Pharmaceutical chemistry and pharmacology are both fundamental to understand the processes of absorption, distribution, metabolism and excretion, and to foresee the potential toxicity issues.

Knowledge of these concepts is required not only to discuss the therapeutic use of drugs, but also to understand the whole process of the pharmaceutical industry from discovery to post-marketing vigilance.

- 1) *Knowledge and understanding:* Knowledge of molecular basis of drug's action
- 2) *Ability to apply knowledge and understanding:* Ability to independently apply acquired knowledge to identify the most suitable class(es) of drugs to treat a given therapeutic need.
- 3) *Communication skills:* Ability to use the specific language of this specialist discipline.
- 4) *Autonomy of judgement:* Being able to evaluate the potential therapeutic application and the possible toxicity/side effect of individual classes of drugs.

The module will be taught by using text materials flanked by video insights provided by the lecturer.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module PT2: **Basic Concepts in Pharmaceutical Industry**

Lecturers: Prof. Dr. Gabriele Costantino; Prof. Dr. Francesca Buttini (University of Parma, Italy)

While it may seem apparent that discovery of new drugs is the real advancement provided by pharmaceutical industry, it must be clear that development, production and quality control are equally important in providing high quality and effective medicines at a population level. This module will introduce students to the basic concepts which drive modern pharmaceutical and biotechnological industries. Students will be exposed to the most common routes through which medicines are administered and how the pharmaceutical form (i.e. tablets, injections, cream, ...) impacts the efficacy. Basic technology processes will be discussed in detail and analysed for their importance in defining the quality of the finished medicinal products. Students will wander around the importance of the pre-formulation steps, and their scale up to the industrial formulation process. Moreover, the concept of the Good Manufacturing Practices (GMP) and their industrial and regulatory relevance will be introduced. At the end of the module the student is expected to have acquired:

- 1) *Knowledge and understanding:* Knowledge of excipients, production methods and control procedures of pharmaceutical forms
- 2) *Ability to apply knowledge and understanding:* Ability to independently apply acquired knowledge to identify the most appropriate excipients and preparation methods for the development of a given dosage form.
- 3) *Communication skills:* Ability to use the specific language of this specialist discipline.
- 4) *Autonomy of judgement:* Being able to evaluate the implications and results of studies aimed at clarifying the influence of dosage form on the activity of the active ingredient.

The module will be taught by using text materials flanked by video demonstrations of the basic technological processes.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module PT3: **Good Manufacturing Practice (GMP) and Quality Controls**

Lecturer: Emanuela Previtali (Qomnia, Italy); The module was originally conceptualised, created and taught jointly by Emanuela Previtali and Luciano Gambini (Qomnia, Italy)

Good Manufacturing Practice (GMP) training is essential for science graduates, covering the rules and standards that ensure the quality, safety, and consistency of pharmaceutical production. This module provides participants with in-demand knowledge of GMP and cGMP ("current" GMP), emphasizing continuous improvement and risk minimisation in manufacturing processes.

Participants are introduced to key GMP principles and requirements, including the structure and history of GMP, manufacturing workflows from raw materials to finished products, relevant guidelines and standards, organisational roles (including Annex 16 EU GMP), facility layout and environmental controls, hygiene and pest control, equipment requirements, cleanroom classification and validation, documentation, production and in-process controls, quality control and laboratory organization, quality management systems (including change control, deviations, and CAPA), supplier qualification, quality agreements, and special considerations for investigational medicinal products.

Each unit includes introductory materials such as slides, videos, key definitions, and reference documents. Learning is reinforced through multiple-choice and essay-based questionnaires based on real GMP deviations, with guided discussion of answers to explain their rationale. Students are expected to review the introductory materials before each lesson.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module PT4: Fundamentals in Epidemiology and Clinical Trials

Lecturers: Prof. Dr. Bernard Omolo (University of South Carolina, USA); Prof. Dr. Markus Neuhäuser (University of Applied Sciences Koblenz, Germany)

This module introduces key epidemiological concepts for quantitatively describing population health, health inequalities, and their determinants. Epidemiology focuses on understanding the causes and distribution of health in populations to prevent disease and promote health, with emphasis on what, how, and whom to measure while minimizing bias. These skills support critical evaluation of public health evidence.

Using R, students learn to connect theory with real data by performing basic analyses, including descriptive statistics, measures of occurrence, association, uncertainty, and confounding adjustment. They develop the ability to apply epidemiological methods across public health contexts, select appropriate data collection approaches, and interpret results for research, policy, and practice.

The module covers measures of disease occurrence (incidence, prevalence, risk, rates) to assess disease burden; measures of association (ratios, differences) to identify risk factors; and measures of uncertainty, including random and systematic error, confounding, and selection and information bias. It also introduces common study designs such as cohort, cross-sectional, and case-control studies, with a focus on conceptual understanding.

Finally, the module addresses clinical trials, including key concepts like randomization, placebo control, and blinding; trial phases and experimental designs; and relevant statistical aspects such as power, sample size calculation, subgroup and interim analyses, and bioequivalence testing for generic drugs.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module PT5: Hygiene in Pharmaceutical Manufacturing Processes

Lecturer: Dr. Rita Spannenberger (BioNTech, Germany)

After completing this module, students will have a basic understanding of Good Manufacturing Practices (GMP) in the pharmaceutical industry. Students will be familiar with all the contamination risks and will be able to develop a good strategy against them. They will be able to identify the various microorganisms and how to defend against them.

Students will understand the most important features of a cleanroom and how air monitoring and circulation work. They will also understand how an environmental monitoring plan is set up and what processes it must go through to obtain a manufacturing licence. Even a CAPA processing and change management will no longer be a challenge for students.

Students will be familiar with all the relevant sterilisation processes and additionally know how to behave in a clean room, what is allowed and what is not. They will be able to use the airlocks without any problems and know exactly how to gown up.

Finally, students will be familiar with the documentation requirements and be able to handle data in accordance with the ALCOA+ rules without any issues.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Portfolio exam (online submission)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module PT6: Herbal Production Biotechnology

Lecturer: Prof. Isaac Kingsley Amponsah (Kwame Nkrumah University of Science & Technology, Ghana)

Ghana's growing herbal medicine industry contributes significantly to employment, healthcare, and income generation. While formal university-level education has brought greater scientific scrutiny to the sector, Ghana has yet to fully harness biotechnology to develop competitive, high-value herbal products.

Globally, technologies such as fermentation, microbial biotransformation, and nano-biotechnology have transformed poorly active or poorly absorbed plant compounds like resveratrol, quercetin, and various triterpenoids into therapeutically potent, commercially successful products. The enzymatic transformation of green tea into black tea further illustrates how biotechnology can fundamentally alter a plant's chemical profile and commercial value. Application of herbal biotechnology will place technical demands on both manufacturers and regulators, for which most are currently unprepared.

This module addresses these gaps by providing structured, practically oriented training in biotechnology applications for herbal medicine production and molecular authentication-based quality control; a timely intervention to make Ghana's herbal industry innovative, technically grounded, and globally competitive.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3



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Innovation Management and Intercultural Cooperation (IM)



Module IM1: Innovation Management

Lecturer: Prof. Dr. Claudia Hensel (University of Applied Sciences Mainz, Germany)

The interdisciplinary module "Innovation Management" is structured to provide students with the critical skills and knowledge to create innovative solutions that support the Sustainable Development Goals (SDGs). Over 90 hours of blended learning, students will delve into the principles of innovation, problem-solving, and evidence-based argumentation, with a strong emphasis on creativity, critical thinking, and ethical decision-making. The module encompasses theoretical lectures, practical workshops, and collaborative projects, facilitating a comprehensive understanding of how innovation can effectively address global challenges. By the end of the module, students will have honed their abilities to analyze societal problems, develop and prototype innovative solutions, and communicate their ideas persuasively, preparing them to contribute meaningfully to sustainable development efforts.

It combines theoretical insights with practical exercises and projects, encouraging students to explore the principles of innovation, problem-solving, and effective presentation techniques. The module focuses on fostering creativity, critical thinking, and ethical decision-making to address real-world challenges.

Key learning outcomes include the ability to analyze and evaluate the role of innovation in addressing global challenges, apply problem-solving techniques to prioritize societal issues, utilize evidence-based reasoning to support decisions, and develop persuasive arguments for innovative solutions considering ethical and social implications. Teaching methods encompass asynchronous video lectures, synchronous face-to-face tutorials, online team coaching, and self-study assignments.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Portfolio exam (online submission)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module IM2: **Entrepreneurship**

Lecturers: Dr. Helia Schönthaler; Dr. Ralf Dahm (Institute of Molecular Biology Mainz, Germany)

Turning a scientific idea into a startup is a powerful way to translate research into real-world impact, but it requires acquiring new skills and navigating multiple stages. An inventor must evaluate the invention, protect intellectual property through patenting, decide on the appropriate exploitation strategy (licensing or creating a spin-off), and develop and implement a business plan. Although risks are involved, careful planning, strategic guidance, and a strong focus on market needs can turn an invention into a successful venture.

This Entrepreneurship module provides a structured overview of the entire process, covering the invention phase, invention evaluation, access to advisory and support, patent strategy and application, decisions on exploitation, pathways through licensing or spin-off, business plan development, creation of a business pitch (pitch deck), and the practical steps involved in launching a startup.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module IM3: Intercultural Communication and Mediation

Lecturer: Prof. Dr. Claudia Hensel (University of Applied Sciences Mainz, Germany)

In a world characterized by increasing globalization and cultural interconnectivity, intercultural competence has become a vital skill for both personal and professional success. This module provides a comprehensive exploration of cultural diversity across continents, incorporating immersive Virtual Reality (VR) technology to enhance learning experiences. Designed for interdisciplinary engagement, the module is structured around Bloom's Taxonomy to facilitate progressive learning outcomes – from remembering and understanding cultural knowledge to applying, analyzing, evaluating, and creating culturally responsive solutions.

The module is divided into thematic units focusing on Asia, Africa, Europe, the Americas, and Oceania. Each unit explores the unique cultural norms, traditions, and communication styles of these regions through interactive VR experiences, case studies, group discussions, and reflective exercises. Assessments include quizzes, reflective essays, group projects, comparative analysis papers, and digital storytelling, ensuring a comprehensive evaluation of students' understanding and application of inter-cultural competence.

Teaching methods combine online face-to-face sessions with self-paced learning, utilizing a blend of interactive lectures, VR simulations, group collaborations, and self-reflection tasks. By engaging with this module, students will develop a nuanced understanding of cultural dimensions, enhance their cross-cultural communication skills, and cultivate cultural sensitivity. The module also encourages students to reflect on their personal cultural biases and develop strategies for effective interaction in multicultural environments. Ultimately this module aims to prepare students to become informed, empathetic, and effective global citizens.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Oral exam (online)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module IM4: Scientific Communication

Lecturers: Dr. Helia Schönthaler; Dr. Ralf Dahm (Institute of Molecular Biology Mainz, Germany)

Effective science communication is a key skill for advancing careers, securing funding, building collaborations, managing projects, publishing results, and gaining recognition. Communicating clearly with non-experts also promotes understanding of scientific concepts, supports informed decision-making on issues such as health and climate change, builds trust in science, and contributes to a more scientifically literate society.

This module equips participants with the skills to communicate scientific data, concepts, and ideas effectively to diverse audiences. It covers how to understand, engage, and persuade target audiences; simplify complex information without losing accuracy; craft and tailor clear messages; and use storytelling techniques to make science more relatable and memorable. It also addresses visual communication to enhance understanding, as well as public speaking skills, including preparation, delivery, and overcoming anxiety. Students learn how to seek and incorporate feedback to continuously improve, with regular summaries reinforcing key concepts throughout the module.

Hands-on activities complement the theory, allowing students to practice message development, visual design, and audience engagement. If time permits, students will develop and present a science communication project, applying the skills learned and receiving structured feedback.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3



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Facility, Energy and Environmental Management (EM)



Module EM1: Facility Management

Lecturer: currently supervised by Michel Alt (Technical University Mittelhessen, Germany); The module was originally conceptualised, created and taught by Franziska Grasmück (Technical University Mittelhessen, Germany)

The module “Systems Engineering in Facility Management” introduces the technical systems and equipment essential for operating, securing, and optimizing buildings and infrastructure. As a core part of technical facility management, it covers HVAC systems for indoor climate and air quality, electrical systems for power supply, lighting, and backup solutions, sanitary systems for water and wastewater, as well as safety, communication, compressed air, hydraulic systems, and building automation.

Key tasks include planning and installing systems, operation and monitoring, maintenance and servicing, and the optimization and modernization of existing installations to ensure compliance with safety standards and regulations. The module also emphasizes diagnosing technical issues and developing solutions to improve system performance, alongside adapting systems to local building regulations, infrastructure, and climatic conditions.

A further focus is on energy efficiency and sustainability, including methods to improve system performance and the implementation of energy management systems. Students are introduced to current developments in facility management, such as digitalization, modern plant technologies, and future trends, including the use of IoT and sensors for system monitoring and optimization.

Overall, the module prepares students to address technical and organizational challenges in facility management by developing in-depth knowledge of systems and equipment, including compressed air and hydraulics, and the ability to analyze conditions and apply state-of-the-art solutions in practice.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module EM2: **Environmental Management**

Lecturer: Prof. Dr.-Ing. Sebastian Schrems (Technical University Mittelhessen, Germany)

The module provides students with in-depth knowledge of the key aspects, methods and concepts of environmental protection. It aims to create a deep understanding of the historical development and importance of environmental protection. Students will explore the influences of environmental history on public opinion, business strategies and legal frameworks.

A central component of the module is the fundamentals of sustainability and its integration into corporate environmental protection measures and environmental management systems. Students will learn how sustainability principles are applied in organisations and the role of environmental management systems.

Furthermore, methods for evaluating environmental impacts are dealt with in depth. Different types of footprints, such as the carbon footprint, water footprint and ecological footprint, are introduced to equip students with tools to measure and analyse environmental impacts.

The section on resources and raw materials provides a detailed insight into the classification of natural resources according to VDI 4800 and discusses the potential for conflict due to regionally limited availability. The German resource efficiency programme Progress is used as a case study.

Finally, the importance of resource efficiency is emphasised. Students analyse the reasons for the increased demand for resources, understand the concept of resource criticality and explore how resource efficiency in production can contribute to the conservation of natural resources.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module EM3: Energy Management

Lecturer: Michel Alt (Technical University Mittelhessen, Germany)

The module provides a comprehensive exploration of key topics in the field. Covering both theoretical foundations and interactive applications, this module equips students with essential knowledge for the energy sector. The module addresses several subtopics, leading from the fundamentals to latest optimizations and integration into real world scenarios.

Beginning with the fundamentals of energy technology, students delve into the principles underlying energy systems, including generation, conversion and use as well as looking into different forms of energy sources, such as oil, coal, sunlight, wind and water.

The following unit of measurement technology, control engineering and automation focuses on techniques for monitoring and regulating technical processes. Students gain hands-on experience with software simulation of e.g. sensors, actuators, and control systems.

Due to sustainability and mobile applications, there is a subtopic examining specifically energy sources like solar, wind and water, emphasizing their environmental impact, efficiency, and integration into existing grids and mobile applications. To be aware of the usage of this energy, students explore various methods of energy conversion (e.g., from mechanical to electrical) and learn about energy storage technologies. Furthermore, safety protocols, electromagnetic interference, and compliance with standards are discussed to ensure safe energy systems.

Finally, the module concludes by addressing strategies for efficient energy use and optimization in industrial, residential and mobile settings.

By engaging with these topics, students gain a holistic understanding of energy systems, preparing them for any task in renewable energy, power generation, and sustainability. The course is designed to be interactive and supported by various media, such as tests for self-monitoring, videos or text- sections to deepen the knowledge gained.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3



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Health Care and Smart Medical Technologies (HC)



Module HC1: Sustainable Operations Management in Healthcare

Lecturer: Dr. Khalil Dindarian (Siemens, Germany)

The module provides students with a practical and strategic understanding of how healthcare organizations design and manage their operations in complex and rapidly changing environments.

The module addresses key challenges such as rising costs, workforce shortages, digital transformation, and sustainability requirements. Students explore how healthcare systems create value, optimize processes, and improve patient outcomes while balancing efficiency and quality.

Across six interconnected topics – ranging from healthcare systems and value creation to capacity planning, lean management, integrated care models, and digital transformation – students gain a comprehensive, real-world perspective on healthcare operations.

The course combines theoretical insights with case studies, simulations, and applied exercises, enabling students to translate concepts into practice.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Term paper (online submission)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module HC2: Standards in Ghana's Healthcare System

Lecturer: Dr. Richard Adjei Akuffo (Noguchi Memorial Institute for Medical Research, Ghana)

Ghana's healthcare system comprises standardized policies and regulations overseen by the Ministry of Health (MOH) and implemented by the Ghana Health Service (GHS), with the aim of attaining universal health coverage (UHC) and improved quality of care for people in Ghana. This module will introduce students to various standards of Ghana's healthcare system, including but not limited to the following: overview of Healthcare Governance and regulation, Clinical Standards in Ghana's healthcare system, Licensing and professional standards, Quality assurance and safety standards, and service delivery standards. A brief overview of Ghana's pharmaceutical sector and patient pathways shall also be presented to inform adaptation of biomanufacturing practices within Ghana's healthcare system.

This module is intended to present an overview of Ghana's healthcare standards with a view to ensuring that participants become familiar with the regulatory, licensing, and other professional standards of the Ghana healthcare system. It will be delivered online with the help of videos, recommended reading list, and quizzes.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

Module HC3: **Coaching and Leadership Development in Healthcare Contexts**

Lecturer: Herman Yobo Addae (Lead-it Africa, Ghana)

The module is structured to move participants beyond theoretical leadership concepts toward practical, results-oriented leadership behaviours suited to regulated healthcare and manufacturing environments. The module integrates five key themes:

1. Personal Effectiveness & Leadership
2. Strengthening Performance and Execution Capability
3. Coaching and People Leadership Skills
4. Communicating for Results in Healthcare
5. Accountability & Ethical Leadership - Leading Change in Regulated Environments.

Using proven project-based learning methods, participants shall undertake a work-based leadership project within their academic or professional context. This ensures strong skills acquisition, deliberate practice, and reinforcement of positive everyday behaviours that translate into measurable performance outcomes.

Upon completion, students will demonstrate strengthened leadership presence, coaching capability, and the ability to deliver results through teams, empowering them to contribute meaningfully to building sustainable biopharmaceutical manufacturing capacity.

The program will be delivered primarily through structured self-learning (approximately 80%), supported by curated digital content, healthcare case studies, reflective exercises, and practical leadership toolkits. The live online sessions will adopt a Socratic and highly interactive format, incorporating simulations, scenario discussions, peer coaching practice, and expert facilitation to deepen learning and accountability.

Teaching Mode	Blended Learning; 90 hrs of study 10 online contact hours per semester + 80 hrs self-study
Assessment	Project work (online submission)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

GxP – Compliance and Risk Assessment (GR)



GR1: Good Manufacturing Practices and Quality Management Systems

Lecturer: Dr. Heinrich Prinz (PDM-Consulting, Germany)

Imagine that you are sitting on an airplane, ready for take-off. You probably do not spend much time thinking about the thousands of components that make up the aircraft, the materials they are made of, or the countless checks performed before the plane ever leaves the ground. You simply trust that everything has been designed, tested, checked, and maintained to keep you safe. Now think about something much more familiar: taking a painkiller. You are unlikely to wonder whether the tablet contains the right amount of active ingredient, whether it might contain any impurity, or whether every step of its manufacture was properly controlled. And yet, behind that small tablet is a remarkably complex system designed to make sure that you can trust it. During this module you will learn how to build quality into a medicinal product applying the worldwide used **GMP — Good Manufacturing Practice** regulation as one core part of the system. There is a systematic approach behind it called **PQS — Pharmaceutical Quality (Management) System** to make sure that quality is built into the product. GMP requirements **are extensive** and **can differ** between regions around the world, however, what will be studied are the **principles behind GMP** to make the tablet safe!

In this module students will thus learn the basic requirements for a quality management system and gain insight into risk analysis and quality assurance within a company environment. Students will moreover learn about the specific activities and tasks that quality controls must fulfil and which role the Qualified Person plays as well as which regulatory requirements apply in the manufacturing process of medicinal products.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3

GR3: Specific Requirements for Manufacturing and Quality Control

Lecturer: Dr. Heinrich Prinz (PDM-Consulting, Germany)

Imagine that you are sitting on an airplane, ready for take-off. You probably do not spend much time thinking about the thousands of components that make up the aircraft, the materials they are made of, or the countless checks performed before the plane ever leaves the ground. You simply trust that everything has been designed, tested, checked, and maintained to keep you safe. Now think about something much more familiar: taking a painkiller. You are unlikely to wonder whether the tablet contains the right amount of active ingredient, whether it might contain any impurity, or whether every step of its manufacture was properly controlled. And yet, behind that small tablet is a remarkably complex system designed to make sure that you can trust it. During this module you will learn how to build quality into a medicinal product applying the worldwide used **GMP — Good Manufacturing Practice** regulation as one core part for a safe, high quality and efficient medicinal product. Students will dive into the expectations for manufacturing and quality control to assure the usability of medication. Additionally, students will learn about the most critical parts and gain an in-depth understanding of applicable requirements for sterile, biotechnological or medicinal products in manufacturing and relevant quality control.

Teaching Mode	Blended Learning; 90 hrs of study 90 hrs self-study; no online contact hours
Assessment	Written exam (on-site)
Size	5 - 30 students per semester Note: fewer or more students per semester are subject to the discretion of the lecturer(s)
Location	Online
Language	English
ECTS	3



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Appendix I

German Grading Scale

The grades for the individual examinations in accordance with § 7 (2) of the Framework regulations of Koblenz University of Applied Sciences for the examination in the Certificate programme from 27.04.2023 are determined by the respective examiners. The following grades are to be used for the assessment of the examinations:

1 = very good = excellent performance;

2 = good = a performance that is significantly above the average requirements,

3 = satisfactory = a performance that meets average requirements;

4 = sufficient = a performance that still fulfils the requirements despite its shortcomings;

5 = insufficient = a performance that no longer fulfils the requirements due to significant deficiencies

Individual grades can be raised or lowered by 0.3 to intermediate values in order to differentiate the assessment of an examination; the grades 0.7, 4.3, 4.7 and 5.3 are excluded.

*Further information on the specific calculation of grades per assessment and overall grades, please consult the **Framework regulations of Koblenz University of Applied Sciences for the examination in the Certificate programme from 27.04.2023**.*