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| **Module** | **Bioprocessing and Bioanalytics** |
| **Code** | MSLS_V2_2 |
| **Degree Programme** | Master of Science in Life Sciences (MSLS) |
| **ECTS Credits** | 5 |
| **Workload** | 150 h: Contact 60 h; Self-study 90 h |
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| **Lecturers** | • Prof. Dr. Caspar Demuth<br>• Prof. Dr. Regine Eibl<br>• Prof. Dr. Lukas Neutsch<br>• Dr. Jan Ott<br>• Guest lecturers |
| **Entry Requirements** | This module builds on a Bachelor's level study program (or its equivalent) in biotechnology or a related field, which conveys basic knowledge in the following subject areas:<br>• Cultivation systems for microorganisms, animal as well as human cell lines from laboratory to industrial scale<br>• Bioreactor cultivations in batch, fedbatch, and continuous mode<br>• Monitoring systems in biotechnology, data acquisition, statistical evaluation and modelling<br>• Biochemistry and analytical chemistry (i.e. common metabolic pathways, basic knowledge on enzyme regulation, analytical methods for proteins and metabolites)<br>• cGMP, clinical trials & registration processes, role of regulatory bodies |
| **Learning Outcomes and Competencies** | On completion the module, students will be able to understand the overall concept of bioengineering, a technology in which biological systems are used to manufacture a specific product of interest (can also be cell biomass). This principle is exemplified in selected industrial applications and research questions. Students will acquire knowledge and competencies on how to combine technical equipment (including reusable systems) with process control strategies and bioanalytical methods to meet defined productivity and quality goals. The dynamic decision-making processes in |

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| | modern biotechnological production will become tangible, taking into account technical, biological and financial limitations.<br><br>For a deeper understanding of the associated market area and economic framework, students will have opportunity to develop a business case in the field of biotechnology and related technologies. Supported by a panel of lecturers, they will learn how to balance technical, financial, legal, social and ethical aspects when commercializing scientific inventions, emerging products, or innovative technologies. The case studies will encourage students to think creatively and constructively and consider critically the implications of their decisions and recommendations, which are often made with limited information and time. Start-Ups and similar business ventures will be in the focus of this course part.<br><br>The skills and competencies acquired by the students will include:<br>• The designing of bioprocesses according to latest techno-economical standards, including single-use platforms, medical cell products (e.g. cell and gene therapeutics) and emerging, less conventional (e.g. microalgae) host systems<br>• Knowledge on the layout of modern production equipment and facilities<br>• Risk assessment for different types of processing strategies & setups<br>• State of the art monitoring and control strategies for bioprocesses, in line with current PAT, QbD and regulatory demands<br>• Developing a holistic view for the gene-to-product chain<br>• Following and critically analysing up-to-date scientific and patent literature<br>• Evaluating new business opportunities and summarizing key data in a report format<br>• Promoting business concepts, in written form and in oral presentations, based on innovative, science-driven applications to different classes of target audience |
| **Module Content** | Working with selected examples of industrial bioprocesses, the following topics, tools and methods will be introduced and explored:<br>• Examples of biopharmaceutical production with single-use and stainless steel equipment (use of mammalian, insect, plant and microbial cells, with a focus on antibodies, vaccines, cell and gene therapeutics)<br>• Modern equipment in upstream and downstream processing, formulation and filling (e.g. systems for freezing, storage, tempering, mixing and connecting/reconnecting, bioreactors, filtration and chromatography, fill and finish)<br>• Traditional and modern cGMP production facilities<br>• Flexible manufacturing and “Facility of the Future” production concepts<br>• Perfusion and continuous production<br>• Criteria for the choice of host organisms in biopharmaceutical production, industrial biosynthesis or biotransformation<br>• Interlinked effects of the expression system, process control strategy and target molecule on product formation and the cells’ metabolic state<br>• Techno-economical assessment of existing and new technologies, production concepts, products and applications with regard to conceptual novelty, functionality, regulatory compliance, consumer acceptance and marketability<br>• Application of advanced sensor systems, measurement strategies and process validation concepts incl. PAT (process analytical technology) and QbD (quality by design) |

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| | • "Building a Business Case for Innovation" (BBCI): Development of compelling business cases in biotech and adjacent fields using<br>- competitive benchmarking,<br>- value chain analysis,<br>- financial analysis,<br>- risk analysis<br>- IP landscape assessment and<br>- market planning |
| **Teaching / Learning Methods** | Basic knowledge will be acquired in contact lessons, given by lecturers as well as guest lecturers. Presenting key findings in an effective and audience-targeted form and writing of reports (guided by supervisors) is a core part of the module. In order to apply and extend this knowledge and successfully carry out case studies, students will be required to read and discuss relevant scientific (English and German) literature as well as to work with e-learning tools (communication platforms, process simulation) in self-study mode. |
| **Assessment of Learning Outcome** | Written or oral exam:<br>• 40% (2 ECTS) manufacturing systems (R. Eibl, J. Ott & guest lecturers): final written report and oral presentation<br>• 60% (3 ECTS) BBCI case analysis (L. Neutsch, C. Demuth, guest lecturers & Coaches), including presentations (oral), interim deliverables (short reports), shaping & final report (written). |
| **Bibliography** | Selected original scientific publications and monographs or book chapters will depend on the individual case study. Recommended reading in addition to individual literature work:<br>• Dunn, I.J., E. Heinzle, J. Ingham, and J.E. Prenosil. 2003. Biological Reaction Engineering: Dynamic Modelling Fundamentals with Simulation Examples. Wiley-VCH Verlag GmbH, Weinheim, Germany.<br>• Eibl, R., D. Eibl, 2019. Single-use technology in biopharmaceutical manufacture, Wiley.<br>• DECHEMA recommendations of the working group SUT<br>• Gellissen, G. (Ed.). 2005. Production of Recombinant Proteins. Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim, Germany.<br>• Liese, A., K. Seelbach, and C. Wandray (Eds.). 2000. Industrial Biotransformations. Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim, Germany.<br>• Meier, H.-P., and D. Schmidhalter (Eds). 2014. Industrial Scale Suspension Culture of Living Cells. Wiley-VCH Verlag GmbH & Co. KGaA, Weinheim, Germany.<br>• Schügerl, L., and K.H. Bellgardt (Eds.). 2000. Bioreaction Engineering. Modelling and Control. Springer-Verlag Berlin Heidelberg, Germany. |
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| **Comments** | |
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