

Module	Downstream and Safety
Code	MSLS_V2_3
Degree Programme	Master of Science in Life Sciences (MSLS)
ECTS Credits	5
Workload	150 h: Contact and exercises 60 h; Self-study 90 h
Module Coordinator	<p>Name Prof. Dr. Dieter Eibl</p> <p>Phone +41 (0)58 934 57 11</p> <p>Email dieter.eibl@zhaw.ch</p> <p>Address ZHAW Zurich University of Applied Sciences Life Sciences and Facility Management Campus Grüental PO Box CH-8820 Wädenswil</p>
Lecturers	<ul style="list-style-type: none"> • Prof. Dr. Dieter Eibl • Dr. Sabina Gerber • Guest lecturers
Entry Requirements	<p>The module builds on a Bachelor's level study programme in biotechnology, chemistry, pharmacy or similar. Prerequisite is the basic knowledge in the following topics:</p> <ul style="list-style-type: none"> • cultivation systems for microorganisms and cell lines from lab to pilot scale • biochemistry and analytical chemistry (i.e. structure and properties of proteins, analytical tools for protein characterisation and quantification) • contaminants and impurities in biological processes like viruses, endotoxins, prions, etc.
Learning Outcomes and Competences	<p>After completing the module students are able to understand the concept of downstream processes in pharmaceutical biotechnology and its implication not only on biological and technical but also on safety and regulatory issues. Thus, they will be able to:</p> <ul style="list-style-type: none"> • evaluate, select and use equipment for downstream processing appropriate to scale as well as the product and its characteristics. • evaluate the interdependence of up- and downstream processes in biotechnology • apply and evaluate methods of downstream processing with a focus on chromatography • apply and evaluate in-process control and quality control methods for protein purification • apply and evaluate the most important cleaning and quality assurance steps according to GMP guidelines (swissmedic, EMA, FDA, ICH).

	<ul style="list-style-type: none"> • follow and analyse up-to-date scientific literature on downstream processes
Module Content	<p>Module content is the theoretical basics and the industrial application of downstream processes as they are used in pharmaceutical biotechnology. Special focus is laid on the theoretical background and the practical application of purification strategies for products derived from biotechnological processes.</p> <ul style="list-style-type: none"> • Overview of industrial protein purification process (including excursions) • Clarification, capture, intermediate purification, polishing, stabilisation • In-process controls in downstream processing • Supply chain management in downstream processing • Secondary material flow • Quality assurance and safety, approval and guidelines, process validation • Regulatory affairs and GMP guidelines for chromatography in protein purification processes • Company workshops for selection, up-scaling and dimension of suitable equipment • Practical course: <ul style="list-style-type: none"> • Purification of a monoclonal antibody from CCS and analysis of product and impurities • Evaluation of the protein purification process (target definition, quality control and impurity evaluation)
Teaching / Learning Methods	<p>Basic knowledge is acquired in lectures. In order to apply and extend this knowledge and successfully carry out the case study and the practical course, students are required to read and discuss relevant scientific (English and German) literature in self-study mode. Excursions and company workshops give insight to the actual industrial practice.</p>
Assessment of Learning Outcome	<ul style="list-style-type: none"> • Short report and oral exam on practical course (40%) • Average of in-term (during semester) assessments (30%) • Short report and oral presentation (30%)
Bibliography	<p>Selected original papers and monographs depending on the individual case study.</p> <ul style="list-style-type: none"> • P. L. Show, C. W. Ooi, T. C. Ling, Bioprocess Engineering: Downstream Processing, Taylor & Francis Ltd, 2019, ISBN: 978-1-1386-0575-6 • N. Labrou, Protein Downstream Processing, Humana Press, 2016, ISBN: 978-1-4939-6040-8 • J.A. Wesselingh, J. Krijgsman, Downstream Processing in Biotechnology, Delft Academic Press, 2013, ISBN-13: 978-9065623188 • N. K. Prasad, Downstream Process Technology: A new Horizon in Biotechnology, Phi Learning, 2010, ISBN: 978-81-203-4040-4 • U. Gottschalk, Process Scale Purification of Antibodies, Wiley, 2009, ISBN: 978-0-470-20962-2 • D. Forciniti, Industrial Bioseparations: Principles and Practice, Blackwell Publishing, Oxford, 2008, ISBN: 978-0-8138-2085-9 • A.M. Desai, Downstream Processing of Proteins: Methods and Protocols, Humana Press, 2000, ISBN 978-0-89603-564-5
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Comments	
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