

Master in Life Sciences

A cooperation between
BFH, FHNW, HES-SO, ZFH

Module title	Design of Biopharmaceutical Production Facilities
Code	BP3
Degree Programme	Master of Science in Life Sciences
Group	Bio/Pharma
Workload	3 ECTS (90 student working hours: 42 lessons contact = 32 h; 58 h self-study)
Module Coordinator	<p>Name: Dr. Dieter Eibl Phone: +41 (0)58 934 57 11 Email: dieter.eibl@zhaw.ch Address: ZHAW Life Sciences and Facility Management, Campus Grüental, 8820 Wädenswil</p>
Lecturers	<ul style="list-style-type: none"> • Dr. Dieter Eibl, ZHAW • Stefan Seidel, ZHAW • Dr. Martin Krahe, Bideco AG • Dr. Henry Weichert, Sartorius Stedim Biotech • Dr. Johannes Wagner, Sartorius Stedim Biotech • Dr. Georg Dorn, GE Healthcare • Dr. Robert Morenweiser, GE Healthcare • Andreas Flaggmeyer, Pall Life Sciences • Valentin Rüttimann, Pall Life Sciences • Olaf Stoll, S&G Gebäudetechnik AG
Entry requirements	<ul style="list-style-type: none"> • BSc in Biotechnology, Chemistry, Mechanical Engineering or Plant Engineering • Study of provided reading material • Usage of software Visio • Self-test on Moodle
Learning outcomes and competences	<p>After completing the module, students will be able to:</p> <ul style="list-style-type: none"> • Plan and design biopharmaceutical production facilities This concerns both traditional biopharmaceutical production facilities and facilities of the future. • Choose the optimal facility set-up under consideration of compliance and regulatory aspects, special features of newly constructed and rebuilt facilities, supply chain management, Industry 4.0 demands, automation concepts and project management • Use software HakoBio
Module contents	<ul style="list-style-type: none"> • Overview of modern design concepts of biopharmaceutical production facilities: From the manufacture of the drug substance to the drug product, pros and cons • Facility concepts (vertical or horizontal arrangement, conventional biopharmaceutical production facility vs. facility of the future) • Modularization of production facilities (standard personnel airlock, clean room and technical interstitial area, technical process chase and HVAC concept) • Room concept (zone concept) of the production level ("Closed systems" in "Controlled -Non-Classified Room" and "Controlled-No-Classified (CNC) Room Concept") • Closed processing (where are the open gaps?)

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	<ul style="list-style-type: none"> • Space and concepts of utilities and services (WFI, steam, ventilation, waste products, containment, storage) • Compliance and regulatory aspects • Special features of newly constructed or rebuilt facilities • Supply chain management of biopharmaceutical production facilities • Industry 4.0, automation concepts of biopharmaceutical production facilities • Project management for the realization of biopharmaceutical production facilities 																								
Teaching / learning methods	<ul style="list-style-type: none"> • Lectures (company workshops included) • Literature study and case study work • Presentations of the current state of the case study work 																								
Assessment of learning outcome	<ol style="list-style-type: none"> 1. Self-test on Moodle (30%) 2. Presentation on progress of the case study work and defense of the case study work: Every subgroup has to present and answer (own mark) (30%) 3. The report of the case study work (in groups) to be handed in 3 weeks after the end of the module (40%) 																								
Format	Winter School																								
Timing of the module	Autumn Semester, CW 4 Submission of the case study work in CW 7 <table border="1" style="margin-top: 10px;"> <thead> <tr> <th>Day of the block week</th> <th><1</th> <th>1</th> <th>2</th> <th>3</th> <th>4</th> <th>5</th> <th>>5</th> </tr> </thead> <tbody> <tr> <td>Contact teaching (lessons)</td> <td></td> <td>8</td> <td>9</td> <td>9</td> <td>9</td> <td>7</td> <td></td> </tr> <tr> <td>Self-study (hours)</td> <td>24</td> <td></td> <td></td> <td></td> <td>2</td> <td></td> <td>32</td> </tr> </tbody> </table>	Day of the block week	<1	1	2	3	4	5	>5	Contact teaching (lessons)		8	9	9	9	7		Self-study (hours)	24				2		32
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Self-study (hours)	24				2		32																		
Venue	Wädenswil																								
Bibliography	<ul style="list-style-type: none"> • Eibl R., Eibl D. (2019) Single-Use Technology in Biopharmaceutical Manufacture, John Wiley & Sons; ISBN: 9781119477839 • ISPE Guidance Documents • Jagschies G., Lindskog E., Lacki K., Galliher P. (2017) Biopharmaceutical Processing: Development, Design, and Implementation of Manufacturing Processes; Elsevier; ISBN: 9780081006238 • Jeffery N. Odum (2013) Biopharmaceutical Facility Design and Validation; in Encyclopedia of Industrial Biotechnology; DOI: 10.1002/9780470054581.eib654 																								
Language	English																								
Links to other modules	Specialisation module ZHAW "Bioprocessing and Bioanalytics" (Production systems)																								
Comments																									
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