



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"> • Dieter Eibl, ZHAW • Stefan Seidel, ZHAW • Martin Krahe, Bideco AG • Henry Weichert, Sartorius • Georg Dorn, Cytiva • Fabrice Gachot, Cytiva • Nicole Fontourcy, Pall Life Sciences • Valentin Rüttimann, Pall Life Sciences • Olaf Stoll, S&G Gebäudetechnik AG • Pascal Wirth, Wirth+Wirth Architekten
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 or AutoCAD • Self-test on MSLS Community Centre • See also information under "comments"
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 Accelerator Vision Platform
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")



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	<ul style="list-style-type: none"> • Closed processing (where are the open gaps?) • 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 MSLS Community Centre (30%) 2. Individual grading of the activity during the project work (30%) 3. Presentation on progress of the case study work and defense of the case study work: Every subgroup has to present and answer (separate mark for each subgroup) (10%) 4. The report of the case study work (in groups) to be handed in 3 weeks after the end of the module (30%) 																								
Format	Winter School																								
Timing of the module	<p>Autumn Semester, CW 4 Submission of the case study work in CW 7</p> <table border="1"> <tr> <td>Day of the block week</td> <td><1</td> <td>1</td> <td>2</td> <td>3</td> <td>4</td> <td>5</td> <td>>5</td> </tr> <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> </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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Contact teaching (lessons)		8	9	9	9	7																			
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	<p>There is a participant limit in this module. Registrations will be prioritized according to the following order:</p> <ol style="list-style-type: none"> 1. Students for whom BP3 is a compulsory module 2. Students from the BP-Cluster 3. Students who need the ECTS for the graduation in the semester concerned 																								



	4. The remaining places will be drawn by lot Whether participation is possible will be communicated by the end of week 37.
Last Update	21.04.2022