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	**Name**: Dr. Stefan Seidel **Phone**: +41 (0)58 934 56 78 **Email**: stefan.seidel@zhaw.ch **Address**: ZHAW Life Sciences and Facility Management, Campus Grüental, 8820 Wädenswil
Lecturers	• Stefan Seidel, ZHAW • Martin Krahe, Bideco AG • Henry Weichert, Sartorius • Nicole Fontourcy, Cytiva • Valentin Rüttimann, Cytiva • Olaf Stoll, S&G Gebäudetechnik AG • Pascal Wirth, Wirth+Wirth Architekten
Entry requirements	• BSc in Biotechnology, Chemistry, Mechanical Engineering or Plant Engineering • Study of provided reading material • Usage of software Visio • Self-test on MSLS Community Centre • **See also information under "comments"**
Learning outcomes and competences	After completing the module, students will be able to: • 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	• 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-Classifield (CNC) Room Concept")

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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

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<tr><td>Teaching / learning methods</td><td>

Lectures (company workshops included)
Literature study and case study work
Presentations of the current state of the case study work

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<tr><td>Assessment of learning outcome</td><td>
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%)
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<tr><td>Format</td><td>Winter School</td></tr>
<tr><td>Timing of the module</td><td>
Autumn Semester, CW 4
Submission of the case study work in CW 7
<table>
<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>
<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>
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<tr><td>Venue</td><td>Wädenswil</td></tr>
<tr><td>Bibliography</td><td>

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

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<tr><td>Language</td><td>English</td></tr>
<tr><td>Links to other modules</td><td>Specialisation module ZHAW “Bioprocessing and Bioanalytics” (Production systems)</td></tr>
<tr><td>Comments</td><td>There is a participant limit in this module. Registrations will be prioritized according to the following order:</td></tr>
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	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	28.02.2024