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. 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
Lecturers	• 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	• 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	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 HakoBio
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") • Closed processing (where are the open gaps?)

<table>
<tr><td></td><td>

- 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

</td></tr>
<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

</td></tr>
<tr><td>Assessment of learning outcome</td><td>

1. Self-test on MSLS Community Centre (30%)
2. 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) (30%)
3. The report of the case study work (in groups) to be handed in 3 weeks after the end of the module (40%)

</td></tr>
<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>
</table>
</td></tr>
<tr><td>Venue</td><td>Wädenswil and/or online</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

</td></tr>
<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></td></tr>
<tr><td>Last Update</td><td>07.04.2021</td></tr>
</table>