

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 • F. Gachot, GE Healthcare • N. Fontourcy, Pall Life Sciences • D. Soehngen, 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") |

Master in Life Sciences

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

| | <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 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 |
| 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 | | | | | | | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Last Update | 01.04.2020 | | | | | | | | | | | | | | | | | | | | | | | | |