Zurich University of Applied Sciences

Institute of Chemistry and Biotechnology

Center for Biochemical Engineering and Cell Cultivation Techniques

Design of Biopharmaceutical Production Facilities

BP3 - Master of Science in Life Sciences

Introduction of the module

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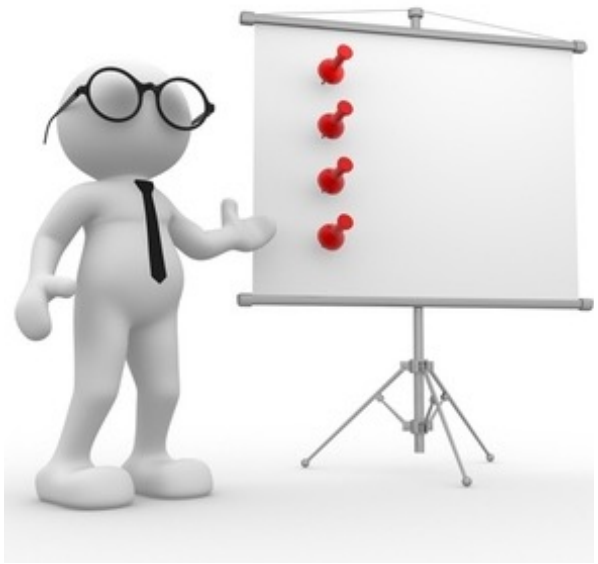
Life Sciences und Facility Management

Welcome to the cooperative Module BP3 “Design of Biopharmaceutical Production Facilities”, part of the consecutive master’s programme in Life Sciences

Agenda



- Online communication and virtual rooms
- Teaching team
- Module BP3 Background information
- Organization of the workshop and the case study
- Daily schedule

Online communication and virtual rooms

- Lecture, presentations and discussions in MS Teams folder:
  - BP3 Design of Biopharmaceutical Production Facilities

- Group work in the MS Teams group folders:
  - BP3 Group 1, BP3 Group 2, BP3 Group 3, BP3 Group 4
  - and the respective MS channels pro BP3 Group:
    - Project management
    - Upstream Processing (USP)
    - Downstream Processing (DSP)
    - Media preparation (MP) & Buffer preparation (BP)
    - Clean utilities & Logistics

Teaching team

- Bideco AG: M. Krahe, A. La Vita, L. Hugentobler, A. Meier, S. Kiesewetter
- Cytiva: G. Dorn; F. Gachot
- Pall International: D. Soehngen, N. Fontourcy, V. Rütimann
- S&G Gebäudetechnik AG: O. Stoll
- Sartorius: H. Weichert
- Wirth+Wirth Architekten: P. Wirth
- ZHAW: D. Eibl, S. Seidel, C. Schirmer, F. Mozaffari, N. Weiss

Module BP3 Background information

- MSLS Community Centre (https://mslscommunitycentre.ch/)
- The most important information about the workshop and the case study are contained in the following documents:
  - Daily routine of the project week and daily tasks
    Schedule_BP3_AS21.pdf
  - Objectives, organization and framework of the workshop and case study
    Workshop Guideline_BP3_AS21.pdf
  - Pharmaceutical and technical requirements of the project (case study) to be worked on
    User Requirement Specifications_BP3_AS21_Group_1-4.pdf
  - Information about the mAb process (case study)
    Process description_BP3_AS21.pdf

Module BP3 – Workshop guideline (1)

- As part of group works, the students will create a conceptual design (CD) of a biopharmaceutical production facility in a case study .
  - The design of the biopharmaceutical production facility is based on Chinese hamster ovary (CHO) cell-derived monoclonal antibody (mAb) processes.
  - Information on yields, productivity and technologies on the process is given in: User Requirement Specifications_BP3_AS21_Group_1-4.pdf and Process description_BP3_AS21.pdf.
  - The knowledge acquisition and knowledge transfer take place through:
    - Self-study
    - Input lecture
    - Case studies
    - Group works
    - Presentations
    - Technical discussions

Module BP3 – Workshop guideline (2)

- Project management
  - Four groups
    - Group 1 (20 people)
    - Group 2 (19 people)
    - Group 3 (19 people)
    - Group 4 (20 people)
  - Each group forms the following five subgroups:
    1. Project management (4-5 people)
    2. Upstream Processing (USP) (4 people)
    3. Downstream Processing (DSP) (4 people)
    4. Media preparation (MP) & Buffer preparation (BP) (4 people)
    5. Clean utilities & Logistics (3-4 people)

Module BP3 – Workshop guideline (3)

- Each group must create its own concept study.
- The subgroups are responsible for designing of their respective tasks and the deliverables as listed in the URS and Table 1 of the workshop guideline.

Table 1: Deliverables and responsibilities of the subgroups

	Project management	USP	DSP	MP & BP	Clean utilities	Date of presentation
Plant on a page	support	responsible	responsible	responsible	support	24.01.2022
Occupancy list	responsible	support	support	support	support	24.01.2022
List of necessary clean facility utilities	support	support	support	support	responsible	24.01.2022
Area schedule, Biosafety Level and Room list	responsible	support	support	support	support	25.01.2022 27.01.2022
Height concept	responsible	support	support	support	support	25.01.2022
Zone concept	responsible	support	support	support	support	25.01.2022 26.01.2022
Size of functions and of systems	support	responsible	responsible	responsible	support	26.01.2022
Accelerator Vision Platform (HakoBio)	support	support	support	support	support	26.01.2022
Staff estimation and Room list	responsible	support	support	support	support	27.01.2022
Presentation of the intermediate state of the case study	responsible	support	support	support	support	28.01.2022
Definitions and abbreviations	responsible	support	support	support	support	constantly

Module BP3 – Workshop guideline (4)

- Bideco AG and ZHAW employee:
  - Group 1: **Cedric Schirmer** (ZHAW, scrm@zhaw.ch) and Sven Kiesewetter (28.01.22) (BIDECO AG, s.kiesewetter@bideco.com)
  - Group 2: **Noémi Weiss** (ZHAW, wesn@zhaw.ch) and Lukas Hugentobler (24.01. to 27.01.22) (BIDECO AG, l.hugentobler@bideco.com) and Sven Kiesewetter (28.01.22) (BIDECO AG, s.kiesewetter@bideco.com)
  - Group 3: **Fruhar Mozaffari** (ZHAW, mozf@zhaw.ch) and Lukas Hugentobler (24.01. to 27.01.22) (BIDECO AG, l.hugentobler@bideco.com) and Sven Kiesewetter (28.01.22) (BIDECO AG, s.kiesewetter@bideco.com)
  - Group 4: **Adrian Meier** (BIDECO AG, a.meier@bideco.com) and Sven Kiesewetter (28.01.22) (BIDECO AG, s.kiesewetter@bideco.com)
- Supports team: **Dieter Eibl** (eibl@zhaw.ch) and **Stefan Seidel** (seis@zhaw.ch)
- The process equipment specialists from Cytiva, Pall, S&G Gebäudetechnik, Sartorius and Wirth+Wirth Architekten support the teams where necessary.
- All deliverables are summarized in the document "Workshop Guideline_BP3_AS21.pdf " , page 6.

Grouping

	Group 1	Group 2	Group 3	Group 4
Group supervisors	Cedric Schirmer (ZHAW, scrm@zhaw.ch) and Sven Kiesewetter (28.01.22) (BIDECO AG, s.kiesewetter@bideco.com)	Noémi Weiss (ZHAW, wesn@zhaw.ch) and Lukas Hugentobler (24.01. to 27.01.22) (BIDECO AG, l.hugentobler@bideco.com) and Sven Kiesewetter (28.01.22) (BIDECO AG, s.kiesewetter@bideco.com)	Fruhar Mozaffari (ZHAW, mozf@zhaw.ch) and Lukas Hugentobler (24.01. to 27.01.22) (BIDECO AG, l.hugentobler@bideco.com) and Sven Kiesewetter (28.01.22) (BIDECO AG, s.kiesewetter@bideco.com)	Adrian Meier (BIDECO AG, a.meier@bideco.com) and Sven Kiesewetter (28.01.22) (BIDECO AG, s.kiesewetter@bideco.com)

Students

Last Name	First Name	Last Name	First Name	Last Name	First Name	Last Name	First Name
Ali	Dilara	Eckert	Malte	Näf	Adrian	Thater	Raphael
Anderka	Isabelle Myriam	George	Remy Matthew	Pesen	Pelin	Vives Marti	Guillem
Bodmer	Timo	Ghaffari	Saeideh	Polini	Elisa	Žilková	Lydie
Buchmüller	Lena	Gianfreda	Elisa	Schürch	Stefanie	Zoss	Simon
Domingo Iglesias	Clara	Kocí	Milan	Späne	Philipp	Pollien	Jessy
Antille	Brice	Disière	Maxime	Genilloud	Franck	Selmani	Nora
Ayer	Baptiste	Doan	Catherine	Nicollier	Alexandre	Thomos Guignanga	Rhudy Darlène
Baechler	Romain	Ehrsam	Arnaud	Noël	Jérémie	Weber	Joachim
Baumgartner	Gaëtan	Favre	Simon	Pantelidis	Alexandros	Rahimi	Tara
Da Rocha Ribeiro	Fábio	Gaillard	Clément	Khan	Salman Khan	Romang	Michael
Ballikaya	Tugba	Gopalakrishnan	Abiram	Kölbener	Christa	Ruggle	Cedric William
Braun	Chiara	Grigioni	Jan Nicolas Andrea	Kreuzer	Jan	Schmidt	Florian Sebastian
Brkan	Daniela	Grossmann	Jana	Kuleta	Natalia Karolina	Schurter	David
Brown	Luca	Hutter	Brian Hermann	Lopez Sosa	Alejandra	Shafieechashmi	Seyedehsara
Bühlmann	Vanessa	Imboden	Sara	Memeti	Nurdzane	Stehlin	Jonas Alois
Dutli	Benjo Basil	Imstepf	Nicolas	Zukovic	Dzenneta	Strassmann	Marc Silvan
Erni	Lukas Pius	Ismaili	Dafina	Müller	Benjamin	Suter	Simon Joel
Fischer	Kevin	Jonuzi	Argjent	Nedic	Maja	Thattil	Ann-Maria Francis
Flückiger	Simon Rafael	Kalbermatten	Claudio Lucca	Xaaji	Yusuf	Walker	Emely
Frei	Annik					Misini	Elvira

Module BP3 – Workshop guideline (5)

- By the end of module BP3 (deadline: 18. February 2022) a project folder has to be submitted (digital version on mslscommunitycentre.ch) of each group.
- The project folder includes the following documents:

1. URS (User Requirement Specifications)
2. Plant on a page
3. Occupancy list
4. List of necessary clean facility utilities
5. Area schedule, Biosafety Level and Room list
6. Size of functions and of systems
7. Zone concept
8. Height concept
9. Staff estimation
10. Presentation of the stage of the case study as of Friday, 28. January 2022
11. Definitions and abbreviations

Module BP3

Assessment of learning outcome

- 1. Individual entry exam (exam on mslscommunitycenter and Accelerator Vision Platform (HakoBio)) **(30%)**
- 2. Presentation on progress of the case study work and defense of the case study work: Each subgroup has to present and answer **(30%)**
- 3. Report of the case study work (in groups, project folder) to be handed in 3 weeks (18. February 2022) after the end of the module **(40%)**

➢ *Evaluation criteria see "Case study" MSLS Community Centre*

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Daily schedule - Monday

Lesson	Time	Content	Teacher / Rooms
1-2	09:00-10:30	Welcome and introduction to the module Overview of modern design concepts of biopharmaceutical production facilities	D. Eibl M. Krahe (Bideco) Online - MS Teams
break			

3	10:50-11:20	Project work:
		• Self-study of the module documents
		  ○ User Requirement Specifications
		  ○ Process description
		  ○ Workshop Guideline
			all

4	11:30 - 12:30	Project work: • Team building • Project Management • Project Execution Plan • Deliverable List	Group 1 - MS Teams Group 2 - MS Teams Group 3 - MS Teams Group 4 - MS Teams
Lunch break	12:30-13:15		
5-6	13:15-14:45	Project work: • Plant on a Page USP & DSP • Buffer and Media prep, • Occupancy List • List of necessary facility utilities	Group 1 - MS Teams Group 2 - MS Teams Group 3 - MS Teams Group 4 - MS Teams
break			
7	15:15-16:00		
8	16:15-17:00	Presentation Group 1 and Group 2 & Results: • Plant on a Page • Occupancy List • List of necessary facility utilities	Online – MS Teams


Question ?