Biomanufacturing

(formerly Single-Use Technology in Biopharmaceutical Manufacture)

Content

- History and achievements of the old platform
- Activities in 2022
- Why a new platform?
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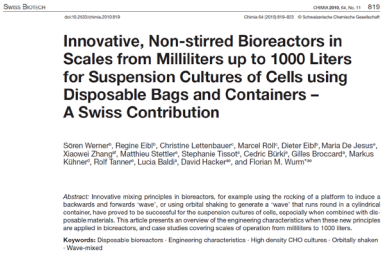
History of the old platform

- Founded in 2011
  - To become an internationally recognized research partner
    - ✓ Support of developers, manufacturers and users of SUT
- CH: Cradle of single-use bioreactor technology
  - 1st single-use bioreactor
    - ✓ 1998: Wave Reactor
  - 1st orbitally shaken single-use bioreactor
    - ✓ 2009: Cooperation: Adolf Kühner AG, EPFL/ExcellGene SA



Innovative, Non-stirred Bioreactors in Scales from Milliliters up to 1000 Liters for Suspension Cultures of Cells using Disposable Bags and Containers – A Swiss Contribution

Main achievements of the old platform (1)

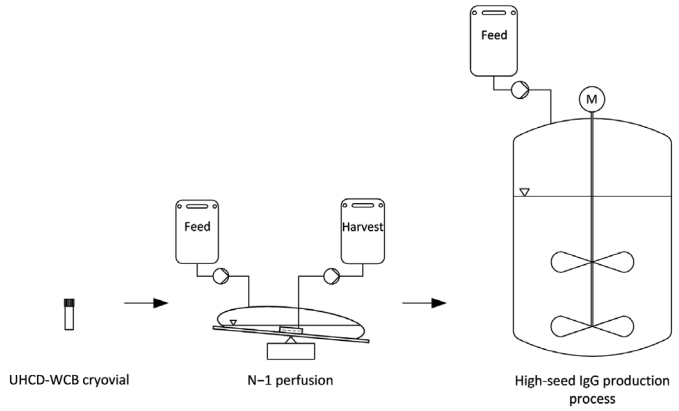
- International research cooperations
  - USA, UK, Sweden, Netherlands, Belgium, France, Germany, Switzerland
  - Projects: approx. 6 Mio. CHF
    - ✓ CTI/Innosuisse, EU, Eurostar, directly financed
  - Numerous publications
    - ✓ > 100 conference contributions
    - ✓ > 50 peer-reviewed articles, 30 book chapters, 4 text books, 2 special issue scientific journals

Main achievements of the old platform (2)

- Close cooperation with DECHEMA
  - Organization of 3 joint international conferences
  - 8 recommendations/status papers
  - 1 joint mini-encyclopedia
  - Numerous common scientific papers

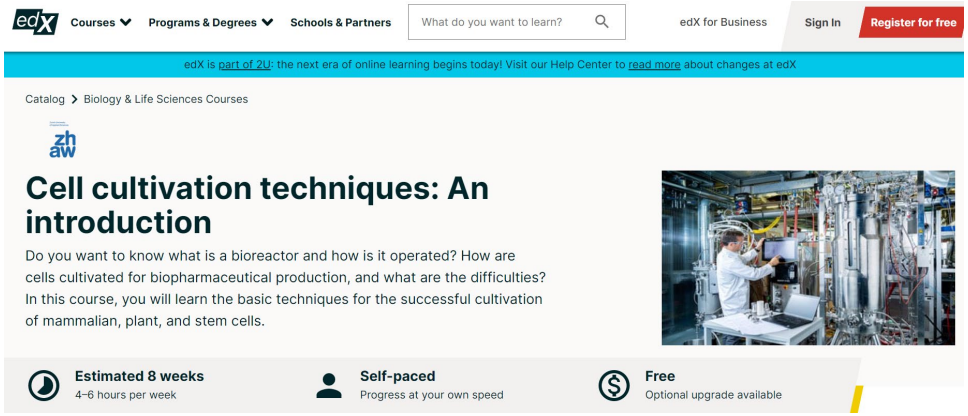
Activities in 2022 (1)

- Intensified and continuous production processes based on novel SUT
  - Research (complete single-use USP line with Dynadrive 50 L)
    - ✓ High seed fed-batch mAb productions
    - ✓ Continuous mAb productions
    - ✓ hMSC and hiPSC expansions
  - Scientific exchange
    - ✓ ECI Conference (Marseille), Himmelfahrtstagung (Mainz) ESACT Meeting (Lisbon), ECA Conference SUT (online) and Forum A3P (Lausanne)



Activities in 2022 (2)

- Summer School „Animal cell and stem cell cultivations in reusable and single-use bioreactors“ from 25.8.-2.9.2022 (3 ECTS)
  - 18 participants from 6 countries
- SUT is an integral part of our edX course "Cell Cultivation Techniques for Beginners"
  - Start: 07/2022
  - 4 parts
  - More than 700 participants



Why a new platform?

- CH: Activities in biomanufacturing have increased in recent years
- Hybrid facilities dominate
- SUT well-established in biomanufacturing
  - USP, DSP, formulation, fill & finish
  - R&D, pre- & clinical productions, commercial manufacture
  - USP: Mainstream technology
- A broader audience should be addressed!!!

Aim and people/members

- Development of biopharmaceutical production processes providing vaccines, protein and cell & gene therapeutics
  - USP, DSP, formulation, fill & finish
  - 3 UASs, 9 working groups with expertise
  - Modern equipment for complete biopharma-ceutical production processes
  - Lead: Regine Eibl & Thomas Villiger

Planned activities

- Update of the new platform web page (asap)
- Online meeting of the UAS working groups (spring)
- Search for active members (permanent)
  - Industry and academia
- Submission of joint Innosuisse projects
- Conference attendance
  - Himmelfahrtstagung (Weimar), ECI conference SUT (Boston), …..


Q&A