

# Biomanufacturing

(formerly Single-Use Technology in Biopharmaceutical Manufacture)



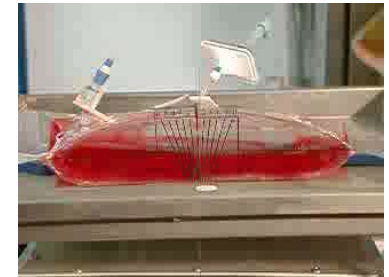
## Content



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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



Swiss Biotech 10/2020/Nov 2020/19 0194-2018, Vol. 11, 819

### 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

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**Abstract:** Innovative mixing principles in bioreactors, for example using the rocking of a platform to induce a back-and-forth "wave" or using orbital shaking to generate a "wave" that runs round in a cylindrical container, have proved to be successful for the suspension cultures of cells, especially when combined with disposable materials. This article presents an overview of the engineering characteristics when these new principles are applied in bioreactors, and case studies covering scales of operation from milliliters to 1000 liters.

**Keywords:** Disposable bioreactors - Engineering characteristics - High density CHO cultures - Orbitally shaken - Wave-mixing



Kühnershaker

## 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



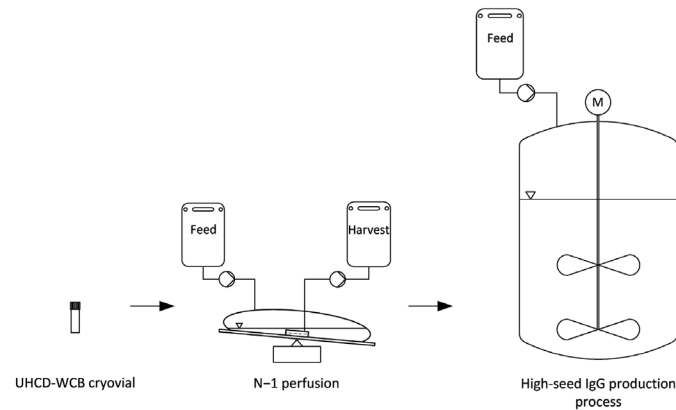
## Main achievements of the old platform (2)

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



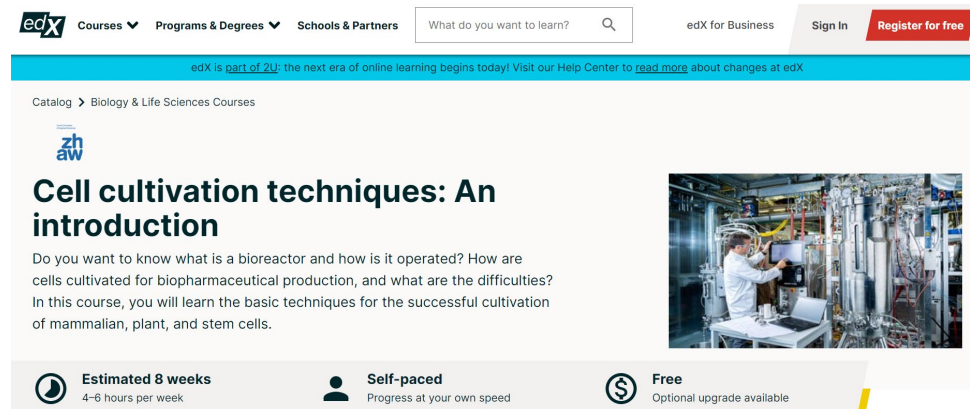
## Activities in 2022 <sup>(1)</sup>

- 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 <sup>(2)</sup>

- 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



The screenshot shows the edX course page for "Cell cultivation techniques: An introduction" by ZHAW. The page includes a navigation bar with "edX Courses", "Programs & Degrees", and "Schools & Partners". A search bar is present with the text "What do you want to learn?". There are links for "edX for Business", "Sign In", and "Register for free". A blue banner below the navigation bar states: "edX is part of ZU: the next era of online learning begins today! Visit our Help Center to read more about changes at edX". The main content area shows the course title "Cell cultivation techniques: An introduction" with a description: "Do you want to know what is a bioreactor and how is it operated? How are cells cultivated for biopharmaceutical production, and what are the difficulties? In this course, you will learn the basic techniques for the successful cultivation of mammalian, plant, and stem cells." A photograph of a person in a lab coat working with bioreactors is shown on the right. At the bottom, there are three icons with text: "Estimated 8 weeks" (4-6 hours per week), "Self-paced" (Progress at your own speed), and "Free" (Optional upgrade available).

## 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 biopharmaceutical 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), .....

