



Life Sciences and
Facility Management



BioTech 2010

Single-Use Technology in Biopharmaceutical Manufacturing

7 & 8 June 2010 Conference

**9 June 2010 Post-conference
Workshops**

**Campus Grüental, Wädenswil
Switzerland**

Integration of disposable techniques in biopharmaceutical manufacturing

09.00–09.30 Registration and coffee

Session Chair **Cathy Kroll**, Swiss Biotech Association

09.30–09.50 Welcome message
Tobias Merseburger, ZHAW Wädenswil and
Cathy Kroll, Swiss Biotech Association

09.50–10.20 Disposables in biomanufacturing:
Where we are – a user's report
Alain Pralong, Crucell N.V. (Netherlands)

10.20–10.50 Disposables in biomanufacturing:
Where we are – a manufacturer's report
Thomas Paust and **Thorsten Peuker**,
Sartorius Stedim Biotech GmbH (Germany)

10.50–11.20 Implementation of new bioreactor & information
technology into existing facilities
Detlef Eisenkrätzer, Roche Diagnostics GmbH
(Germany)

11.20–13.00 Lunch, exhibition and poster session

New disposable technology for biopharmaceutical manufacturing

Session I Automated screening system and upstreaming

Session Chair **Regine Eibl**, ZHAW Wädenswil

13.00–13.30 The RoboLector, a system for automated microtiter plate cultivations with full on-line measuring capability
Jochen Büchs, RWTH Aachen University (Germany)

13.30–14.00 Novel single-use bioreactors using a pneumatic mixing mechanism: Case studies of large scale evaluation (250 L) and scale-down model (2 L) development
Daniel Giroux¹ and **Andrew Yunghans**², ¹PBS Biotech, Inc., ²Amgen Bioprocessing Center (USA)

14.00–14.30 Cultivation of different eucaryotic cell types in single use bioreactors – case studies with different products
Susann Koch, Probiogen AG (Germany)

14.30–15.00 Production of viral, Virus Like Particle (VLP) and soluble subunit vaccines in mammalian and microbial single-use stirred tank bioreactors
Geoff Hodge, Xcellerex Inc. (USA)

Session II Downstreaming, formulation and filling

Session Chair **Dieter Eibl**, ZHAW Wädenswil

13.00–13.30 Process considerations for clarification and downstream processing of high titer and high cell density PER.C6® harvests using single-use technologies
Gregory Zarbis-Papastoitsis, PERCIVIA, LLC (USA)

13.30–14.00 Process intensification with ready-to-use and single-use systems: downstream processing of a monoclonal antibody
Andreas Muranyi, GE Healthcare Bio-Sciences AB (Sweden)

14.00–14.30 Simplifying formulation and filling operations with single-use technology: a breakthrough in aseptic processing
Alain Rachon, MILLIPORE S.A.S (France)

14.30–15.00 A new service for the biotech/pharma industry: Single-use fill and finish
Jean Pascal Zambaux, Disposable-Lab SAS (France)

15.00–15.30 Coffee break and exhibition

Session III Bag manufacturing, quality assurance and regulation of disposables

Session Chair **Tobias Merseburger**, ZHAW Wädenswil

15.30–16.00 Manufacture of disposables and quality assurance
Charlotte Masy, ATMI Life Sciences (Belgium)

16.00–16.30 Quality foundation and innovation in single-use systems
Christian Julien, Bio Meissner Filtration Products, Inc. (USA)

16.30–17.00 Recommendations for testing extractables and leachables, and the status of the harmonization of testing standards
Jerold Martin, Bio-Process Systems Alliance and Pall Life Sciences (USA)

17.00–17.30 Disposables from the view of the regulatory authority
Daniel Müller, Regierungspräsidium Tübingen – Leitstelle Arzneimittelüberwachung Baden-Württemberg (Germany)

17.30–18.30 Exhibition and poster session

19.00–
open end Conference dinner

Workshops and networking/part 1

08.30–09.00 Registration

Session Chair **Daniel Gygax**, Biotechnet Switzerland

09.00–09.40 The impact of disposables on the manufacturing of biosimilars
Irfan Cinkaya, Merckle Biotec GmbH (Germany)

09.40 – 10.10 Coffee break and exhibition

10.10–11.50 **Workshops and networking**

W1: Disposable solutions for screening and upstream processing
Adolf Kühner AG; Applikon Biotechnology B.V. & ReseaChem GmbH; Bayer Technology Services GmbH & Roche Diagnostics GmbH; INFORS HT; m2p-labs GmbH

W2: Disposable solutions for upstream processing
ATMI Life Sciences; MILLIPORE S.A.S; Sartorius Stedim Biotech GmbH; PBS Biotech, Inc.; Xcellerex, Inc.

W3: Disposable solutions for downstreaming and filling
GE Healthcare; Meissner Filtration Products, Inc. & Bruendler AG; MILLIPORE S.A.S; Pall Life Sciences; Sartorius Stedim Biotech GmbH

W4: Cost modeling
BioPharm Services Ltd.

11.50–13.00 Lunch, exhibition and poster session

Workshops and networking/part 2

13.00–14.40 **Workshops and networking**

W1: Disposable solutions for screening and upstream processing

Adolf Kühner AG; Applikon Biotechnology B.V. & ReseaChem GmbH; Bayer Technology Services GmbH & Roche Diagnostics GmbH; INFORS HT; m2p-labs GmbH

W2: Disposable solutions for upstream processing

ATMI Life Sciences; MILLIPORE S.A.S; Sartorius Stedim Biotech GmbH; PBS Biotech, Inc.; Xcellerex, Inc.

W3: Disposable solutions for downstreaming and filling

GE Healthcare; Meissner Filtration Products, Inc. & Bruendler AG; MILLIPORE S.A.S; Pall Life Sciences; Sartorius Stedim Biotech GmbH

W4: Cost modeling

BioPharm Services Ltd.

14.40–15.00 Coffee break

Podium discussion and networking

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- 15.00–16.00 **Podium discussion**
Single-use technology in biopharmaceutical
manufacture – smaller, cheaper, greener and faster?
Chair **Dieter Sell**, DECHEMA
-
- 16.00–16.10 **Poster awards and closing remarks**
Tobias Merseburger, ZHAW Wädenswil
-
- 16.15–17.15 **Network founding**
Single-use technology in biomanufacturing:
A platform for manufacturers and users
(by invitation only)
-
- 17.15 **Aperitif**
-
- 19.00–
open end **Alumni get-together**
-

Wednesday, 9 June 2010

Post-conference Workshops



sartorius stedim
biotech



ATMI®

Scope of the conference

We are now living in an age where single-use (also referred to as 'disposable') devices are having more and more influence on the development of modern biotechnological processes. Driven by expanding healthcare needs and cost pressure on the biopharmaceutical industry, bags for medium hold and storage, single-use mixers, pumps, couplers, valves, membrane absorbers, centrifuges, depth filter systems and even bioreactors are increasingly used where possible. This concerns R&D, pre- and clinical sample production, and the first commercial biomanufacturing processes.

In keeping up with this international development, conference participants receive an up-to-date overview of obtainable single-use devices and facility design based on their use. The program includes talks and networking on the first day, followed by workshops on the second. These workshops enable participants to become familiar with common and new disposable equipment produced by companies with leading market positions.

In the conference three main topics are focused on:

- Integration of disposable devices in biopharmaceutical manufacturing
- New disposable technology for biopharmaceutical manufacturing
- Networking and technical platforms for single-use component manufacturers, systems integrators, contract manufacturers, end-use biopharmaceutical researchers, manufacturers and regulators

Target participants are those using or planning to use disposables in industry and R&D, process engineers from the pharmaceutical industry and related sectors, specialists in apparatus engineering and facility design, and finally students in the fields of biotechnology and pharmacy. By taking part in the conference, participants gain a comprehensive understanding of the potential and existing limitations of disposables. In addition, current and apparent trends are presented and discussed.

We would like to draw participants' attention to the post-conference workshops on Wednesday, 9 June 2010, which are being organized by companies.

For those participants particularly interested in disposable sensor technology, we would also recommend the 15. Heiligenstädter Kolloquium in Heilbad Heiligenstadt (Germany) from 27-29 September 2010. The sessions on disposable sensor technology will be realized in cooperation with our institute in Wädenswil.

Committee

Scientific Committee

Regine Eibl	Institute of Biotechnology, ZHAW, Wädenswil
Cathy Kroll	Swiss Biotech Association
Tobias Merseburger	Institute of Biotechnology, ZHAW, Wädenswil
Alain Pralong	Crucell N.V.
Susann Koch	Probiogen AG
Oreste Ghisalba	Ghisalba Life Sciences GmbH

Organising Committee

Beat Ritschard	Zurich Park Side
Dieter Beckmann	Institute for Bioprocessing and Analytical Measurement Techniques
Dieter Eibl	Institute of Biotechnology, ZHAW, Wädenswil
Reinhard Glück	Swiss Biotech Association
Daniel Gygax	Biotechnet Switzerland, Basel
Adrian Sigrist	Unitectra, Zürich/Bern
Stefan Spichiger	Netzwerk Wädenswil (Alumni)
Ernst Stocker	Mayor of Wädenswil
Dieter Sell	DECHEMA

Registration

www.biotech2010.ch/registration

Fees

	before 7 May 2010*	after 7 May 2010
7 and 8 June 2010 (2 days)	CHF 250.–	CHF 300.–
7 or 8 June 2010 (1 day)	CHF 150.–	CHF 200.–

- * Early registration provides free admission to BioTech 2010 for all students (international student ID number to be given), but does not include meals, the conference dinner, conference proceedings and accommodation. Students presenting a poster will be granted free admission to the BioTech 2010 with meals, conference dinner and conference proceedings included.

Deadlines

22 March 2010	Abstracts
29 March 2010	Notification of acceptance (abstracts)
07 May 2010	Early registration deadline
31 May 2010	Registration (and payment) deadline

Contact

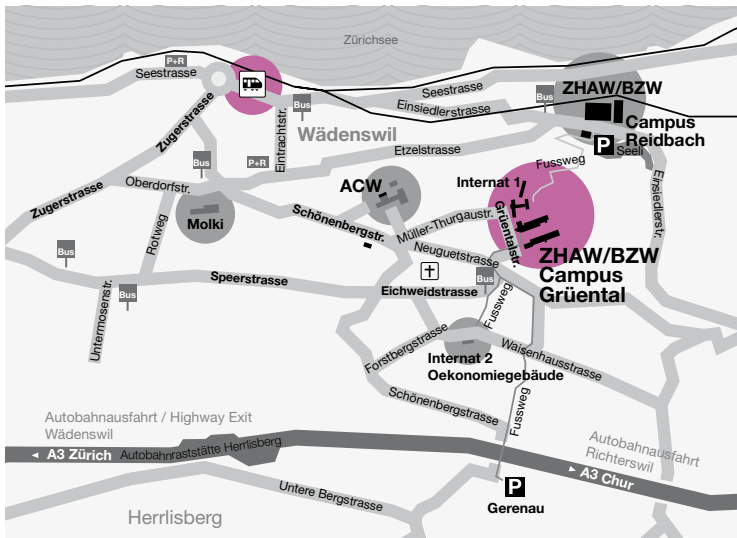
Participants	Irène Tinguely, phone +41 58 934 59 80
Exhibitors and sponsors	Marianne Ernst, phone +41 58 934 57 50

Postal address

Zurich University of Applied Sciences
School of Life Sciences and Facility Management
Grüntal, 8820 Wädenswil
Switzerland

Venue

BioTech2010 is to be held at the ZHAW School of Life Sciences and Facility Management in Wädenswil, which is a member of the Zurich Universities of Applied Sciences and Arts (ZFH). Wädenswil is a picturesque town of about 20,000 inhabitants on the south shore of the Lake of Zurich. The Grüental Campus, where the symposium takes place, can be easily reached by public transport.



How to find us – From Zurich to Wädenswil

by train (for details see: www.sbb.ch)

- From Zurich's main railway station (Hauptbahnhof) to Wädenswil, trains five times an hour (S2, S8, Interregio), journey time 20–30 minutes
- From Zurich airport to Wädenswil, direct trains twice an hour (S2), journey time 35 minutes

by car

- Leave the A3 motorway (Zurich – Chur) at the exit 'Wädenswil' and follow the signs "ZHAW Tagung".

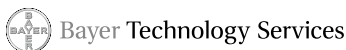
From Wädenswil railway station to the ZHAW

- by public transport: buses number 123 and 126 (bus stop "Hochschule")
- by taxi from Wädenswil railway station (approx. 15 CHF one way):
Wädi Taxi +41 44 780 52 52 or City Taxi +41 44 780 77 77
- on foot, approx. 20 minutes walk uphill

Accommodation

For recommended hotels, see www.biotech2010.ch

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