



BioTech 2013 Single-Use Technology in Biopharmaceutical Manufacturing

Wädenswil, Switzerland
3rd and 4th June, 2013

Post-conference Workshops: 5th June, 2013

Campus Grüental, Wädenswil
Switzerland

Eventpartners



GE Healthcare



Life Sciences



sartorius stedim
biotech

Sponsors



Partners



DECHEMA

Gesellschaft für Chemische Technik
und Biotechnologie e.V.



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Association

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Commission for Technology and Innovation CTI

Single-use technology in biopharmaceutical manufacturing: today

09.00–09.30 Registration and coffee (*Building GA*)

Welcome message and keynote lectures (*Room GA 203*)

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

09.30–09.50 Welcome message | **Jean-Marc Piveteau**, Zurich University of Applied Sciences, CH and **Cathy Kroll**, Swiss Biotech Association, CH

09.50–10.35 Single-use technology in biomanufacturing: an industry review of SUS applications, technology and 10-year trends | **Eric Langer**, BioPlan Associates Inc., US

10.35–11.20 Process4Success – Flexible biomanufacturing processes addressing the needs of the future | **Thorsten Peuker**, Sartorius Stedim Biotech GmbH, DE

11.20–13.00 Lunch (*Building GC*) and exhibition (*Building GA*)

Single-use technology in biopharmaceutical manufacturing: tomorrow

Parallel session 1a: Vaccines and cell therapeutics *(Room GA 203)*

Session Chair **Regine Eibl**, Zurich University of Applied Sciences, CH

13.00–13.30 Viral vaccine development and production: current state and trends | **Alain Pralong**, GlaxoSmithKline, BE

13.30–14.00 Practical applications of single use technology for the production of recombinant VLP and nanoparticle vaccines | **Timothy Hahn**, Novavax Inc., US

14.00–14.30 Development of a single-use system based production platform for stem cell expansion | **Christian van den Bos**, Lonza Cologne AG, DE

14.30–15.00 hMSC production in disposable bioreactors with regards to GMP and PAT | **Peter Czermak**, Technische Hochschule Mittelhessen and Kansas State University, DE/US

Parallel session 1b: New developments and trends in up-streaming, downstreaming, formulation and filling *(Room GB 217)*

Session Chair **Detlef Eisenkrätzer**, Roche Diagnostics GmbH, DE

13.00–13.25 New Levitronix single-use pump series PuraLev®: characteristics and investigations of mechanical stress | **Stephan C. Kaiser**, Zurich University of Applied Sciences, CH and **Wolfgang Dornfeld**, Levitronix GmbH, CH

13.25–13.50 Improved bioreactor design for laboratory to production suite operations | **Henry Charlton**, Pall Corporation, UK

13.50–14.15 Eppendorf's single-use solutions: rigid-wall bioreactors from 100mL- up to 50L | **Christof Knocke**, Vaudaux Eppendorf AG, CH

14.15–14.40 Linear scalability for viral entities production in iCEL-Lis™ disposable fixed-bed bioreactor from bench-scale to industrial scale | **Jean-Christophe Drugmand**, ATMI LifeSciences, BE

14.40–15.05 Next generation downstream template for continuous mAb processing | **Sébastien Ribault**, Merck Millipore, FR

15.05–15.30 Coffee break and exhibition (*Building GA*)

Parallel session 2a: Microbial and plant cell-based processes
(Room GA 203)

Session Chair **Franz Baumberger**, Biotechnet, CH

15.30–16.00 Single-use and hazardous substances—from plant design to routine production | **Rainer Glöckler**, Lonza AG, CH

16.00–16.30 Microbial cultivation in different scales in the CELL-tainer® wave-mixed single-use bioreactor | **Stefan Junne**, TU Berlin, DE

16.30–17.00 Single-use technology and modern cosmetics | **Cornelia Schürch**, Mibelle Biochemistry, CH

17.00–17.30 Pharmaceutical production of recombinant proteins in a wave-based single-use process with Bryotechnology | **Holger Niederkrüger**, greenovation Biotech GmbH, DE

Parallel session 2b: PAT and Single-use (Room GB 217)

Session Chair **Andreas Schneider**, Roche Diagnostics AG, CH

15.30–15.55 PAT solutions in upstream processing to enable QbD for biopharmaceutical products | **Jens Traenkle**, Bayer Technology Services GmbH, DE

15.55–16.20 DASware design: the comprehensive DoE solution for bioprocess development | **Karl Rix**, DASGIP GmbH, DE

16.20–16.45 Applied chemometrics enabling efficient bioprocess development and robust manufacturing | **Andree Ellert**, Sartorius Stedim Biotech GmbH, DE

16.45–17.10 Next generation single-use SmartFactories: lessons from Silicon Valley | **Barbara Paldus**, Finesse Solutions LLC, US

17.10–17.35 Optrodes – biotech's Swiss army knife | **Daniel Riechers**, PreSens Precision Sensing GmbH, DE

17.35–18.30 Poster session and exhibition (*Building GA*)

19.00 onward Conference dinner (*Building GC*)

Single-use technology in biopharmaceutical manufacturing: Today and tomorrow

08.30–09.00 Registration (*Building GA*)

Keynote lecture (*Room GA 203*)

Session Chair **Oreste Ghisalba**, Ghisalba Life Sciences GmbH, CH

09.00–09.40 Best practices for successful implementation of single-use technology and validation | **Philipp Hess**, PHA Philipp Hess Associates, NL

09.40 – 10.10 Coffee break and exhibition (*Building GA*)

Workshops and networking part 1 (*Building GA*)

- 10.10–11.50 **W1: Platform technologies and integrative solutions**
Sartorius Stedim Biotech GmbH/GE Healthcare/
Pall Life Sciences
- W2: Platform technologies and integrative solutions**
Thermo Scientific/Merck Millipore/Meissner Filtration
Products, Inc./ATMI LifeSciences
- W3: PAT enabling concepts and single-use sensors**
Finesse Solutions LLC/Sartorius Stedim Biotech
GmbH/Sysmex Digitana AG/C-CIT
- W4: New single-use systems**
Levitronix GmbH/3M/Filtrox AG/Pall Life Sciences
- W5: Cost modeling**
BioPharm Services Ltd.
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11.50–13.00 Lunch (*Building GC*) and exhibition (*Building GA*)

Workshops and networking part 2 (*Building GA*)

- 13.00–14.40 **W1: Platform technologies and integrative solutions**
Sartorius Stedim Biotech GmbH/GE Healthcare/
Pall Life Sciences
- W2: Platform technologies and integrative solutions**
Thermo Scientific/Merck Millipore/Meissner Filtration
Products, Inc./ATMI LifeSciences
- W3: PAT enabling concepts and single-use sensors**
Finesse Solutions LLC/Sartorius Stedim Biotech
GmbH/Sysmex Digitana AG/C-CIT
- W4: New single-use systems**
Levitronix GmbH/3M/Filtrox AG/Pall Life Sciences
- W5: Cost modeling**
BioPharm Services Ltd.
-

14.40–15.00 Coffee break (*Building GA*)

Session: Single-use technology plastics – risks and acceptance (*Room GA 203*)

Session Chair **Miriam Monge**, Biopharm Services Ltd., GB

- 15.00–15.15 Leachable tests of bag materials | **Christina Fritz**,
Roche Diagnostics GmbH, DE
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- 15.15–15.30 Supplier key to single-use risk mitigation | **Christian
Julien**, Meissner Filtration Products, Inc., US
-
- 15.30–15.45 Risk analyses of single-use systems | **Markus Tanner**,
Werthenstein BioPharma GmbH, CH
-
- 15.45–16.00 The regulatory opportunities of single-use systems |
Ali Afnan, Step Change Pharma, Inc., US
-

16.00–17.00 **Podium discussion:**
Single-use technology plastics – risks and acceptance

Ali Afnan

President, Step Change Pharma, Inc., US

Detlef Eisenkrätzer

Director Fermentation Development, Roche Diagnostics GmbH, DE

Christel Fenge

Vice President, Sartorius Stedim Biotech GmbH, DE

Jerold Martin

Sr. V.P., Global Scientific Affairs, Biopharmaceuticals, Pall Corporation, US

Miriam Monge

Vice President, BioPharm Services Ltd., GB

Alain Pralong

VP New Product Introduction and Industrialization, GlaxoSmithKline, BE

Markus Tanner

Director Biotechnology, Werthenstein BioPharma GmbH, CH

Poster awards and closing remarks (*Room GA 203*)

Session Chair **Tobias Merseburger**, Zurich University of Applied Sciences, CH

17.00–17.15 Poster awards and closing remarks

Networking

17.15 *Apéritif (Building GA)*

19.00 onward *Alumni social event (Campus Reidbach)*

Wednesday 5th June 2013

Post-Conference Workshop 2013 *(Building GD)*

09.00–10.00	DECHEMA Temporary Working Group “Single-use technologies in biopharmaceutical production” Meeting By invitation only
10.00–11.00	DECHEMA, ISPE, BPSA, PDA Initial meeting, speed dating and coffee By invitation only
11.00–13.00	DECHEMA, ISPE, BPSA, PDA Discussion on potential cooperation By invitation only
13.00–14.00	DECHEMA, ISPE, BPSA, PDA Lunch By invitation only

Committee

Scientific Committee

Regine Eibl	Zurich University of Applied Sciences, CH
Tobias Merseburger	Zurich University of Applied Sciences, CH
Alain Pralong	GlaxoSmithKline, BE
Christian van den Bos	Lonza Cologne AG, DE
Detlef Eisenkrätzer	Roche Diagnostics GmbH, DE
Christel Fenge	Sartorius Stedim Biotech GmbH, DE
Markus Tanner	Werthenstein Biopharma GmbH, CH
Oreste Ghisalba	Ghisalba Life Sciences GmbH, CH

Organising Committee

Dieter Eibl	Zurich University of Applied Sciences, CH
Andreas Schneider	Roche Diagnostics AG, CH
Karin Thiemann	DECHEMA, DE
Domenico Alexakis	Swiss Biotech Association, CH
Daniel Gygax	Biotechnet, CH
Matthias Bleisch	ALUMNI ZHAW Life Sciences, CH
Philipp Kutter	Mayor of Wädenswil, CH

Scope of the conference

We are now living in an age where single-use (also referred to as 'disposable') devices are used in development and manufacturing of modern biotechnological products such as antibodies and vaccines. In fact the very first fully disposable manufacturing facilities have become a reality. Nevertheless, single-use devices still have their limitations. The issues most frequently discussed are the possible secretion of leachables/extractables and the lack of single-use sensors, resulting in lower levels of instrumentation and automation compared to their conventional counterparts. More recently new fields for the application of single-use bioreactors have been found, such as production of stem cell-, microbial cell- and plant cell-based targets. However, further limitations exist for these applications, such as limited oxygen transfer rates and mixing in high viscosity.

This conference will update the participants with the latest knowledge and developments in the field of single-use technology in biopharmaceutical manufacturing, examining technological, technical and economic aspects. The programme includes presentations, followed by a number of parallel workshops, run by leading companies in the sector. The conference will end with a podium discussion on risks and acceptance of plastics used in single-use devices. The conference will also provide excellent opportunities for networking and the chance to develop relationships with manufacturers, suppliers, users and regulatory affair specialists.

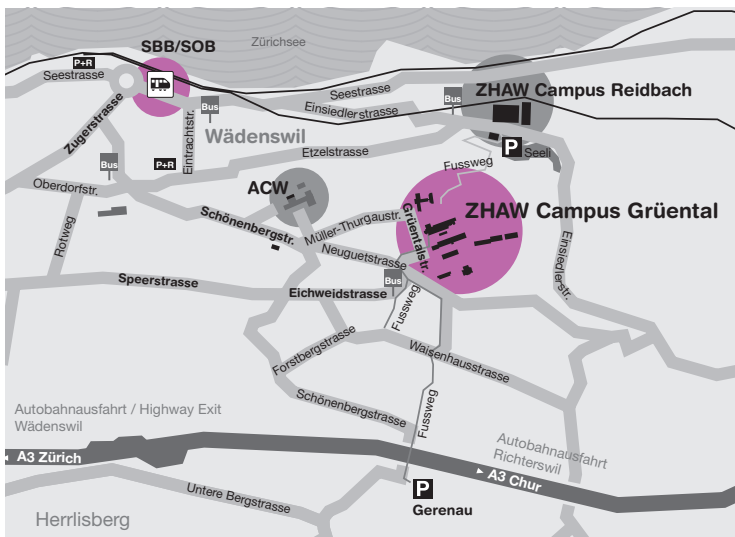
Target participants include:

- those using or planning to use single-use devices in manufacturing and R&D, process engineers from the pharmaceutical industry and related sectors, specialists in apparatus engineering and facility design, and students in the fields of biotechnology and pharmacy.
- quality assurance and regulatory affair specialists interested in an update and the chance to exchange knowledge on the topic of single-use technology.

By taking part in this event on modern biomanufacturing, participants will gain a better understanding of how to select the correct single-use device for a specific application, how to successfully implement single-use devices and how to meet regulatory requirements.

Venue

BioTech2013 will be held at the ZHAW School of Life Sciences and Facility Management in Wädenswil, a member of the Zurich Universities of Applied Sciences and Arts (ZFH). Wädenswil is a picturesque town with about 20,000 inhabitants on the south shore of the Lake of Zurich. The Grüental Campus, where the symposium takes place, can easily be 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, five trains 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 “Wädenswil” exit 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
- By foot, approx. 20 minutes walk uphill

Accommodation

For recommended hotels, see www.biotech2013.ch

Registration

www.biotech2013.ch/registration

Fees

	before* 30 th April 2013	after 30 th April 2013
3 rd and 4 th June, 2013 (2 days)	CHF 350.–	CHF 450.–
3 rd or 4 th June, 2013 (1 day)	CHF 200.–	CHF 300.–

Conference fee includes the gala dinner on Monday

Students:

Early registration* provides free admission to BioTech 2013 for all students (international student ID number required), but does not include meals, the conference dinner, conference proceedings booklet or accommodation.

Students presenting a poster will be granted free admission to BioTech 2013 including meals, conference dinner and conference proceedings booklet.

Deadlines

22 nd April 2013	Abstracts
29 th April 2013	Notification of acceptance (abstracts)
30 th April 2013	Early registration deadline
27 th May 2013	Registration (and payment) deadline

Contact

Participants	Irène Tinguely Tel. +41 58 934 59 80 irene.tinguely@zhaw.ch
Exhibitors and sponsors	Marianne Ernst Tel. +41 58 934 57 50 sekr.biot.fe.ibt@zhaw.ch

Postal address

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