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Single Use Technologies VI: Established,
Emergent, Agile, Sustainable?

Proceedings

9-10-2023

Conference program - SINGLE USE TECHNOLOGIES VI

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Program

SINGLE USE TECHNOLOGIES VI: ESTABLISHED, EMERGENT, AGILE, SUSTAINABLE?

September 10-13, 2023

**Hyatt Regency Hotel
Boston, Massachusetts,
USA**

Conference Chairs

Magali Barbaroux, Sartorius, France

Sheryl Kane, Takeda, USA

Seongkyu Yoon, University of Massachusetts, USA



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Robert Repetto, Pfizer

Previous conference in this series

Single-Use Technologies: Bridging Polymer Science to Biotechnology Applications

October 18-21, 2015

Leesburg, VA, USA

Conference Chairs:

Ekta Mahajan, Genentech, Inc., USA

Gary Lye, Department of Biochemical Engineering, University College London, UK

Single-Use Technologies: Bridging Polymer Science to Biotechnology Applications II

May 7-10, 2017

Tomar, Portugal

Conference Chairs:

Ekta Mahajan, Genentech, Inc., USA

Gary Lye, Department of Biochemical Engineering, University College London, UK

Regine Eibl, Zurich University of Applied Science, Switzerland

Single-Use Technologies: Bridging Polymer Science to Biotechnology Applications III

September 23 – 26, 2018

Snowbird, Utah, USA

Conference Chairs:

Weibing Ding, Amgen, USA

Martina Micheletti, University College London, United Kingdom

Robert Repetto, Pfizer, USA

Single-Use Technologies IV Webinar

May 20, May 25, June 1, 2021

Conference Chairs:

Magali Barbaroux, Sartorius, France

Weibing Ding, Amgen, USA

Martina Micheletti, University College London, United Kingdom

Single-Use Technologies V

March 20-23, 2022

Marseille, France

Conference Chairs:

Magali Barbaroux, Sartorius, France

Martina Micheletti, University College London, United Kingdom

Conference Sponsors

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Special Notes and Locations

- The Pre-conference Workshop and the Technical Sessions will be held in Ballroom B (4th Floor).
- Meals at the hotel will be in Ballroom A (4th Floor).
- The poster session will be in the Adrienne Salon.
- The ECI office is the Cambridge Room.
- Wifi Access in the conference area: **Network: @Hyatt Meeting**

Password: ECI23

- Speakers – Please have your presentation loaded onto the conference computer prior to the session start (preferably the day before).
- Speakers – Please leave at least 3-5 minutes for questions and discussion.
- Please do not smoke at any conference functions.
- Turn your mobile telephones to vibrate or off during technical sessions.
- After the conference, ECI will send an updated participant list to all participants. Please check your listing now and if it needs updating, you may correct it at any time by logging into your ECI account.
- Audiotaping, videotaping and photography of presentations are prohibited.

Sunday, September 10, 2023

1:15 – 2:00 pm Early conference check-in for workshop attendees (Ballroom Foyer)

PRE-CONFERENCE WORKSHOP: ESTABLISHED

Session Chairs: Miriam Monge (Sartorius)
Nelly Montenay (Sartorius)
Stephanie Ketcham (BMS)

Overview

This workshop aims to address four key industry challenges that the single-use bioprocessing industry is currently facing. Through short fire introductions followed by guided moderated interactive breakout sessions, the sessions aim to provide specific learning objectives for each industry challenge. Don't miss out on this highly interactive learning opportunity with industry experts.

2:00 – 2:15 pm Introductory remarks by pre-conference workshop chairs

2:15 – 2:30 pm Risk Assessment, Annex 1 and New Modalities
Lorraine Borland, Sartorius

2:30 – 2:45 pm Sustainability
Shwetha Ravi Devine, DPS Global engineering
Matteo Alaria, Sartorius

2:45 – 3:00 pm Standardization of Single-use Designs
Alex diBenedetto, Roche-Genentech

3:00 – 3:15 pm Industry forum overview – updates on active industry workstreams
Monica Cardona, MilliporeSigma
Magali Barbaroux (Sartorius)

3:15 – 4:15 pm Coffee Break and Breakout Sessions

4:15 – 5:45 pm Conference check-in for those not attending workshop (Ballroom Foyer)

4:15 – 5:15 pm Feedback from each breakout team

5:15 – 5:30 pm Closing remarks

5:30 – 5:45 pm Stretch Break

5:45 – 6:15 pm Welcome drink

6:15 – 6:45 pm Chairs' opening remarks

6:45 – 7:45 pm **Keynote**
John Schiel (NIST)
Big Ideas, Bold Goals, and the Future of Biomanufacturing

8:00 – 9:30 pm Dinner at the hotel

Monday, September 11, 2023

07:30 – 08:30 am Breakfast

SESSION 1: ESTABLISHED

Session Chairs: Gary Gilleskie (NC State University)
John Puglia (ThermoFisher)

08:30 – 08:45 am Introductory remarks by section chairs

08:45 – 09:15 am **Workflow for identifying and monitoring antioxidant additives in single-use systems**

Weifeng Lin, Thermo Fisher Scientific, USA

09:15 – 09:45 am **Implementing X-ray for single use systems sterilization: Current status**

Samuel Dorey, Sartorius Stedim FMT SAS, France

09:45 – 10:15 am **Advanced numerical characterization of a wave-mixed bioreactor used in the biopharmaceutical industry**

Stefan Seidel, Zurich University of Applied Sciences, Switzerland

10:15 – 10:45 am Coffee Break

10:45 – 11:15 am **Design of a GMP-ready single-pass tangential flow filtration (SPTFF) and inline diafiltration (LILDF) system for continuous manufacturing operations**

Lara Fernandez Cerezo, Merck & Co., Inc, USA

11:15 – 11:45 am **Emerging trends in single use technology for manufacturing of antibody-drug conjugates**

Asmita Pawar, Lonza AG, Switzerland

11:45 – 12:15 pm **Discussion**

12:15 – 01:45 pm Lunch

2:00 – 3:30 pm **Duck Boat Tour** (Departing the hotel promptly at 14:15)

POSTER SESSION

Session Chairs: Stephanie Ketcham (BMS)
Brendan Lucey (Entegris)

4:00 – 4:10 pm Introductory remarks by session chairs

4:10 – 6:15 pm **Poster Session** (with Drink and Snacks)

Dinner on your own / Free evening

Tuesday, September 12, 2023

07:30 – 08:30 am Breakfast

SESSION 2: EMERGENT

Session Chairs: Shawn Wang (Kite Pharma)
Takeshi Nishiura (Northwest Fluid Solutions)

08:30 – 08:45 am Introductory remarks by session chairs

08:45 – 09:15 am **Material considerations for cell & gene therapy products**
Ekta Mahajan, Genentech, USA

09:15 – 09:45 am **The integration of SU, automation & robotics to enable new therapy modalities**
David Pollard, Sartorius, USA

09:45 – 10:15 am **The role of membrane chemistry in Lentiviral vector clarification recovery for cell and gene therapies**
Noor Mujahid, UCL Department of Biochemical Engineering, United Kingdom

10:15 – 10:45 am Coffee Break

10:45 – 11:15 am **SUD inclined settling bioreactor for gentle expansion, concentration and harvest of gene and cell therapies**
Dhinakar Kompala, Sudhin Biopharma, USA

11:15 – 11:45 am **3D printing technology: Supply chain independent single-use plastic ware and bioreactors for cell culture**
Lena Achleitner, University of Natural Resources and Life Sciences, Austria

11:45 am – 12:15 pm **Discussion**

12:15 – 1:15 pm Lunch

SESSION 3: AGILE

Session Chairs: Andrea Rayat (University College London)
Christian Wood (Moderna)
Jeffrey Carter (Cytiva)

1:15 – 1:30 pm Introductory remarks by session chairs

1:30 – 2:00 pm **Next generation processes: Single use technology and key enablers**
Melissa Semple, Cytiva, USA

2:00 – 2:30 pm **Simplified Extractables and Leachables Assessment Using Prior Knowledge and IT solutions**
Armin Hauk, Sartorius-Stedim Biotech GmbH, Germany

2:30 – 3:00 pm Coffee Break

3:00 – 3:30 pm **Agile response to COVID supply disruptions to strengthen raw material resiliency and ensure uninterrupted supply**
Elizabeth Rainbeau, Amgen Inc, USA

Tuesday, September 12, 2023 (Continued)

- 3:30 – 4:00 pm **Single use digitization and information management: enabling agile and sustainable systems**
Shane Kelly, Fastnet Biopharma, USA
- 4:00 – 4:30 pm **Discussion**
- 4:30 – 4:45 pm Break
- 4:45 – 5:15 pm Drinks and snacks
- 5:15 – 6:15 pm **Keynote**
Willian E. Bentley, University of Maryland, USA
Bio ↔ Electronic Information Processing: An Emerging Technology for Biomanufacturing
- 6:15 – 6:30 pm Break
- 6:30 pm Depart hotel for dinner
- 7:00 – 9:00 pm Reception followed by Banquet Dinner and awards at the UMASS Faculty Club

Wednesday, September 13, 2022

- 07:30 – 08:30 am Breakfast
- SESSION 4: SUSTAINABLE** (Sponsored by Südpack Medica AG)
Session Chairs: Philip Smith (GSK)
Nelly Montenay (Sartorius)
- 08:30 – 08:45 am Introductory remarks by session chairs
- 08:45 – 09:15 am **Driving environmental sustainability in the biopharmaceutical industry**
Matteo Alaria, Sartorius, Italy
- 09:15 – 09:45 am **Process sustainability through new technologies: Single-use centrifuge implications on process and product efficiency**
John Puglia, Thermo Fisher Scientific, USA
- 09:45 – 10:15 am **Can sustainability concepts for food packaging be used as a benchmark for single use packaging in the biotech industry?**
Jurgen Betz, Richard Mochel, Südpack Medica, Switzerland
- 10:15 – 10:45 am Coffee Break
- 10:45 – 11:15 am **How EcoDesign methodologies can be leveraged to reduce the carbon footprint throughout a product lifecycle**
Jonathan Molinari, GSK, USA
- 11:15 – 11:45 am **Bioreactivity testing in single use technologies; industry position paper**
Nicole Hunter, Watson-Marlow Fluid Technology Solutions, United Kingdom
- 11:45 am – 12:15 pm **Discussion**
- 12:15 – 12:30 pm Chairs' closing remarks
- 12:30 – 1:30 pm Lunch

Wednesday, September 13, 2023, Afternoon – OPTIONAL Site Visits

As we have in years past, we are offering ECI SUT VI participants the chance to tour an industry site right after the conference ends. This year we have two different tour options on offer, with the following expected timing (traffic dependent):

- 1- Repligen, a single use supplier
 - 1:30 pm – conference ends
 - 1:45 pm – buses start to pick up tour participants at 1 Ave de Lafayette, Boston
 - 2:00 pm – buses leave the hotel
 - 3:00 pm – buses arrive in Hopkinton
 - 3:15 – 5:00 pm (timing up to you) – tour of Hopkinton
 - ~5 pm – buses leave Hopkinton and return participants to 1 Ave de Lafayette, Boston
 - 6:30 pm - buses arrive back at hotel (traffic dependent)

- 2- Landmark Bio, a CDMO using single-use technologies to manufacture therapeutics 1:30 pm – conference ends
 - 1:45 pm – buses start to pick up tour participants at 1 Ave de Lafayette, Boston
 - 2:00 pm – buses leave the hotel

- 2:30 pm – buses arrive in Watertown
- 2:30 – 4:30 pm (timing up to you) – tour of facility
- ~4:30 pm – buses leave Watertown and return participants to 1 Ave de Lafayette, Boston
- 5:15 pm - buses arrive back at hotel (traffic dependent)

Poster Presentations

1. **A mathematical approach to evaluate equivalence in E&L assessments of SUS**
Armin Hauk, Sartorius-Stedim Biotech GmbH, Germany
2. **Is component part standardization of established systems possible?**
Marcus Bayer, Hamilton, Switzerland
3. **Flexibility by design via integrated, configurable platform solutions**
Floriane Cohen, Univercells Technologies, Belgium
4. **Process intensification using SeptraPor® ultrafiltration hollow fibers for single-pass tangential flow filtration**
Jessica McRoskey, Meissner, USA
5. **Process intensification in downstream TFF purification using SeptraPor® ultrafiltration (UF) hollow fiber filters**
Jessica McRoskey, Meissner, USA
6. **The improved performance and reliability of dual functionality filters having combined hydrophilic / hydrophobic membrane characteristics**
Thomas Lazzara, Meissner Inc., USA
7. **Sample-free operation in cell-culture simulations using single-use pH sensor with built-in self-calibration capability**
CD Feng, Broadley-James Corporation, USA
8. **Environmental impacts of gamma versus X-ray irradiation sterilization**
Robert Barrentine, Saint-Gobain Life Sciences, USA
9. **Developing a universal single-use skid for continuous purification operations**
Chad Varner, Sanofi, USA
10. **Ultimus® film: The next generation of single-use film**
Diana Perez, MilliporeSigma, USA
11. **Development of a dissolved CO2 sensor in true single-use format**
Stefan Bardeck, METTLER TOLEDO, Switzerland
12. **Benefits of high-purity biopharma processing thermoplastic tubing in single-use systems**
Sweden Yocom, DuPont, USA