

Program

Single-Use Technologies III: Scientific and Technological Advancements

September 23 - 26, 2018

Snowbird Resort, Snowbird, Utah, USA

Conference Co-Chairs

Weibing Ding
Amgen, USA

Martina Micheletti
University College London, United Kingdom

Robert Repetto
Pfizer, USA



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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

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Conference Sponsors

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Thermo Fisher Scientific

Sunday, September 23, 2018

- 13:00 – 14:00 Early conference check-in (check-in to continue during workshops)
- Pre-conference parallel workshops** (Superior and Maybird rooms)
- 14:00 – 18:00 **Workshop 1: Fundamentals of bioprocess and cell/gene therapy**
Chair: Gary Lye, University College London, United Kingdom
- 14:10 – 14:50 **Introduction to bioprocessing: Products, operations and quality control**
Andrea Rayat, University College London, United Kingdom
- 14:50 – 15:20 **Single-use technology in industrial manufacture of therapeutic antibodies**
TBA
- 15:20 – 15:40 **Stretch Break**
- 15:40 – 16:10 **Stem cells and tissue engineering: Background and clinical applications**
Gary Lye, University College London, United Kingdom
- 16:10 – 16:40 **Introduction to gene therapies and their clinical applications**
TBA
- 16:40 – 17:10 **Scale-up and regulatory considerations in cell and gene therapy manufacture**
Qasim Rafiq, University College London, United Kingdom
- 17:10 – 17:40 **Characterisation and influence of bioreactor design and flow dynamics on stem cell differentiation processes**
Jasmin Samaras, University College London, United Kingdom

Room locations and notes

- Technical Sessions will be held in Ballroom 1.
- Poster Sessions will be in the Ballroom Mezzanine and Atrium Overlook.
- Meals locations will be announced on site.
- Audio, still photo and video recording by any device (e.g., cameras, cell phones, laptops, PDAs, watches) is strictly prohibited during the technical sessions, unless the author and ECI have granted prior permission.
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- Speakers – Please leave discussion time as previously directed by your session chair.
- Please do not smoke at any conference functions.
- Turn your mobile telephones to vibrate or off during technical sessions.
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- 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.
- Emergency Contact Information: Because of privacy concerns, ECI does not collect or maintain emergency contact information for conference participants. If you would like to have this information available in case of emergency, please use the reverse side of your name badge.

Sunday, September 23, 2018 (continued)

- 14:00 – 18:00 **Workshop 2: Basics of polymers**
Chair: Magali Barbaroux, Sartorius Stedim FMT SAS, France
- 14:00 – 14:25 **Introduction to polymers**
Jerome Vachon, Lead Scientist, SABIC, Netherlands
- 14:25 – 14:50 **Review of main thermoplastics and material selection strategy versus the application**
Jerome Vachon, Lead Scientist, SABIC, Netherlands
- 14:50 – 15:15 **An example of thermoset – Silicone**
Csilla Kollar, TS&D Scientist – Medical Solutions, Dow Silicones Corporation, USA
- 15:15 – 15:40 **Film extrusion**
Jürgen Betz, Head of Research and Development, Suedpack Verpackungen, Germany
- 15:40 – 15:55 **Stretch Break**
- 15:55 – 16:20 **Injection moulding**
Todd Andrews, Global Sales and Business Development Manager, Colder, USA
- 16:20 – 18:00 **Sterilization**
Betty Howard, Manager - Radiation Technical Team, STERIS, USA
- 18:00 – 18:30 Welcome drink (Ballroom 1 lobby)
- 18:30 – 19:00 Chairs' opening remarks
- 19:00 – 20:00 **Keynote Presentation**
Process intensification in biomanufacturing driven by advances in single use technologies
Stefan Schmidt, BioAtrium AG, Switzerland
- 20:00 – 21:30 Dinner

Monday, September 24, 2018

07:30 - 08:30 Breakfast

Session 1: Polymers in new biopharmaceutical applications

(Sponsored by Südpack Medica AG)

Chairs: Magali Barbaroux, Sartorius, France
Sheryl Kane, Amgen, USA

08:30 - 08:35 Session chairs introduction

08:35 – 08:55 **A deep dive into the process of designing and developing a single-use aseptic connector**

Todd Andrews, CPC, USA

08:55 – 09:15 **Speed up biopharma devices' release to market**

Nelly Montenay, Sartorius Stedim Biotech, France

09:15 – 09:35 **Use of SUS for non-conventional synthetic manufacturing platforms**

Anuradha Vaidya, Biogen, USA

09:35 – 09:55 **Polymer hydrogels: A biocompatible material with multiple potential uses in single-use sensors**

Jules Magda, University of Utah, USA

09:55 – 10:30 **Panel discussions (session chairs lead with presenters)**

10:30 – 11:00 Coffee break
(Sponsored by Pall Biotech)

Session 2: Interaction of polymers with bioprocess fluids and bioproducts (including extractables and leachables and impact of particulates)

Chairs: Chor Sing Tan, GE Healthcare, USA
Xueyuan Wang, Bayer Healthcare, USA

11:00 – 11:05 Session chairs introduction

11:05 – 11:25 **pH evolution in solution after contact with multilayer films after different g-irradiation doses and thus reconciliation of pH and TOC with carboxylic acids detected by ion chromatography**

Samuel Dorey, Sartorius Stedim FMT SAS, France

11:25 – 12:00 **Panel discussions (session chairs lead with presenter and other panelists)**

12:00 – 13:30 Lunch

Monday, September 24, 2018 (continued)

- 13:30 – 17:00 Afternoon *ad hoc* discussions, meetings and leisure time
- Group trip on the aerial tram - information on the meeting place and post tram ride activities will be available at Sunday check-in.
- 17:00 – 18:30 **Parallel workshops** (Superior and Maybird rooms)
- Workshop 1: Training challenges and End-user POU testing**
Workshop leads: Mike Goodwin, Thermo Fisher Scientific; Arthi Narayanan, Genentech Inc.
- Workshop 2: DP F&F applications using SUS in bioprocessing and regulatory requirements**
Workshop leads: Ernie Jenness, MilliporeSigma; Razvan Miclea, Amgen
- 18:30 – 20:00 Dinner
- 20:00 – 21:30 **Poster Session / Social Hour**

Tuesday, September 25, 2018

07:30 - 08:30 Breakfast

Session 3: Sensors and their integration with single-use technology

Chairs: Gernot John, Presens, Germany
Prashant Tathireddy, Applied Biosensors, USA

08:30 – 08:35 Session chairs introduction

08:35 – 08:55 **Automated foam control in single-use bioreactors using the single use foam probe**

Jordan Cobia, Thermo Fisher Scientific, USA

08:55 – 09:15 **Responsive hydrogel sensor for monitoring antibody production**

Nicholas Frazier, Applied Biosensors, USA

09:15 – 09:35 **Probing for solutions: Evaluating new pH sensors for upstream single-use applications**

Nick Rummel, Genentech, USA

09:35 – 09:55 **Data analytics and soft sensors for single use bioprocessing**

Patrick Sagmeister, Exputec GmbH, Austria

09:55 – 10:30 **Panel discussions (session chairs lead with presenters)**

10:30 – 11:00 Coffee break

Session 4: Single-Use advantages in continuous and connected processing

(Sponsored by ARTeSYN® Biosolutions)

Chairs: Ruben Carbonell, North Carolina State University, USA
Ekta Mahajan, Genentech, USA

11:00 – 11:05 Session chairs introduction

11:05 – 11:25 **Pilot scale implementation of a single-use, high intensity, integrated process system**

Robert Kottmeier, Pfizer Inc., USA

11:25 – 11:45 **Continuous bioprocessing in single-use bioreactors: Beyond stirred tank-based solutions**

Stefan Junne, Technische Universität Berlin, Germany

11:45 – 12:05 **Continuous process performance enhancements for 50-500 L S.U.B.s**

Ben Madsen, Thermo Fisher Scientific, USA

Tuesday, September 25, 2018 (continued)

- 12:05 – 12:25 **Low-footprint, intensified, single-use platform for the production of viral vaccines**
Alex Chatel, Univercells, Belgium
- 13:00 – 14:00 Lunch
- Session 5: Single-use adoption for cell and gene therapy applications**
Chairs: Tiffany Hood, MilliporeSigma, USA
 Margarida Serra, iBET, Portugal
- 14:00 – 14:05 Session chairs introduction
- 14:05 – 14:25 **Understanding the science behind the liquid leak and microbial ingress mechanisms as the foundation for single-use container closure integrity (SU-CCI)**
Marc Hogreve, Sartorius Stedim Biotech GmbH, Germany
- 14:25 – 14:45 **Automated approaches to process development and manufacture of human T-cells and mesenchymal stem cells using single-use bioreactor technologies**
Qasim Rafiq, University College London, United Kingdom
- 14:45 – 15:05 **Engineering scalable manufacturing of high-quality human MSC for cell therapy: From up to downstream processing integration to cell proteome characterization**
Margarida Serra, iBET, Portugal
- 15:05 – 15:25 **Creating commercial opportunities for regenerative medicine by introducing closed, automated solutions with single-use principles**
Matthew Marsh, Hitachi Chemical Advanced Therapeutic Solutions, USA
- 15:25 – 16:00 **Panel discussions (session chairs lead with presenters)**
- 16:00 – 18:00 Free time
- 18:00 – 19:00 **Poster Session / Social Hour**
- 19:00 – 20:00 **Keynote Presentation**
Polymer interfaces and biopharmaceuticals: Chemistry, designs and challenges
David W. Grainger, University of Utah, USA
- 20:00 – 22:00 Banquet Dinner

Wednesday, September 26, 2018

07:30 - 09:00 Breakfast

Session 6: Single-Use performance

Chairs: Regine Eibl-Schindler, ZHAW, Switzerland
Stefan Junne, TU Berlin, German

09:00 – 09:05 Session chairs introduction

09:05 – 09:25 **Single-use equipment for handling and manufacturing of highly potent APIs**
Diego Schmidhalter, Lonza AG, Switzerland

09:25 – 9:55 **Particulate contamination in single-use systems: real versus perceived risk**
Klaus Wormuth, Sartorius Stedim Biotech, Germany

9:55 – 10:15 **Comparison of single-use and steel fermenters for K_{La} and aggressive microbial cultures**
Jason Brown, Thermo Fisher Scientific, USA

10:15 – 10:35 **Single-use and sustainability: Continued studies using LCA tools**
William Whitford, GE Healthcare, USA

10:35 – 11:10 **Panel discussions (session chairs lead with presenters)**

11:10 – 11:30 Chairs' concluding remarks

11:30 – 12:30 Lunch

Poster Presentations

Session 1

1. **Purity testing protocols for silicone tubing**
Csilla Kollar, Dow Silicones Corporation, USA
2. **Embedded particles in single-use films: Cosmetic defect or integrity risk?**
Klaus Wormuth, Sartorius Stedim Biotech, Germany
3. **TuFlux TPE tubing for pharma processing**
Pradnya Parulekar, RAUMEDIC, USA

Session 2

4. **The proper use of extractables data - aspects beyond extractables-measurment**
Samuel Dorey, Sartorius Stedim FMT SAS, Germany
5. **WITHDRAWN**

Session 3

6. **Qualification of low drift single-use pH sensors for use in single-use bioreactor platforms**
Jason Brown, Thermo Fisher Scientific, USA
7. **Single use shake flasks with integrated sensors as easy to use bioprocessing tool**
Gernot John, PreSens Precision Sensing GmbH, Germany
8. **Mixing operations for 50 L to 2000 L single-use mixer: Liquid-Liquid mixing characterization and slurry suspension**
Jordan Cobia, Thermo Fisher Scientific, USA
9. **Study of accuracy and selectivity of a hydrogel-based sensor array by Design of Experiments (DOE)**
Prashant Tathireddy, Applied Biosensors, USA
10. **Single-Use pH sensor via a coplanar pH glass electrode design**
CD Feng, Broadley-James Corp., USA

Session 4

11. **WITHDRAWN**
12. **Extractables and leachables in continuous processing system**
Benben Song, PALL Corporation, USA
13. **Single use plastic settlers for clarifying cell culture broth, selective removal of dead cells and affinity capture of antibodies on protein A beads**
Dhinakar Kompala, Sudhin Biopharma Company, USA
14. **Optimization of the single use bioreactor for growth and bead-to-bead transfer of Vero cells cultured on microcarriers**
Ben Madsen, Thermo Fisher Scientific, USA

Session 5

Session 5

15. **Scalable, high performance single-use technology to meet gene therapy production demands**
Alex Chatel, Univercells, Belgium
16. **Manufacturing human mesenchymal stem cells at clinical scale: Process and regulatory challenges**
Dieter Eibl, Zurich University of Applied Sciences, Switzerland
17. **Bioprocessing and engineering characterisation of T-cell therapy manufacture in an ambr® 250 bioreactor**
Qasim Rafiq, University College London, United Kingdom
18. **Sterile media hold scale-up using MOBIUS® single-use technology**
Adam Sokolnicki, EMDMillipore, USA
19. **Engineering scalable manufacturing of high-quality human MSC for cell therapy: From up to downstream processing integration to cell proteome characterization**
Margarida Serra, iBET, ITQB-NOVA, Portugal
20. **Is it ever too early to close and/or automate manufacturing of cell therapies?**
Matthew Marsh, Hitachi Chemical Advanced Therapeutics Solutions, USA
21. **Harvesting exosomes for therapeutic applications**
Mikhail Skliar, University of Utah, USA
22. **Case study: Leveraging automation and custom single-use systems to streamline media production and enable scalability for CAR-T manufacturing**
Takeshi Nishiura, Juno Therapeutics, USA
23. **Process development for increased MSC production in single use stirred tank bioreactors**
Tiffany Hood, MilliporeSigma, USA
24. **Improved DynaBead removal using designed-for-purpose BioProcess containers**
Jordan Cobia, Thermo Fisher Scientific, USA
25. **Growth behavior of human adipose tissue-derived stromal/stem cells in single-use spinner flasks: Numerical and experimental investigations**
Valentin Jossen, Zurich University of Applied Sciences, Switzerland
26. **Study on mixing and fluid dynamics in single-use shaken systems**
Yi Li, University College London, United Kingdom

Session 6

27. **Adaptive combination of SSB and SUB equipment to master complexity in clinical manufacturing in the clinical supply center**
Christian Beck, Roche Diagnostics GmbH, Germany
28. **Comparison of alternative single use harvest technologies for large scale harvests of mammalian cell culture processes**
Daniel Bock, Boehringer-Ingelheim, USA

29. **New approach for qualifying liquid handling in single-use bags**
Frederic Bazin, Sartorius Stedim FMT SAS, France
30. **Understanding the functional limits of single use components through pressure testing**
Michael Goodwin, Thermo Fisher Scientific, USA
31. **Small volume single use facility strategy - Harvest case study**
Katherine Fong, Genentech, USA
32. **Use of the Ambr 250 to enable rapid clone selection and process development for large scale manufacturing processes**
Martina Micheletti, University College London, United Kingdom
33. **Closed system approach to cell expansion**
Michael Zumbum, Sartorius-Stedim North America, USA
34. **Transitioning to facility using Single Use Technology (SUT)**
Karthik Veeravalli, Genetech, USA
35. **How to develop health-promoting food supplements by using single-use bioreactors**
Philipp Jakob Meier, ZHAW/ICBT, Switzerland
36. **Manufacturing single use systems with quality in mind: How to assure performance, robustness, and sterility of single use systems**
Kara Fouhy, MilliporeSigma, USA
37. **A challenge with single-use technology: Protecting bulk Drug Substance (DS) during cold chain handling, storage and transport**
Joe Cintavey, Gore & Associates, USA