Program

Single-Use Technologies III:
Scientific and Technological Advancements

September 23 - 26, 2018

Snowbird Resort, Snowbird, Utah, USA

Conference Co-Chairs

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Amgen, USA

Martina Micheletti
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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

Engineering Conferences International (ECI) is a not-for-profit global engineering conferences program, originally established in 1962, that provides opportunities for the exploration of problems and issues of concern to engineers and scientists from many disciplines.

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Magali Barbaroux (Sartorius)

Susan Burke (GE Healthcare)

Regine Eibl-Schindler (Zurich University of Applied Science)

Mike Goodwin (ThermoFisher)

Gary Lye (University College London)

Ekta Mahajan (Roche Genentech)

Conference Sponsors

ARTeSYN® Biosolutions

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Südpack Medica AG

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.
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- 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

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 Zumbrum, 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