

Single-Use Technologies III: Scientific and Technological Advancements

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Editors:

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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...N/A**
Andrea Rayat, University College London, United Kingdom
- 14:50 – 15:20 **Single-use technology in industrial manufacture of therapeutic antibodies...N/A**
TBA
- 15:20 – 15:40 **Stretch Break**
- 15:40 – 16:10 **Stem cells and tissue engineering: Background and clinical applications...N/A**
Gary Lye, University College London, United Kingdom
- 16:10 – 16:40 **Introduction to gene therapies and their clinical applications...N/A**
TBA
- 16:40 – 17:10 **Scale-up and regulatory considerations in cell and gene therapy manufacture...N/A**
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...N/A**
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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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...N/A**
Jerome Vachon, Lead Scientist, SABIC, Netherlands
- 14:25 – 14:50 **Review of main thermoplastics and material selection strategy versus the application...N/A**
Jerome Vachon, Lead Scientist, SABIC, Netherlands
- 14:50 – 15:15 **An example of thermoset – Silicone...134**
Csilla Kollar, TS&D Scientist – Medical Solutions, Dow Silicones Corporation, USA
- 15:15 – 15:40 **Film extrusion...N/A**
Jürgen Betz, Head of Research and Development, Suedpack Verpackungen, Germany
- 15:40 – 15:55 **Stretch Break**
- 15:55 – 16:20 **Injection moulding...N/A**
Todd Andrews, Global Sales and Business Development Manager, Colder, USA
- 16:20 – 18:00 **Sterilization...N/A**
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...103
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...1**

Todd Andrews, CPC, USA

08:55 – 09:15 **Speed up biopharma devices' release to market...2**

Nelly Montenay, Sartorius Stedim Biotech, France

09:15 – 09:35 **Use of SUS for non-conventional synthetic manufacturing platforms...3**

Anuradha Vaidya, Biogen, USA

09:35 – 09:55 **Polymer hydrogels: A biocompatible material with multiple potential uses in single-use sensors...4**

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...89**

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

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- 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...46**

Jordan Cobia, Thermo Fisher Scientific, USA

08:55 – 09:15 **Responsive hydrogel sensor for monitoring antibody production...5**

Nicholas Frazier, Applied Biosensors, USA

09:15 – 09:35 **Probing for solutions: Evaluating new pH sensors for upstream single-use applications...6**

Nick Rummel, Genentech, USA

09:35 – 09:55 **Data analytics and soft sensors for single use bioprocessing...7**

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...8**

Robert Kottmeier, Pfizer Inc., USA

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Stefan Junne, Technische Universität Berlin, Germany

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Ben Madsen, Thermo Fisher Scientific, USA

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Alex Chatel, Univercells, Belgium
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Chairs: Tiffany Hood, MilliporeSigma, USA
 Margarida Serra, iBET, Portugal
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David W. Grainger, University of Utah, USA
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Chairs: Regine Eibl-Schindler, ZHAW, Switzerland
Stefan Junne, TU Berlin, German

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Joe Cintavey, Gore & Associates, USA