

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

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Editors:

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Sunday, May 7, 2017

13:00 – 14:00 Early conference check-in (Check-in will continue during workshops)

Pre-Conference Parallel Workshops

1) Basics of biotechnology and bioprocessing

Session Co-chairs: Gary Lye, University College London, United Kingdom
Qasim Rafiq, University College London, United Kingdom

14:00 - 14:50 **Bioprocessing 101: Cells to proteins, operations to processes, control to quality1**
Gary Lye, University College London, United Kingdom

14:50 - 15:30 **Manufacturing of therapeutic antibodies and opportunities for single use technologies2**
Veronica Carvalhal, Genentech, USA

15:30 - 16:10 **Manufacturing processes and strategies for cell and gene therapy products3**
Qasim Rafiq, University College London, United Kingdom

16:10 - 16:50 Round Table Q&A

2) Basics of polymers/sterilization

Session Co-chairs: Trishna Ray-Chaudhuri, Genentech Inc., BPOG/BPSA, USA
Diane Hahm, DuPont, USA

14:00 - 15:00 **Polymer overview**
Topics Covered: Common chemistry
Resins used in single use biopharma bags overview
Soft and sealable resins: LDPE, EVA, LLDPE, mPE
Barrier resins: EVOH, nylons
Toughness resins: copolyester elastomer, ionomer
Tie layers
Molecular weight distribution
Grade selection for process
Resins used in Single Use Biopharma Processing
Regulatory
Extractable substances
Additives
Karlheinz Hausmann, DuPont, Switzerland

15:00 - 15:40 **Extrusion and Film Structures**
Topics Covered: Extrusion and equipment
Blown v cast
Placement of layers
Orientation

Key Physical Properties for films
Tiffani Burt, Sealed Air, USA

Sunday, May 7, 2017 (continued)

| | |
|---------------|--|
| 15:40 - 15:55 | Stretch break |
| 15:50 - 16:30 | Polymer Properties for Single-Use Technology Topics Covered: Physical and mechanical requirements to consider Relationship between material properties and performance attributes in application Material testing strategies Susan Burke, GE Healthcare, USA |
| 16:30 - 18:00 | Sterilization Topics Covered: Radiation Sterilization (Gamma, E-Beam X-Ray) Gas Sterilization (Steam, VHP, EO) Known effects of Sterilization on classes of polymers Oliver Vrain, Synergy Health, Ireland |
| 18:00 - 18:30 | Welcome Drink |
| 18:30 - 19:00 | Opening Remarks |
| 19:00 - 20:00 | Keynote: Recent Advances in Contact Lens Materials: Chemistry, Formulation, Process and Lens Design Considerations Jay F. Kunzler, Künzler Biomedical LLC, USA |
| 20:00 - 21:30 | Dinner |

NOTES

- Technical sessions will be in the Infante Room. Poster sessions will be in the Convento Room.
- Locations of parallel sessions and meals will be announced on site.
- Audiotaping, videotaping and photography of presentations are prohibited.
- Speakers – Please leave at least 5 minutes for questions and discussion.
- Speakers – Please ensure your talk adheres to your given time allotment. Talks that go over their allotment reduce time for valuable discussion and can disrupt the conference program.
- Turn your cellular 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.
- Please do not smoke at any conference functions.
- Please write your name in the front of this program booklet so it can be returned if misplaced.

Monday, May 8, 2017

07:30 - 08:30 Breakfast

Session 1: Properties of polymers as applicable to Biopharma

Sponsored by Südpack Medica AG

Session Chairs: Magali Barbaroux, Sartorius-Stedim Biotech, France
Sheryl Kane, Amgen, USA

08:30 - 09:00 **Tie layer technology for multilayer coextrusion of single-use biopharma bags4**

Barry A. Morris, DuPont, USA

09:00 - 09:30 **What are gels and how to reduce them?21**

Xueyuan Wang, Russell Wong, Bayer Healthcare, USA

09:30 - 10:00 **Influence of γ -irradiated biopharmaceutical films22**

Samuel Dorey, Magali Barbaroux; Fanny Gaston, Nathalie Dupuy; Sylvain Marque, Sartorius Stedim FMT SAS, France

10:00 - 10:30 **Rapid prototyping of a single-use bioreactor: conceptional design studies to final product38**

Stephan C. Kaiser, Thermo Fisher Scientific, USA

10:30 - 11:00 Coffee break

Session 2: The infamous extractables/leachables

Sponsored by Merck

Session Chairs: Xueyuan Wang, Bayer Healthcare, USA

Isabelle Uettwiller, Sartorius Stedim FMT SAS, France

11:00 - 11:30 **On the "Fate of Leachables" in biopharmaceutical up-stream and down-stream processes39**

Armin Hauk, Ina Pahl; Roberto Menzel, Samuel Dorey; Isabelle Uettwiller, Sartorius Stedim FMT SAS, France

11:30 - 12:00 **Standardized extraction protocols for single use components: insights and lessons learned from Implementation of USP, BPOG, and historical protocols56**

James Hathcock, Pall Corporation, USA

12:00 - 12:30 **The journey of a polymer producer to support customers E&L needs57**

Jerome Vachon, SABIC, Netherlands

12:30 - 13:00 **Case Study: Subjecting A well-characterized biocontainer film to the standardized bpo extractables protocol71**

Christian Julien, Meissner Filtration Products, Inc., USA

13:00 - 14:00 Lunch

14:15 - 17:30 Afternoon guided excursion to the Templar Castle (Convento de Cristo), a UNESCO World Heritage Site

Monday, May 8, 2017 (continued)

Parallel Workshops

- 17:30 - 19:00 **Workshop 1**
GMP requirements for single use
Ganesh Vissvesvaran, Genentech, USA
Topics covered: Standardization of GMP requirements, Flexibility in single use components, selection and specification of single –use equipment
- 17:30 - 19:00 **Workshop 2**
Enabling needs to support single use adoption
Hana Sheikh, Genentech, USA
Topics covered: Training needs in single use, integrity testing, particulates, shipping drug substance bags
- 19:00 - 19:30 Report out from two workshops
- 19:30 - 21:00 Dinner
- 21:00 - 22:00 Poster Session / Social Hour

Tuesday, May 9, 2017

07:30 - 08:30

Breakfast

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

Session Chairs: Torsten Mayr, Graz University of Technology, Austria
Martina Micheletti, University College London, United Kingdom

08:30 - 09:00

Roll-to-Roll pilot line for large-scale manufacturing of microfluidic devices72

Martin Smolka, Haase, Jan Hesse, Barbara Stadlober, Joanneum Research Forschungsgesellschaft mbH, Austria

09:00 - 09:30

Integrated optical sensors for disposable microfluidics85

Torsten Mayr, Joseph Ehgartner, Philip Sulzer, Shiwen Sun, Martin Strobl, Bernhard Müller, Birgit Ungerböck, Graz University of Technology/Institute of Analytical Chemistry, Austria

09:30 - 10:00

Contactless microwave sensors and their application in biological single use87

Thomas Nacke, Daniel Martin, Robert Kuehler, Brian Gahill, Ralf Klukas, Iris Pogendorf, Caspar Demuth, Yahor Zaikou, Institute for Bioprocessing and Analytical Measurement/ Zurich University of Applied Sciences, Germany

10:00 - 10:30

Live biomass sensors and their integration and application in single use technology88

John Carvel, Aditya Bhat, Aber Instruments, United Kingdom

10:30 - 11:00

Coffee break

11:00 - 12:00

Keynote: Of SUT and stainless89

Manuel Carrondo, Instituto de Biologia Experimental e Tecnológica, Portugal

12:00 - 13:00

Lunch

Session 4: Interaction of plastic with cells/protein

Session Chairs: Weibing Ding, Amgen, USA
Susan Burke, GE Healthcare, USA

13:00 - 13:30

Protein-specific empirical model of protein adsorption on surfaces114

Dan Nicolau, McGill University, Canada

13:30 - 14:00

Hydroperoxide generation in irradiation-sterilized SUS and potential risks of protein oxidation130

Matthew Hammond, Samuel Dorey, Jonathan Cutting, Amgen/SSB, USA

14:00 - 14:30

Chemical identity and mechanisms of action and formation of a cell growth inhibitory leachable compound from disposable polycarbonate plastic vessels131

Zara Melkoumian, Corning Inc., USA

Tuesday, May 9, 2017 (continued)

14:30 - 15:00 **Leachables from single-use systems and impact to product quality132**
Nina Xiao, Genentech, Inc., USA

15:00 - 15:30 Coffee break

Parallel workshops

15:30 - 17:00 **Workshop 3**
Emerging application in single use
Michael Goodwin, Thermo Fisher Scientific, USA
Topics covered: Continuous processing and Single Use, Single-Use in Cell and Gene Therapy Manufacture, Conjugation

15:30 - 17:00 **Workshop 4**
Environmental impact of single-use
Ross Acucena, GE Healthcare, USA

17:00 - 17:30 Report out from two workshops

17:30 - 18:00 Break

18:00 - 20:00 Poster Session / Social Hour

20:00 - 22:00 Banquet Dinner

Wednesday, May 10, 2017

07:30 - 08:30 Breakfast

Session 5: Challenges of scale-up of single use systems

Sponsored by Thermo Fisher Scientific

Session Chairs: Andre Pastor, Bayer AG, Germany

Simone Biel, Merck, Germany

08:30 - 09:00 **Standardized expansion of human adipose tissue-derived stromal/stem cells (hASCs) in wave-mixed single-use bioreactors with one-dimensional motion133**

Valentin Jossen, Zurich University of Applied Sciences, Switzerland

09:00 - 09:30 **Characterization of a single-use stirred-tank bioreactor vessel for microcarrier-based adherent cell culture processes using experimental and computational fluid dynamics studies134**

Marco Rotondi, Aston University, United Kingdom

09:30 - 10:00 **Mixing and fluid dynamics characteristics in single-use bioreactors for improved design and scalability135**

Martina Micheletti, Gregorio Rodriguez, Andrea Ducci, Gary Lye, University College London, United Kingdom

10:00 - 10:30 Coffee break

Session 6: Advances in application of single use technology

Session Chairs: Peter Neubauer, Technical University of Berlin, Germany

Sara Ullsten, GE Healthcare, Sweden

10:30 - 11:00 **Implementation of single-use technologies for antibody conjugation processes136**

Dana A. Olson, Rachel Hendricks, Xin Xin Lin, Ekta Mahajan, Matt Hutchinson, Genentech, Inc., USA

11:00 - 11:30 **Microbial cultivation in rocking single-use bioreactors137**

Stefan Junne, Anna-Maria Marbà Ardébol, Tutku Kurt, Howard Ramirez, Vera Meyer, Peter Neubauer, Technical University of Berlin, Germany

11:30 - 12:00 **An automated single-use platform for production of patient specific cell therapies138**

Gary Lye, University College London, United Kingdom

12:00 - 12:30 **Single use droplet Based Microfluidics – Screening Tools for Biotechnology and Life-Sciences139**

Alexander Groß, Thomas Henkel, Mark Kielpinsky, Martin Roth, Alexander Mendel, Jialan Cao, Stefen Schneider, and J.M. Köhler, Technische Universität Ilmenau, Institute for Photonic Technologie IPHT-Jena, Fraunhofer Institute for Chemical Technology, Germany

12:30 - 12:40 Closing Remarks

Wednesday, May 10, 2017 (continued)

12:40 - 13:40

Lunch and departures

Poster Presentations

1. **A risk-based framework to manage single-use systems over lifecycle: Design, cleaning, operation, ongoing process verification160**
Pedro Felizardo, 4Tune Engineering Ltd, Portugal
2. **Application of alternative cell separation systems for the harvest of mammalian cell culture processes in a fully disposable single-use facility161**
Daniel Bock, Boehringer Ingelheim, USA
3. **Characterization of silicone tubing – Effect of pressure and irradiation on tubing diameter162**
Lise Tan-Sien-Hee, DOW CORNING, Belgium
4. **Cell culture scale-up in BioBLU® c rigid-wall, single-use bioreactors164**
Steffen Ostermann, Eppendorf AG Bioprocess Center, Germany
5. **Test method development for next-generation bioprocessing applications165**
Andrew Burns, GE Global Research, USA
6. **Large-scale assessment of Extractables and Leachables in single-use bags for biomanufacturing using ultra high performance liquid chromatography coupled to quadrupole-orbitrap mass spectrometry166**
Noemi Dorival, NIBRT, Ireland
7. **Case study: Development of a helium-based supplier integrity testing method for Single-use Systems (SUS) integrated into a global Container Closure Integrity (CCI) strategy167**
Marc Hogreve, Sartorius Stedim Biotech GmbH, Germany
8. **Improving single use bioreactor design and process development using the HyPerforma 5:1 S.U.B168**
Michael Goodwin, Thermo Fisher Scientific, USA
9. **Fed-Batch E. coli cultures in a shaken, single-use 24-well miniature bioreactor170**
Mary A. Lunson, University College London, United Kingdom
10. **Monitoring of metabolic parameters of mammal cells cultures in microfluidic devices using integrated optical chemical sensors171**
Bernhard Mueller, Graz University of Technology, Austria
11. **Sensors for single-use bioreactors - a review of perspectives and challenges172**
Caspar Demuth, Zurich University of Applied Sciences, Switzerland
12. **Analysis of leachable Bis Di-tert-butyl Phenyl Phosphate (bdtbpb) in bioprocessing films173**
Ross Acucena, General Electric Corp, USA
13. **Production and purification of influenza virus like particles using single-use technologies174**
Sofia B. Carvalho, iBET, Portugal
14. **Assessing the impact of single use systems on patient safety175**
Chrisitan Heiss, Merck, Germany

15. **Extractables studies on single-use components in the manufacture of antibody drug conjugates (ADCs)176**
Susan Burke, GE Healthcare, Sweden
16. **Study on mixing and suspension characteristics in single-use shaken microwell systems177**
Yi Li, University College London, United Kingdom
17. **BPOG model solvent comparison for extractables testing for single use systems178**
Paul Killian, MilliporeSigma, USA
18. **Online capacitance measurement for biomass monitoring over cultivation scales and platforms179**
Stuart Tindal, Sartorius Stedim Biotech GmbH, Germany
19. **Utilizing single-use technology for diabetes monitoring via breath acetone180**
Ronny Priefer, New England Breath Technologies/Western New England University, USA
20. **Role of enzyme immobilization in the formulation of enzymes for single use181**
Juan M. Bolivar, Graz University of Technology, Austria
21. **Development of a pre-screening method for bDtBPP, a cytotoxic leachable from single-use bioprocessing containers182**
Christine Ta, NIBRT, Ireland
22. **Leak testing of single-use biocontainer for bulk product storage and transport using flow measurement instrument183**
Kevin Chau, Pall Corporation, USA
23. **XDR-500 MO—Single-use fermentor for microbial processes184**
Jozsef Vasi, GE Healthcare, Sweden
24. **Single-use primary capture technology with the promise to deliver new standards for the economics, convenience and reliability of mAb bioprocessing186**
Oliver Hardick, Puridify / UCL, United Kingdom
25. **Comparative study for the production of MABs in single-use (SUB) vs. stainless-steel bioreactors (SSB) based on product quality and stress factors187**
Christian Beck, Roche Diagnostics GmbH, Germany
26. **Particulate contamination in single use systems: Measurement challenges188**
Klaus Wormuth, Sartorius Stedim Biotech, Germany
27. **Cellular response of CHO cells following exposure to extractables and leachables from single-use bioreactors190**
Sara Carillo, NIBRT, Ireland
28. **Managing risk and consistency in the raw material supply chain for single use systems191**
Tiffani M. Burt, Sealed Air Corporation, USA
29. **Recommendations for the engineering characterization of single-use bioreactors192**
Stephan C. Kaiser, Thermo Fisher Scientific, USA

30. **Process development of human mesenchymal stem cell microcarrier culture using a single-use automated microbioreactor platform193**
Qasim Rafiq, University College London, United Kingdom
31. **Case study: Relevance of ASTM and ISTA standard shipping simulation studies for the validation of real world shipping of drug substances194**
Frederic Bazin, Sartorius Stedim FMT SAS, France
32. **Effect of agitation on protein aggregation in vials made from glass or plastics195**
Birgit Mueller-Chorus, West Pharmaceutical Services, Germany
33. **Combining single-use bioreactor technology and TIPS method to make IC/BEVS-based productions more efficient197**
Renate Lombriser, Zurich University of Applied Sciences, Switzerland
34. **Optical glucose sensor for single use microfluidic reactors198**
Philipp Sulzer, Graz University of Technology, Austria
35. **Collaborative progress toward standardization of user requirements for single-use bioprocess technology199**
Trishna Ray-Chaudhuri, Genentech, USA ; Susan Burke, GE Healthcare, USA