Program

Single Use Technologies II: Bridging Polymer Science to Bioprocess Applications

May 7-10, 2017

Hotel dos Templários
Tomar, Portugal

Conference Co-Chairs

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Thermo Fisher Scientific

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 quality**
Gary Lye, University College London, United Kingdom

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

15:30 - 16:10 **Manufacturing processes and strategies for cell and gene therapy products**
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 bags** Barry A. Morris, DuPont, USA
09:00 - 09:30	**What are gels and how to reduce them?** Xueyuan Wang, Russell Wong, Bayer Healthcare, USA
09:30 - 10:00	**Influence of γ-irradiated biopharmaceutical films** 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 product** 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 processes** 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 protocols** James Hathcock, Pall Corporation, USA
12:00 - 12:30	**The journey of a polymer producer to support customers E&L needs** Jerome Vachon, SABIC, Netherlands
12:30 - 13:00	**Case Study: Subjecting A well-characterized biocontainer film to the standardized bpog extractables protocol** 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 devices** Martin Smolka, Haase, Jan Hesse, Barbara Stadlober, Joanneum Research Forschungsgesellschaft mbH, Austria
09:00 - 09:30	**Integrated optical sensors for disposable microfluidics** 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 use** 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 technology** John Carvel, Aditya Bhat, Aber Instruments, United Kingdom
10:30 - 11:00	Coffee break
11:00 - 12:00	**Keynote: Of SUT and stainless** 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 surfaces** Dan Nicolau, McGill University, Canada
13:30 - 14:00	**Hydroperoxide generation in irradiation-sterilized SUS and potential risks of protein oxidation** 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 vessels** Zara Melkoumian, Corning Inc., USA

Tuesday, May 9, 2017 (continued)

14:30 - 15:00	**Leachables from single-use systems and impact to product quality** 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 motion** 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 studies** Marco Rotondi, Aston University, United Kingdom
09:30 - 10:00	**Mixing and fluid dynamics characteristics in single-use bioreactors for improved design and scalability** 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 processes** 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 bioreactors** 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 therapies** Gary Lye, University College London, United Kingdom
12:00 - 12:30	**Single use droplet Based Microfluidics – Screening Tools for Biotechnology and Life-Sciences** 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 verification**
   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 facility**
   Daniel Bock, Boehringer Ingelheim, USA

3. **Characterization of silicone tubing – Effect of pressure and irradiation on tubing diameter**
   Lise Tan-Sien-Hee, DOW CORNING, Belgium

4. **Cell culture scale-up in BioBLU® c rigid-wall, single-use bioreactors**
   Steffen Ostermann, Eppendorf AG Bioprocess Center, Germany

5. **Test method development for next-generation bioprocessing applications**
   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 spectrometry**
   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) strategy**
   Marc Hogreve, Sartorius Stedim Biotech GmbH, Germany

8. **Improving single use bioreactor design and process development using the HyPerforma 5:1 S.U.B**
   Michael Goodwin, Thermo Fisher Scientific, USA

9. **Fed-Batch E. coli cultures in a shaken, single-use 24-well miniature bioreactor**
   Mary A. Lunson, University College London, United Kingdom

10. **Monitoring of metabolic parameters of mammal cells cultures in microfluidic devices using integrated optical chemical sensors**
    Bernhard Mueller, Graz University of Technology, Austria

11. **Sensors for single-use bioreactors - a review of perspectives and challenges**
    Caspar Demuth, Zurich University of Applied Sciences, Switzerland

12. **Analysis of leachable Bis Di-tert-butyl Phenyl Phosphate (bdtbpp) in bioprocessing films**
    Ross Acucena, General Electric Corp, USA

13. **Production and purification of influenza virus like particles using single-use technologies**
    Sofia B. Carvalho, iBET, Portugal

14. **Assessing the impact of single use systems on patient safety**
    Chrisitan Heiss, Merck, Germany

15. **Extractables studies on single-use components in the manufacture of antibody drug conjugates (ADCs)**
Susan Burke, GE Healthcare, Sweden

16. **Study on mixing and suspension characteristics in single-use shaken microwell systems**
Yi Li, University College London, United Kingdom

17. **BPOG model solvent comparison for extractables testing for single use systems**
Paul Killian, MilliporeSigma, USA

18. **Online capacitance measurement for biomass monitoring over cultivation scales and platforms**
Stuart Tindal, Sartorius Stedim Biotech GmbH, Germany

19. **Utilizing single-use technology for diabetes monitoring via breath acetone**
Ronny Priefer, New England Breath Technologies/Western New England University, USA

20. **Role of enzyme immobilization in the formulation of enzymes for single use**
Juan M. Bolivar, Graz University of Technology, Austria

21. **Development of a pre-screening method for bDtBPP, a cytotoxic leachable from single-use bioprocessing containers**
Christine Ta, NIBRT, Ireland

22. **Leak testing of single-use biocontainer for bulk product storage and transport using flow measurement instrument**
Kevin Chau, Pall Corporation, USA

23. **XDR-500 MO—Single-use fermentor for microbial processes**
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 bioprocessing**
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 factors**
Christian Beck, Roche Diagnostics GmbH, Germany

26. **Particulate contamination in single use systems: Measurement challenges**
Klaus Wormuth, Sartorius Stedim Biotech, Germany

27. **Cellular response of CHO cells following exposure to extractables and leachables from single-use bioreactors**
Sara Carillo, NIBRT, Ireland

28. **Managing risk and consistency in the raw material supply chain for single use systems**
Tiffani M. Burt, Sealed Air Corporation, USA

29. **Recommendations for the engineering characterization of single-use bioreactors**
Stephan C. Kaiser, Thermo Fisher Scientific, USA

30. **Process development of human mesenchymal stem cell microcarrier culture using a single-use automated microbioreactor platform**
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 substances**
Frederic Bazin, Sartorius Stedim FMT SAS, France

32. **Effect of agitation on protein aggregation in vials made from glass or plastics**
Birgit Mueller-Chorus, West Pharmaceutical Services, Germany

33. **Combining single-use bioreactor technology and TIPS method to make IC/BEVS-based productions more efficient**
Renate Lombriser, Zurich University of Applied Sciences, Switzerland

34. **Optical glucose sensor for single use microfluidic reactors**
Philipp Sulzer, Graz University of Technology, Austria

35. **Collaborative progress toward standardization of user requirements for single-use bioprocess technology**
Trishna Ray-Chaudhuri, Genentech, USA ; Susan Burke, GE Healthcare, USA