Program

Single Use Technologies II: Bridging Polymer Science to Bioprocess Applications

May 7-10, 2017
Hotel dos Templários
Tomar, Portugal

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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 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
   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 bpmog 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 Ardebol, 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, Stefan 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
    Christian 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