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Conference Program

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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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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.
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- Please do not smoke at any conference functions.
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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 (bdtbpb) 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