

## ***Preliminary Program***

*(March 9, 2017)*

# **Single Use Technologies: Bridging Polymer Science to Bioprocess Applications**

**May 7-10, 2017**

**Hotel dos Templários  
Tomar, Portugal**

### **Conference Co-Chairs**

**Ekta Mahajan**

Genentech, Inc., USA

**Gary Lye**

University College London, UK

**Regine Eibl**

Zurich University of Applied Science, Switzerland



**Engineering Conference International**  
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**Sunday, May 7, 2017**

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

**Pre-Conference Workshop**

1) Basics of biotechnology and bioprocessing  
Session Co-chairs: Gary Lye, UCL  
Qasim Rafiq, UCL

14:00 - 14:50 **Bioprocessing 101: cells to proteins, operations to processes, control to quality**  
Gary Lye, University College London

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

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

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

2) Basics of polymers/sterilization  
Session Co-chairs: Trishna Ray-Chaudhuri  
Diane Hahm

14:00 - 14:40 **Polymer overview**  
Karlheinz Hausmann, DuPont

14:40 - 15:20 **Resins used in pharmaceutical industry**  
Karlheinz Hausmann, DuPont

15:20 - 15:35 Stretch break

15:35 - 16:15 **Film structure design**  
Tiffani Burt, Sealed Air

16:15 - 16:50 **Film quality/testing**  
Sabrina, Merck

16:50 - 17:30 **Sterilization**  
Oliver Vrain, Steris

17:30 - 18:00 **Effect of sterilization on polymers**  
Olivier Vrain, Steris

18:00 - 18:30 Welcome Drink

18:30 - 19:00 Opening Remarks

19:00 - 20:00

**Keynote Speaker:** Jay F. Kunzler, Künzler Biomedical LLC

20:00 - 21:30

Dinner

**Monday, May 8, 2017**

07:30 - 08:30 Breakfast

**Session 1: Properties of polymers as applicable to Biopharma**

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

08:30 - 09:00 **Tie layer technology for multilayer coextrusion of single-use biopharma bags**  
Barry A. Morris, DuPont

09:00 - 09:30 **What are gels and how to reduce them**  
Xueyuan Wang, Russell Wong, Bayer

09:30 - 10:00 **Study of  $\gamma$ -irradiated biopharmaceutical films**  
Samuel Dorey, Magali Barbaroux; Fanny Gaston, Nathalie Dupuy; Sylvain Marque, Sartorius Stedim Biotech

10:00 - 10:30 **Rapid prototyping of a single-use bioreactor: conceptional design studies to final product**  
Stephan C. Kaiser, Thomas Fisher

10:30 - 11:00 Coffee break

**Session 2: The infamous extractables/leachables**

Session Chairs: Xueyuan Wang, Bayer Healthcare, USA  
Isabelle Uettwiller, Sartorius Stedim Biotech, 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 Biotech

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

12:00 - 12:30 **The journey of a polymer producer to support customers E&L needs:**  
Jerome Vachon, Sabic

12:30 - 13:00 **Case Study: Subjecting A well-characterized biocontainer film to the standardized bpog extractables protocol**  
christian julien

13:00 - 14:00 Lunch

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

## **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 equipmen
- 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
- 21:30 - 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, UK

08:30 - 09:00

#### **Roll-to-Roll pilot line for large-scale manufacturing of microfluidic devices**

Haase, Jan Hesse, Barbara Stadlober, Joanneum Research  
Forschungsgesellschaft mbH

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

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

10:00 - 10:30

#### **Live biomass sensors and their integration and application in single use technology**

John carvel, Aditya Bhat, Aber Instruments

10:30 - 11:00

Coffee break

11:00 - 12:00

#### **Keynote: Of SUT and stainless**

Manuel Carrondo, Instituto de Biologia Experimental e Tecnológica

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, Faculty of Engineering

13:30 - 14:00

#### **Hydroperoxide generation in irradiation-sterilized SUS and potential risks of protein oxidation**

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

14:00 - 14:30

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

Ye Fang, Dow Corning

14:30 - 15:00

#### **Leachables from single-use systems and impact to product quality**

Nina Xiao

15:00 - 15:30 Coffee break

**Parallel workshops**

15:30 - 17:00 **Workshop 3**  
**Emerging application in single use**  
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**

Session Chairs: Robert Repetto, Pfizer, USA  
Jincai Li, WuXi Apptec, China

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

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

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

10:00 - 10:30 Coffee break

**Session 6: Advances in application of single use technology**

Session Chairs: Peter Neubauer, TU Berlin, Germany  
Sara Ullsten, GE Healthcare, USA

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

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, TU Berlin

11:30 - 12:00 **An automated single-use platform for production of patient specific cell therapies**  
Gary Lye, University College London

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

12:40 - 13:40 Lunch



