Final Program

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Single-Use Technologies: Bridging Polymer Science to Biotechnology Applications

October 18-21, 2015
Lansdowne Resort
Leesburg, VA, USA

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Sunday, October 18, 2015

16:00 – 17:30  Conference check-in (Main lobby)
17:30 – 19:00  Dinner (Riverside Hearth)
19:00 – 19:30  Opening remarks from chair/co-chair/ECI liaison
19:30 – 20:30  Keynote Speaker
   **Advancing bioprocessing from the bench to the bedside: The single-use revolution**
   Govind Rao, University of Maryland, Baltimore Campus, USA
20:30 – 22:00  Poster session/Wine tasting

**NOTES**

- Technical Sessions will be held in Lansdowne Ballroom A.
- Poster Sessions will be held in the Terrace Ballroom.
- All meals, except the conference banquet, will be in the Riverside Hearth Restaurant.
- The conference banquet on Tuesday will be held in the Clubhouse Ballroom.
- Audiotaping, videotaping and photography of presentations are prohibited.
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Monday, October, 19, 2015

07:30 – 08:30  Breakfast

**Session 1 - Properties of a Good Plastic**
Session Co-chairs: Magali Barbaroux (Sartorius, France)  
Sally Kline (Amgen, USA)

08:30 – 08:40  Session Chairs/co-chair remarks

08:40 – 09:10  **Approach to biomaterials selection using a risk-based approach**  
Patricia Rafidison, Dow Corning, France

09:10 – 09:40  **Thermodynamics of migration in polymers: Can contamination from materials in contact be predicted, controlled and possibly avoided?**  
Olivier Vitrac, INRA, France

09:40 – 10:10  **The effects of irradiation technologies on some polymers commonly used in SUDs**  
Olivier Vrain, Synergy Health, Ireland

10:10 – 10:40  Coffee break  
Sponsored by Merck and Co., Inc.

10:40 – 11:10  **Polyolefins and their influence on single use technology for bioprocessing**  
Amy E. Plancon, SABIC Europe, The Netherlands

11:10 – 11:40  **Overview of the links between material properties and film extrusion process**  
Ingo Schnellenbach, Südpack Medica, Switzerland

11:40 – 13:00  Lunch

**Session 2 - The infamous Extractables/Leachables**
Session Chair: Joseph St. Laurent (Chemic Laboratories Inc., USA)  
Trishna Ray Chauhuri (Genentech Inc., USA)

13:00 – 13:10  Session Chairs/co-chair remarks

13:10 – 13:40  **Headache be gone: Clearance of extractables and leachables in single-use technologies through ultrafiltration/diafiltration**  
Kate Lee, Genentech, USA

13:40 – 14:10  **Limitation and detection of bis(2,4-di-tert-butylphenyl)phosphate (bDtBPP) from bioprocess container materials**  
Isabelle Uettwiller, Sartorius Stedim FMT SAS, France

14:10 – 14:40  **Silicone tubing extractables and their relationship to particulates**  
Csilla Kollar, Dow Corning, USA

14:40 – 15:10  **Application of BPOG standardized extractables protocol to container films: The impact of different sample conditions and analytical procedures on E&L profile**  
Mohamad Awada, Thermo Fisher Scinetific, USA

15:10 – 15:40  Coffee break  
Sponsored by Gore and Associates, Inc.
Session 3 - Interaction of Plastics with Cells/Proteins
Session Chairs: Jincai Li (WuXi AppTec Co., Ltd., China)
Weibing Ding (Amgen Inc., USA)

15:40 – 15:50  Session Chairs/co-chair remarks

15:50 – 16:20  Impact of a toxic single-use bio-process container film leachable on Chinese hamster ovary cells
Heather Nunn, Amgen Inc., USA

16:20 – 16:50  Wakey wakey sleepyhead- A case study in adapting single use bioreactors to a sensitive cell line
Ganesh Prasad Vissvesvaran, Genentech Inc., USA

16:50 – 17:20  Case study: Identification, characterization and mitigation of growth inhibitory leachable compound from disposable plastic vessels
Zara Melkoumian, Corning Inc, USA

17:20 – 17:50  Characterizing changes in protein quality attributes to assess leachable risks from single-use bioprocess containers
Nina J. Xiao, Genentech Inc, USA

18:30 – 19:30  Dinner

19:30 – 21:00  Poster session
Tuesday, October 20, 2015

07:30 – 08:30  Breakfast

**Session 4 - Challenges of Single Use**

*Sponsored by Südpack Medica*

Session Co-chairs: Martina Micheletti (University College London)  
Russell Wong (Bayer HealthCare)

08:30 – 08:40  Session Chairs/co-chair remarks

08:40 – 09:10  **Single use sensors: Sensing a need for change**  
David Pollard, Merck & Co., USA

09:10 – 09:40  **Preventing leaks in a single use system**  
Trishna Ray-Chaudhuri, Genentech Inc., USA

09:40 – 10:10  **Flexural fatigue behavior of rocking bioreactor films**  
Donald Buckley, Andrew Burns, GE Global Research

10:10 – 10:40  Coffee break  
*Sponsored by Meissner*

10:40 – 11:10  **Sensors for continuous monitoring of disposable bioreactors**  
Kenneth F. Reardon, Colorado State University

11:10 – 11:40  **Container Closure Integrity (CCI) for single-use systems (SUS): Regulatory trends, challenges and technology transfer of test methods**  
Marc Hogreve, Carole Langlois, Sartoius-Stedim, Germany

11:40 – 12:10  **Large scale freeze-thaw bag system for protein bulk storage: Prototypes development**  
Philippe Lam, Genentech Inc. USA

12:10 – 13:00  Lunch

13:00 – 16:00  **Organized excursion to Udvar-Hazy Center**  
Board buses at 13:00

16:30 – 18:30  **Workshop: Panel discussion on standards and standardization**  
Workshop Co-Chairs: Jim Vogel, Christopher Smalley

19:00 – 20:00  **Keynote Speaker**  
**Single use polymeric materials: The science of safety**  
Mitchell Cheeseman, Steptoe & Johnson LLP, USA

20:00 – 22:00  Conference banquet
**Wednesday, October 21, 2015**

07:30 – 08:30  Breakfast

**Session 5 - Overlap with Other Industry Users**  
Session chairs: Yuh-Fun Maa (Genentech, USA)  
Peter Neubauer (Technische Universität Berlin, Germany)

08:30 – 08:40  Session Chairs/co-chair remarks

08:40 – 09:10  Applying practices from the medical device industry to ensure patient safety of single-use products in the biotechnology industry  
Jan Oberdoerster, WL Gore & Associates, USA

09:10 – 09:40  Homogenizing biologic drug substance bulk using single use mixing systems  
Benson Gikanga, Genentech, USA

09:40 – 10:10  Single-use bioreactor technologies for early stage development of microalgae cultivation processes  
Gary Lye, University College London, United Kingdom

10:10 – 10:40  Coffee break  
*Sponsored by Dow Corning Corporation and GE Healthcare*

**Session 6 - How Flexible is Flexible?**  
*Sponsored by Thermo Fisher*

Session Chairs:  
Robert Repetto (Pfizer, USA)  
Mohamad Awada (Thermo Fisher, USA)

10:40 – 10:50  Session Chairs/co-chair remarks

10:50 – 11:20  Interchangeability of SUS - Functional specification and materials of construction  
Chris Smalley, Merck & Co., Inc. USA

11:20 – 11:50  Challenges and status: Single-use bioreactors for microbial processes  
Peter Neubauer, TU Berlin, Germany

11:50 – 12:20  Successfully employing single-use bioreactors for different expression systems  
Valentin Jossen, Zurich University of Applied Sciences, Switzerland

12:20 – 12:40  Closing remarks

12:40 – 13:40  Lunch and departure
Poster Presentations

Session 1 - Properties of a Good Plastic

1. **What's in the bag?**
   Rebecca L. Olsen, DuPont Packaging & Industrial Polymers, USA

2. **Material science enabled quality by design: The new standard in SUS development**
   Christian Julien, Meissner Filtration Products, Inc, USA

3. **Conversion of polymers – properties and processing**
   Philipp Jordan, RAUMEDIC AG, Germany

4. **AComDim applied to evaluate gamma irradiation impact on multilayer PE based films**
   Fanny Gaston, University of Aix-Marseille, France

Session 2 - The infamous Extractables/Leachables

5. **Static vs. dynamic extraction – Comparing best practice for Single Use Technology**
   Paul Killian, EMD Millipore, USA

6. **Single-use bag extractable case study: Lessons learned**
   Jayanthi Grebin, Entegris, USA

7. **Monitoring clearance of extractables and leachables from Single-Use Technologies by NMR**
   Nicholas Magarian, Genentech, USA

8. **Hazard and risk assessments for impurities, residual solvents, extractables, and leachables.**
   Jan Oberdoerster, WL Gore & Associates, USA

9. **The practical application of BPOG E&L protocols to viral clearance filters**
   Jessica Shea, EMD Millipore, USA

10. **Adopting a fully single-use process to improve speed to clinic: A leachables case study**
    Jessica Shea, EMD Millipore, USA

Session 3 - Interaction of Plastics with Cells/Proteins

11. **Challenges of scale down model for disposable bioreactors: Case studies on growth & product quality impacts**
    Jincai Li, WuXi AppTec, China

12. **Assessing cell lines for cell growth assays as alternative for existing cytotoxicity assays**
    Alexander Tappe, Sartorius Stedim Biotech GmbH, Germany

13. **An approach to evaluate new Single-Use film types**
    Katharina Blaschczok, Zurich University of Applied Sciences, Switzerland

14. **Identification of antioxidant by-products based on their specific chemistry and their potential detection during SUS extractable study**
    Samuel Dorey, Sartorius Stedim FMT SAS, France

15.
Session 4 - Challenges of Single Use

16. Engineering characterisation of a rocked-bag bioreactor to evaluate key effectors of successful mammalian cell culture  
   Gary J. Lye, University College London, United Kingdom

17. Single Use bioreactors: Geometry does matter  
   Colin Jaques, Lonza Biologics, USA

18. Appraisal of the mixing performance of Single-Use shaken bioreactors  
   Gregorio Rodriguez, University College London, United Kingdom

19. Single-use capacitance measurement of cell viability  
   Dan Kopec, Sartorius Stedim North America Inc., USA

20. Single-Use bioprocess containers: Raw material control strategy for optimal cell growth  
   Susan E. Burke, GE Healthcare, USA

21. Implementation and characterization of solvent detergent viral inactivation in Single Use bags  
   Michael A. Cunningham, EMD Millipore, USA

22. Integration considerations for replacing stainless steel tanks with Single-Use mixers  
   Hana Sheikh, Genentech, USA

23. Cell culture scale translation from a 24-well Single-Use miniature bioreactor and subsequent impact on product and broth quality  
   Gary J. Lye, University College London, United Kingdom

24. Risk reduction in Single Use assemblies by implementing Helium Integrity Test (HIT) and a new point of use leak test using flowstar LGR  
   Anil Kumar, Pall Life Sciences, USA

25. Evaluation of sweeping as an alternative to sparging in a rectangular single-use bioreactor  
   Jean-Francois P. Hamel, Massachusetts Institute of Technology, USA

26. Evaluation of single-use bioreactors for the production of a Hepatitis C vaccine candidate  
   Ricardo Silva, iBET, Portugal

Session 5 - Overlap with Other Industry Users

27. Particulates reduction efforts in Single Use technologies: A case study  
   Klaus Wormuth, Sartorius Stedim Biotech, Germany

28. Robust, fast and accurate pH sensing platform solution targeting Single Use application  
   Srinivas Rao, Senova Systems, USA

Session 6 - How Flexible is Flexible?

29. Microbial applications of Single Use bioreactor systems  
   James D. Rutley, Synthace Ltd, United Kingdom

30. Grey space bioprocessing: Myth or reality?  
   Diana Lok, Genentech, USA