

# Single-Use Technologies: Bridging Polymer Science to Biotechnology Applications

October 18-21, 2015

Lansdowne Resort  
Leesburg, VA, USA

## Conference Co-Chairs

**Ekta Mahajan**  
**Genentech, Inc.**  
**USA**

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



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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 <b>Advancing bioprocessing from the bench to the bedside: The single-use revolution</b> 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.
- Speakers – Please leave at least 5 minutes for questions and discussion.
- Please do not smoke at any conference functions.
- Turn your cellular telephones to vibrate or off during technical sessions.
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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 Scientific, USA

15:10 – 15:40

Coffee break  
*Sponsored by Gore and Associates, Inc.*

**Monday, October, 19, 2015 (continued)**

**Session 3 - Interaction of Plastics with Cells/Proteins**

Session Chairs: Jincal 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 Melkounian, 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, Sartorius-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