

# 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

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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.
- 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.
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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