

Single-Use Technologies: Bridging Polymer Science to Biotechnology Applications

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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 F
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? ÁG
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 Á I
Kate Lee, Genentech, USA

13:40 – 14:10

Limitation and detection of bis(2,4-di-tert-butylphenyl)phosphate (bDtBPP) from bioprocess container materials Á I
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** Å H
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** ÁÍ G

Jan Oberdoerster, WL Gore & Associates, USA

09:10 – 09:40 **Homogenizing biologic drug substance bulk using single use mixing systems** ÁÍ H

Benson Gikanga, Genentech, USA

09:40 – 10:10 **Single-use bioreactor technologies for early stage development of microalgae cultivation processes** ÁÍ I

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** ÁÍ J

Chris Smalley, Merck & Co., Inc. USA

11:20 – 11:50 **Challenges and status: Single-use bioreactors for microbial processes** ÁÍ K

Peter Neubauer, TU Berlin, Germany

11:50 – 12:20 **Successfully employing single-use bioreactors for different expression systems** ÁÍ L

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? '8]ggYW]b['Ai 'h]UnYf':]a 'lc' CdHja]nY'DYfZ:fa UbW'%'**
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 'B#5**
Samuel Dorey, Sartorius Stedim FMT SAS, France
15. **5 b' -bj Ygh][U]cb'Gh Xnrcb'h Y-a dUWicZUb -bWc'a dU]V'Y:]fU]cb'cZ6 Ybnm'5 'Wc\ c'`I g]b['U
Dc`mYh Yfgi `z`bY'A Ya VfUbY/ÆJÍ
////////// &@e|/Ozq |^EÖ:ã d |Ë ^`^i. Å**

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. **9b[]bYf]b['7\ UFUWf]gU]cb'cZUFcW'YX'6 U['6]cfYUWcf'hc'9j Ui UH'?Ym9 ZYWcf'g'cZ
Gi VVWggZ `A Ua a U]Ub'7Y''7i `hi fY'&\$(**
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