

Single-Use News L-e-t-t-e-r-s

March 2014

This periodic newsletter serves as a central resource for information and updates on the exploding role of Single-Use Technologies in the World of Bioprocess Science and includes regular contributions from the following important “lettered” sources (in alphabetical order):

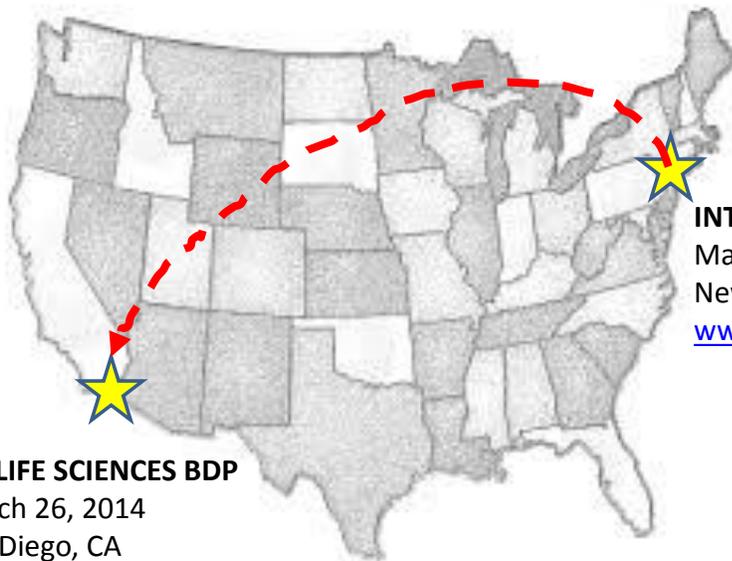
ASME-BPE (American Society of Mechanical Engineers-BioProcessing Equipment), **ASTM INTERNATIONAL**, **BPOG** (BioPhorum Operations Group), **BPSA** (Bio-Process Systems Alliance), **ELSIE** (The Extractables and Leachables Safety Information Exchange), **PDA** (Parenteral Drug Association), **PQRI** (Product Quality Research Institute), and **USP** (U.S. Pharmacopeial Convention)

[See Page 3 for a brief description of each]

Important Single-Use Town Hall Forums will be taking place this month on both sides of the United States:

- On March 18th you are invited to INTERPHEX in New York City, NY to take part in a town hall style meeting to discuss recent and upcoming happenings in the world of Single-Use Technologies. Representatives from major industry organizations will present useful information and an audience-involved discussion will follow the presentation.
- On March 26th, IBC Life Sciences BDP will host a Town Hall Forum in San Diego, CA specifically focusing on Change Control and Change Management in Single-Use Technologies.

Single-Use “MARCH” Across America



INTERPHEX
March 18, 2014
New York, NY
www.interphex.com

IBC LIFE SCIENCES BDP
March 26, 2014
San Diego, CA
www.IBCLifeSciences.com/BDPWeek

ORGANIZATION UPDATES

ASME-BPE

Reported by Mike Zumbrum and Jay Ankers

Balloting for the ASME-BPE 2014 Standard is complete with the publication expected early in the 4th Quarter of 2014. This edition of the Standard will include a Non-mandatory Appendix for extractables and leachables. New topics currently being discussed by ASME (with BPSA and BPOG) include particulates acceptance criteria and testing, single-use hygienic union dimensions and tolerances, and steam-through connections. Also, "Product & Process Contact Surface" definition and use is being discussed between ISPE and ASME BPE. Many of our Polymeric Materials Task Groups will be meeting in the next few months before our next ASME BPE meeting in New Orleans in May; Including Extractables & Leachables, Particulates, Hygienic Unions, and Shelf Life.

ASTM

Reported by Bob Steininger

The SUT Standards Working Group includes members from both the supplier and end-user side of Single-Use Technologies. Monthly phone calls between group members have enjoyed consistent attendance and participation between end-users and suppliers. Members of the Working Group have been participants in the BPSA and BPOG extractable protocol discussion. An updated and a definitive standard within ASTM is the ultimate goal of these discussions. An article related to potential aspects of supply chain changes has been completed with the collaboration of ISPE. Dialog regarding particulates and standardization of single-use components has begun, as well as discussions pertaining to gamma irradiation and value as validation methods. Teleconferences are ongoing and ASTM will hold a meeting in Cambridge, MA in May of 2014.

BPOG

Reported by Tony White

At the same time that important negotiations continue with BPSA to find a joint position on a credible standard extractable/leachable protocol, a second SUT Leadership group is forming with the aim to agree on end-user needs in a series of supply chain and quality areas. The team will unveil their priorities at the upcoming IBC Life Sciences BDP Conference in San Diego, CA at the end of March.

BPSA

Reported by Kevin Ott

BPSA is working to complete a user requirements document for Single-Use based on discussions from last summer's BPSA Summit. Consensus building continues to be a high priority for BPSA as it recognizes the importance of collaboration for the good of the SUT community. Additional ongoing projects by BPSA are a draft Quality Agreement Template, a draft Particulates Guide and an update to the 2007 Component Quality Test References Matrices. The annual BPSA International Single-Use Summit will take place July 9-11, 2014 in Washington, DC. This summit plans to explore important single-use topics including: particulates, supply chain, extractables/leachables, Single-Use News L-e-t-t-e-r-s, and hydrocarbon to fill/finish and recycle/disposal.

BPOG and BPSA

These two organizations continue to work closely together as they have for the past year. Negotiations continue to find common ground on a standardized extractables protocol for single-use components. Good

progress is being made. An upcoming meeting is intended to move talks along and an agreement is projected to be reached very soon.

ELSIE

Reported by Megan Cabill

Since the launch of the ELSIE Safety Information Database in 2011, a core objective of ELSIE is to maintain the Database with comprehensive, up-to-date and peer-reviewed safety information on extractable and leachable compounds to support the risk assessment process, facilitate sharing of insights and minimize duplicative efforts. The ELSIE Safety Database now contains safety information on over 240 compounds and has numerous users from pharmaceutical, biotechnology, and medical device companies. Additionally, the ELSIE Consortium has recently submitted for publication papers on the results of the Materials Pilot Program.

ISPE

(This organization has chosen not to contribute to this publication.)

PDA

Reported by Bob Repetto

The final draft of an article describing current practices and recommendations has been submitted to the PDA Advisory Board. This article was authored by Subject Matter Experts (SMEs) from the end-user side (Biopharm, CMO), the supplier side, and the regulator side (FDA, EMA) of Single-Use. A technical report is also in the works and due to be published in the coming months. It will contain concepts, practices and recommendations which may eventually evolve into best practices or standards in other initiatives. A broader readership will inevitably add additional/different points of view and it is important that we hear from a variety of involved parties to add still more value to this project.

PQRI

Reported by Dennis Jenke

By the end of the year, their goal is to publish a Single-Use "Best Practice" recommendation guide, which will be available to the public in two parts.

USP

(There is no update to report at this time.)

UPCOMING SINGLE-USE MEETINGS

INTERPHEX – NEW YORK, NY

BioProcess International Theater Round Table

March 18-20, 2014

www.interphex.com

IBC LIFE SCIENCES BDP – SAN DIEGO, CA

Town Hall Forum: Change Control and Change Management in Single-Use Systems

March 26, 2014

www.IBCLifeSciences.com/BDPWeek

IBC LIFE SCIENCES – BOSTON, MA

Town Hall Forum: Single-Use Systems

June 9-10, 2014

www.IBCLifeSciences.com/BDPWeek/SingleUse

BPSA – WASHINGTON, DC

International Single-Use Summit

July 9-11, 2014

www.bpsalliance.org

Please come see
us in person at
these exciting
events!!

To subscribe to this free newsletter please send an email to:
info@bioprocessinstitute.com

A brief description of the major organizations involved in Single-Use Technologies can be found below. Please visit their websites for a broader description of their industry involvement, a list of their upcoming meetings and events, and volunteer membership information.



ASME-BPE (American Society of Mechanical Engineers - BioProcessing Equipment Standard) www.asme.org
The ASME-BPE Standard is intended for design, materials, construction, inspection, and testing of vessels, piping and related accessories such as pumps, valves, and fittings for use in the biopharmaceutical industry. This standard (www.asme.org/products/codes-standards/bpe-2012-bioprocessing-equipment) also provides requirements for Single-Use Technologies and components.



ASTM International www.astm.org
ASTM International develops international voluntary consensus standards similar to the ASME BPE. Twelve thousand ASTM standards are used around the world to improve product quality, enhance safety, facilitate market access and trade, and build consumer confidence. ASTM International includes more than 30,000 of the world's top technical experts and business professionals, representing 150 countries. Working in an open and transparent process and using ASTM's advanced electronic infrastructure, ASTM members deliver the test methods, specifications, guides, and practices which support industries and governments worldwide.



BPOG (BioPhorum Operations Group) www.biophorum.com
BPOG consists of experts from biopharma drug substance operations who meet and work together at fact-to-face meetings in the U.S. and Europe on a regular basis. They have 19 member companies with over 500 participating representatives. BPOG has established best practices on a wide range of quality, engineering and organizational topics central to the challenge of mastering a biotech drug substance operations. BPOG is made of up exclusively of end-users.



BPSA (Bio-Process Systems Alliance) www.bpsalliance.org
The BPSA is an industry-led corporate member trade association dedicated to encouraging and accelerating the adoption of Single-Use manufacturing technologies used in the production of biopharmaceuticals and vaccines. BPSA facilitates education, sharing of best practices, development of consensus guides and business-to-business networking opportunities among its member company employees.



ELSIE (The Extractables and Leachables Safety Information Exchange) www.elsiedata.org
ELSIE was formed in 2007 with the core objective of establishing a comprehensive database which provides a jointly-developed and credible source of safety information on extractables and leachables as well as extraction profiles and standardized study protocols for a range of materials commonly used in pharmaceutical, biological and device applications and processes (e.g. container closure systems, devices, manufacturing/processing, etc.).

ISPE

ISPE (International Society for Pharmaceutical Engineering) www.ispe.org
ISPE's Core Purpose is Knowledge Management. The organization seeks, defines and shares best practices in manufacturing, quality and compliance throughout the product lifecycle to the benefit of members and all stakeholders. The Disposables (COP) Community of Practice (www.ispe.org/disposablescop) aims to create a global focal point of support for biopharmaceutical professionals working with Single-Use disposable technologies. This includes bag systems, tubing, filters, connectors, aseptic transfer, controlled freeze-thaw, and other bioprocessing equipment developed in Single-Use formats.



PDA (Parenteral Drug Association) www.pda.org
PDA is the worldwide leading provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical industries. Founded in 1946 as a nonprofit organization, PDA now has over 9,500 members worldwide. Using their expertise, these members are committed to developing scientifically sound technical information for practical uses in order to advance science and its regulations.



PQRI (Product Quality Research Institute) www.pqri.org
The Product Quality Research Institute (PQRI) is a non-profit group of organizations who collaborate to create important information that improves drug product quality and development. This information is shared amongst the participating organizations. PQRI, through its varied collaborations, provides a distinctive environment; focusing input to create a broad and timely impact on regulations, methodology, and creation of industry standards.



USP (U.S. Pharmacopeial Convention) www.usp.org
The USP is a scientific nonprofit organization that sets standards for the quality, purity, strength, and identity of medicines, food ingredients, and supplements. USP's drug standards are enforceable in the United States by the Food and Drug Administration (FDA). These standards are also used in more than 140 other countries.