

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

January 2014

*This periodic newsletter serves as a central resource for information and updates on the exploding role of Single-Use Systems 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), **ISPE** (International Society for Pharmaceutical Engineering), **PDA** (Parenteral Drug Association), **PQRI** (Product Quality Research Institute), and **USP** (U.S. Pharmacopeial Convention). [See Page 3 for a brief description of each.]

It is the worst kept secret in Bioprocessing: *Single-Use Systems are going to change the world.* And just like any poorly kept secret, rumors and misinformation tend to dent progress. What has been missing is a way to facilitate the coordination of standards and best practice efforts in the field of Single-Use Systems (SUS). In an attempt to separate fact from fiction and, at the same time, provide a resource for interested parties about this exciting new arena, this publication was created.

The goals of **Single-Use News L-e-t-t-e-r-s** include:

- facilitating the coordination of SUS Standards and practice efforts among these lettered groups;
- providing a summary and monthly update of each group’s progress – including any upcoming meetings and events – and promote a call for volunteers to get involved; and
- establishing agendas and creating presentations for public seminars.

The **Single-Use News L-e-t-t-e-r-s** project started in 2013 in preparation for a Town Hall session to discuss Single-Use Standardizations and Best Practices at the 10<sup>th</sup> Annual BioProcess International Conference and Exhibition in Boston, MA last September. The presenters represented many of the various groups working on documents to enhance the application of Single-Use Systems in the Bioprocess Industry. The session was viewed as a success. All groups involved saw the value of maintaining an informal dialog *amongst* these

groups to help coordinate the progress *within* these groups. They also shared an interest in providing general status information to the SUS community about each of the groups involved as well as a desire to recruit members and volunteers to help move these efforts along.

After that meeting in Boston, we decided to continue having monthly teleconference meetings and periodic public “Town Hall” meetings and to publish what was discussed in this newsletter.

In an effort to inform interested parties about what each of these industry-driven associations, whom share a common interest in facilitating the use of SUS in pharmaceutical organizations, is working on regarding SUS, representatives from each of the major organizations involved meet on a monthly basis to report on the progress being made within and among these groups. Bioprocessing experts are highly sought after in the industry for their experience, opinions and guidance. Those with less expertise are also encouraged to partake of these volunteer opportunities in order to gain more knowledge and contribute to shaping the future of the industry. You are the qualified people who can write and proof these standards. On Page 3 are descriptions of the organizations currently involved in SUS. These organizations have many things in common and all are gold mines full of information, innovation and know-how. □

To subscribe contact [info@bioprocessinstitute.com](mailto:info@bioprocessinstitute.com).

## ORGANIZATION UPDATES

### ASME-BPE

Reported by Mike Zumbrum

In January 2014, ASME-BPE will hold its annual meeting in San Juan, Puerto Rico. At this time, various experts in the field – including manufacturers and end-users – will discuss how to further improve on the Standard due to be updated this year. Plans are in place to discuss extractables and leachables; specifically, conditions and concentrations of fluids. Non-Mandatory Appendix task groups are in place for Single-Use Systems. It is important to mention that the current 2012 *ASME BPE Standard* mentions Single-Use in its Foreword.

### ASTM

Reported by Jim Bray

The SUT Standards Working Group includes members from both the supplier and end-user side of Single-Use Systems. 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. ASTM has an existing extractables standard which is badly out of date relative to the current state of the art. Members of the Working Group have prepared a paper describing a tiered change control recommendation system which is expected to reach publication in *Pharmaceutical Engineering* by April of 2014.

### BPOG and BPSA

These two organizations have been working closely together for the past year – through intense negotiations, conference calls, and face-to-face meetings – to find common ground on a standardized Extractables Protocol. This is an excellent example of moving the dialogue forward with good scientific discussion. Topics have included areas such as number of solvents, type, temperature, and analytics. An agreement is projected to be reached by the end of February, with a quality matrices document resulting from this by the end of the first quarter of 2014.

### BPOG

Reported by Tony White

The BPOG member companies are currently developing a common view on end-user requirements for the improvement of security and effectiveness of SUS supply chains. The collective views of the group will be presented at a high level during the upcoming BPD Conference in San Diego. The group expects that their consensus will end up endorsing many of the existing initiatives being undertaken by the other bodies here and hope that a consistent end-user position will help focus and accelerate these important initiatives and lead to further productive collaboration in the second half of 2014.

### BPSA

Reported by Kevin Ott and Mani Krisnan

BPSA is currently completing a user requirements document for Single-Use based on discussions from last summer's BPSA Summit. This reflects the current attitude that it is useful for organizations to work together early on for consensus building instead of playing catch-up. Additional activities by BPSA are a draft Quality Agreement Template, a draft Particulates Guide and an update to the 2007 Component Quality Test References Matrices. The always well-attended annual BPSA International Single-Use Summit will take place July 9-11, 2014 in Washington, DC.

### ELSIE

(There is currently nothing new to report on Single-Use in bioprocessing.)

### ISPE

Reported by Pietro Perrone

Several Single-Use events occurred in the last few months with ISPE sponsorship. These include events at the Boston Chapter and the National Meeting. The Single-Use Educational Program at the ISPE

Boston Chapter Product Show featured presentations by end-users on the Real-Life Experiences of Implementing Single-Use products. The program at the ISPE Annual meeting focused on standardization of system design methods, extractables/leachables assessments, and a case study of Single-Use products in fill finish applications. The Disposables Community of Practice is a group within ISPE that is developing a comprehensive Good Practice Guide for Single-Use Technology. The Guide is a practical go-to document providing a road map for implementing Single-Use products. Authors of this document include end-users and suppliers. We have more than half of the sections in the Guide written as a draft and we welcome authors who want to learn and share their experiences in this project.

### PDA

Reported by Bob Repetto

As manufacturing of Single-Use Systems continues to gather steam, PDA is considering developing a forum to help mediate the possibility of conflicting Single-Use Systems guidance as the various SUS organizations listed begin to publish. The purpose of this forum would be simply to initiate a conversation between the various SUS organizations and possibly establish a forum for conflict resolution. Furthermore, a technical report is in PDA's hands for editing, with an expected publication due out by March of 2014. The annual meeting, taking place in April, will include some specific Single-Use topics.

### PQRI and USP

These two organizations co-sponsored a meeting this past December in Rockville, MD, entitled *Suitability and Compatibility for Packaging and Delivery Systems: Extractables and Leachables*.

### USP

Reported by Dennis Jenke

This organization is currently revising Chapter 661, specifically to address plastic packaging systems and their plastic materials of construction. This revision has been published for comments and the comment period has been closed. The Chapter is in the final stages of revision prior to making it effective and enforceable. Recognizing both the similarities and differences between packaging systems and systems used in the manufacturing of pharmaceuticals, USP is developing a section in Chapter 661 which will address plastic systems used in manufacturing and their materials of construction. As SUS is a plastic system used in manufacturing, it is reasonable to expect that SUS would be covered by this section. An expert panel, which included members from BPSA, BPOG, PQRI, ELSIE and experts from individual companies active in pharmaceutical manufacturing, was seated to develop this section and recently conducted its initial meeting in Washington, DC.

## UPCOMING SINGLE-USE ACTIVITY

### INTERPHEX – NEW YORK, NY

*BioProcess International Theater Round Table*

March 18-20, 2014

[www.interphex.com](http://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](http://www.ibclifesciences.com/BDPWeek)

### IBC LIFE SCIENCES – BOSTON, MA

*Town Hall Forum: Single-Use Systems*

June 9-10, 2014

[www.ibclifesciences.com/BDPWeek/SingleUse](http://www.ibclifesciences.com/BDPWeek/SingleUse)

### BPSA – WASHINGTON, DC

*International Single-Use Summit*

July 9-11, 2014

[www.bpsalliance.org](http://www.bpsalliance.org)

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

**A brief description of the major organizations involved in Single-Use Systems 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](http://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](http://www.asme.org/products/codes-standards/bpe-2012-bioprocessing-equipment)) also provides requirements for Single-Use Systems and components.



**ASTM International** [www.astm.org](http://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](http://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](http://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](http://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 (International Society for Pharmaceutical Engineering)** [www.ispe.org](http://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](http://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](http://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](http://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](http://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.

