

Single-Use News

L-e-t-t-e-r-s

May 2015

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]

UPCOMING SINGLE-USE EVENTS

MAY – ASME-BPE COMMITTEE MEETING

ASME BPE's next committee meeting will take place in Philadelphia, PA from May 18-21, 2015. Task groups will be discussing the alignment of definitions, particulates, change control, polymeric hygienic unions, and many other SUT-related issues. During the course of this 3-day meeting, **BPOG** has asked **ASME BPE** to address concerns of end users regarding information on the standardization of hose barbs and clamps in order to minimize leaks. This task group will delve into how to standardize this information. This meeting is open to all who wish to attend, even non-**ASME BPE** members. Please click [HERE](#) for more information.

JUNE – PDA HARMONIZATION WORKSHOP

PDA's June 23-24, 2015 Single Use Systems Workshop entitled *Harmonizing Best Practice Recommendations Connecting Manufacturers, Suppliers and Global Health Authorities* will facilitate a science- and risk-based dialogue to advance the understanding and implementation of SUSs through sharing best practices for the adoption of this emerging technology based on a transparent partnership between SUS suppliers and pharmaceutical manufacturers. A key contribution in this effort is **PDA** Technical Report No. 66: Application of Single-Use Systems in Pharmaceutical Manufacturing. But success requires an ongoing effort from suppliers, regulators and manufacturers to continue the process of building this transparent partnership that lies on a foundation of science- and risk-based dialogue.

JULY – BPSA 5TH INTERNATIONAL SINGLE-USE SUMMIT

The Bio-Process Systems Alliance (**BPSA**) is pleased to announce the 5th Annual International Single-Use Summit (ISUS 2015) will be held July 13-

15, 2015, in Washington, D.C., with a primary focus on the promises and hurdles impacting the single-use-adoption growth curve.

From technical topics to business and regulatory presentations, ISUS 2015 will examine a variety of issues that underscore the emergence of the single-use industry as the “go-to” platform in bioprocessing. The technical discussions, characterized as EPIC Solutions™, will speak to the “Big Five” influences bearing on the growth of single-use (extractables, particulates, integrity, change notification and sustainability) and provide context for all discussions in the 2015 program. Highlights include:

- Patrick Evrard of GSK will speak to the utility of Single-Use Systems and its approach to developing a vaccine for the Ebola virus, which has infected more than 25,000 victims and caused more than 10,000 fatalities in West Africa to date;
- “Hot Topic” panels will focus on a variety of issues, from standardization and harmonization of end user/supplier efforts, to the need for a universal approach to change notification and efforts toward the education and training of single-use laboratory and process talent, among others;
- Ken Gronbach will discuss the “coming demographic storm” and its impact on global demand for goods, services, medicines and personnel;
- Representatives from Capitol Hill and regulatory agencies will discuss the current drug-approval process, prospects, and streamlining.
- Former MA Senator and Fox News commentator Scott Brown will share his perspective on the 2016 elections and the current FDA regulatory climate.

BPSA also plans to release a new technical guide at ISUS 2015: The 2015 **BPSA** Single-Use Manufacturing Component Quality Test Matrices, which will help users when making selections and facilitating qualification, validation and usage of single-use products.

For more information on the summit please visit www.bpsalliance.org. □

SINGLE-USE ALIGNMENT UPDATES

EXTRACTABLES

Terminology has historically been a recurring issue in the harmonization process amongst the lettered groups involved in Single-Use standardization. Through the hard work of these organizations though, progress is being made in the effort to speak the same language in the SUT world. Most agree that all terms and definitions should be as common and repeatable as possible. Continuing efforts across the board reflect the acknowledged difficulty and importance of collaboration. **ASTM** reported that collective responses to the online posting of Ballot 1 make it clear that there is still a fundamental gap in agreement between suppliers (mainly **BPSA** members) and end users (mainly **BPOG** members) on the topics of (1) number of solutions and (2) extraction times. As organizations such as **ASTM** and **ASME** can attest, this type of consensus methodology can only work through compromise. In light of this, **BPOG**, **BPSA** and **ASTM** have agreed to name three representatives each to work together in order to move this effort forward. This “Group of 9” took part in a teleconference on March 27th. A compromise was drafted to adjust the number of solutions and this resulted in a 9-0 vote of agreement. **BPSA** has given their approval to the new language within the draft. It has been agreed upon that this draft will be divided into two parts: Part 1—*Preparation* of Extractable Test Solutions and Part 2—*Analysis* of Extractable Test Solutions. Drafting of Part 1 has already begun and a consensus by the “Group of 9” is expected in May, with a consensus between **BPOG** and **BPSA** expected to follow in June. A ballot is expected to be posted in June. Strategy is also being drafted for Part 2. There is a great deal of SME participation in the process for both Parts 1 and 2. A number of independent studies are being planned to get extractables based on the multiple solutions being considered by **BPOG/BPSA**. Getting data on the potential extractables has been requested by numerous parties who are involved in setting the extractable standard. **ASME BPE** is working on definitions to discuss at their May meeting in Philadelphia in a continuing effort to align with other lettered organizations; the goal is to have these aligned with the **ASTM** effort.

PARTICULATES

ASME BPE will continue to address the topic of Particulates at its May 18-21, 2015 meeting in Philadelphia, PA, for improvement in the 2016 Standard. **ASME BPE** is aligning this effort with **ASTM**, **BPOG** and **BPSA**. **ASTM** reviewed its work groups at their meeting in Lisbon in April and a report will be covered in the next edition of *SU Newsletters*.

CHANGE MANAGEMENT

ASME BPE is currently voting on a Change Control for Polymeric

Materials (a.k.a. SUTs). They will be working hard to gain consensus for incorporation into the **ASME BPE-2016** Standard at their May meeting in Philadelphia.

BPSA and **BPOG** held a joint meeting in New Jersey at the end of April to discuss Change Notification. This meeting promoted further communication and cooperation and the atmosphere was one of a single group working together toward a common goal. The session was well attended by members of both groups. All attendees embraced this approach and agreed it was a good start to this important topic. The focus of the group will be reviewed at the **BPSA** Summit in July and at the BioProcess International meeting in October.

SYSTEM INTEGRITY

Activities are currently taking place within **BPSA**, **ASME BPE** and **ASTM** on this topic. Coordination will be coming soon.

CONNECTORS

ASME-BPE's Polymeric Hygienic Unions Task Group, which is similar to their Metal Fitting Task Group, will be gathering at the meeting in Philadelphia this month. In addition, there will be a kickoff of the hose barb standardization effort at that same meeting.

SUT DESIGN VERIFICATION

The ballot was reviewed at the **ASTM** meeting in Lisbon, Portugal; a report will be covered in the next edition of *Single-Use Newsletters*.

SUT GENERAL

BPSA is finalizing a significant update to their 2007 Quality Test Matrices. It will be a group of tables, organized by type of test and type of component, in a spreadsheet format. It will be rolled out at the **BPSA** Summit in July, and be available on the **BPSA** website for all.

OTHER ACTIVITIES – EDUCATION/INFORMATION JOURNALS

ISPE's has a renewed interest in collaboration between its JETT (Joint Equipment Transition Team) Consortium and **ASME BPE**. The goal would be to update and publish existing JETT documents. **ASME BPE** is willing to help and is shepherding the process along. Although getting the two groups to agree on how to share the rights to these resulting supplemental materials may be a challenge, the value of updated JETT consortium documents is undeniable. An **ASME** task group is looking into how to publish educational and informative journals and papers. It will be made clear that these documents are presented as opinions and experiences, not necessarily as consensus materials. □

A Summary of Current SUT Activities

	ASME-BPE	ASTM	BPOG	BPSA	ELSIE	PDA	PQRI	USP
Leachables							X	X
Extractables	X	X	X	X	X		X	X
SUT Supply Chain			X					
Change Notification/ Change Control	X	X	X	X				
Particulate in SUT	X	X		X				X
SUT System Integrity		X		X		X		X
Connectors	X							
SUT Design Verification	X	X		X				
Biocompatibility		X						X

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 Systems 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 32 member companies with over 1,400 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.).



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 consortium of organizations working together to generate and share timely, relevant, and impactful information that advances drug product quality and development. PQRI provides a unique forum to focus critical thinking, conduct research, exchange information, and propose methodology or guidance to pharmaceutical companies, regulators, and standard setting organizations.



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.

UPCOMING 2015 MEETINGS & EVENTS

ASME-BPE – PHILADELPHIA, PA [REGISTRATION OPEN]

May 18-21, 2015

<http://calendar.asme.org/EventDetail.cfm?EventID=30193>

PDA – BETHESDA, MD [REGISTRATION OPEN]

June 24-25, 2015

2015 PDA Single Use Systems Workshop

Harmonizing Best Practice Recommendations and Standardization Guides and Connecting Manufacturers, Suppliers and Global Health Authorities

www.pda.org/global-event-calendar/event-detail/2015-pda-single-use-system-workshop

BPSA International Single-Use Summit – WASHINGTON, D.C. [REGISTRATION OPEN]

July 13-15, 2015 www.bpsalliance.org/bpsa-summit/

ASME-BPE – PHOENIX, AZ

September 2015

<http://calendar.asme.org/EventDetail.cfm?EventID=30193>

BIOPROCESS INTERNATIONAL – BOSTON, MA

Conference & Exhibition

October 26-29, 2015 [REGISTRATION OPEN]

<http://www.ibclifesciences.com/BPI/overview.xml>

ECI Single-Use Technologies Conference – WASHINGTON, DC

www.engconf.org/15aj

October 2015

ISPE – PHILADELPHIA, PA

November 8-11, 2015

Annual Meeting

www.ispe.org/annualmeeting

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