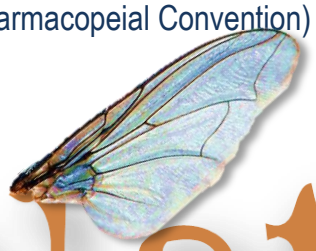
Single-Use News L-e-t-t-e-r-s

July 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.]



Particulate

On June 10th, an important Single-Use Town Hall Forum took place in Boston, Massachusetts at the **IBC Life Sciences Conference**. At that meeting, representatives from the various organizations mentioned in this newsletter provided the audience with information on the topic of *Particulate in Single-Use Technology* from both the end users' and the suppliers' perspectives.

The discussion was lively! The audience commented on the need for more prescriptive best practices, minimum requirements and guidelines on: What to do to ensure minimum particles in SUT? What to do when you encounter a particulate in the SUT? and How to cover the full lifecycle of the SUT, from both the supplier and end user standpoints? Thoughtful contributions from the audience and panel underscored the importance of this topic to the entire SUT community.

The Bio-Process Systems Alliance (BPSA) took the opportunity in Boston to announce the completion of an educational document for suppliers and end users in the SUT industry entitled *"Recommendations for Testing, Evaluation, and Control of Particulates from Single-Use Process Equipment"*. Its purpose is twofold: to serve as a guide to characterization and determination of levels and types of particles in SUTs as well as to recommend procedures to achieve minimal levels of particles in SUT. Please follow this link to read the paper: **www.bpsalliance.org**.

Also in the Boston meeting, the ASME-BPE described the creation of a particulates task group and announced that a statement on particulates is currently being added to the *ASME-BPE 2014 Standard*. ASTM announced that it has initialized an effort to establish a Standard Practice for Characterizing Particulate Burden from Single-Use Systems, the objective of which is to provide a standardized approach for determining a risk/impact assessment of particulate burden within Single-Use Systems. □

ORGANIZATION UPDATES

ASME-BPE

Reported by Mike Zumbrum and Jay Ankers

ASME-BPE held their meeting this past May in New Orleans, LA. The 2014 edition was approved by the BPE Standards committee and by the ASME Board. The 2014 Edition is at the publisher and expected to be available in the fall of 2014. Many SUT-related task groups met in New Orleans. They included: Extractables and Leachables, Particulates, Change Control, Shelf Life and Sterilization. The Particulate Task Group was formed, with members from BPSA, BPOG, ISPE and PDA, and is comprised of both end users and suppliers. A major result of this collaboration of SMEs was the creation of Non-Mandatory Appendix N. The goal of Non-Mandatory Appendix N is to provide guidance to manufacturers and end users of bioprocess equipment that will allow them to develop and manufacture products and systems that meet particle acceptance criteria. Looking ahead, ASME-BPE has initiated discussions with ASTM regarding testing protocol for particulates in single-use systems.

ASTM

ASTM held their biannual meeting in Boston on May 20-22, 2014, which included a workshop focusing on the production and supply chain issues related to raw materials, predominately single-use systems. Nearly 100 individuals representing end users, suppliers, and consultants attended this session, which included a talk on Extractables by the FDA. A set of three standards is due to be drafted and submitted for review in 2014 focusing on WK43741 New Practice for Testing Integrity of Single-use Systems, WK43742 New Practice for Characterizing Particulates Burden from Single-use Systems and WK43975 New Practice for Determining and Characterizing Extractables from Materials used in Single-use Applications.)

BPOG

Reported by Tony White

The BPOG Extractables team is working to make their user requirements and rationale more widely available and will publish a full paper in the October edition of *Pharmaceutical Engineer*. They hope this will clarify as many points as possible and help suppliers work with their requirements. With the SUS Leadership Team now up and running, Bob Repetto and Tony White presented at the BPSA Summit the team's views on the gap in expectation between suppliers and end users. It is felt that this 'gap' in understanding is one of the things impeding progress and adoption in commercial operations. The material--and BPOG's offer of deeper collaboration--was so warmly welcomed by BPSA that BPOG will be arranging a series of public telecoms during Q3 to further socialize their expectation with a wider range of supplier staff in the hope that this lubricates future collaboration efforts. Over the coming year BPOG will be looking to work with BPSA to close many of the aspects of this GMP expectations gap, including working on change notification and supporting and commenting on the BPSA positions on Particulate and Integrity Testing. The details of these collaborations are yet to be worked out, but the intent is clear for end users and suppliers to engage widely via these two organizations.

BPSA

Reported by Jerry Martin & Kevin Ott

BPSA has issued two key documents at their July International Single-Use Summit in Washington, D.C.:

"Recommendations for Testing, Evaluation, and Control of Particulates in Single-Use Process Equipment

This document was painstakingly created over a period of nine months—by Subject Matter Experts from both the supplier and end user sides of the bioprocess industry—in order to meet a need. This informative document not only helps readers to characterize and quantify types and levels of particles in single-use systems and components, but it also recommends procedures for minimizing these types and levels. In addition, the document offers a look ahead to the future and what the industry should expect by way of improvements in particle control in order to protect the health and safety of pharmaceutical patients.

Consensus Quality Agreement Template for Single-Use Biopharmaceutical Manufacturing Products

This Quality Agreement Template is intended to give an example of a common structure and to facilitate a dialog between Suppliers and End Users for Quality Agreements. Such dialog will reveal the specific needs of the end user and the many attributes of the quality system and operating mechanisms of the supplier, which in turn will provide the content for the final Quality Agreement between the two parties. More details on the BPSA International Single-Use Summit will be covered the next edition of *Single-Use News Letters.*

ELSIE

There is no update at this time.

PDA

Reported by Bob Repetto and Duncan Low

The PDA Single-Use Practices and Recommendations Technical Report is progressing through its approvals. Final comments are being addressed. Its final approval is close and publication should take place the near future.

PQRI

There is no update at this time.

USP

There is no update at this time.

UPCOMING SINGLE-USE MEETINGS

IBC BioProcess International Conference – BOSTON, MA
October 20-23, 2014
Town Hall Forum: Standardization of Single-Use Systems: What is the Next Step for the Industry?
www.ibclifesciences.com/BPI/overview.xml

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 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 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.).

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.