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

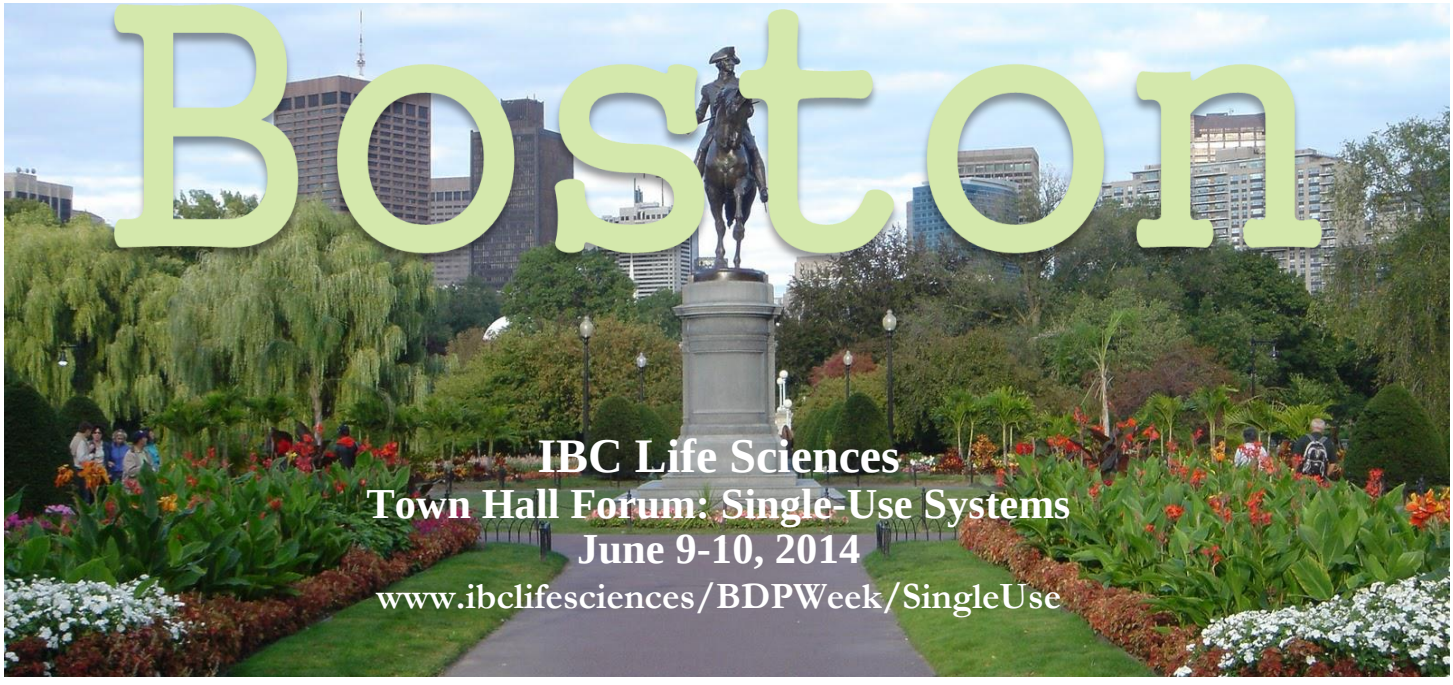
May 2014

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.]

Last month, Single-Use Town Hall Forums took place at two large venues. Both were met with great energy and enthusiasm. The first was held at INTERPHEX (International Pharmaceutical Expo) in New York City. The second was in San Diego at IBC Life Sciences BDP Week Event. Attendance was very good at both town hall meetings. San Diego's crowd took part in an especially lively discussion which was even contentious at times! As predicted, the topic of Single-Use brings out a lot of debate amongst all interested and involved parties. Please join us as the conversation turns to particulate at the IBC Life Sciences Town Hall on June 10th in Boston, MA.□



ORGANIZATION UPDATES

ASME-BPE

Reported by Mike Zumbrum and Jay Ankers

The 2014 BPE Standard is on schedule to be published at the end of Q3. All voting has been completed. The next meeting will take place in New Orleans on May19-22, 2014. During this meeting many ASME-BPE Task Groups are scheduled to discuss topics which include Particulates, Shelf Life, Change Control, Polymeric Unions and Extractables and Leachables. Our fall meeting will take place in Seattle, WA on October 6-9th. Please visit the website for details.

ASTM

Reported by Bob Steininger

ASTM has collaborated with BPOG and various suppliers and end-users on a paper regarding suggestions on Change Control. This is due to be published soon. The E55 workshop will take place in Boston on Mary 20-22nd. This workshop will focus on how standards might be helpful as they relate to Single-Use. ASTM is currently seeking more end-user representatives for these discussions. Please visit the website for more details.

BPOG

Reported by Duncan Low & Bob Repetto

BPOG and BPSA have conducted several face-to-face meetings on the topic of Single-Use as recently as March of 2014. BPOG is currently awaiting feedback from BPSA on extractables. An agreement is expected very soon. A recent Raw Materials team meeting also took place which focused mainly on Single-Use components. A conscious effort is being made not to duplicate the efforts of these two teams.

BPSA

Reported by Jerry Martin & Kevin Ott

Several documents are currently in review, two of which are expected to be completed soon and available to the public at the BPSA International Single-Use Summit this coming July 9-11th. The first focuses on the topic of particulates in single-use process equipment. The second is the Quality Agreement Template. A third document is a revision of Component Quality Test Reference Matrices. This is now being updated to include the addition of new sections as well as current topics such as filters, tubing, connectors and bags. Regarding the BPOG/BPSA negotiations on a joint extractables proposal, BPSA committed to providing BPOG a revised BPSA-endorsed proposal by the end of April.

ELSIE

Reported by Megan Cahill

ELSIE continues to populate the Safety Information Database with safety information on extractables and leachables compounds. Additionally, ELSIE has prepared three papers on evaluation of results from a controlled extraction study Pilot Program. These papers are expected to be published shortly.

PDA

Reported by Bob Repetto and Duncan Low

Review is ongoing for a technical report describing current single-use practices and recommendations. This project contains input from the end-users', the suppliers' and regulators' perspectives. So far the feedback has been good from a scientific advisory board as well as from the FDA. Some rework is necessary to reflect comments and feedback. A target publication date for this project will be late spring/early summer of this year.

PQRI

Reported by Diane Paskiet

Collaborative activities of PQRI participants from industry, academia and government regulatory agencies have resulted in recommendations for threshold and best demonstrated practices for leachables in orally inhaled and nasal drug products. This guidance has provided manufactures a high level strategic process to assess and qualify the safety of extractables and leachables. In 2009, a work plan was approved for extrapolating these same concepts for Parenteral and Ophthalmic Drug Products (PODP) with considerations of factors i.e. dose, duration, patient population, materials and product characteristics of PODP. The scope of the PODP project includes evaluation of materials commonly found in prefilled syringe systems, small and large volume parenterals, and ophthalmic/blow fill seal containers. These same principles of good science can also be translated to disposable systems in the absence of defined and specific regulatory guidance. Chemists and toxicologists are currently concluding research to propose methodology. The recommendations document is planned for 2015.

USP

Reported by Jerry Martin

Final container closure for extractables and leachables is currently in review. The Manufacturing Process Equipment discussion has been tabled pending further negotiations between BPSA and BPOG.

UPCOMING SINGLE-USE MEETINGS

IBC LIFE SCIENCES – BOSTON, MA
Town Hall Forum: Single-Use Systems
June 9-10, 2014
www.ibclifesciences/BDPWeek/SingleUse

BPSA – WASHINGTON, DC
International Single-Use Summit
July 9-11, 2014
www.bpsalliance.org

IBC LIFE SCIENCES – BOSTON, MA
Town Hall Forum: Single-Use Systems
October 20-23, 2014
www.ibclifesciences.com/BPI/overview.xml

REGISTRATION is now open for all of these 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 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.