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

August 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), **DECHEMA** (Gesellschaft für Chemische Technik und Biotechnologie/Society for Chemical Engineering and Biotechnology), **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]

DECHEMA JOINS SINGLE-USE NEWS L-E-T-T-E-R-S EFFORT!

Based in Germany, DECHEMA (*Gesellschaft für Chemische Technik und Biotechnologie/Society for Chemical Engineering and Biotechnology*) is a non-profit network comprised of professional experts in the fields of chemical engineering and biotechnology. Their highly-regarded organization--representing science, industry, politics and the general public--has become the newest lettered organization to join our newsletter group.

The DECHEMA working group "Single-Use-Technology in Biopharmaceutical Manufacturing", which was founded 5 years ago, has reviewed all activities in the field of single-use technology (SUT) in research, manufacturing and application. The result was a position paper about the international scientific and technical state of knowledge, which was published in 2011[1]. The working group, whose leaders are Prof. Dr. Dieter Eibl (Zurich University of Applied Sciences) and PD Dr. Dethardt Müller (Rentschler Biotechnologie GmbH), currently has 85 members. The members are developers and manufacturers of single-use systems as well as appliers from both industry and academia. The prior aim of the working group is the further development and increasing establishment of SUT in German-speaking countries.

In addition to the knowledge exchange (2 meetings per year and monthly telephone conferences), the activities of the members of the working group have focused on: leachable studies[2], bioengineering characterization of single-use bioreactors[3] and a risk analysis for implementation of single-use bioreactors into production processes[4]. Moreover, a mini encyclopedia containing SUT terms and definitions was written together with the platform "Single-Use Technology" of the Swiss Biotechnet[5]. Current and future activities cover the topics: single-use bioreactors for microorganisms, design of single-use facilities, SUT for the development and production of cell therapeutics, and single-use sensors and measurement technique.

References:

1. Eibl D, Eibl R, Köhler P (2012) Report of the Temporary Working Group, Single-use Technology in Biopharmaceutical Production". DECHEMA, Frankfurt am Main (Download: www.dechema.de/Single_Use_Technologie; www.dechema.de/en/posis-path).
2. Eibl R, Steiger N, Fritz C, Eisenkrätzer D, Bär J, Müller D, Eibl D (2014) Recommendation for Leachables Studies: Standardized Cell Culture Test for the Early Identification of Critical Films. DECHEMA, Frankfurt am Main, ISBN: 978-3-89746-149-9. (Download: www.dechema.de/Single_Use_Technologie; www.dechema.de/en/posis-path).
3. Meusel W, Löffelholz C, Husemann U, Dreher T, Greller G, Kauling J, Bauer I, Eibl D, Kleebank S, Kraume M, Pörtner R (2015) Recommendation for the Engineering Characterization of Single-use Bioreactors and Mixing Systems with Experimental methods. DECHEMA, Frankfurt am Main (submitted).
4. Merseburger T, Pahl I, Müller D, Tanner M (2015) Recommendation for a risk analysis for production processes with disposable bioreactors. DECHEMA, Frankfurt am Main (submitted).
5. Badertscher B, Eibl R, Eibl D (2015) Single-Use (Disposable) Technologie von A-Z (German version in press, English version in preparation).

For more information on DECHEMA please visit them at http://www.dechema.de/en/ □

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SINGLE-USE ALIGNMENT UPDATES

EXTRACTABLES

ASTM is moving closer to an Extractables Standard with the help of the Group of 9. A draft has been sent to **BPOG** and **BPSA** and posted on the ASTM workspace for pre-ballot comments. The next step will be determined following receipt of full **BPOG** and **BPSA** feedback and review of comments on the **ASTM** workspace. Further discussions will take place at the upcoming Rockville, MD meeting. An **ASME-BPE** ballot has been approved by the PM Subcommittee and been sent to the Main Committee. The current proposal being balloted for is (a) bringing up to date the current E&L section, (b) defining two types of extractables studies (material-specific and with bioprocess model solutions); and (c) a flowchart in the non-mandatory content of the Standard assisting the evaluation of bioprocess equipment/components, related to extractables and leachables characterization. **ELSIE** is exploring the possibility of hosting a workshop, and additional ways of working together with other groups, such as **BPOG**, on extractables toxocology assessments.

PARTICULATES

A new section is ready for the **ASME-BPE** 2016 Standard on mitigation technique as well as controls both suppliers and end-user can put into place to minimize particulates. There is also a small amount of content for the non-mandatory section on characterization and a few reference standards to refer to for acceptance criteria. More information will be added in the future; the task group is currently anticipating **ASTM**'s work on this before they continue to add to this section.

CHANGE MANAGEMENT

For a second time, **ASME-BPE** is balloting a proposal to the Standards Committee for a new section in the 2016 edition. This ballot has already been approved at the Subcommittee level and has gone to the Main Committee. It is a good start on this very necessary subject, listing examples of significant changes, requiring notification of significant changes, and starting with a recommendation of six months notification for planned changes. Continuing to build on this section will be a priority at the fall **ASME-BPE** meeting. A draft article from the **BPSA/BPOG** team on Change Notification has been submitted to BioProcess International ahead of their upcoming Conference & Exhibition in Boston. More discussions on that article will take place at that October meeting

SYSTEM INTEGRITY

A new **ASME-BPE** task group focusing on integrity of SU systems, primarily leak testing, test methods, etc. has been established. Teleconferences with this task group's members are ongoing and they hope to have an outline and some content by the fall meeting.

CONNECTORS

ASME-BPE's Polymeric Hygienic Unions Task Group has a very informative section in the 2014 standard, including some standardized dimensions, and discussions are ongoing regarding tolerances. They are doing some machining and collecting data over the summer to see what sizes work/fail and will have an update for the next **ASME-BPE** meeting in the fall.

SUT DESIGN VERIFICATION

A **BPOG** team is working on establishing Standard User Requirements.

SUT GENERAL

A new section on **ASME-BPE** requirements for filtration elements and components is ready for PM 2016. They are also working on a helpful guide/journal that would be peer-reviewed by BPE members but would be a separate supplement. This will be discussed more in the fall's meeting. A new **ASME-BPE** task group is now focusing on flexible thermoplastic elastomer tube welding (performance, qualification, inspection, weld procedure and acceptance criteria). The group is expected to have new content to review by the fall's meeting. Lastly, a proposal went to Subcommittee ballot for improving their table of requirements to be on the COC for various components. They are trying to organize the columns, separating SU assemblies versus individual components, amongst other small improvements. More improvements will be forthcoming this fall.

OTHER ACTIVITIES – EDUCATION/INFORMATION JOURNALS

BPSA joined with BPI (Bio-Process International) to conduct a significant survey of End Users regarding Single-Use. This joint **BPSA/BPI** survey, administered to a targeted User audience, was comprised of 38 well-honed questions covering industry concerns, needs, uses, and adoption rates. Data from the results of this survey were presented at the BPSA International Single-Use Summit on July 15. **BPSA** will post a survey result summary on their website after Labor Day.

BPSA has also posted the new *Single-Use Manufacturing Component Quality Test Matrices* document on its Members website for review and comment. Members are invited to recommend edits and/or changes. Comments will be considered on a case-by-case basis for potential inclusion in the Matrices document updates. This document will be made publically available on or before October 1. □

A SUMMARY OF CURRENT SUT ACTIVITIES

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

DECHEMA (Gesellschaft für Chemische Technik und Biotechnologie/Society for Chemical Engineering and Biotechnology) www.dechema.de/en/
DECHEMA is the expert network for chemical engineering and biotechnology in Germany. As a non-profit professional society we represent these fields in science, industry, politics and the general public. DECHEMA promotes scientific and technical exchange among experts from different disciplines, organisations and generations. We consolidate the know-how of over 5,800 individual and sustaining members.

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
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 2015-2016 MEETINGS & EVENTS

2015 MEETINGS

ASME-BPE – SCOTTSDALE, AZ
September 21-24, 2015
http://calendar.asme.org/EventDetail.cfm?EventID=31177

ASTM E55 MEETING – ROCKVILLE, MD
September 30-October 1, 2015
http://www.astm.org/MEETINGS/

ECI SUT Conference – LEESBURG, VA
www.engconf.org/15aj
October 18-21 2015

BIOPROCESS INTERNATIONAL – BOSTON, MA
Conference & Exhibition
October 26-29, 2015 **[REGISTRATION OPEN]**
http://www.ibclifesciences.com/BPI/overview.xml

ISPE – PHILADELPHIA, PA
November 8-11, 2015
Annual Meeting
www.ispe.org/annualmeeting

2016 MEETINGS

BPSA International SU Summit – WASHINGTON, D.C.
July 11-13, 2016

DECHEMA Conference
September 5-7, 2016

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