DISPOSABLE solutions

# Single Use Systems Industry Guidance Activity Update


Pharma iQ
a division of IQPC


The disposable solutions for bio-manufacturing market has received praise by some for its levels of innovation. Also, the market is known for being made up of many industry bodies.

There is a level of collaboration between some of these industry bodies as they join forces to tackle and address certain problem areas within the industry.

Unsurprisingly, it can be a challenge for the industry to keep pace with all of these entities and the best practices that they are putting forward. In response to this, Pharma IQ has created this snapshot guide to a selection of bodies active within the single-use-systems market to provide insight into their achievements over the past year and potential updates to keep an eye out for.

## The Line up

# USP - United States Pharmacopeia Convention

*Established in 1820, the USP is a scientific, independent, volunteer-driven, nonprofit organization.*

## Known for:

• Its strong relationship with the FDA: Working closely with FDA and predecessors for more than 100 years, developing and revising drug quality standards enforceable by FDA. The USP Standards have been recognized in the Federal Food, Drug and Cosmetic (FD&C) Act since it was first enacted in 1938.
• Legally recognized in 39+ countries and Standards used in 140+ countries
• Facilities in India, China, and Brazil
• Translated into Chinese and Spanish

## USP General Chapters

• Standards Numbered <1> to <999>
• Contain tests and specifications
• These chapters are enforceable by the FDA

## USP General Information Chapters

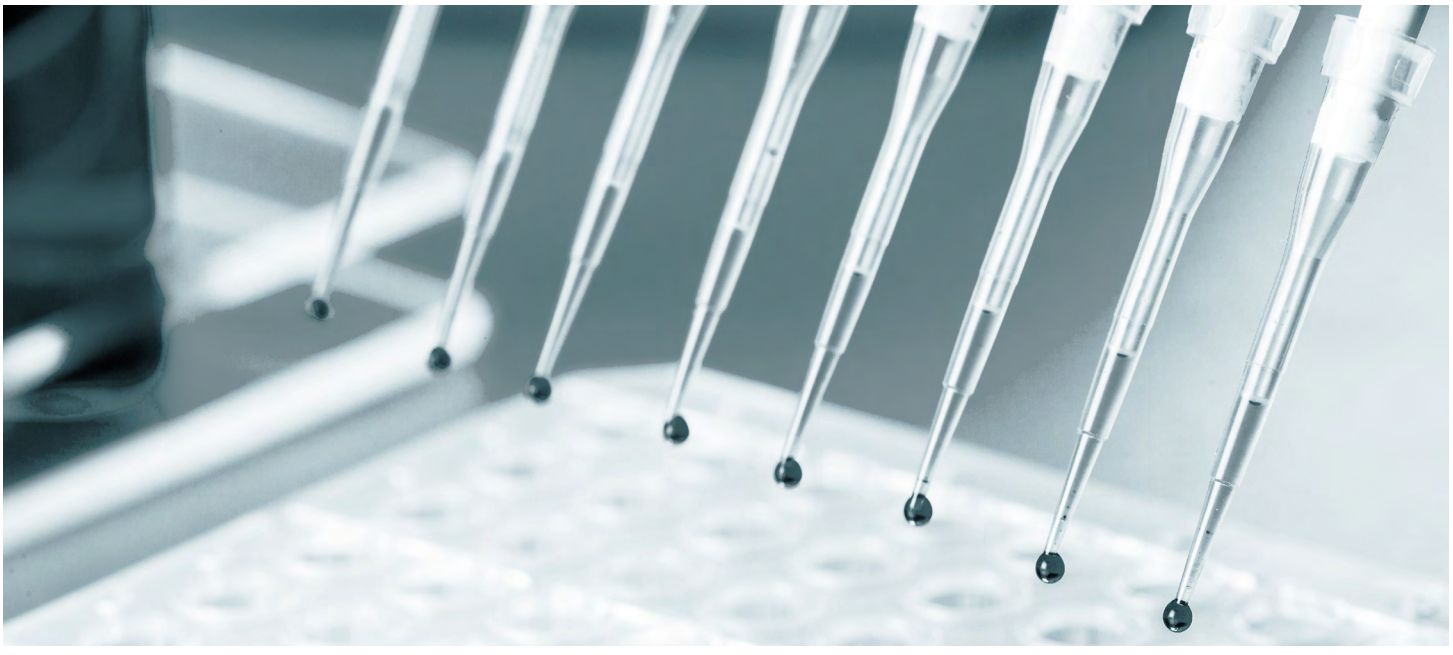
• Standards Numbered <1000> to <1999>
• Provide information; they contain no standards, tests, assays, nor mandatory specifications. These chapters provide additional guidance on the interpretation and use of the General Chapters.

## Recent Projects

• The USP Packaging and Distribution Expert Committee (PD EC) is responsible for packaging chapters covering glass, plastic and elastomeric components, packaging systems and manufacturing components.

• A new chapter <661.3> Plastic Components and Systems Used in Pharmaceutical Manufacturing was published for public comment in the Pharmacopeial Forum (PF - USP's official publication) on May 1, 2016 together with an accompanying general information chapter <1661>.

• Comments were received including a recommendation to place this topic in a separate chapter from the <661> series which covered packaging components. During the current revision the chapter is renumbered as <665> with the accompanying revised general information chapter becoming <1665>. The new chapters are due for publication in the PF on May



1, 2017.

## Collaborations

• Both BPSA and BPOG have produced white papers and guidances before the USP chapter was drafted. The USP took this into account by having members of both BPSA and BPOG on the Expert Panel that drafted <661.3> and now is drafting <665>. It is important to point out that the scope of the <665> is wider than those in BPSA and BPOG guidances which are aimed at the use of SUS in the manufacture of biopharmaceuticals. Chapter <661.3> (<665>) covers pharmaceutical and biopharmaceutical manufacturing using both SUS and MUS systems.

**Website is accessible here.**

## BPSA – Bio-Process Systems Alliance

Formed in 2005 this is an industry led trade association focused on supporting and encouraging the ascent of single use systems in biomanufacturing.

**Known for:** Patrick Evrard, end-user representative and BPSA Director, explained that the BPSA is "One of the interest groups trying to generate guidance documents on Single-use Systems, because until now generally what is done is extrapolating from regulation or guidance documents applicable to primary packaging components and final containers, and translate these for Single-use Systems. For me, BPSA has been, in the last ten years, the most active group issuing guidance documents directly applicable to Single-use Systems."

**Recent Projects**

**•Change Notification**
BPSA is collaborating with BPOG to publish a proposed practice that will align suppliers and customers in the management of supplier change notifications, so as to reduce wasted time and resources and lead to more effective change management.[1]

**•Integrity**
BPSA is close to finishing a Technical Guide that collates the organization's understanding of the technical issues and current approaches to demonstrating systems integrity.

**•Supply Chain**
BPSA is collaborating with BPOG to develop a single use user requirements paper that can be used by users and suppliers alike to align expectations on single-use system design and quality attributes.

**Updates ahead** : Patrick Evrard confirmed that BPSA intent is to continue working on technical guidance documents helping people to apply state-of-the-art approaches for the Single-use industry. "I want to push within BPSA to include more next steps and future perspectives, to shape more what should be the state of the art in the next five years. That's my ambition for BPSA so that they not only cover current state of the art but also move more to a proactive and visionary role."

## BPOG – BioPhorum Operations Group

Established in 2008 – BPOG is a collaborative network. BPOG which shares best practises to further the biotechnology space. There are over 1200 active participants.

**Known for:** BPOG produced the extractables protocol which produced a standardised way of testing single-use systems for manufacturing bio-pharmaceuticals.

The extractables protocol is endorsed by a large number of companies within the BPOG extractables and leachables work group. These firms are applying this as their standard user requirements for bringing in new single-use systems to their

various sites and product manufacturing activities.

> “
>
> My personal view is that the vendors who quickly become good at providing that information up front are the ones that customers will gravitate towards”
>
> *Aidan Sexton at BPOG*

## Recent Projects

**•The road to alignment**
It was noted in a recent newsletter, that at an industry conference this year BPOG produced a five year plan to 2020 giving a timeline of areas that need to be addressed to align SUT standards, best practices as well as enhanced supply chain transparency. The BioProcess Institute newsletter stated: “The fact that some still consider leachables and extractables interchangeable terms is a blatant example of why a milestone timeline like this is such a valuable and necessary tool.”[1]

## Collaborations BPOG

collaborated with BPSA in regards to joint projects

looking at standard change notification forms and a universal template for user requirements.

### A word from Aidan Sexton of Janssen Biologics, who sits on the BPOG Extractables and Leachables Team

*On the topic of information being supplied by vendors up front as a standard:*

“The standardised extraction data should be supplied up front by the vendor to allow us to perform our leachables risk assessments, and to make our patient safety determinations. We feel very strongly that the extractables data information should be freely available. If we wanted to look at getting a single use item (for example a filter, or a bag assembly) we would go to the vendor website, look at that standardised extraction data as per the BPOG protocol requirements and make our component selection based on that data package.

“Based on the standardised data package we would then be clearly able to identify where we need to do further (leachable) studies, to show that the selected materials are safe to use, from a patient safety perspective. The more

information the vendors can provide up front the better. The availability of these data is now a standard requirement for Janssen Biologics.

"My personal view is that the vendors who quickly become good at providing that information up front are the ones that customers will gravitate towards, rather than those vendors that we (the biopharmaceutical manufacturers) find it difficult to get information from."

## Website is accessible here.

## ASME – American Society of Mechanical Engineers

Founded in 1880, the ASME BPE is a volunteer consensus standards writing organisation.

**Known for:** Rather than guidelines or best practices, ASME drives requirements for BioProcess Equipment. This covers systems made of both stainless and polymers as well as multi-use and single-use applications. The Polymer Materials group is comprised of about 25 voting members and about an additional 50 "interested" individuals that attend meetings which occur three times a year. The topics being addressed in the Polymer Materials group include Polymeric Hygienic Unions, Single-use connections, Single-use tube welds, Single use System Integrity, Change Management, E&L and Particulates in Single Use Systems. The entire ASME organisation's standards committees consist of more than 5,500 subject matter experts from around the world, including engineers, designers, manufacturers, users, inspectors and representatives of regulatory agencies.

The ASME BPE standard focuses on designing and building equipment and systems used in biopharmaceutical manufacturing. It covers best practises to advance product purity and safety.

**Recent Projects** The ASME standard is going through a continuous process of review and revisions. A new version is published every two years. ASME members are said to contribute to the progression of around 500 standards.

**Collaborations** The Chair of the ASME Polymer Materials Subcommittee group - Mike Johnson highlighted that he is in frequent contact with the respective leaders of ASTM, BPOG, BPSA and SUTAP on critical industry topics.

For example ASME is currently working with the BPSA to align requirements set forth in the ASME BPE standard with guidelines established by BPSA [1]

**Updates ahead**

The newest edition of the ASME standard is stated for release this monthBPE Standard was released in November 2016.

Work has begun on the 2018 edition with a significant focus on Single-Use products and systems.

# SUTAP

## Known for:

Created in late 2014, this non-for-profit organisation is focused on driving the biopharmaceutical industry in participating in the creation of ASTM standards to assist both suppliers and end users operating with disposables solutions for biomanufacturing.

SUTAP has developed a workflow of five distinct steps supporting consensus standard preparation and maintenance:

(1) SUTAP is capturing input form industry (suppliers, end-users, NRAs, associations);

(2) SUTAP is preparing draft consensus documents according to the ASTM rules;

(3) SUTAP interacts, captures, and consolidates feedback from members in an iterative process;

(4) SUTAP becomes the 'owner' of the documents, initiates and shepherds them through the ASTM iterative balloting process until publication; and

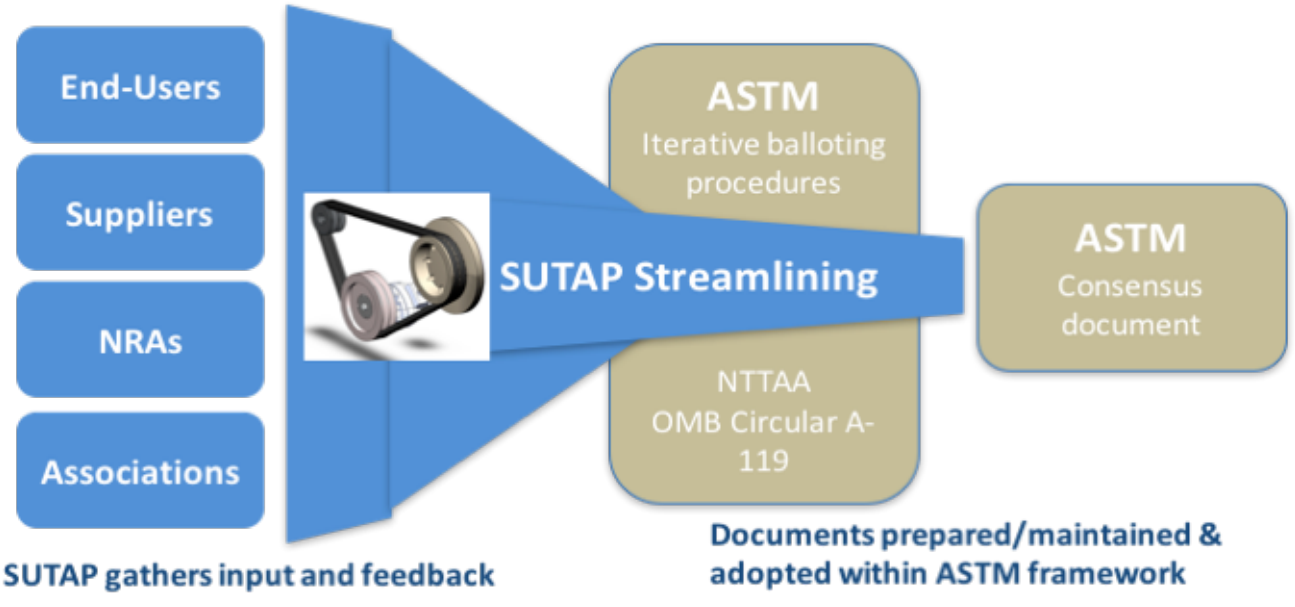
(5) SUTAP updates approved ASTM consensus documents as required to be compliant with regulatory evolution, introduction of new technologies, and understanding, respectively.

Its membership base also includes that of 3rd party laboratories, healthcare organizations and regulatory bodies. The group is focusing on consensus based standard documents in three areas – single use technology, change control management and fill and finish.

## Collaborations

The body has reviewed the working documents of ASTM standards. For instance, Leachables for Endusers, Particulate Burden for Endusers, Particulate Burden for Endusers, Integrity Testing for Suppliers, Controlling Integrity for End-users. SUTAP has also participated in reviewing of the ISPE guide.

## Website is accessible here.



**Resources**

1. http://bioprocessinstitute.com/wordpress/wp-content/uploads/2016/09/Revised-SUS-Newsletter_SEP-2016_Issue-13_160726.pdf
2. http://bioprocessinstitute.com/wordpress/wp-content/uploads/2016/05/SUS-Newsletter_MAY-2016_Issue_160523-1.pdf
3. http://bioprocessinstitute.com/wordpress/wp-content/uploads/2016/04/SUS-Newsletter_MAR-2016_Issue-10.pdf
4. https://www.asme.org/products/codes-standards/bpe-2016-bioprocessing-equipment
5. http://dechema.de/%C3%9Cber+DECHEMA.html
6. https://www.asme.org/about-asme/news/asme-news/notice-of-disciplinary-action
7. https://www.asme.org/about-asme/news/asme-news/new-efests-highlight-fun-excitement