

## The BioProcess Systems Alliance

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Single-use bioprocessing has truly come of age. The savings in time, labor, capital, and resources are clearly recognized within the biopharmaceutical industry. Acceptance of the benefits of single-use systems is evidenced by the highly successful disposables sessions at recent IBC conferences, this supplement series from *BioProcess International*, and the first single-topic conference on single-use technology, to be held 5-7 June 2006 in La Jolla, CA.

In response to the growing demand for single-use systems in biotech manufacturing and related challenges for the emerging single-use bioprocessing industry, the leading providers of single-use products and services have formed an industry organization: the Bio-Process Systems Alliance (BPSA).

"The BPSA was organized to meet the challenges of the emerging single-use bioprocessing industry," said Chris Rombach of Stedim, a BPSA spokesperson. "There is a great need to educate, standardize, and develop guidelines that safeguard the quality of drugs produced using this technology."

The mission of BPSA is to globally promote confidence in application of single-use products in the biotech and pharmaceutical manufacturing industries. The organization aims to achieve this mission through the following goals:

- Facilitate adoption of single-use components and systems
- Establish guidelines and standards
- Provide educational leadership to customers, colleagues, and regulatory bodies.



PHOTO COURTESY OF BPSA

"I believe that the most important benefit will be the creation of the standards and guidelines that will help to facilitate the selection, use, and disposal of single-use products," explained Rombach. "We want to show that there are basic specifications for the products that need to be met, and this is where the customers need to focus on making their selection." The first introduction of the work being done will be presented at IBC's Disposables for Biopharmaceutical Manufacturing conference in June.

### NEED FOR STANDARDS

"What became clear to us is that standards needed to be established, and the disposables industry wanted to be certain that we were the ones that created these rather than allowing someone else to do it," said Rombach. ASME and ISPE were starting to

look at creating some standards, and disposables manufacturers saw the need to demonstrate leadership around those. "It's a matter of us using our collective leadership and strengths for the industry."

This alliance was formed under The Society of the Plastics Industry, Inc. to give greater visibility and a united voice in promoting the benefits of single-use manufacturing. "SPI will give us the help we need to develop appropriate codes and standards, as well as provide expertise in legal and regulatory issues, marketing, and promotion," said Rombach.

SPI is the umbrella organization providing a unified voice for the diverse plastics industry. According to president, William Cardeaux, SPI calls that diversity its strength. "The prospects for single-use growth are enormous," Cardeaux said. "They are at the cutting edge of one of the fastest growing industries in the world. This is a win-win situation for SPI and for the Alliance."

Another sign of the dynamic state of single-use bioprocessing is the rate of growth of this nascent organization. The BPSA, which held its first meeting less than a year ago with just five participants, is now 25 companies strong and growing. The member companies represent all aspects of single-use technology, ranging from manufacturers of plastic films, bioprocess containers, bioreactors, and filters to fittings and connection devices.

"I think the biggest challenge in this young disposables industry will be trying to establish standards while maintaining the flexibility and

## BPSA MEMBERS

Advanced Scientifics  
Alfa Laval  
Applikon  
Arkema  
ATMI  
Baxter Healthcare  
Charter Medical, Ltd.  
Colder Products Company  
Consolidated Polymer Technologies Inc.  
Crane Process Flow Technologies Ltd.  
Dow Corning  
DuPont Fluoropolymer Solutions  
HyClone  
Invitrogen  
J & J Scientific  
Millipore Corporation  
Mitos  
Nalge Nunc  
Pall Life Sciences  
SAFC Biosciences  
Saint Gobain Performance Plastics  
Sartorius  
SciLog  
Stedim  
TC-Tech  
Value Plastics, Inc.  
Wave Biotech, LLC  
Xcellerex

### Web Sites

[www.bpsalliance.org](http://www.bpsalliance.org)  
[www.plasticindustry.org](http://www.plasticindustry.org)

creativity of the product development and supply,” said Rombach. “We all started in this going somewhat in our own direction, and so now trying to bring us back collectively to a more unified presentation of products is going to be the most difficult thing.” Rombach also emphasized the need to maintain the flexibility that disposables bring, and finding the right balance is going to be the biggest challenge.

“The biopharmaceutical industry is reluctant to change. Until the recent past, single-use systems lacked the functionality needed to globally replace stainless steel technology. Because of that, in many cases single-use technology wasn’t even considered,” said Rombach. “However, as more single-use systems become available, we’re confident that the

adoption of the technology will continue to gain momentum. That’s because these products are addressing so many of the issues the customers are facing: the need for reducing cost and adding flexibility and speed.”

### LEADING THROUGH EXPERIENCE

The organization brings together diverse knowledge necessary for integration of successful single-use bioprocess systems. This provides a comprehensive understanding for development, implementation, validation, and operation of single-use bioprocesses. The BPSA also provides a forum for development of compatible technologies and standards to facilitate the use of disposables for pharmaceutical manufacturing.

The elected officers of the BPSA include chairman Rick Sullivan of HyClone, a business unit of Fisher Biosciences; vice-chair Lisa Krallis-Nixon of Charter Medical; secretary-treasurer Ken Bibbo of Alfa Laval; and director-at-large Don Jahn of Dow Corning.

The BPSA is organized into three committees that reflect its initial points of emphasis: Chris Rombach of Stedim is chair of the committee on identity and marketing. Roberta Landon of Millipore Corporation chairs the education committee. Tom Murphy of TC-Tech and Dave Bacehowski of HyClone are cochairs of the committee on guidelines and standards.

“The primary goal is to elevate the level of excellence across the industry,” said Rombach. “I think that any company involved in disposables manufacturing will become a BPSA member if they’re not already.”

### GROWING MEMBERSHIP

Although the BPSA is relatively new and growing quickly, the organization is built on the decades of industry experience of its members. The most recent meeting, held 7 February 2006 in Tampa, included 36 participants from 25 companies.

“We started with our first meeting last summer, with only three or four of us at Chicago O’Hare Airport, and the last meeting we had we had nearly

40 people,” said Rombach. “It’s been surprising to us, those of us who were the original founding members, to see the level of excitement and the rapid adoption of people becoming members. That has really impressed all of us.”

The guidelines and standards committee, the largest group in the organization, has quickly coalesced into a highly efficient working group. At the recent meeting in Tampa, the committee members made significant progress framing the parameters by which standards and guidelines will be established.

The education committee is engaged in packaging the information produced by the guidelines and standards committee. The identity and marketing committee is responsible for “getting the word out” to the biopharmaceutical industry. This group initially focused on establishing an identity for the organization and the infrastructure for delivering the alliance’s messages. The BPSA has established a website ([www.bpsalliance.org](http://www.bpsalliance.org)) as a primary channel of communication.

*BioProcess International* has offered to publish BPSA’s proceedings and guidelines.

“*BioProcess International* magazine is eager to support the BPSA in its mission to promote the application of single-use products in the biotech and pharmaceutical manufacturing industry,” said Stephanie Shaffer, associate publisher of *BioProcess International*.

*BioProcess International* has a clear history of leadership in chronicling the advances in single-use technology through its popular annual disposables supplements. “The magazine is excited to participate in advancing the state of the art of single-use technology through the publication of BPSA planned guidelines and standards,” added Shaffer. 🌐

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