



## Industry Interest Groups

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### What is the BPSA? Is Pall Biotech Involved with the BPSA?

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The Bio-Process Systems Alliance, or BPSA, is the only industry interest group which focuses solely on single-use technologies and is open both to end users and suppliers. Pall Biotech has been supporting the BPSA since its inception in 2005. Dr H el ene Pora, Vice President for Technical Communication & Regulatory Strategy at Pall Biotech, is a member of the board.

BPSA is an international, industry-led non-profit group whose aim is to encourage and advance the adoption and implementation of single-use manufacturing systems worldwide. This is achieved through education, best practice sharing, development of consensus guidelines, and business-to-business networking opportunities.

Issue specific committees are created to educate and inform stakeholders through publication of white papers, guidance documents, and presentations. Amongst these, the most noteworthy are:

- **BPSA Sustainability Council** → provides member stakeholders with information about the environmental impact of single-use technology and to take actions to show the importance of sustainability to the BPSA. The team's programs include member tours of waste management sites, an active social media presence, an up-to-date listing of single-use systems (SUS) studies, and existing recycling/reuse programs.
- **BPSA Cell and Gene Therapy (CGT) Committee** → provides guidance to the CGT market on lessons learned from adopting single-use technologies in bioprocessing of proteins and mAbs and their applications.
- **BPSA Integrity Testing Task Force Committee** → addresses the issues of enhancing the assurance of integrity of single-use systems (SUS) and SUS leak integrity testing.

- **Transit Testing** Committee → provides suppliers and biomanufacturers with an approach to packaging transit qualification based on both real and laboratory simulations according to requirements of international standards and industry practice.

Results of the work from these issue specific committees is published in key collaborative papers and can be found on the BPSA website ([www.bpsalliance.org](http://www.bpsalliance.org)). Of these publications Pall Biotech was a significant contributor to the following: "*Design, Control and Monitoring of Single-Use Systems for Integrity Assurance*" and "*The Role of Single-Use Polymeric Solutions in Enabling Cell and Gene Therapy Production*".

The BPSA's success, and need, in Europe has led to expanding its geographical outreach and taking a more pro-active role in Europe. The BPSA European Advisory Council (EAC) has recently been created under the leadership of Dr Stephen Brown (Executive Director at Naobios) and Hélène Pora (Vice President for Technical Communication & Regulatory Strategy at Pall Biotech).

BPSA also cooperates with other organizations to drive improvements around the use of single-use technologies. A good example is the white paper generated with BioPhorum Operations Group (BPOG) to address change notification issues: "*An Industry Proposal for Change Notification Practices for Single-Use Biomanufacturing Systems*". And the collaborative work with BPOG to develop industry-wide harmonization between suppliers and end users by creating a consistent and complete technical package that includes a quality audit guide and internal/external quality release.



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