



Bio-Process Systems Alliance

*Advancing Single-Use Worldwide*

**1<sup>st</sup> Annual BPSA Business Roundtable:  
“Identifying and Overcoming Hurdles to the Implementation of Single Use”**

**June 1, 2008 BPSA Meeting Summary**

53 individuals representing 22 member companies and including 5 end-user guests met at the Hilton San Diego hotel on a beautiful Sunday afternoon, June 1 for the **BPSA Business Round Table** discussion focused on “*Overcoming the Hurdles to the Implementation of Single-Use.*”

**Kevin Ott**, BPSA Executive Director, kicked off the meeting with a review of the day’s objectives and a reminder of the antitrust regulations which apply to BPSA/SPI proceedings, as printed on the agendas.

**Chairman’s Welcome**

BPSA Chairman **Rick Sullivan** welcomed the membership and reviewed BPSA’s mission: to facilitate the use of Single-Use materials through developing guidelines, providing education to the industry & regulators, and sharing best practices.

**Extractables and Leachables: What are the Major Concerns? What are the Solutions?**

BPSA Technology Committee chair **Jerry Martin** provided an excellent in-depth look at the work currently being conducted by the Extractables & Leachables sub-committee to provide suppliers, end-users, and regulators with practical and specific guidance on applying a risk-based approach to characterizing extractables, leachables, and process contaminants. The committee anticipates publishing its third paper on the topic later this year. Reprints of the initial two papers are at [www.bpsalliance.org](http://www.bpsalliance.org).

**Neutralizing Hurdles to Safe Disposal: A Technical Perspective with Thoughts on Best Practices:**

**John Boehm**, BPSA Education Committee chair, discussed his committee’s efforts to understand and communicate industry best practices regarding disposal of single-use systems after use. A wide range of options exist, ranging from landfilling to recycling to co-generation. The committee’s first published paper on the topic which provides an overview of disposal options can be found at [www.bpsalliance.org](http://www.bpsalliance.org). BPSA members are encouraged to share information they have regarding disposal, including relevant contacts at end-user companies, with John.

**Strategies for Implementation of a New Bioprocess Container in Commercial Biologics**

**Rachael Fitzgerald** of Bristol Myers Squibb in Syracuse, NY presented an excellent review of her company’s experiences with the implementation of BioProcess Containers (BPCs), including an overview of the process BMS uses to qualify new single-use components. Rachael had a number of specific suggestions for producers of single-use components to consider in order to facilitate the adoption of single-use technology. Examples include early involvement by suppliers and providing the right level of validation support & data.

### **The 2008 BPI/BPSA End User Survey: Summary and Perspectives:**

**Brian Caine**, publisher of BioProcess International, reviewed the results of an industry survey conducted by his publication to assess the adoption of single-use components. Detailed results of the survey can be found at [www.bpsalliance.org](http://www.bpsalliance.org). Clearly, the biopharmaceutical industry continues to embrace the use of single-use components and our membership has a lot to gain from this trend.

### **BPSA Committee Chair Reports:**

Following the technical presentations, each program committee leader reviewed highlights of their respective committee's current activities.

Kevin Ott reviewed the current BPSA membership and financial status for Ken Bibbo, BPSA Treasurer. The BPSA organization continues to grow, although member company mergers have had an impact on the membership numbers. Kevin emphasized the need to recruit end-user members.

**Denise DeTomasso**, BPSA Marketing Committee chair, reviewed the Marketing Committee's 2008 objectives and called for individuals who would be interested in working with her on this committee to contact her to discuss potential projects and activities.

Jerry Martin, BPSA Technology Committee chair, reviewed the venues in which the committee either has presented or will present the Extractables and Leachables sub-committee's positions regarding suppliers' and end-users' extractables and leachables responsibilities.

John Boehm, BPSA Education Committee chair, requested membership input to provide best practices and end-user contacts as related to the disposal of used Single-Use systems.

### **Addressing and Acting on Member's Future Needs: What Can BPSA Do For You?**

Kevin Ott, BPSA Executive Director, lead a brainstorming session at the close of the meeting which lead to identification of a number of opportunities for ways BPSA can continue to add value to member companies.

### **Reception and Networking Event**

The meeting adjourned with a reception sponsored by **Charter Medical** and **Pall Corporation** that provided an excellent opportunity to network with other producers of Single-Use systems as well as with representatives of relevant media, and end-users.

### **Fall BPSA Meeting**

Our next BPSA meeting will be held in conjunction with the BioProcess International conference in Anaheim, CA in late September. This will be a meeting you won't want to miss! Contact Kevin Ott, BPSA Executive Director, or visit [www.bpsalliance.org](http://www.bpsalliance.org) for further details regarding our fall meeting or membership in BPSA.

Requests for copies of slides presented at the meeting should be directed to [kott@plasticsindustry.org](mailto:kott@plasticsindustry.org).

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