



Bio-Process Systems Alliance

Advancing Single-Use Worldwide

Press Release

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For Immediate Release

Bio-Processing Trade Group Announces Availability of Industry – Authored Extractables & Leachables Guide

Guidance Document Intended for Users/Suppliers of Single-Use Systems to Assist with Regulatory Expectations, Reduction of Redundant Testing

The Bio-Process Systems Alliance (BPSA), the trade association of the single-use bio-processing industry, today released its 2010-2011 technical guide: ***Recommendations for Testing and Evaluation of Extractables from Single-Use Process Equipment***. The guide is available for order at www.bpsalliance.org.

The 22-page color guide is intended as a “best practices” document, to help suppliers and users of disposable single-use components and systems develop appropriate fluid-specific extractables data that may have applicability in risk-based decisions in bio-process component selections, process validation and regulatory filings.

Extractables evaluation in bio-processing is needed to assess the potential impact of process equipment migrants on process intermediates or finished drug product. The guide includes charts, graphs and decision trees to help users and suppliers initiate and document extractables evaluations that align with FDA Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, and is inclusive of key references and definitions.

The new guide, also known as the “102 Guide” is a compendium of recommendations that builds upon the “101 Guide”, published in 2007, that is available for complimentary download on the BPSA website www.bpsalliance.org.

The new BPSA Extractables Guide was developed by company experts within the BPSA organization, with specialized knowledge of extractables processes and program testing and evaluation. The document is the result of an 18-month commitment by BPSA volunteers to educate and inform end-users and suppliers of the rigorous requirements and hurdles in

undertaking the development of appropriate, documentable extractables and leachables data, and to help users and suppliers minimize duplicative testing.

The Guide can be ordered online at www.bpsalliance.org. It is discounted for BPSA members. Bulk order discounts are also available. For further information, e-mail Kevin Ott, BPSA Executive Director at otk@socma.com, or go to www.bpsalliance.org.

The Bio-Process Systems Alliance (BPSA) was organized in 2005 to encourage and accelerate the adoption and implementation of single-use manufacturing systems through education, sharing of best practices, development of consensus guidelines and business-to-business networking opportunities. BPSA is an Affiliate of SOCMA Visions, and is managed independently as a non-profit industry trade association.