



Bio-Process Systems Alliance

Advancing Single-Use Worldwide

Bio-Process Systems Alliance Releases 2021 Transit Testing Guide

Guide defines roles and responsibilities of suppliers and users of polymeric single-use systems

ARLINGTON, Va., Feb. 18, 2021 /PRNewswire/ -- The [Bio-Process Systems Alliance](https://www.bpsalliance.org) (BPSA), the international association of the single-use bio-processing industry, is pleased to announce the release of its 2021 technical guide: **Transit Testing Guidance for Single-Use Components and Assemblies**.

The safety and performance of single-use bioprocess polymeric equipment, employed to manufacture biologic therapies and vaccines, is based on sterility and integrity and other stringent validation controls.

Delivery of single-use (SU) products requires that equipment be handled both mechanically and manually throughout the entire supply chain, from the point of manufacture to the point of use. In this vein, understanding supply chain hazards related to human error, shock, vibration, heat, compression and atmosphere will help determine the need and approach for in-depth, risk-based transit testing.

As detailed in the guide, a risk assessment may be based on the process step, the type of distribution cycle, historical data, or the nature/scope of a packaging change or new design being implemented. The guide will assist the reader in determining the proper approach, or need for, transit safety testing either in a field or laboratory setting.

The full-color, illustrated guide includes a comprehensive set of terms and definitions, and appendices inclusive of ASTM, FDA, PDA, ISTA, EMA and ISO references, among others.

The 28-page illustrated guidance document represents an 18-month project, funded by BPSA, and produced by a wealth of subject-matter experts in the areas of transportation, packaging, quality assurance, vaccine and biologic production and physical product testing.

The writing team was led by Smithers. Additional authors are subject matter experts (SMEs) from Sartorius-Stedim Biotech, Entegris, Inc., Repligen Corporation, CPC, Pall Medistad BV, Sanofi Pasteur Ltd, and the Michigan State University School of Packaging. The guide is available for complimentary download at www.bpsalliance.org

About BPSA

The Bio-Process Systems Alliance (BPSA), an affiliate of SOCMA, was formed in 2005 as an industry-led international association dedicated to encouraging and accelerating the adoption of single-use manufacturing technologies used in the production of biopharmaceuticals, cell and gene therapies and vaccines.
www.bpsalliance.org.

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