

COLLABORATIVE PROGRESS TOWARD STANDARDIZATION OF USER REQUIREMENTS FOR SINGLE-USE BIOPROCESS TECHNOLOGY

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Over the past decade, the application of single-use technology in the production of biopharmaceuticals has gained popularity because of the advantages it offers for improved versatility and efficiency with certain unit operations. However, the technology lacks the standardization of stainless steel and glass technologies that have had a lengthier history in the industry. There has been inconsistent messaging about how to manage single-use systems among end-user, suppliers, and throughout the supply chain. The drawbacks to the lack of standardization include: difficulties with implementation of single-use technologies, insufficient data packages for the systems, slower responses from suppliers with respect to implementing continuous improvement initiatives and advances in technology innovation, as well as regulatory uncertainty.

A partnership has been established between a consortium of end-users and suppliers led by the BioPhorum Operations Group (BPOG) and Bio-Process Systems Alliance (BPSA) to work toward advancing the knowledge level and application of single-use technology to equivalent or better than that of stainless steel. One area of focus is on standardization. A cross-functional team of end-users and suppliers have been tasked with developing an approach to standardizing single-use user requirements (SUUR).

This poster will provide an overview of the SUUR team's approach to standardization of single-use requirements. This includes the development of a universal template for user requirements (URS) and a supporting document that provides a structure for suppliers to give additional details of how they will demonstrate conformance to the user requirements. This will help to facilitate more informed decisions regarding single-use technology and serve to address gaps in understanding between end-users and suppliers.