Standardize for Success

We're making progress on standardizing single-use systems – and it could mean a more cost-effective supply chain

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Recent years have seen considerable growth in the adoption of single-use technologies in the biopharmaceutical industry. By eliminating the long, resource-intensive decontamination and sterilization steps associated with multi-use equipment, single-use has proven that it can help biopharmaceutical organizations boost operational efficiency, improve product quality and consistency, and reduce costs. However, increased demand for single-use is straining supply chains and delivery timelines – an issue I believe standardization can alleviate.

Standardization has historically proven challenging because biopharmaceutical organizations typically require highly specialized (often custom) single-use designs to meet their workflow needs. And if standardization practices are not properly executed and managed, it can be difficult to control configurations that have been functionally optimized and qualified for use in multiple applications. If the same design is being used across different workflows and facilities, for example, we must employ appropriate processes to ensure that any subsequent revisions will not impact the various applications.

Today, there is increasing focus on combining the attributes of several custom designs into one system for use as standard across different bioprocessing workflows. This helps to establish shorter lead times for single-use and simplify purchasing and inventory efforts, making these technologies more readily and sustainably available. Importantly, standardization also removes the risk of variation in the manufacturing process by enabling biopharmaceutical companies to implement more efficient, repeatable, and consistent processes that are quick to deploy and maintain – thereby boosting productivity. Ultimately, standardization can help biopharmaceutical organizations eliminate production bottlenecks and accelerate the release of new therapeutics to market.

Various industry groups have advocated for greater standardization in single-use and guidelines have emerged. The BioPhorum Operations Group (BPOG) standard methods, for example, are designed to enforce industry-wide leachable and extractable testing protocols for components used in the manufacture of single-use systems. Typically, manufacturers of single-use go to great length and investment to perform leachable and extractable testing of their products, a burden that standardizing on specific components could reduce. Following the BPOG standards has also made it easier for biopharmaceutical organizations to directly compare different components using the relevant test data to verify suitability for use in their operations. Ultimately, reliance on BPOG standards simplifies and accelerates the adoption of single-use technologies in the safest and most effective way.

The progress that has been made so far in standardizing single-use technologies has unlocked significant productivity gains for the biopharmaceutical industry – and I believe there is more innovation to come! Developers of single-use systems are constantly devising new technologies and optimized designs that offer the highest standards of performance, consistency, reliability, and safety. And, as we look to the future, single-use standardization will play a vital role in building a stronger and more cost-effective biopharma supply chain.