The Cost Savings Of Blow-Fill-Seal: More Than A Million Reasons To Switch

Source: Weiler Engineering, Inc.
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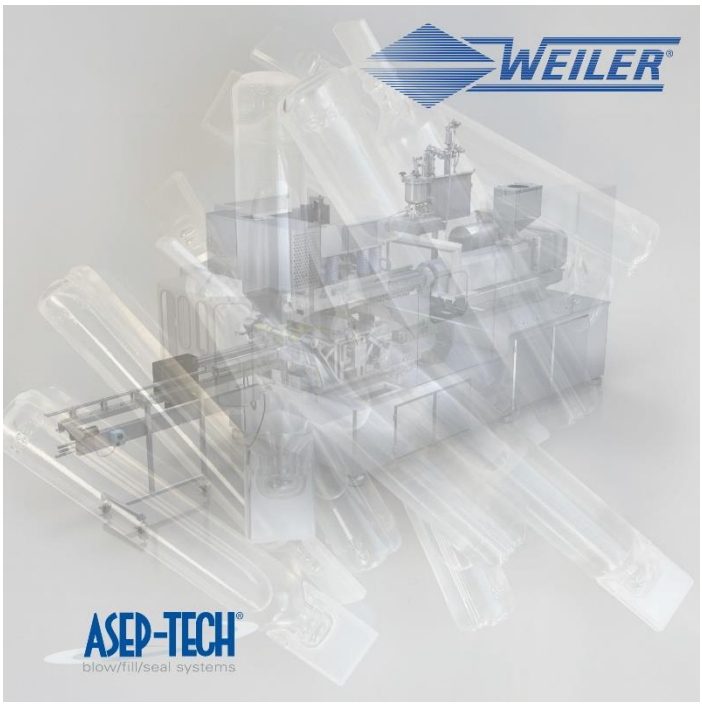

Doing business in the pharmaceutical industry comes at not only a high cost but also at a high risk. For these reasons, there are concerns associated with making any major adjustments to a company's manufacturing practices. It is difficult to imagine why a pharmaceutical manufacturer would want to do that. The traditional methods used today are the same ones the industry has relied on for decades. Nonetheless, there are few things in multiple facets of our lives that have not seen a facelift at some point over the last 50 years. By avoiding change, even as the capabilities and technologies available advance, the industry is potentially relying on practices that are no longer the most effective or the most efficient.

This is especially true when it comes to glass packaging versus blow-fill-seal (B/F/S) packaging. Despite the benefits of B/F/S over glass, some pharmaceutical companies refuse to make the switch because of a number of objections. One of these is the high capital cost of B/F/S equipment. On the surface, the numbers can be intimidating, but a closer look reveals an investment in B/F/S may yield incredible long-term savings.

The Packaging Battle: Glass Versus B/F/S

Before looking at the cost of B/F/S, it is important to consider other reasons why a manufacturer might want to use it, specifically when it comes to patient safety. Glass has a long history of use for packaging in the pharmaceutical industry. Despite its tenure, there are several disadvantages to using glass for pharmaceutical packaging, including sterility risks and breakage. The biggest issue with glass packaging is the presence of particulates, which is the result of glass delamination. These particulates can be especially dangerous if delivered intravenously to a patient through their medication.

And while it would seem the risk of particulates would be low considering how long glass has been in use, this is not the case. In 2016 alone, there were 13 recalls related to the presence of particulates.[1]

In an effort to overcome these obstacles, some manufacturers have turned to plastic for their product's packaging. In a matter of seconds, a B/F/S container can be formed, filled, and sealed in ISO 5 (Class A) conditions, which drastically reduces the risk of foreign particulates and microbial contamination. Not only is the risk of particulates, delamination, and breakage eliminated with B/F/S packaging, but the technology lends itself well to the growing trend of single-dose packs for OTC medications. Also, because of the extrusion process used to form a B/F/S vial or container, resin can be melted into any shape, making packaging more efficient and the weight of the shipment lighter. This added flexibility gives B/F/S yet another advantage over glass.

A Look at The Numbers

With the prospect of paying out millions over the course of the drug development life cycle, a pharmaceutical manufacturer will look for any possible areas where it can achieve cost savings. This is true when it comes to buying new equipment, especially if the existing equipment does not need to be replaced. However, rather than concentrating on the upfront cost, a company should instead look to the cost-per-unit over time to determine the real value of B/F/S.

Because B/F/S machines are customizable, pricing varies for each project. In the scenario below, a B/F/S machine was set up to fill 40 three-milliliter vials per 14-second cycle in a simple sodium chloride solution. As a result, the company was able to achieve an output of 10,286 B/F/S vials per hour.

The following chart breaks down the estimated total cost of this equipment (including capital, operating expenses, and components) over the course of one year at the desired output of 4,540,200 per month:

While .036 cents per vial already seems considerably low, the true value of B/F/S savings is realized when comparing an output of 4,540,200 vials per month in a B/F/S vial versus a glass vial:

Add in the operating costs of a facility filling glass vials, and that number is likely to rise substantially. Considering the Tufts Center for the Study of Drug Development recently estimated the cost of bringing a drug to market at $2.8 billion,[2] a saving of this magnitude can have a sizable impact for manufacturers trying to reduce costs without sacrificing quality.

Can B/F/S Be Used For Primary Packaging of Biologics?

Regardless of whether a company uses glass or plastic, determining the right packaging choice for any pharmaceutical can be challenging. This applies especially to the growing market of biologics, where there is a critical need to maintain stability of the protein

through the manufacturing process. That is why stability testing is needed to determine the compatibility of a product with any potential packaging options. To identify any physical or chemical incompatibilities, the product is stored in the selected packaging for an extended period of time. At the end of that time frame, a chemical analysis is completed to determine if the product has been degraded and the impact of the leachables, if any. Stability testing can also establish any permeation risks.

In a recent analysis by Catalent,[3] a leading CDMO in the life sciences industry, the data sets between glass and a B/F/S vial, ADVASEPT®, were compared for packaging of a large molecule drug product. Leveraging the company's biologic facility, Catalent formulated a monoclonal antibody (mAb) and then conducted a 24-month compatibility study using the same bulk mAb filled in both traditional glass vials and ADVASEPT vials. The data from the stability study concluded that the mAb was comparable in glass and ADVASEPT vials, making B/F/S technology a viable option for the primary packaging of biologics.

Plastic may not be the optimal packaging for every drug, but a manufacturer will never know for sure if it does not complete the right testing. Should a thorough analysis conclude there is compatibility between a protein and a B/F/S package, the cost savings could be substantial. However, the added value of protecting the efficacy of your product and the safety of the patient goes well beyond the bottom line.

1. U.S. Food and Drug Administration, *2016 Safety Alerts for Human Medical Products* — https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm479348.htm
2. Tufts Center for the Study of Drug Development, *Tufts CSDD Assessment of Cost to Develop and Win Marketing Approval for a New Drug Now Published* — http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published
3. BioProcess Online, *Blow-Fill-Seal For Biologics: Breaking Through The Glass Ceiling Of Pharmaceutical Packaging* — https://www.bioprocessonline.com/doc/blow-fill-seal-for-biologics-breaking-through-the-glass-ceiling-of-pharmaceutical-packaging-0001