

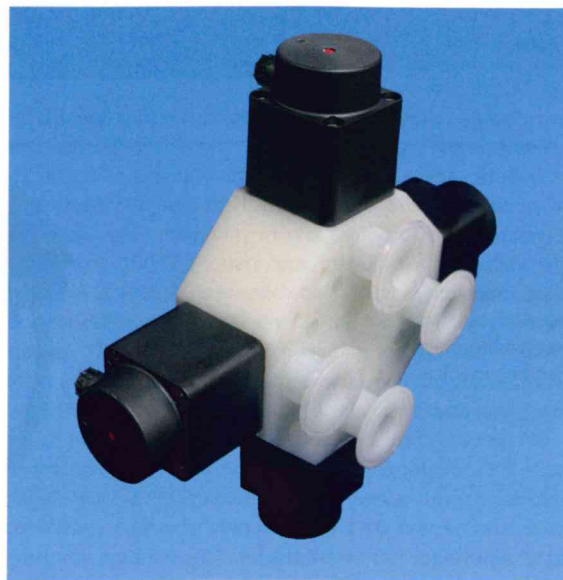
Performance Plastics: The Rx for Biopharm Manufacturing

Plastics in Life Sciences and Medical

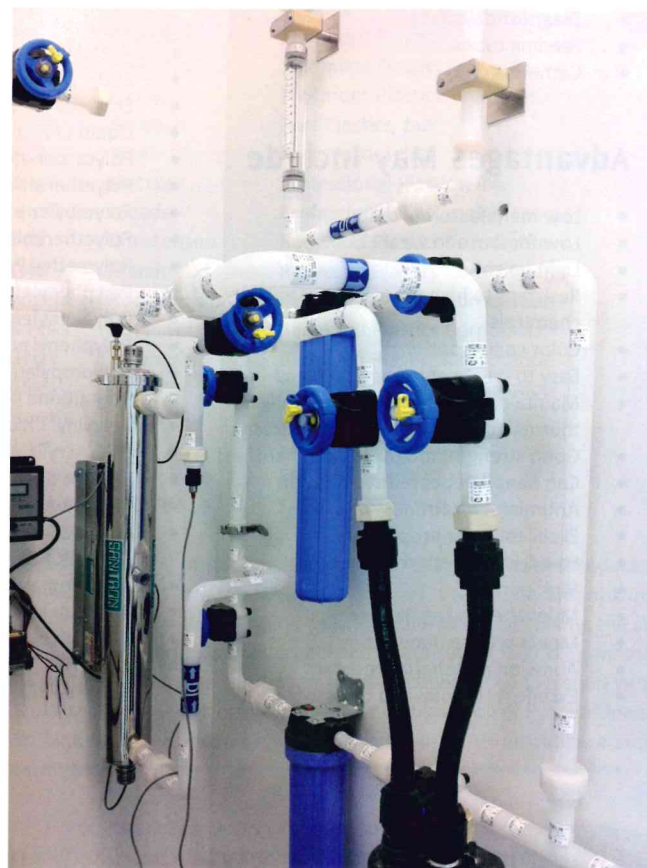
by Adam Herbert

While plastics have been widely used in various biopharm applications for decades, there are still many areas of biopharm upstream manufacturing that have held to metallic components. Many biopharm manufacturing facilities and equipment are predominately constructed with stainless steel process components such as piping, valves, filter housings and tanks. What's ironic is that the final packaging of those finished biopharm products are commonly plastic bags, bottles and containers. For example, a syringe with a plastic body is used to deliver vaccines directly into the human body. If the last component to touch a biopharm product is commonly plastic, how do we overcome the resistance to adopting plastics in upstream manufacturing, and what does the future hold for plastics in biopharm manufacturing?

A look at the recent history of plastics in biopharm manufacturing shows some promise for performance plastics. Over the past two decades, the leading thermoplastic pipe, valve and fitting (PVF) manufacturers have had their wins. They've found customers willing to consider alternate materials, have worked with those clients to convince them of the benefits of plastics and to get the products installed. If the plastic component manufacturers pooled their customer lists together, the reference list would be respectable, especially for an industry entrenched in a metal-first mindset.



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Asahi/America's Purad® PVDF piping system with beadless welds for a pharmaceutical highly purified water system.

Looking ahead, the future for plastics looks bright in biopharm manufacturing. Let's break the biopharm market down further into three segments. The first segment is biotech, which we'll define as startup or research and development (R&D) focused companies using microorganisms and biological substances for a unique manufacturing process. The biotech market has matured to a point where plastics are now the predominately chosen material of construction in their new facilities. Whether designed by the facility owner or an engineering firm, they are now choosing plastics as the first material specification. A good example of this would be polypropylene and polyvinylidene fluoride piping systems for high purity water systems. There

are still many metallic-based components in this segment, but the customer base is open to engaging plastic manufacturers.

The second segment, pharmaceutical, would be your traditional large volume manufacturer of drugs and vaccines by a synthetic chemical process. This market has been the hold out when it comes to metals. There are rigorous manufacturing specification and validation requirements in place to protect the public that make material changes in the manufacturing process a burdensome task. Years ago, it was a very difficult sales process to convince a pharmaceutical facility not only of the benefits of plastics, but of the return on investment to make a validated process change. This segment seems to be more open minded now. They have watched their counterparts in biotech successfully use plastics in manufacturing and are more likely to engage plastics component manufacturers in dialogs. The Great Recession also helped give them a nudge as companies were forced to look at new ideas and cost saving measures. With some perseverance and good business development, plastics can continue to penetrate this segment.

The third and final segment is third-party OEM equipment such as process delivery and blending. These OEMs can be in a challenging position as they



Asahi/America's PolyPure® PPN diaphragm valves and pressure regulators installed on high purity water polishing equipment.

have customers in both the biotech and pharmaceutical segments that may have a different willingness to embrace plastics. They have to design and build their equipment to meet their diverse customer base. Recently, there has been a lot of interest on the OEM level to switch to plastics. They are seeing their competitors successfully switch to plastics and want to match the leading technology. Or, they have a process compatibility issue such as heavy salt-based media where the chemical resistance of plastics is beneficial. The biopharm OEMs are still in the early stages of this switch, and many are constructing hybrid systems. These hybrid systems may contain a mixture of plastic and metal components. This market is a very exciting opportunity that requires dedication from the plastic manufacturers to fully integrate plastics into their equipment.

Looking at these three segments in detail, the future looks bright for plastics in biopharm manufacturing. So how do the manufacturers and distributors of plastic products continue to grow market share in biopharm?

First, by getting back to the basics and remembering who our real competitor is: metals. We get too focused on competing with each other in our established markets, which only commoditizes our products or drives out margin from custom solutions. Bring yourself back in time 50 years and convince the customer of the basic benefits of plastics and how they will see a return on investment when switching from metals.

Second, think outside the box by providing industry-specific solutions. The biopharm market is well established and the metallic suppliers have been providing dedicated solutions and products specific to their needs. We may need to modify our current product offerings to meet their individual requirements.

Third, be dedicated to playing the long game. The pharmaceutical segment will continue to take years to develop, but the opportunity is real. Working with OEM accounts in new equipment design is a complex and time-consuming process.

Just as the opportunities are out there, so are the success stories which are grounded in the basic benefits of plastics. Plastic piping systems do not leach out high levels of metallic ions into high purity water and can be extruded incredibly smooth to limit biofilm growth. Plastic does not rouge or require routine passivation maintenance like steel does. Plastic systems are lightweight and easy to install. Salts and acids can easily corrode metal components such as manifold valves and waste piping. Remember, the best benefit to plastics is their perseverance in applications where metal fails.

Adam Herbert is business development team manager for Asahi/America, Inc. For more information, contact him at 655 Andover Street, Lawrence, MA 01843-1032 USA; phone (781) 321-5409 or (800) 343-3618, fax (800) 426-7058, email asahi@asahi-america.com, www.asahi-america.com.