How to Create Seamless Transitions

The biopharm industry is embracing new connections. Advancements in steam and aseptic technologies are making it easier to integrate disposables with stainless systems while minimizing contamination risks

'Such fast, efficient connections provide a major advantage in the race to move drugs to market.' By John Boehm

Single-use systems have been used in the biopharm industry for more than a decade. In recent years, however, the incorporation of these disposable systems has become a more accepted practice that shows no signs of slowing. While disposables once focused primarily on lower cost media, the deployment of single-use technologies has spread throughout the production process &#151 even downstream to final fill operations. Disposable systems, ranging from flexible bags and tube sets to filtration products and connection devices, are being used to collect, store and transfer process fluids. Manufacturers who have integrated these single-use systems into their processes and operations are realizing increased productivity, reduced operating costs and minimized risk. For instance, by using disposables, downtime associated with cleaning and cleaning validation is reduced. This leads to productivity increases and helps manufacturers get product to market faster. The diminished requirement for cleaning or cleaning validation also leads to a decrease in labor, chemical, water and utility expenses. Additionally, capital investment for new construction can be lowered due to reduced equipment and floor space requirements, thus improving overall ROI. Disposables also add flexibility to processes and operations. Unlike fixed piping systems that too often require time-consuming modification, disposables enable quick changeover for media transfer between existing equipment. This is especially beneficial when frequent product changeover is required as is typical with contract manufacturers. The flexibility of disposable systems also helps manufacturers respond to product demand variation. As production requirements increase or decrease, it is possible to change the size or quantity of single-use bag assemblies to accommodate market changes. Since pre-sterilized single-use systems typically take up less storage space than traditional containers, less storage space has to be allocated in preparation for demand spikes. Single-use systems minimize the risk of cross-contamination. Due to the high value of today's biopharmaceutical media, reducing the potential for product contamination is vitally important to manufacturers. Utilizing pre-sterilized single-use systems addresses a number of concerns. Media bag, tubing, filter and connection systems can be gamma irradiated prior to introduction to the production facility to ensure the system is sterile. New advancements in steam and aseptic

connection technologies further minimize contamination risks when integrating disposable systems with traditional stainless systems. The connection is an integral component in any disposable system. Over the last few years, there have been a number of advancements in bag, tubing and filter technologies, but all these items have to be put together to create a complete system. Connections used to connect and disconnect tubing on single-use bags and stainless manifold systems create a quick and easy link. Such fast, efficient connections provide a major advantage in the race to move drugs to market. Therefore, the selection of the proper connection solution can be critical to success. Following are three points to consider when integrating disposable systems and evaluating connection options.

#1: Demand Reliability

Unreliable or leaking connections not only present safety hazards, but they also increase contamination risks. Product contamination can compromise the integrity of a process, delay product availability and even tarnish corporate reputation. Manufacturers should demand secure, leak-free connections that protect against potential product contamination or loss. A reliable approach to link single-use systems to stainless processing equipment is to utilize SIP-style connections. For example, a new patented three-port design allows steam to pass directly through the lower two ports to "steam on" to stainless equipment without the concern associated with "dead legs" that can trap microorganisms. After the SIP cycle is completed, the connector's valve is actuated, creating a sterile flow path. Media can then be safely transferred without the cleaning and validation concerns associated with reusable components. This technology is ideal for feeding, harvesting and sampling applications.

#2: Flexibility is Paramount

The advancement of single-use technologies brings the challenge of connecting all the various elements together &#151 bags, filters, tubing assemblies, process equipment, etc. Finding the right interface between these systems and existing stainless equipment can be a daunting task. One way manufacturers can add flexibility to their operations is by using a connection with an integral coupling adaptor to incorporate plastic disposable couplings into their solution. For example, a new integral sanitary termination attaches to hard-plumbed systems with tri-clover clamps. Once attached, it permits a quick and easy connection to disposable systems that incorporate plastic couplings. These terminations are available in several sizes to address the diverse requirements of companies integrating disposables. Greater flexibility also is being built into connections used for steam-in-place processes. There are new connections that incorporate a repositionable valve that extends steam-in-place capability to two cycles. The flexibility of such "steam on" and "steam off" functionality minimizes contamination concerns and increases operational efficiency. The "steam off" cycle minimizes cross-contamination risks to operators and the production environment after disconnection from equipment. For example, manufacturers producing an infectious agent, such as a viral vaccine, can now perform multiple harvests without an increased risk of contamination to

product, personnel or the production environment.

#3: Partner for Success

It is important to align with a supplier that can offer a broad range of connection solutions including differing sizes and termination options as well as relevant material types. For instance, connection materials must be compatible with a manufacturer's varying process requirements. Materials must meet stringent biocompatibility requirements to address concerns associated with leachables and extractables. Media, chemical and temperature compatibility along with sterilization requirements help determine which materials are suitable for a given application. Before making a final connection selection, consult with the supplier not only about material requirements but also about detailed specifications and validation testing, flow and mounting requirements. If your organization is dedicated to a disposable integration plan, it also would be beneficial to consider a supplier that has expertise in single-use technology and is committed to the long-term advancement of single-use technology. Ultimately, knowledgeable suppliers will work with you in the early design stages to help you specify the optimum connection for your application. They also will avail themselves throughout the integration process to ensure an easy and successful transition to disposables. *John Boehm is the bioprocessing business unit manager at Colder Products Co., 1001 Westgate Dr., St. Paul, MN 55114, a leading manufacturer of quick disconnect couplings for industrial, biopharmaceutical, medical, chemical and packaging markets. He joined the company in 2001 and has held various positions in engineering, marketing and business development. He has a bachelor's degree in mechanical engineering, as well as an MBA, and is an active member of the ISPE and BPSA. Questions about this article can be directed to him at 651-645-0091. More information is available at www.colder.com*

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