

Singled Out

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Single-use technologies are becoming increasingly common in many manufacturing situations, especially those that require high levels of sanitation and isolation for consumer safety. Although stainless steel offers a number of unique benefits, disposables are undoubtedly emerging as a leader in the high-stakes world of pharmaceutical manufacturing.

When building a new plant or upgrading an existing facility, manufacturers must now decide whether to use traditional stainless steel, combine stainless steel options with disposable solutions or use single-use technologies almost exclusively. What is the best option for today's pharmaceutical manufacturing facilities? To find out more about the benefits of single-use solutions and why some plants may be reluctant to part ways with stainless, Pharmaceutical Processing spoke with suppliers of single-use equipment.

Crossing Out Contamination

One of the key features of single-use technologies is their potential to completely eliminate cross-contamination during pharmaceutical manufacturing processes. "In respect to the processes that are totally single use, [the technology] basically eliminates cross-contamination," explains Derek Masser, Life Sciences Sales Manager for ASI (Advanced Scientifics). "You're in essence replacing the entire fluid path ... so there is no longer a need to worry about certain valves or cleaning certain polish finishes."

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One of the “primary reasons pharmaceutical manufacturing facilities use single-use equipment is to eliminate cleaning requirements and to reduce/eliminate the risks for product cross-contamination and microbial contamination,” says Roman Rodriguez, Mobius Group Product Manager at Merck Millipore. “Single-use equipment is delivered pre-assembled and gamma sterilized. The consumables are discarded after use, which removes the need for cleaning, and improves the turn-around time. In some instances, the use of single-use technologies can minimize the number or duration of personnel ingress into controlled environments, which can also minimize microbial contamination.”

Putting a Cap on Capital

In addition to the sanitation benefits that come with the implementation of single-use technologies, many companies are also able to reduce their capital investment through the use of disposables.

“Studies have shown that new installation of a single-use-system (SUS) is a less costly investment than traditional hard-piped stainless steel systems,” says John Stover, Product Technical Director at NewAge Industries’ AdvantaPure.

“Additionally, the manufacturing footprint is considerably smaller than permanent systems; reducing manufacturing costs associated with the size of the manufacturing space.”

“In a Greenfield facility without resident utilities and without PW/WFI generation systems, there are numerous examples and economic models that demonstrate cost reductions,” says Rodriguez. He explains that “For facilities that already have captive utilities but are looking to enhance their flexibility and capacity, single-use systems can certainly help delay capital investments.” Single-use technology can reduce capital investment in other ways, too, since “Single-use components drastically reduce the costs related to the initial cleaning validation and qualification.”

An organization in Massachusetts that used single-use products almost exclusively “was able to reduce their capital expenditure by about 75 percent” when building their facility, Masser explains.

Making the Move

Once manufacturers have decided to implement single-use materials, they must then decide if their entire process will rely on single-use technology or if disposable components will be used sparingly.

“Nearly all biopharmaceutical manufacturers use disposables today,” explains Rodriguez. “Some for basic applications, such as liquid storage, and some for complex systems, like bioreactors.” He says that CMOs are “very interested” in disposables, “especially as they plan construction of new facilities.” But he notes that “The majority of the end users today are implementing step by step.”

Masser explains that generally, he sees end users asking for as much single-use as

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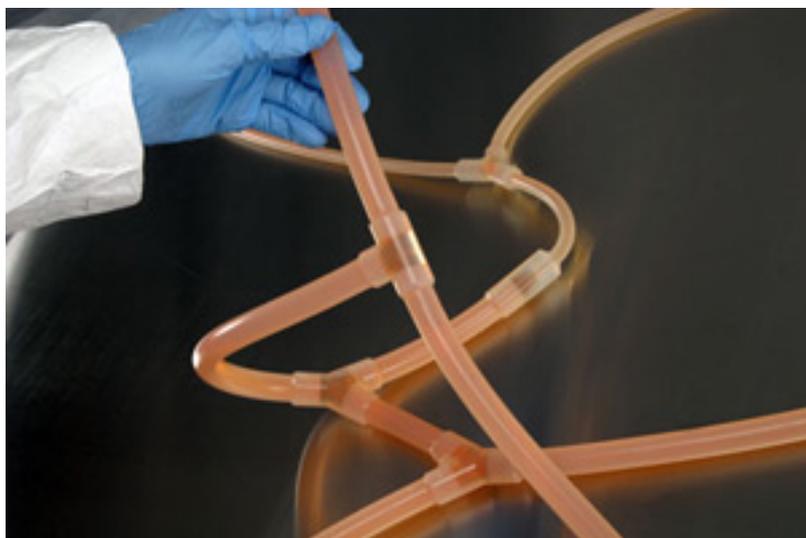
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possible, but that “It’s unique to the individual organization, their regulatory and validation group, their internal expertise and comfort levels.” He deals with customers where almost “the entire processing fluid path — from media preparation through the perfusion bioreactor, through harvest and all the way downstream through purification — is completely single use,” yet the chromatography column is still a traditional, multi-use system, mostly for cost reasons. Many companies are faced with big business decisions when it comes to implementing these new technologies — especially if they have already put a great deal of capital into their stainless infrastructure. “Are they willing to divest of that? There’s a business decision that has to be made there,” says Masser.

Stover agrees that older legacy systems are often difficult to replace. “Companies that are looking at the use of a SUS for the first time take longer to decide to implement a SUS because it usually requires a new learning curve of information to understand all the aspects of adopting a SUS when they’ve been used to conventional stainless steel systems.”

Disposing of Disposables

Disposables are synonymous with waste, but “due their bio-hazardous nature and multilayered construction, traditional recycling (separating different types of plastics) has been proven to be challenging,” says Rodriguez. “There are other recycling methods that are employable and EMD Millipore is piloting one such process.” Currently, however, “The primary method of final disposal is landfill or incineration with or without cogeneration” for many organizations.



Stover also cites incineration as the most common method: “Incineration is a popular method of disposal — especially when the users have a regular ability to incinerate waste on-site or have contracts in place with companies that offer incineration services.”

Although incineration may appear to be less environmentally friendly than recycling, Rodriguez notes that “Single use has been demonstrated to be ‘greener’ when compared to traditional facilities due to the reduced need for water and energy.”

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Why Stick with Stainless?

Although single-use systems offer sanitation and cost benefits, “There are restrictions and limits associated with every approach,” explains Rodriguez. He notes that “Stainless steel equipment offers some advantages. For example, it is unlikely that facilities operating with 5,000 or larger volume bioreactors will be able to accommodate their entire process using single-use technologies.”

In addition, “Facilities that are designed to produce one or a few of the same molecules over and over again can benefit greatly from the use of multi-use technologies, as the cost of cleaning/cleaning validation can be spread across many production lots,” Rodriguez adds. Generally, “Familiarity, robustness and cost are often cited as reluctance of customers to switch from traditional stainless steel equipment to single use.”

“Traditional stainless steel equipment offers a better ability to use higher temperature and/or pressure process parameters,” Stover explains. “Also, by reducing the amount of polymer materials used in the system, there is a decreasing need to study extractables and leachables that are associated with the use of polymeric-made components.”

The Future of Single-Use Technology

Although many plants are currently still relying on stainless or a combination of stainless and single use, the experts foresee single-use technology becoming increasingly popular. “Because of the adaptability a SUS has, the reduced risk of cross-contamination, and the reduction of cost associated with cleaning validation and sterilization ... the use of SUS will only escalate and eventually will be as common as reusable systems, if not more,” says Stover.

“Without a doubt, if you look at the large build out of new facilities and new capacities ... in the U.S. but especially in Europe,” they are “going with single-use,” explains Masser. Because of the reduced risk of cross-contamination, reduced footprint, reduced need for personnel and reduced capital investment, plants are embracing the benefits of single-use technology.

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