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# Single-use systems gaining popularity in bioprocessing

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Manufacturing plants must be able to add new products to the mix, rapidly convert processes, and quickly make operational adjustments as needed. These changeovers must be executed while meeting required safety, time-to-market and efficiency goals. Many manufacturers are implanting single-use systems to meet these deliverables, which are gaining ground in biopharmaceutical manufacturing facilities in India as the advantages of disposable process equipment over traditional stainless steel process equipment become obvious.

Indian biopharmaceutical companies are now using disposable assemblies at an ever increasing rate. Single-use technologies are becoming available for an increasing number and range of applications, with all its inherent advantages over traditional equipment.

Early adoption of single-use process equipment depends on the manufacturing environments that require bioprocessing flexibility such as in the development and manufacture of biologics. Particularly when the unit needs to quickly accommodate new products and process modifications. Speedy installation, startup and flexibility in switching products are the obvious advantages for speed-to-market. Under such conditions, manufacturers of oncology drugs and other high value biologics are finding traditional stainless steel equipment like storage tanks and transfer lines cumbersome because of the amount of time taken in installing, starting, cleaning, sterilizing and validating them. Another significant advantage seen is the reduced risks of product contamination.

Instances of integrating single use solutions i.e plastics and existing steel equipment, as in hybrid systems are also very prevalent in the biotech industry as companies seek to protect their capital investments in traditional systems. In some cases, manufacturers seeking to ensure product safety by eliminating the risks of product cross contamination, have moved to disposable systems completely or incorporated hybrid solutions at critical stages in their production processes.

Single-use solutions have proved useful in facilities requiring extensive revamping in terms of:

- Reducing the risk of cross contamination to a minimum. No product carryover validation study.
- Reducing the risk of microbial contamination by limiting the use of valves and manifolds traditionally used for transport of product and buffers.
- Flexibility of movement from one product to another i.e. no equipment decontamination.
- Minimum validation prior to start up.

Mobius mixing systems have demonstrated that by reducing downtime for cleaning validation and process engineering, manufacturers can increase production capacity in multi-product facilities. Reduced downtime for validation, cleaning-in-place (CIP) and sterilization-in-place (SIP) automatically increase the number of days the production line is available for manufacturing every month. Mobius pre-sterilized bags have proved handy for sterile applications like sampling, transfers and storage. NovaSeal sealing technology is a boon to securely crimp and cut the disposable assembly into two sterile fluid paths. Sterile capsules that are gamma-irradiated, available in a wide range of media, membranes and sizes for flexibility, make

scale-up easy while minimizing hold-up volumes and other production losses.

Perhaps, one of the biggest concern areas in traditional processes has been that of quick and contamination-free installation and cleaning of fluid pathways. Piping bends, joints and on-line sampling ports are difficult to install and clean. Single-use Lynx connectors allow the integration of steamable hard-piped process equipment with disposable sterile fluid paths. This results in economical, easy and reliable sterile connections for secure transfer or sampling of sterile fluids.

Early adopters of this technology are realizing the savings accruing from quicker installation as compared to stainless steel, the relatively lower capital and operating costs and the tremendous savings from lower utilities demand, particularly for clean steam and water for injection (WFI). There are significant savings from reduced labor and time spent on CIP and SIP.

While there are many suppliers of single-use solutions, the crux of the problem is to get integrators and not just vendors of different components. Companies such as Millipore address this need by partnering the industry with the widest range of integrated solutions for mixing/compounding, storage/holding, filtration, sterile connections, sterile transfers and filling including the critical expertise in validation. Validation of single-use solutions demands a different kind of validation. Validation here, requires expertise on product compatibility, leachables and extractables testing. The advantage of films from companies such as Millipore is that product contact layers are kept the same from sampling to filling systems, hence single product contact validation study is sufficient.

A new innovation in the industry in the form of Mobius FlexReady combines single-use assemblies (Flexware), innovative separation devices, and process-ready hardware systems. The platform can be wheeled quickly to wherever the process requires it and can be quickly and safely adapted to the process requirements.

The disposable single-use technology has arrived in India. Particularly in manufacturing environments (CRAMS) where speed-to-market, product safety for regulated markets and flexibility are key concerns. More so in the manufacture and development of biologics and anti-cancer drugs.