BioSpectrum the business of Bio & Health Sciences

"Biopharma manufacturers can benefit by adopting a global single-use supply chain strategy"

10 November 2023 | Views

Biomanufacturing has been and continues to be transformed by the rapid innovation and adoption of single use technology (SUT). SUT has changed how bioprocesses are designed, scaled, operated, controlled, and the speed at which new technology can be incorporated into biomanufacturing. With the Department of Biotechnology, Government of India, ready to launch a new policy framework for biomanufacturing in India, the biotech industry is all geared up to excel in this field. In coversation with BioSpectrum, Ganesh Jabaji Bade, Head, Biopharma, IMEA, Avantor talks in detail about the future of SUT in India.

What are the latest offerings in single use technology?

In recent years, the single-use market has grown significantly to meet the demand for the rapid development of vaccines. Accelerated by the COVID-19 vaccine global rollouts, the critical use of single-use systems has seen growing demand for single-use bioprocessing technologies and equipment. With the effects of the pandemic single-use manufacturing came to the forefront of managing high demand. As necessary tools in the development and commercial manufacture of potential vaccines and therapeutics, single-use technologies have allowed for the timely delivery of vaccines.

According to a research report by Markets and Markets (2021), the global single-use bioprocessing market is expected to reach $20.8 billion by 2026 from $8.2 billion in 2021, at a growth rate of 20.5% during the forecast period. There has been a growing demand for single-use assemblies and single-use systems in bioprocessing, driven by a demand to increase titers, decrease batch sizes, and improve manufacturing speed for monoclonal antibodies (mAbs).

Single-use manufacturers such as Avantor offer a range of single-use products for aseptic sampling, mixing, fluid transfer and storage using tubing, collection bottles or bags, adaptors, extensions, manifolds, and other components. Single-use systems can be designed from these components and implemented in a number of ways, including single-use perfusion systems for

harvesting, chromatography systems for purification, single-use virus removal systems, and single-use sterile filtration systems. Overall, single-use allows for greater speed gained through decreased turnaround time between batches and through the ability to facilitate multiproduct, flexible manufacturing—using manufacturing capacity for more than just one product.

Single-use systems also help minimise the risk for cross-contamination and eliminate added time and cost spent on cleaning and sanitization in place procedures. The ability to standardize single-use assemblies at biomanufacturing facilities allows for greater reproducibility and batch-to-batch consistency across operations and reduces operating errors. This has driven faster research and development activities in addition to faster bioprocess scale up for processes from pilot to production for biomanufacturing.

In drug manufacturing steps, buffers and salts are the largest constituents by volume used in the process. The large variety of materials used requires flexible, cost-efficient infrastructure and on-time delivery to meet process demand. An example of where single-use systems can add value in this space is with single-use in-line dilution systems that provide biomanufacturers with greater precision and control for the ability to optimise pH, conductivity, and other parameters required for low pressure liquid chromatography purification for enhanced process efficiency.

How are Indian pharma manufacturers adopting single-use technology?

In recent years, the demand for single-use solutions for therapy development has grown exponentially. Single-use assemblies and solutions are designed to be component-based systems, compared to traditional stainless-steel equipment, which often requires a large physical site footprint, laborious cleaning, and additional cleaning-related validations. With the rapid speed and efficiency needed to create novel vaccines, single-use solutions provide the needed flexibility required to develop therapies quickly and at scale, with some COVID-19 vaccines being a prime example of the benefit of using this technology . These assemblies have enabled manufacturers to rapidly scale-up, and overcome challenges with manufacturing setup as well as contamination, which are common when using traditional stainless-steel equipment. Single-use technologies allow biomanufacturers to operate at a speed appropriate to global demand. Investments in single-use systems will also support growing customer demand for monoclonal antibodies (mAbs), novel cell and gene therapies for oncology, and other diseases, as well as vaccines.

The last few years have proven pivotal for contract manufacturing and development organisations (CMOs and CDMOs) in India and AMEA. With rapid development in potent compounds, and ambitious plans to expand this process in the future, many of these facilities have achieved fast paced growth with no signs of slowing down. For them it is very important to have a low turnaround time since they will be running multiproduct facilities. Similarly, process compression, continuous manufacturing and pharmaceutical products using more potent compounds which require better levels of containment than they have in the past are trends which are emerging.

Antibody Drug Conjugate (ADC), Oncology drug manufacturers are sectors which prefer single-use from containment perspective and operator safety. Injectable complex generics is another area where single-use is preferred.

Single-use and closed system processing is also playing a vital role in another Pharmaceutical R&D area, that of Cell & Gene Therapy (CGT). Within CGT, various upscaling risks can be minimized by utilizing these processing methods. For instance, customizable sampling platforms such as Avantor’s OmniTop Sample Tubes system with an adjustable volume sampling system (AVSS) are beneficial in CGT due to the precision and control they offer while drawing the sample, eliminating the volume loss typically associated with these scenarios. On the other hand, the implementation of closed-system processing using ready-to-use sterilised solutions mitigates the risk of contamination and enhances speed and flexibility while facilitating automation.

What are the challenges associated?

As COVID-19 vaccines brought mRNA vaccines to the market at a rapid pace, continued growth in vaccines is expected through expanded access, improvements to existing products, and net new products. As such, manufacturing must evolve to support this growth. Capital-rich investment in fixed facilities that commit to a given form of production for a given target pose significant costs and challenges to manufacturers, and single-use offers a solution through the natural flexibility it offers biomanufacturers.

But with the rapid growth of single-use systems by drug manufacturers with multiple locations across the globe, there are also many risks associated with underestimating the regulatory compliance, manufacturing and quality requirements of these systems. For example, using single-use systems introduces new logistics challenges that, if not properly understood and planned for, can leave biopharma manufacturers vulnerable to supply chain complexities.

Most of the manufacturing process steps of single-use assemblies are manual requiring skilled operators the absence of which eventually leads to manufacturing challenges and high lead time. Leakage in single-use bags is another challenge for the industry which can lead product loss & contamination.

To minimise these risks, biopharma manufacturers can benefit by adopting a global single-use supply chain strategy early in the drug development life cycle and carefully evaluating their chosen single-use equipment and materials suppliers.

What is the future of single-use technology in the Indian context?

The Asia Pacific's growing bioprocessing market has resulted in multiple investments from several global companies. These investments assist to serve the key companies to create a regional presence and take advantage of the untapped avenues.

A boost in government expenditure towards the development of R&D facilities of major pharmaceutical organizations, high spending ability in the region and growing awareness of the benefits of single-use bioreactors are expected to propel Asia-Pacific’s growth of single-use systems in the biopharma market.

India is a diverse market for pharmaceuticals manufacturing. In recent years, the Indian government has demonstrated strong initiatives to promote the pharmaceutical sector, including a $1.3 billion fund to encourage companies to manufacture pharmaceutical ingredients domestically by 2023. With the growth of the pharmaceuticals industry, the country is a high-potential market for single-use systems, backed by strong government support, rising private investments, the growing trend of outsourcing to emerging Asian markets, and the presence of a skilled workforce. In fact, India, Japan, Brazil, and RoAPAC are expected to be the new revenue pockets for market players. Also, the high investment in bio-manufacturing infrastructure is a key factor responsible for the high-growth potential of these markets.

Through collaborative efforts between biomanufacturers and suppliers, resilient support systems can be established by incorporating innovative and flexible material workflows, reducing system-based risk, and implementing robust formulation strategies. Ultimately, biopharma manufacturers benefit from collaborating with suppliers who are proficient in both the high quality raw materials and single-use technology space to adopt the technical, quality and regulatory best practices needed to facilitate consistent product quality, and ultimately bring treatments and therapies to market faster.