

Single-use Assemblies Market Size, Share & Trends Analysis Report By Product (Bag Assemblies, Filtration Assemblies), By Application (Filtration, Storage), By Solution (Customized, Standard), And Segment Forecasts, 2022 - 2030

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Abstracts

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Single-use Assemblies Market Growth & Trends

The global single-use assemblies market size is expected to reach USD 39.96 billion by 2030, registering a CAGR of 18.57% during the forecast period, according to a new report by Grand View Research, Inc. Life science companies are eager to avoid the cost and time of cleaning needed with stainless steel. The augmented expansion of the international biotech industries has offered a growth environment, in which novel, disposable technologies are becoming more significant. As pharmaceutical companies, distributors, CDMOs, and manufacturers converge around the benefits of single-use assemblies, the industry will grow at a faster pace during the forecast period. From therapies for rare diseases to cancer research, the impact of single-use technology in accelerating cutting-edge research into these conditions is set to grow, thereby propelling industry growth.

In addition, the growing biologics market will further offer lucrative opportunities during the study period. Eradicating the risk of contamination is the major challenge faced by biopharmaceutical manufacturers, which currently involves high-level monitoring of critical manufacturing solutions. Single-use assemblies support manufacturers in overcoming this difficulty by eliminating or reducing the necessity for sterilization between the batches, thereby filtering the operational capability. SUTs are considered

one of the important areas of growth among biomanufacturing companies, as several biopharmaceutical companies are venturing into disposable assembly offerings for the production of all sorts of biopharmaceuticals.

Moreover, SUTs are now being heavily adopted for the clinical manufacturing of biopharmaceuticals and have become more conventional within commercial manufacturing facilities. SUTs permit biologics manufacturers to reduce the facilities' footprint by almost 20% due to the need for utilities, which generate steam, water, and clean-in-place solutions. Furthermore, as per the research by BioProcess International, the engineers estimated that the capital expenditure for the single-use facility is 25-45% less than for a facility established on stainless-steel equipment. Similarly, they also estimated that single-use facilities need half the energy and water during operations and can be built in 18 months. Whereas the stainless-steel facility takes three years. Owing to such advantages, the adoption of single-use assemblies is increasing, thereby driving industry growth.

In recent years, CMOs have been integrating single-use assemblies into most or all their bioprocess. CMOs broadly use single-use assemblies for quicker processing and process changeover time. The quick turnaround time and flexibility between process runs and various client projects allowed by single-use assemblies can enhance the CMO efficiency, which, in turn, aids in the reduction of the overall costs. In addition, the growing number of CMO facilities are essentially fully single-use. CMOs adoption of single-use technology can save on campaign and facility costs, which helps reduce the operating costs and capital investments. Furthermore, single-use assemblies in CMOs decrease the complexity and reduces lead times in upstream processes.

They also enhance the quality of products by preventing cross-contamination in downstream processes, especially for processes handling potent or toxic materials, such as antibody-drug conjugates and viral vectors. Moreover, stringent regulatory requirements in the manufacturing systems also endorse the adoption of single-use assemblies in CMOs. COVID-19 has augmented an already rapidly rising demand for single-use assemblies as the SUTs allow for the speedy production and development of therapies and vaccines and improve accuracy and time. For instance, Aramus single-use bag assembly developed by Entegris, Inc. was used for the storage of COVID-19 vaccines as the vaccines need extremely low temperatures to preserve. With low leachable and extractable and an extensive operating-temperature variety, the patented single-use bags were ideal for cold chain storage and collection.

In addition, key manufacturers are also accelerating investment projects or increasing

their capital expenditures. For instance, Pall Corp., invested USD 114 million to upsurge its single-use output. These investments comprise additional manufacturing capacity at 6 current manufacturing facilities in the United States and Europe. Moreover, MilliporeSigma, Thermo Fisher, and Cytiva have also augmented growth plans to support the industry's backlog. For instance, in March 2021 Merck announced the addition of a single-use assembly production unit at its Life Science Center in Molsheim, France. The investment of USD 26.25 million will accelerate the European expansion plans of the company for single-use products critical to manufacturing vaccines and lifesaving therapies. On the other hand, regulatory concerns due to leachable and extractable might hamper the growth of disposable assemblies in the forecast period.

Leachable and extractable are set of undesired impurities in the product stream, these are compounds that can move into the product from manufacturing systems, packaging containers, or other product-contact systems. Extractable is extracted from the contact materials under extreme conditions, such as treatment with a harsh solvent or elevated temperature conditions. Leachable compounds, on the other hand, are those that are leached into the final product from contact materials during normal or real-time storage conditions. North America dominated the global industry in 2021 due to the growth in the biotechnology and pharmaceutical industries, advancement in SUT products, and increasing incidence of diseases, such as cancer coupled with increasing investments and funding in drug discovery research. Asia Pacific is expected to grow at a considerable CAGR over the forecast years owing to the strategic activities by key players coupled with funding by the government for biopharmaceutical R&D.

Single-use Assemblies Market Report Highlights

The filtration assemblies segment led the industry in 2021. Increased regulatory prospects and the need to diminish the risk of contamination have promoted the use of filtration assemblies for bulk and final fill operations

The bag assemblies segment is expected to grow at a lucrative CAGR over the forecast period. Advantages, such as no need for validation or cleaning, lower shipping cost due to less weight, and low maintenance cost & capital investment drive the segment growth

The filtration application segment held a larger revenue share in 2021. Implementation of single-use assemblies for filtration is rapidly increasing owing to benefits as it is time- & cost-effective and ready to use, unlike the conventional filtration systems

The customized solutions segment captured the highest revenue share in 2021. Several companies offer customized solutions to fast-track pharmaceutical manufacturing and drug development

The pharmaceutical & biotechnological companies end-user segment led the global industry in 2021. The growth of the current manufacturing facilities for biopharmaceuticals drives the demand for single-use assemblies

The CROs & CMOs segment is expected to grow at the fastest CAGR over the forecast period. In recent years, CMOs have been integrating single-use technology into most or all their bioprocess

The quick turnaround time and flexibility between process runs and various client projects allowed by single-use equipment can enhance the CMO efficiency, which aids in the reduction of the overall costs

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FIG. 55 Middle East and Africa Single-use Assemblies Market, 2018 - 2030 (USD Million)

FIG. 56 South Africa Single-use Assemblies Market, 2018 - 2030 (USD Million)

FIG. 57 Saudi Arabia Single-use Assemblies Market, 2018 - 2030 (USD Million)

FIG. 58 UAE Single-use Assemblies Market, 2018 - 2030 (USD Million)

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