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Single-Use Assemblies Global Market Insights 2026, Analysis and Forecast to 2031

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Abstracts

Market Overview and Introduction

Single-use assemblies constitute a transformative segment within the biopharmaceutical manufacturing industry. These assemblies are pre-sterilized, disposable fluid path systems manufactured from medical-grade plastics, engineered to replace traditional reusable stainless-steel infrastructure. They facilitate critical bioprocess steps including fluid transfer, mixing, filtration, storage, and containment. A typical single-use assembly integrates various components such as 2D or 3D bioprocess bags, tubing, connectors, clamps, sensors, and filters into a cohesive, ready-to-use unit.

The adoption of Single-Use Technologies (SUT) marks a paradigm shift in bioprocessing. While the technology has existed since the late 1990s, the industry witnessed a significant inflection point between 2009 and 2010. During this period, biopharmaceutical manufacturers began aggressive integration of SUT to enhance operational flexibility. Unlike stainless steel systems, which require extensive Clean-in-Place (CIP) and Steam-in-Place (SIP) protocols, single-use assemblies offer a 'plug-and-play' capability. This eliminates cross-contamination risks, drastically reduces water and energy consumption associated with cleaning, and accelerates time-to-market for new biologics.

As of 2026, the market is navigating a critical regulatory milestone. The United States Pharmacopeia (USP) chapter , titled 'Plastic Components and Systems Used in the Manufacturing of Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products,' is set to become effective in May 2026. This standard, along with the guidance chapter , represents the culmination of years of collaboration between

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end-users, suppliers, and regulators. First released as a draft in the Pharmacopeial Forum in September 2020 and officially published in May 2022, the deferred implementation date allowed the industry time to align with rigorous standardization regarding extractables and leachables (E&L). This regulatory clarity is expected to further legitimize and accelerate the adoption of single-use assemblies in commercial manufacturing (GMP) environments.

Market Size and Growth Forecast

The global market for single-use assemblies has matured from a niche solution to a dominant manufacturing standard for biologics.

Estimated Market Size (2026): The market is valued between 6.0 billion USD and 9.5 billion USD. This valuation reflects the widespread installation of single-use bioreactors and mixing systems in both legacy facilities and new greenfield projects.

Forecasted Growth (CAGR 2026–2031): The market is projected to expand at a Compound Annual Growth Rate (CAGR) of 14.5% to 17.5% through 2031.

This robust growth trajectory is underpinned by the increasing pipeline of biologic drugs, particularly monoclonal antibodies (mAbs), vaccines, and cell and gene therapies (CGT), which predominantly rely on single-use platforms due to their small-batch and high-mix nature.

Regional Market Analysis

The consumption of single-use assemblies varies globally, influenced by the maturity of the local biopharma sector, the presence of Contract Manufacturing Organizations (CMOs), and regional investment in healthcare infrastructure.

North America

Estimated Growth Rate: 14% – 16%

North America remains the largest market share holder. The region hosts the headquarters of major technology providers and a dense concentration of early-stage biotech firms in hubs like Boston and San

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Francisco. The adoption rate of SUT in commercial manufacturing is highest here. The United States leads demand, driven by massive investments in personalized medicine and reshoring of drug manufacturing supply chains.

Europe

Estimated Growth Rate: 13% – 16%

Europe represents a highly mature market with strong manufacturing bases in Germany, Switzerland, Ireland, and France. The region is characterized by a mix of traditional stainless-steel facilities transitioning to hybrid models and new single-use facilities. European regulatory bodies have been instrumental in shaping the quality standards for plastics in bioprocessing.

Asia-Pacific (APAC)

Estimated Growth Rate: 17% – 22%

The APAC region is the fastest-growing market. China and India are rapidly expanding their domestic biomanufacturing capabilities to reduce reliance on imports.

Taiwan, China: The market in Taiwan, China is witnessing significant acceleration, driven by government initiatives to foster a biotechnology corridor. CDMOs in Taiwan, China are increasingly adopting single-use assemblies to attract international clients requiring flexible, high-speed production.

Other key growth engines include South Korea and Singapore, which serve as regional hubs for high-value biologic manufacturing.

Latin America

Estimated Growth Rate: 10% – 14%

Growth is driven by Brazil and Mexico, where there is rising demand for biosimilars and vaccines. The market is shifting from purely importing

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finished drugs to establishing local fill-finish capabilities using single-use systems.

Middle East and Africa (MEA)

Estimated Growth Rate: 9% – 13%

While currently a smaller share of the global market, the MEA region is seeing investment in vaccine self-sufficiency, particularly in Saudi Arabia and the UAE, promoting the adoption of modular single-use facilities.

Market Segmentation by Type

Bag Assemblies?This is the largest segment by revenue. It encompasses 2D bags for storage and sampling (50mL to 50L) and 3D bags for bioreactors and mixing (50L to 3000L). The trend is shifting towards film technologies with superior gas barrier properties and lower extractable profiles to ensure drug stability during long-term storage or freezing.

Filtration Assemblies?Filtration assemblies are critical for sterility assurance. This segment includes capsule filters attached to tubing and connectors, used for buffer filtration, media filtration, and final fill-finish operations. The demand is driven by the industry's move toward 'closed processing' to minimize contamination risks.

Mixing System Assemblies?Single-use mixing systems are replacing stainless steel vessels for buffer and media preparation. These assemblies typically consist of a bag with an integrated impeller or mixing element. They are crucial for improving the turnover time in facilities, as they eliminate the cleaning validation steps required for steel tanks.

Bottle Assemblies?Used primarily for small-volume fluid transfer, sampling, and seed train expansion. While simpler than bag assemblies, they remain essential for R&D and pilot-scale operations.

Other Assemblies?This category includes tubing manifolds, transfer sets, and sensor assemblies (pH, dissolved oxygen, pressure). The integration of single-use sensors is a high-growth area, enabling real-time monitoring without

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invasive sampling.

Market Segmentation by Application

Biopharmaceutical & Pharmaceutical Companies?These entities are the primary end-users. Large pharma companies are adopting single-use assemblies for clinical trial material production and increasingly for commercial manufacturing of high-potency ingredients where containment is paramount (e.g., ADCs - Antibody-Drug Conjugates).

CROs & CMOs (Contract Research & Manufacturing Organizations)?CMOs are the most aggressive adopters of single-use assemblies. Their business model relies on the ability to switch rapidly between different client products without cross-contamination. Single-use technology allows CMOs to operate 'multiproduct' facilities with reduced capital investment compared to stainless steel.

Academic & Research Institutes?Universities and government labs utilize these assemblies for fundamental research and process development. The scalability of single-use systems allows research data to be easily translated to larger industrial scales.

Industry Value Chain Analysis

The value chain of the single-use assemblies market is complex and relies heavily on material science and supply chain integrity.

Raw Material Suppliers (Resin and Film Manufacturers): The chain begins with producers of medical-grade resins (polyethylene, polypropylene, EVOH). Developing a bioprocess film is a capital-intensive process requiring years of validation. The industry is currently seeing a consolidation of film formulations to ensure supply security.

Component Manufacturers: Companies that mold connectors, extrude tubing, and manufacture filters. Precision injection molding and cleanroom extrusion are key capabilities here.

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Assembly and Integration (System Integrators): This is the core activity of the key market players. They source components (often vertically integrated) and assemble them in ISO Class 7 cleanrooms according to client designs.

Sterilization Services: Completed assemblies must be sterilized. Gamma irradiation (Cobalt-60) is the industry standard, but capacity constraints are driving interest in X-ray sterilization as a viable alternative.

Distribution and Logistics: Maintaining the integrity of the sterile barrier during shipping is critical.

Key Market Players

The market is consolidated, with a few major players dominating the global supply chain.

Thermo Fisher Scientific Inc.: A dominant leader offering an end-to-end portfolio. Their acquisition strategies have strengthened their position in bioprocessing. They provide widely used films and bioreactor systems, known for their global logistics network.

Sartorius AG: A pioneer in single-use technologies. Sartorius focuses heavily on fluid management and fermentation. Their integrated solutions often feature proprietary automation, making them a preferred partner for scalable bioprocessing.

Danaher Corporation: Through its operating companies (Cytiva and Pall), Danaher holds a massive market share. They offer one of the most comprehensive portfolios, ranging from upstream bioreactor bags to downstream filtration assemblies.

Merck KGaA: Operating as MilliporeSigma in the US and Canada, they are a legacy leader in filtration. Their single-use offering is robust in downstream processing and formulation.

Avantor Inc.: Known for their strength in fluid handling and global distribution. Avantor has expanded its manufacturing footprint to support single-use customization.

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Saint-Gobain S.A.: Leveraging deep expertise in material science, Saint-Gobain is a key supplier of high-performance tubing, connectors, and bags, often acting as a component supplier to other integrators as well as selling direct assemblies.

Entegris Inc.: Focuses on high-purity fluid handling. Their acquisition of CMC Materials and other assets has expanded their presence in the biopharma life sciences sector, particularly in cold-chain logistics for frozen bulk drug substances.

Repligen Corporation: Specialists in intensified bioprocessing. Their hollow fiber filtration technologies and chromatography systems are integral to modern single-use downstream workflows.

Parker-Hannifin Corporation: While broadly industrial, their Bioscience division provides specialized filtration, fluid connect solutions, and sensing technologies critical for assembly integrity.

Market Opportunities

Cell and Gene Therapy (CGT) Expansion: CGT workflows are inherently small-volume and patient-specific (autologous therapies). Single-use assemblies are the only viable economic option for these therapies, as cleaning validation for patient-specific batches is impractical. This sector presents the highest growth potential for specialized, small-scale assemblies.

Regional Localization and Supply Chain Redundancy: Post-pandemic, there is a massive opportunity for suppliers who can offer 'in-region for region' manufacturing. Establishing assembly hubs in APAC and Europe to serve local clients reduces lead times and carbon footprints.

Biosimilars Market: As patents for blockbuster biologics expire, the biosimilars market is booming. Manufacturers of biosimilars are price-sensitive and favor single-use facilities to lower upfront capital expenditure (CapEx) and reduce the cost of goods sold (COGS).

Market Challenges

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Leachables and Extractables (L&E): The interaction between plastic surfaces and liquid drug products is a primary safety concern. While USP provides a standard, the burden of data generation falls on suppliers. proving safety for novel drug formulations remains a technical challenge.

Plastic Waste and Sustainability: The 'single-use' nature creates significant plastic waste. While LCAs (Life Cycle Assessments) often show single-use is favorable regarding water and energy, the visible plastic waste is a reputational risk. The industry faces the challenge of developing recycling programs for multi-layer bioprocess films, which are notoriously difficult to recycle.

Supply Chain Vulnerability: The industry relies on a limited number of resin suppliers. Disruptions in raw material availability (as seen during the COVID-19 pandemic) can halt global drug production. Building resilient, multi-sourced supply chains is a persistent challenge.

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Figure 2021-2026 Saint-Gobain S.A. Single-Use Assemblies Market Share
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