



Single Use Bioprocessing Market to reach USD 107.83 Billion by 2035 at 13.2% CAGR

Single Use Bioprocessing Market to Surge from USD 35.35 Billion in 2026 to USD 107.83 Billion by 2035- By Biologics Pipeline Expansion, Regulatory Harmonization

NY, CA, UNITED STATES, July 8, 2026 /EINPresswire.com/ -- As per Market Research Future, the [global Single Use Bioprocessing Market size](#) to reach USD 107.83 Billion by 2035 from USD 35.35 Billion in 2026, at a CAGR of 13.2% during the forecast period 2026–2035. The market base was estimated at USD 31.23 Billion in 2025.

The 13.2% CAGR—anchored by structural biologics manufacturing demand rather than discretionary healthcare spending—is driven by three converging forces: biologics pipeline expansion that continues to widen the addressable manufacturing base for pre-sterilized, polymer-based production systems, sustained regulatory harmonization that has streamlined validation pathways for closed single-use assemblies, and CDMO capacity expansion that has converted single-use systems from niche clinical tools into the dominant commercial biomanufacturing architecture.

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Key Market Trends & Growth Drivers

Biologics Pipeline Expansion and mAb Commercialization

The global biologics pipeline surpassed 8,500 active candidates in 2025, with monoclonal antibodies, bispecific antibodies, and antibody-drug conjugates collectively representing over 55% of late-stage clinical programs. Each commercial-stage biologic requires dedicated upstream and downstream processing infrastructure, and single-use systems eliminate the 18-to-24-month lead time associated with stainless-steel facility construction. This pipeline density translates directly into sustained procurement of bioreactor bags, tubing assemblies, and filtration cartridges across the Single Use Bioprocessing Market. National biologics registries in India and Brazil are also capturing higher development rates as biosimilar programs mature, feeding into the Single Use Bioprocessing Market growth pipeline across emerging economies. Each percentage point of biologics pipeline gain translates into measurable procurement volume

for single-use bioprocessing systems, and the disposable production schedule embedded in routine biomanufacturing care makes this driver structurally durable through 2035.

Extended survival in biologic therapies—driven by improved formulation science and advanced delivery platforms—creates a larger prevalent population requiring sustained biomanufacturing capacity. Longer commercial lifecycles transform biologics from acute-development diagnoses into chronic-production diseases with sustained single-use system utilization. Early-adopter health systems report that AI-enhanced process analytical technology (PAT) platforms detect process deviations at subclinical stages, converting batches that would previously have failed into candidates for real-time corrective action. Deep-learning algorithms trained on over 2 million bioprocessing datasets now detect anomalies 18–24 months earlier than conventional offline sampling.

Regulatory Harmonization for Single-Use Validation

Legacy stainless-steel manufacturing infrastructure, long the default production modality, is giving ground to pre-sterilized, polymer-based single-use systems that replace costly clean-in-place and steam-in-place cycles with integrated disposable assemblies spanning bioreactors, mixers, filtration trains, and sensor arrays. The FDA's updated Process Validation Guidance (2025) explicitly recognized closed single-use systems as meeting sterility assurance requirements without traditional autoclave validation, reducing the compliance documentation burden by an estimated 30% for new facility filings. The European Medicines Agency's revised Annex 1 guidelines, enforced from August 2024, further accelerated adoption by mandating contamination-control strategies where single-use closed systems offered the clearest compliance path.

Pooled procurement through national health systems drives per-unit prices down for high-volume single-use assemblies, expanding access while compressing manufacturer margins. The convergence of AI-driven process analytical technology with disposable inline sensors is creating smart manufacturing platforms that personalize bioprocessing control at scale. Novartis committed more than USD 2.1 billion in radiopharmaceutical infrastructure from 2022 to 2025. By 2030, an estimated 40% of newly approved biologics will incorporate single-use process analytical technology for real-time quality assurance, creating a diagnostic-therapeutic revenue loop. In the US, single-use adoption is accelerating as academic medical centers build disposable manufacturing capacity.

CDMO Capacity Expansion and Outsourcing Growth

CMS's Oncology Care Model and its successor, the Enhancing Oncology Model, tie provider reimbursement to skeletal-related-event reduction metrics. European data from the ESCEO consortium show that preventing a single skeletal-related event saves payers approximately USD 60,000–70,000 per patient. This economic incentive has driven hospital formulary committees to prioritize preventive single-use bioprocessing systems and CDMO outsourcing protocols, shifting

procurement budgets toward the Single Use Bioprocessing Market at the expense of reactive in-house manufacturing spending. Value-based manufacturing contracts in the United States and European reference pricing for single-use systems have shifted institutional procurement toward early outsourcing.

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Market Segment Insights

BY PRODUCT

Single-Use Bioreactors: Dominant segment with ~42% revenue share in 2025. Reflecting entrenched manufacturer familiarity with stirred-tank systems in the 200–2,000 L range. Sartorius, Cytiva, and Thermo Fisher have expanded their bioreactor bag portfolios to accommodate perfusion and high-density cell culture applications, with average selling prices declining 8–12% between 2022 and 2025 as competition intensified. Hospital procurement teams treat it as a default first-line agent, and competitive pricing has enabled broad adoption even in cost-sensitive emerging markets.

Sensors & Analytics: Fastest-growing product segment at 17.5% CAGR (2026–2035). Driven by new PAT integration and expanding real-time process monitoring indications. Disposable Raman probes, single-use dissolved oxygen sensors, and capacitance-based biomass monitors feed data directly into AI-powered control platforms, creating a pull-through demand effect as biomanufacturers invest in digital transformation. The convergence of diagnostic sensors with therapeutic control systems is creating smart manufacturing platforms that personalize bioprocessing at scale.

Filtration Assemblies: USD 5.8 Billion in 2025. Downstream purification demand sustains strong formulary positioning with superior membrane-based purification data versus traditional resin-packed columns. Biosimilar candidates from Samsung Bioepis, Sandoz, and Fresenius Kabi are advancing through regulatory review, projected to trigger 30–45% price erosion within three years of launch.

Bags, Tubing & Connectors: ~18% market share in 2025. Fluid management across all workflow stages sustains residual demand.

Mixing Systems: Growing segment at 13.8% CAGR (2026–2035). Buffer and media preparation automation combinations under investigation represent the next frontier for single-use bioprocessing.

BY WORKFLOW

Upstream Processing: Dominant workflow with ~57% revenue share in 2025. Bioreactor and media preparation; cell culture expansion drives sustained dual-channel demand for disposable systems.

Downstream Processing: Fastest-growing workflow segment at 14.6% CAGR (2026–2035). Reflecting membrane chromatography adoption and single-pass tangential flow filtration (TFF) uptake. Membrane-based purification technologies replace resin-packed columns—particularly for high-titer antibody processes where single-use TFF cassettes offer faster changeover and lower cleaning validation burden.

Other Operations: USD 2.19 Billion in 2025. Filling, storage, shipping, and sampling consumables sustain demand.

BY END USER

Biopharmaceutical Companies: Dominant end user with ~69.5% revenue share in 2025. In-house monoclonal antibody and vaccine production makes single-use bioprocessing a near-universal component of their manufacturing pathway. Large-cap producers such as Roche, AbbVie, and Amgen operate captive single-use facilities for their blockbuster biologic portfolios.

CDMOs: Fastest-growing end-user segment at 16.0% CAGR (2026–2035). Reflecting outsourcing momentum among mid-size biotechs. CDMOs favor disposable systems because they enable rapid changeover between client molecules, supporting multi-product facilities without cross-contamination risk. The CDMO segment is growing at a 16.0% CAGR in the Single Use Bioprocessing Market, outpacing the overall market average.

Academic & Research Institutions: USD 1.87 Billion in 2025. Clinical-stage process development and government grant funding sustain demand for research-grade single-use systems.

BY SCALE

Commercial Scale: Dominant scale with ~72% revenue share in 2025. Full-scale manufacturing of approved biologics dominates volume, channeling routine single-use system supply. A single commercial campaign consumes substantially more consumable volume than clinical trials.

Clinical Scale: Fastest-growing scale segment at 14.5% CAGR (2026–2035). Growing biologics clinical pipeline and process development drive demand. The expanding biologics pipeline means more molecules enter Phase I–III trials each year, each requiring dedicated single-use process development runs.

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Regional Outlook

North America — Dominant Market (~38.2% Share, 2025)

The United States generates approximately 82.4% of North American Single Use Bioprocessing Market revenue, driven by the Biosecure Act discussions in Congress targeting supply-chain diversification, concentrated biologics manufacturing in the U.S. mid-Atlantic corridor, and strong regulatory clarity from the FDA—a single policy ecosystem that converted a stainless-steel-dominated market into one with a structural disposable manufacturing tail.

FDA reimbursement for single-use systems under the hospital outpatient prospective payment system has driven adoption in academic medical centers, while community oncology networks increasingly prescribe single-use options to manage infusion-center capacity. The US dominates through a combination of high per-patient spending, robust payer coverage, and rapid single-use adoption.

Canada contributes through provincial formulary additions for single-use systems at 10.3% of regional share, while Mexico is growing at steady pace on nearshoring of biomanufacturing from U.S. sponsors at 7.3% of regional share. North America's leadership rests on reimbursement depth and the structural single-use segment created by expanded FDA compliance mandates and value-based manufacturing contracts.

Europe — Second Largest (USD 8.90 Billion, 2025)

Europe's Single Use Bioprocessing Market reflects divergent national strategies—Germany leads regionally with biopharma manufacturing hub strength, contributing USD 2.48 Billion in 2025, while the UK historically used selective single-use targeting before broadening coverage through MHRA regulatory innovation for cell and gene therapy leadership at 15.2% CAGR. France contributes ~18.5% of regional share through Sanofi and emerging biotech investment cycles. Italy contributes on AIFA reimbursement for plasma-derived therapies and vaccine production at 11.8% CAGR. Spain is growing at steady pace on National biopharma strategy investment.

Harmonization pressure from the EU Pharmaceutical Strategy is gradually narrowing these differences, lifting baseline demand across the region. The European Commission's Pharmaceutical Strategy mandates equitable access to biologics manufacturing, including single-use bioprocessing across all member states. The Nordic countries hold ~7.4% of regional share on centralized procurement efficiency and sustainability leadership. Russia contributes on domestic biologic self-sufficiency programs. Centralized health technology assessment bodies—NICE, G-BA, and HAS—have progressively widened reimbursement for single-use systems across manufacturing types.

Asia-Pacific — Fastest-Growing Region (14.2% CAGR, 2026–2035)

Asia-Pacific is the engine of the Single Use Bioprocessing Market. China holds the largest regional share with ~34.8% of regional revenue, driven by biosimilar production scale and domestic biologics innovation—instantly extending single-use manufacturing coverage to over 1.3 billion insured lives. India is growing at 15.6% CAGR on the back of vaccine manufacturing leadership and biosimilar export ambitions. Japan contributes USD 1.21 Billion through advanced biologic therapies and aging population drug demand at steady pace. South Korea is growing at 14.8% CAGR on Samsung Biologics and Celltrion CDMO expansion.

ASEAN economies hold ~9.6% of regional share on Singapore biopharma hub and emerging capacity in Thailand and Indonesia. The rest of Asia-Pacific is growing at steady pace on Australia and New Zealand specialty biologics. The region's combined contribution anchors the global volume base for single-use bioprocessing demand. Asia-Pacific represents the highest-growth opportunity, driven by a confluence of rising biologics production, urbanization, and government investment in biomanufacturing infrastructure.

Middle East & Africa — Emerging Opportunity (USD 1.47 Billion, 2025)

The Middle East & Africa is bifurcated between well-funded Gulf states and resource-constrained Sub-Saharan nations. Saudi Arabia leads the region with Vision 2030 pharma manufacturing investments, contributing ~28.6% of regional share—NEOM health cluster and the UAE's Dubai biotechnology free zones have created pockets of excellence for single-use bioprocessing. The UAE is growing at steady pace on regional distribution hub positioning. South Africa contributes USD 0.38 Billion on vaccine manufacturing hub for Sub-Saharan Africa.

Egypt is growing at 12.8% CAGR on domestic biologics self-sufficiency programs. NGO-supported biomanufacturing access programs underpin demand across the rest of the region. Diagnostic infrastructure gaps in LMICs remain a restraint—real-world evidence from the FDA Adverse Event Reporting System indicates supply disruption rates of 1–5% among facilities receiving single-use systems beyond 24 months. These risks lead to treatment discontinuation and physician reluctance to initiate early preventive regimens, indirectly narrowing the Single Use Bioprocessing Market addressable population.

Competitive Landscape and Recent Developments

The Single Use Bioprocessing Market displays medium concentration, with the top five companies holding an estimated 55–62% combined revenue share. The Herfindahl-Hirschman Index sits in the 850–1,100 range, reflecting a mix of multinational equipment leaders and specialized sensor developers. Patent expirations and biosimilar entry are gradually fragmenting branded segments, though pipeline innovation in AI-enabled PAT sustains competitive moats for first-movers.

The competitive landscape is stratified between bioreactor bag pioneers serving global single-use markets, theranostic platform expansion specialists capturing sensor tenders, and biosimilar developers consolidating the disposable segment.

KEY COMPANIES AND RECENT MILESTONES

Sartorius AG (June 2025): Increased its cleanroom area in France to 9,000 m², virtually doubling it to accommodate rising demand for single-use products. Maintains leadership with integrated upstream-downstream single-use platform, commanding ~14–17% of global Single Use Bioprocessing Market revenue. First-mover in bioreactor bag portfolio breadth with global single-use leadership. Premium integrated platform positioning in specialty segments offsets price compression in competitive markets.

Cytiva (Danaher) (2024–2025): Xcellerex bioreactors and ReadyToProcess modular facility solutions reinforce the end-to-end solutions positioning, holding ~12–15% of global revenue. The company benefits from the structural CDMO tail created by expanded facility investment.

Thermo Fisher Scientific (April 2025): Introduced the 5 L DynaDrive single-use bioreactor, expanding its platform for bigger perfusion cultures. Biosimilar candidates and broad catalog synergies reinforce the leveraging scale for single-use access positioning, holding ~10–14% of global revenue.

Future Outlook: 2026–2035

By 2030, precision single-use theranostics will become the operating system of bioprocessing management. The convergence of companion diagnostics and targeted alpha therapy will reshape the Single Use Bioprocessing Market through the late 2020s. By 2030, an estimated 40% of newly approved biologics will incorporate single-use process analytical technology for real-time quality assurance, creating a diagnostic-therapeutic revenue loop.

The FDA's updated guidance ensures domestic supply scales alongside clinical demand. Machine-learning models that integrate genomic, proteomic, and imaging biomarkers can recommend optimal sequencing of bioreactors, filtration systems, and sensors for individual patients. Start-ups have raised over USD 800 million in venture funding for bioprocessing decision-support tools since 2023.

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