

Prefilled Syringes - Market Share Analysis, Industry Trends & Statistics, Growth Forecasts (2026 - 2031)

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Report description:

Prefilled Syringes Market Analysis

The Prefilled Syringes Market is expected to grow from USD 9.71 billion in 2025 to USD 10.77 billion in 2026 and is forecast to reach USD 18.08 billion by 2031 at 10.93% CAGR over 2026-2031.

Growth is propelled by surging GLP-1 obesity therapeutics, post-pandemic fill-finish capacity additions, and regulatory moves that favor integrated safety devices. Polymer barrel innovation is challenging the long-held dominance of glass systems, while regional dynamics show North America preserving scale leadership and Asia-Pacific delivering the fastest volume gains. Intensifying demand for self-injection, particularly for high-viscosity biologics, pushes manufacturers to upgrade delivery formats, invest in nested lines, and migrate toward cyclic olefin polymer (COP) platforms. Competitive differentiation now pivots on container-drug compatibility, passive safety features, and the ability to supply ready-to-use configurations at high output.

Global Prefilled Syringes Market Trends and Insights

Rising Self-Injection of GLP-1 Obesity Drugs

Global GLP-1 sales are on course to climb from USD 40 billion in 2023 to USD 150 billion by 2032, igniting sustained demand for advanced self-injection formats. Novo Nordisk has earmarked USD 4.1 billion for new US fill-finish lines and EUR 2.1 billion for French injector-pen expansion, demonstrating the scale of infrastructure now directed to this therapeutic area. BD's Neopak

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XtraFlow syringe with thinner-wall cannulas facilitates high-viscosity dosing, supporting broad patient self-administration while lowering nurse workloads. Adherence studies consistently show higher persistence with prefilled devices, easing the shift from clinic-based to home-based care and embedding a durable growth vector for the prefilled syringes market.

Shift to Biologic-Friendly Cyclic Olefin Polymer (COP) Syringes

Pharmaceutical firms are embracing COP barrels to mitigate silicone-oil interactions that trigger protein aggregation in sensitive biologics, a concern documented in controlled stability trials. COP syringes exhibit lower particulate counts and satisfy ISO/EN 10993 biocompatibility criteria, making them suitable for next-generation drugs. SCHOTT Pharma's TOPPAC freeze platform is purpose-built for temperature-sensitive mRNA therapies, while expanded German polymer capacity underscores the shift away from glass. As biosimilar launches intensify, differentiated delivery systems based on COP barrels are emerging as a competitive lever in the prefilled syringes market.

Glass Delamination Recalls in High-pH Biologics

Delamination erupts when solution pH and ion content leach glass flakes into drug product, a failure mechanism that has forced multiple recalls and FDA warning letters. High-pH biologics are particularly vulnerable, prompting regulators to mandate exhaustive container-closure compatibility studies before approval. Even though prefilled formats outperform vials on many stress metrics, any residual risk spurs pharmaceutical teams to explore polymer alternatives. The resulting material churn injects uncertainty and adds testing costs, tempering near-term growth in the prefilled syringes market.

Other drivers and restraints analyzed in the detailed report include:

Needlestick-Injury Directive Accelerating Safety-Engineered Demand
Post-COVID Vaccine Fill-Finish Expansion
High CAPEX of Nested PFS Lines Detering CMOs

For complete list of drivers and restraints, kindly check the Table Of Contents.

Segment Analysis

Glass syringes held 68.25% of the prefilled syringes market revenue in 2025, benefiting from entrenched regulatory familiarity and scalable borosilicate supply. Yet plastics are sprinting ahead with an 11.71% CAGR as pharma companies migrate to COP barrels that avoid silicone interactions and reduce subvisible particles. The prefilled syringes market size for polymer formats is set to more than double by 2031, underscoring the shift in container-selection criteria from cost to drug-product compatibility. COP's neutrality toward sensitive proteins, verified under ISO/EN 10993, positions it as the go-to material for mRNA, gene-therapy, and high-viscosity GLP-1 formulations. Early adopters such as SCHOTT Pharma now scale dedicated polymer lines in Germany and the US, signaling an irreversible tilt in procurement strategies.

Momentum away from glass also picks up speed as delamination recalls raise red flags among regulators and quality heads. Polymer barrels stored in nitrogen-filled pouches exhibit stability comparable to glass at 2-8 C without the free silicone layer found in legacy syringes. As biologic pipelines expand—now representing more than half of global R&D assets—procurement teams increasingly view polymer as risk insurance. Nevertheless, glass retains advantages in oxidative barrier and legacy change-control files, ensuring a prolonged coexistence between the two materials within the prefilled syringes market.

The 1-2.5 mL class dominated 2025 shipments at 51.68%, reflecting its fit with most single-dose biologic regimens. The 1 mL segment, however, is the dynamo, advancing at an 11.73% CAGR thanks to concentrated GLP-1 formulations and high-potency oncology drugs that favor micro-dosing. Given tighter tolerances at sub-milliliter volumes, suppliers are retrofitting fillers with

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in-line vision systems to guarantee dispense accuracy within 2%. This investment wave enlarges the prefilled syringes market share for smaller barrels as payers and clinicians unite around a lower injection burden.

Conversely, attempts to push beyond 2.5 mL often collide with ISO 11040-4 dimensional limits, causing sporadic plunger jams and line stoppages. Dual-chamber versions above 5 mL face still steeper hurdles, raising validation costs. The economics thus favor high-concentration formulations housed in compact barrels, aligning manufacturing throughput with value-based care imperatives.

The Prefilled Syringes Market Report is Segmented by Material (Glass, Plastic), Barrel Volume (Less Than or Equal To 1 ML, 1 To 2.5 ML, More Than 2.5 ML), Product Type (With Needle, Without Needle), Application (Diabetes, Anaphylaxis, Vaccination, Rheumatoid Arthritis, Oncology, Other Applications), and Geography (North America, Europe, and More). The Market Forecasts are Provided in Terms of Value (USD).

Geography Analysis

North America accounted for 38.40% of 2025 revenue, anchored by deep biologic pipelines and robust safety regulations. BD is enlarging US capacity by 40%, and SCHOTT Pharma is spending USD 371 million on its first American plant, moves designed to meet reshoring policies and GLP-1 volume spikes. Ready access to FDA combination-product pathways streamlines launches, while OSHA mandates ensure steady demand for passive-safety formats. Federal incentives under Executive Order 14017 further sweeten the case for domestic production, cementing the region's leadership in the prefilled syringes market.

Europe maintains healthy mid-single-digit progress, drawing support from stringent needlestick directives that prioritize safety-engineered devices. Gerresheimer is doubling Eastern European output while running innovation centers in Germany and Switzerland. EMA's well-trodden biosimilar route smooths product approvals, encouraging sponsors to opt for differentiated syringe presentations. Meanwhile, Brexit complexities have nudged some firms to build dual inventory hubs, but overall supply resilience remains intact.

Asia-Pacific is the pace-setter with an 11.79% CAGR through 2031. China's NMPA fast-track, embedded in the 2025 reform plan, accelerates biosimilar roll-outs and elevates local syringe demand. Japan's aging demographics amplify self-injection uptake, and India's competitive biosimilar clusters expand export capacity. Nipro's decision to open a North Carolina plant highlights the two-way supply flows now linking Asia with the West. Regional governments back local device manufacturing to curb import deficits, bolstering long-run volume upside for the prefilled syringes market.

List of Companies Covered in this Report:

Beckton Dickinson Gerresheimer SCHOTT West Pharmaceutical Services Terumo Stevanato Group Nipro Catalent Pharma Solutions Vetter Pharma Haselmeier GmbH Baxter Fresenius Nemera Taisei Kako Co. Ltd. Oval Medical Technologies SHL Medical Owen Mumford Plas-Tech Engineering Inc. Laboratoire Aguettant S.A. Credence MedSystems Aptar Pharma

Additional Benefits:

- > The market estimate (ME) sheet in Excel format
- > 3 months of analyst support

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