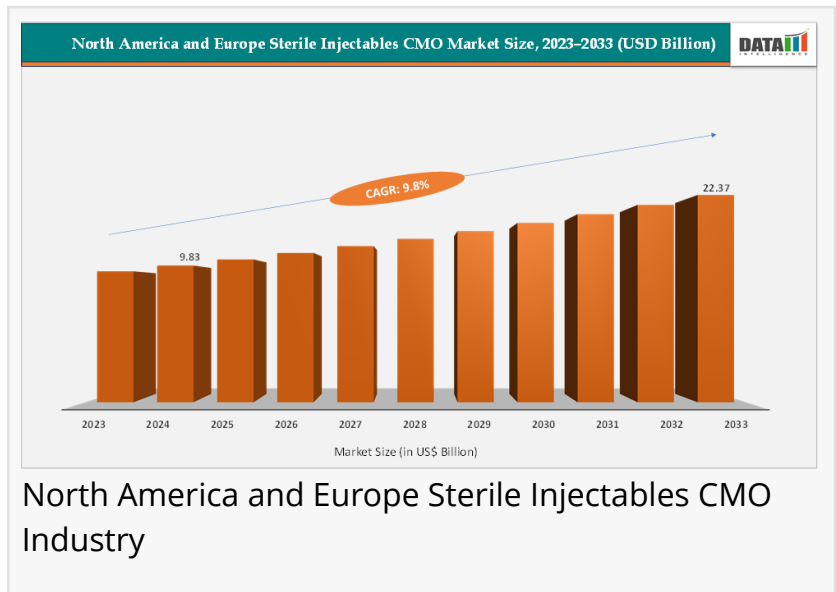


North America and Europe Sterile Injectables CMO Market Set to hit \$22.37B by 2033 Amid Strong Outsourced Manufacturing

Sterile Injectables CMO Market Strengthens in North America & Europe With 9.8% CAGR to 2033

AUSTIN, TX, UNITED STATES, November 18, 2025 /EINPresswire.com/ -- Market Size and Growth

According to DataM Intelligence, the [North America and Europe Sterile Injectables CMO Market](#) reached USD 9.83 billion in 2024, up from USD 9.15 billion in 2023, and is projected to grow to USD 22.37 billion by 2033, registering a CAGR of 9.8% during 2025–2033.



According to a recent NCBI analysis, the estimated manufacturing cost for sterile vaccine formulation is approximately US\$0.12 per ampoule and about US\$0.35 per vial.



Future Outlook: NA & Europe Sterile Injectables CMO Market to Reach \$22.37B by 2033"

DataM Intelligence 4Market Research LLP

Norbrook in Northern Ireland has enhanced its sterile injectable production capabilities through a £1.3 million investment, adding a new modular cleanroom and upgraded HVAC systems to meet the latest EU GMP Annex 1 standards. The upgraded facility supports the manufacture of critical sterile injectable veterinary

medicines.

Simtra BioPharma Solutions formerly known as Baxter BioPharma has invested more than US\$250 million to expand its sterile fill-finish operations in Bloomington, Indiana, driven by the rising demand for [biologics](#) and injectable therapeutics.

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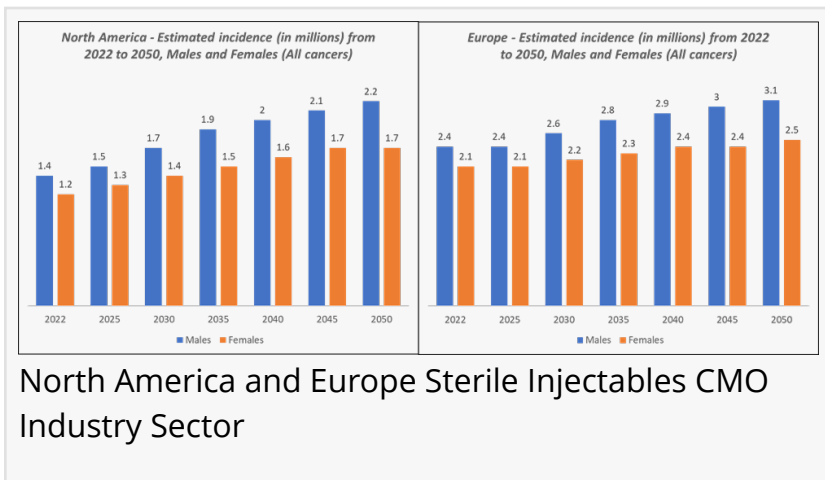
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Key Highlights from This Report

1. North America remained the leading region in the sterile injectables CMO market, accounting for 59.51% of total revenue in 2024.
2. On the basis of therapeutic area, the oncology segment emerged as the top contributor, capturing 32.39% of the market revenue in 2024.

Growth Drivers

1. Over 45% of new drug approvals in 2024 were sterile injectable formulations, particularly biologics and oncology drugs.
2. Global biopharmaceutical R&D investment reached USD 280 billion in 2024, with over 35% allocated to injectable therapeutics.
3. More than 320 sterile injectables facilities in North America & Europe reported capacity constraints in 2024, increasing outsourcing reliance.
4. The injectable pipeline expanded from 4,900 candidates in 2023 to 6,100 in 2024, pushing demand for high-throughput fill-finish capabilities.
5. Automated & robotics-enabled fill-finish systems adoption grew 70% YoY, improving sterility assurance and reducing production errors.

Market Segmentation Analysis

By Service

Aseptic Fill-Finish Services lead with 55% share (USD 10.1 billion in 2024), projected to reach USD

32 billion by 2032 at 16.2% CAGR.

Lyophilization Services account for 25% share, growing at 14.8% CAGR.

Analytical & Packaging Services represent the remaining 20%.

By Molecule Type

Biologics dominate with 58% share, driven by monoclonal antibodies and cell/gene therapies.

Small Molecules hold 42%, driven by oncology and anti-infectives.

By Dosage Form

Vials represent 65% share, remaining the preferred sterile format.

Prefilled Syringes growing fastest at 18% CAGR, supported by self-injectable biologics.

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Regional Insights

North America

Valued at USD 11.2 billion in 2024, projected to reach USD 35.6 billion by 2032 at 59.51% CAGR. The U.S. FDA approved 52 sterile injectables in 2024, boosting CMO demand.

Over 60% of U.S. biotech startups outsource sterile fill-finish operations.

Major expansions announced across New Jersey, Indiana, and Ontario facilities.

Europe

Valued at USD 7.2 billion in 2024, expected to reach USD 22.1 billion by 2032 at 15% CAGR. EU GMP Annex 1 revisions accelerated investment in advanced aseptic technologies.

Germany, Switzerland, and Ireland remain major hubs for sterile manufacturing.

Key Players:

Catalent, Inc | | Thermo Fisher Scientific Inc. | | Recipharm AB | | Jubilant HollisterStier | | Grand River Aseptic Manufacturing | | Afton Scientific Lonza | | Catalent | | Baxter BioPharma Solutions | | Siegfried | | Vetter Pharma | | Recipharm | | Thermo Fisher | | Alcam | | PCI Pharma | | B

Braun OEM

Key Highlights

1. Lonza expanded sterile fill-finish capacity in Switzerland with a USD 400M investment.
2. Catalent reported a 22% YoY increase in biologics injectable manufacturing revenue.
3. Vetter Pharma launched next-gen automated syringe filling technology.
4. Thermo Fisher completed three facility expansions across the U.S. and Italy.

Recent Developments

Catalent inaugurated a high-speed prefilled syringe line in Indiana (2025).

Lonza partnered with multiple biotech companies for mAb fill-finish programs (2024).

Siegfried acquired two EU aseptic facilities to expand the injectable portfolio (2025).

Recipharm launched an advanced Annex 1-compliant isolator platform (2024).

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Conclusion:

The North America and Europe Sterile Injectables CMO market is set for strong, sustained growth as demand for biologics, [oncology therapies](#), and advanced injectable formulations continues to rise. With major capacity expansions, strict regulatory alignment, and increasing outsourcing by pharma and biotech companies, the region remains a global hub for sterile manufacturing excellence.

Market Outlook

Fill-finish services to exceed USD 32 billion by 2032.

Prefilled syringes to capture 28% of the market by 2032.

Biologics-focused sterile injectables to grow at 17% CAGR.

Related Reports:

Sterile Injectables CMO Market Rising at 13.1% CAGR - DataM Intelligence @
<https://www.datamintelligence.com/research-report/sterile-injectables-cmo-market>

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