Top 10 Best Sterile Fill-Finish CDMOs in 2026 (Ranked)

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Editorial ranking methodology

This editorial ranking evaluates ten CDMOs with publicly disclosed sterile fill-finish capabilities as of August 2026. Rankings reflect a qualitative assessment of five disclosed factors: operating footprint and scale (30%), container-format and modality breadth (25%), regulatory and quality information (20%), maturity of announced capacity expansion (15%), and the depth of current public capability disclosure (10%). The evidence is not standardized across companies, so the ranking is a directional editorial comparison rather than a certification of quality, available capacity, or technical fit. Sponsors should validate current, site-specific capacity, inspection history, and technical fit before contracting.

1. Lonza
2. Thermo Fisher Scientific (Patheon)
3. Catalent (a Novo Holdings company)
4. Samsung Biologics
5. WuXi Biologics
6. Vetter Pharma
7. Boehringer Ingelheim (BioXcellence)
8. CordenPharma
9. Recipharm
10. Fareva

Executive Summary

Sterile fill-finish, the aseptic transfer of a finished sterile drug product into vials, pre-filled syringes (PFS), or cartridges, is the final and most contamination-sensitive step in manufacturing injectable medicines. Demand for outsourced capacity has surged alongside biologics and GLP-1 (glucagon-like peptide-1) therapy growth: the global sterile injectables contract development and manufacturing organization (CDMO market was estimated at $37.82 billion in 2025 and is projected to reach $87.34 billion by 2033, an 11.2% compound annual growth rate (CAGR), according to Grand View Research (Source: grandviewresearch.com). Within that market, large-molecule biologics already account for 61.4% of revenue (Source: grandviewresearch.com), and pre-filled syringes are the fastest-growing container format at a 9.3% CAGR through 2030 (Source: grandviewresearch.com).

This report ranks ten CDMOs with publicly disclosed sterile fill-finish capabilities as of August 2026: **Lonza**, **Thermo Fisher Scientific (Patheon)**, **Catalent** (a Novo Holdings company), **Samsung Biologics**, **WuXi Biologics**, **Vetter Pharma**, **Boehringer Ingelheim (BioXcellence)**, **CordenPharma**, **Recipharm**, and **Fareva**. The ranking applies the disclosed-factor methodology above and should be read as a directional editorial comparison, not a certification of quality or capacity availability. Lonza and Thermo Fisher Scientific lead on combined scale and balance-sheet depth, the latter producing more than 130 million sterile vials annually (Source: patheon.com) and having completed a September 2025 acquisition of Sanofi's Ridgefield, New Jersey sterile site (Source: ir.thermofisher.com). Catalent, now owned by Novo Holdings following a $16.5 billion acquisition completed December 18, 2024 (Source: catalent.com), illustrates a broader consolidation trend as biologics originators internalize fill-finish capacity.

Two structural forces shape competitive positioning across the field. First, the European Commission's revised Annex 1 to EU Good Manufacturing Practice, effective August 25, 2023, requires every sterile manufacturer to maintain a documented Contamination Control Strategy (Source: health.ec.europa.eu), pushing CDMOs toward isolator-based filling. Second, GLP-1 demand has triggered billions in new capacity commitments, including Novo Nordisk's $4.1 billion second fill-finish facility in Clayton, North Carolina (Source: globenewswire.com) and CordenPharma's $981 million GLP-1 peptide expansion (Source: fiercepharma.com). L.E.K. Consulting assesses that aseptic fill-finish demand growth will continue to outpace capacity for the next five to ten years despite this investment wave (Source: lek.com).

For sponsors selecting a partner, container-format specialization matters: WuXi Biologics' DP5 facility handles 17 to 20 million PFS units annually (Source: wuxibiologics.com), while Vetter Pharma, a pure-play specialist, filled 238 million injectable units in 2025 on $1.26 billion (€1.26 billion) in sales (Source: vetter-pharma.com). No single CDMO dominates every modality, format, and region simultaneously, so this report presents a detailed feature comparison, benchmark data, and a Frequently Asked Questions section to support structured evaluation.

Introduction and Background

Sterile fill-finish is the final, most failure-intolerant stage of injectable drug manufacturing: the aseptic transfer of a sterile drug substance into its final container, whether a vial, a pre-filled syringe (PFS), a cartridge, or an ampoule, under conditions engineered to exclude microbial, particulate, and endotoxin contamination. CDMOs that specialize in this step underpin the global supply of vaccines, monoclonal antibodies, GLP-1 therapies, and other parenteral (injected) medicines. Demand for outsourced aseptic capacity has intensified as biologics have come to dominate the injectable pipeline: large-molecule products accounted for 61.4% of global revenue in the sterile injectables CDMO market in 2025, according to Grand View Research (Source: grandviewresearch.com).

The global sterile injectables CDMO market was estimated at $37.82 billion in 2025 and is projected to reach $87.34 billion by 2033, an 11.2% CAGR (Source: grandviewresearch.com). A related segment, sterile injectable contract manufacturing, was sized at $15,997.7 million in 2024 with a projected 12.3% CAGR through 2030 (Source: grandviewresearch.com). Within it, fill-finish pharmaceutical contract manufacturing specifically was valued at $17.95 billion in 2024, expected to reach $29.06 billion by 2030 at an 8.3% CAGR (Source: grandviewresearch.com), with prefilled syringes the fastest-growing format at a 9.3% CAGR (Source: grandviewresearch.com).

Two forces are reshaping the competitive field covered in this report. First, the European Commission's revised Annex 1 to EU GMP (Manufacture of Sterile Medicinal Products), which took effect August 25, 2023, requires every sterile manufacturer to maintain a documented Contamination Control Strategy (CCS), applying Quality Risk Management to ensure contamination is prevented in the final product (Source: health.ec.europa.eu). The guidance recognizes both RABS and isolators as beneficial technologies; technology selection and any alternative approach should be justified through the site-specific CCS. The Parenteral Drug Association (PDA) describes the CCS as a comprehensive document demonstrating that contamination risks are controlled at every production stage (Source: pda.org). In the United States, FDA's 2004 Guidance for Industry on aseptic processing describes the agency's current thinking and is intended to help manufacturers meet CGMP requirements under 21 CFR parts 210 and 211; it is guidance rather than the binding regulation itself (Source: fda.gov). Second, GLP-1 weight-loss and diabetes therapies have driven a wave of multi-billion-dollar capacity investment across the industry, detailed later in this report.

This report ranks ten CDMOs with publicly disclosed sterile fill-finish capabilities as of August 2026: Lonza, Thermo Fisher Scientific (Patheon), Catalent, Samsung Biologics, WuXi Biologics, Vetter Pharma, Boehringer Ingelheim (BioXcellence), CordenPharma, Recipharm, and Fareva. The ranking uses the disclosed-factor methodology above; it compares published filling lines, annual unit throughput, modality breadth, regulatory information, and recent capital investment, but does not certify quality or capacity availability.

Lonza

Capabilities

Lonza, founded in 1897 (Source: lonza.com) and headquartered in Switzerland, describes itself as one of the world's largest CDMOs (Source: lonza.com), employing approximately 20,000 people across more than 30 sites on five continents (Source: lonza.com). Its biologics drug product network centers on GMP operations in Stein and Visp, Switzerland, complemented by a Center of Excellence in Basel, offering liquid and lyophilized vial filling, cartridges, prefilled syringes, and ampoules across a wide potency range (Source: lonza.com). In October 2025, Lonza received Swissmedic approval for a new aseptic filling line in Stein using advanced isolator and containment technology built to fulfill GMP Annex 1 requirements, supporting monoclonal antibodies, bispecific antibodies, and antibody-drug conjugates (ADCs) (Source: lonza.com).

Adoption

A larger, separate Stein expansion, a 20,000-square-meter facility supported by a CHF 500 million investment, is scheduled to open in Q4 2027, adding vial filling, PFS/cartridge filling, and vial lyophilization (Source: lonza.com) (Source: lonza.com). Lonza reports more than 150 successful biologics drug product technology transfers in the past five years (Source: lonza.com) and more than 22 active growth projects scaling drug product capacity (Source: lonza.com). The company posted CHF 6.5 billion in company-wide sales with CHF 2.1 billion CORE EBITDA for full-year 2025 (Source: lonza.com), scale that funds parallel investment across its Swiss and Chinese network.

Strengths and Limitations

Lonza's strengths are breadth of modality coverage, from simple monoclonal antibodies to complex ADCs (Source: lonza.com), and a heavily capitalized, multi-year expansion pipeline backed by a 100% success rate the company claims for CMC modules under Annex-1 compliant solutions (Source: lonza.com). A documented limitation is capacity timing: several of Lonza's newest large-scale drug product lines, including the Q4 2027 Stein facility, are not yet operational, so near-term sterile fill-finish capacity remains concentrated at existing Stein and Visp lines.

Thermo Fisher Scientific (Patheon)

Capabilities

Thermo Fisher Scientific's Patheon pharma services brand operates sterile fill-finish CGMP facilities across North America, Europe, and Asia-Pacific supporting biologics, small molecules, and mRNA therapeutics (Source: patheon.com), producing more than 130 million sterile liquid and lyophilized vials annually (Source: patheon.com). Its network supports liquid-filled vials (2 to 500 mL commercial range), lyophilized vials, prefilled syringes (0.5 to 20 mL), and prefilled cartridges (Source: patheon.com). Individual sites specialize: Monza, Italy focuses on prefilled syringe, cartridge, and mRNA drug substance manufacturing, including lipid nanoparticle (LNP) formulation, and supplies more than 20 countries (Source: patheon.com); Ferentino, Italy is a 14,034-square-meter integrated sterile liquid and lyophilized site with high-potency handling up to category 3b (Source: patheon.com); Greenville, North Carolina is described by the company as its North American "flagship site" for sterile fill-finish (Source: pharmamanufacturing.com).

Adoption

In April 2025, Thermo Fisher announced a $2 billion, four-year commitment to U.S. manufacturing and research and development, with $1.5 billion earmarked for capital expenditures including additional sterile fill-finish lines at Greenville (Source: pharmamanufacturing.com). On September 2, 2025, the company completed acquisition of Sanofi's sterile fill-finish and packaging site in Ridgefield, New Jersey, adding more than 200 employees and a third U.S. sterile fill-finish site alongside Greenville and Plainville, Massachusetts (Source: ir.thermofisher.com). Thermo Fisher Scientific reported full-year 2024 company-wide revenue of $42.88 billion (Source: ir.thermofisher.com).

Strengths and Limitations

Thermo Fisher's principal strength is network depth, six facilities globally supporting aseptic manufacturing and sterile fill-finish (Source: patheon.com), backed by a $42.88 billion parent company. Regulatory reach is broad, with Monza alone holding approvals from ANVISA, Japan's PMDA, the U.S. FDA, and the EMA, among others (Source: patheon.com). A limitation is that sterile fill-finish is one of several service lines inside a much larger life-sciences tools conglomerate, so fill-finish-specific unit economics are not separately broken out in company financial disclosures.

Catalent (a Novo Holdings Company)

Capabilities

Catalent, formed in 2007 (Source: catalent.com) and now privately owned, fills vials, prefilled syringes, and cartridges under aseptic CGMP conditions with more than 30 years of experience across monoclonal antibodies, bispecifics, ADCs, and fusion proteins (Source: catalent.com). Its vial filling supports 2R to 20R ISO formats using time-pressure, piston-pump, and peristaltic dispensing (Source: catalent.com), and its Limoges, France site fills syringes and cartridges using isolator-based aseptic processing (Source: biologics.catalent.com). The company states its isolator- and RABS-based aseptic fills meet current EU Annex 1 expectations, with a sustained inspection record across EU and U.S. health authorities (Source: catalent.com). Catalent operates close to 40 sites worldwide with more than 3,000 scientists and technicians (Source: catalent.com).

Adoption

Novo Holdings completed its acquisition of Catalent in an all-cash transaction with a total enterprise value of approximately $16.5 billion on December 18, 2024 (Source: catalent.com). As part of that transaction, three Catalent sterile fill-finish sites (Anagni, Italy; Bloomington, Indiana; and Brussels, Belgium), together employing more than 3,000 people, were sold onward to Novo Nordisk (Source: globenewswire.com); Catalent has confirmed that as of December 2024 the former Bloomington site is fully owned and operated by Novo Nordisk and is no longer part of Catalent's network (Source: catalent.com). In its last full year as a public company, Catalent reported fiscal 2024 net revenue of $4.38 billion, up 3% year over year (Source: businesswire.com).

Strengths and Limitations

Catalent's institutional strength is documented regulatory throughput: the company states it has assisted in 50% of all FDA approvals over the past ten years (Source: novoholdings.dk). Its principal limitation, evident from 2024's restructuring, is that the ownership change removed three sterile fill-finish sites from its own network, so prospective sponsors should verify which specific facilities remain under Catalent versus Novo Nordisk before contracting.

Samsung Biologics

Capabilities

Samsung Biologics, founded in 2011 and headquartered in Songdo, Incheon, South Korea (Source: en.wikipedia.org), operates aseptic fill-finish lines with flexible batch sizes from 5 L to 2,500 L and stated capacity for up to 350,000 vials per day, providing clinical and commercial-scale aseptic filling for vials and prefilled syringes with fully integrated lyophilization (Source: samsungbiologics.com) (Source: samsungbiologics.com). The company's total bioreactor capacity across its plants is 845 kL, spanning Plant 1 through Plant 5 plus a U.S. facility in Rockville, Maryland (Source: samsungbiologics.com), and its drug product services carry more than 460 global regulatory approvals across FDA, EMA, and PMDA (Source: samsungbiologics.com).

Adoption

Samsung Biologics has held CDMO Leadership Awards for 13 consecutive years (Source: samsungbiologics.com). Plant 5, the first facility of its Bio Campus II expansion, added 180,000 liters of capacity and cost roughly 1.98 trillion won (about $1.36 billion), and the company is simultaneously advancing prefilled syringe and N-1 perfusion capabilities (Source: en.yna.co.kr) (Source: samsungbiologics.com). In 2021 Samsung Biologics and

Moderna signed a Manufacturing Services and Supply Agreement for large-scale, commercial fill-finish manufacturing of the mRNA-1273 COVID-19 vaccine at Samsung's Incheon facilities, using a dedicated production line equipped for aseptic fill-finish, labeling, and packaging (Source: samsungbiologics.com). The company reported FY2025 revenue of KRW 4,557 billion (Source: samsungbiologics.com).

Strengths and Limitations

Samsung Biologics' disclosed fill-finish strengths include flexible batch sizes and stated throughput of up to 350,000 vials per day; its separately reported bioreactor volume is a drug-substance measure and should not be used as a fill-finish comparison metric. Its published capability pages describe fill-finish operations in general aseptic terms without publicly itemizing isolator versus RABS technology line by line, so sponsors evaluating specific containment technology should request site-level detail directly.

WuXi Biologics

Capabilities

WuXi Biologics operates a dedicated drug product network across DP1, DP2, and DP5 in Wuxi, DP9 in Hangzhou, and DP7 in Leverkusen, Germany, accommodating formats from 2R to 50R vials as well as liquid, lyophilized, and prefilled syringe products (Source: wuxibiologics.com). DP1 was the first sterile drug product facility in China to pass FDA, EMA, and NMPA inspections (Source: wuxibiologics.com), and has completed more than 1,100 batches with a 100% aseptic process simulation success rate (Source: wuxibiologics.com). DP5 is dedicated to large-scale PFS manufacturing, offering 1 to 3 mL syringes at up to 17 to 20 million units per year using an isolator-based filling system (Source: wuxibiologics.com). All WuXi Biologics facilities provide isolator-based, fully automated drug product formulation and filling under FDA, EMA, and NMPA standards (Source: wuxibiologics.com).

Adoption

In November 2024, WuXi Biologics announced a new isolator-technology PFS line at its Leverkusen, Germany site capable of 400 syringes per minute and at least 17 million syringes a year, targeted for GMP compliance by 2026 (Source: wuxibiologics.com). As of December 31, 2025, the company employed more than 13,000 people and was supporting 945 integrated client projects, including 25 in commercial manufacturing (Source: wuxibiologics.com), and it received its eighth consecutive year of CDMO Leadership Awards recognition in 2025 (Source: wuxibiologics.com). WuXi Biologics reported FY2024 revenue of RMB 18,675.4 million, up 9.6% year over year, with non-COVID revenue up 13.1% (Source: wuxibiologics.com).

Strengths and Limitations

WuXi Biologics' strength is breadth of clinical-to-commercial drug product infrastructure, with a 99% success rate across more than 2,530 clinical drug product batches (Source: wuxibiologics.com), and dedicated PFS capacity that scaled quickly after its first commercial PFS facility opened in June 2022 (Source: wuxibiologics.com). Because the network is concentrated in China and Germany, sponsors requiring North American fill-finish sites will need to look elsewhere within the WuXi group or to other CDMOs on this list.

Vetter Pharma

Capabilities

Vetter, a German family-owned CDMO founded in 1950 (Source: vetter-pharma.com), has provided fill and finish services for injectable therapies for more than four decades (Source: vetter-pharma.com), filling 238 million injectable drug product units in 2025 across 20 aseptic filling lines at facilities in the U.S. and Europe (Source: vetter-pharma.com). Its three commercial fill and finish sites in southern Germany operate 17 filling lines handling batch sizes from under 10,000 to as many as 500,000 units, offering lyophilization at every aseptic site (Source: vetter-pharma.com). Vetter developed a patented hybrid cleanroom system, V-CRT, intended to achieve isolator-like quality standards while retaining the flexibility of a restricted access barrier system (RABS) (Source: vetter-pharma.com). About 80% of Vetter's active customer projects involve complex biologics (Source: vetter-pharma.com).

Adoption

Vetter generated 1.26 billion euros in 2025 sales from its specialized aseptic filling services and employs more than 7,300 people worldwide (Source: vetter-pharma.com). The company is investing heavily in new capacity: a $285 million clinical manufacturing facility broke ground in Des Plaines, Illinois, targeted for media fill readiness by the end of 2029 (Source: vetter-pharma.com), and a roughly 480 million euro ($574.3 million) first construction phase for a new commercial production facility began in Saarlouis, Germany, on a 40-hectare site targeted for 2031 (Source: fiercepharma.com).

Strengths and Limitations

As a pure-play fill-finish specialist rather than a diversified life-sciences conglomerate, Vetter's strength is depth of aseptic filling expertise and a transparently disclosed filled-unit track record. A limitation is scale relative to the largest diversified CDMOs on this list: Vetter's newest large facilities in Illinois and Saarlouis will not be operational until 2029 and 2031 respectively, so near-term incremental capacity is limited.

Boehringer Ingelheim (BioXcellence)

Capabilities

Boehringer Ingelheim's BioXcellence contract manufacturing business operates biopharmaceutical facilities in Biberach, Germany; Vienna, Austria; Fremont, California; and Shanghai, China (Source: bioprocessonline.com), with roughly 430,000 liters of total bioreactor capacity, all cGMP-certified and licensed by the EMA, FDA, and Japan's MHLW (Source: bioprocessonline.com). Biberach is described in trade coverage as Europe's largest multi-product mammalian cell culture plant (Source: themedicinemaker.com). The Shanghai (OASIS) site added an isolator-based fill-finish line for aseptic filling of liquids in vials, giving the site drug substance, drug product, and quality control under one roof (Source: fiercepharma.com). BioXcellence describes its network as handling the entire production chain "from DNA to aseptic filling" (Source: bioprocessonline.com).

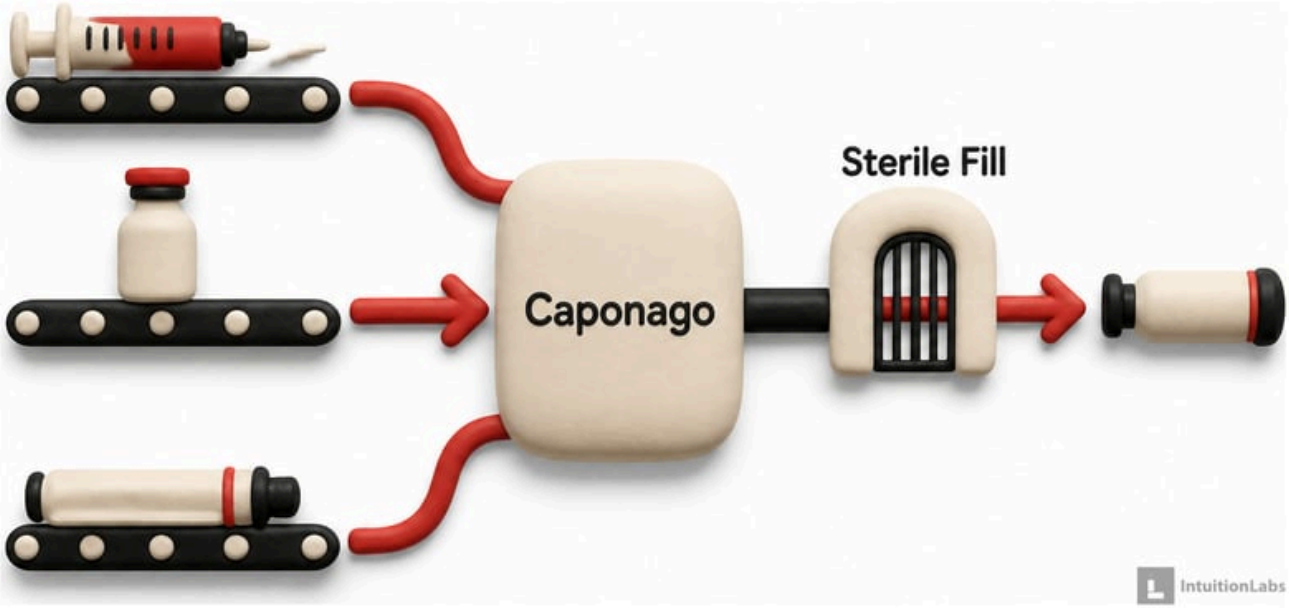
Adoption

BioXcellence traces its contract manufacturing roots to 1998 (Source: themedicinemaker.com) and states it has brought 49 biologics to market with partners, transferring and optimizing more than 150 development and manufacturing projects (Source: bioprocessonline.com). The Shanghai facility qualified in 2025 for China's NMPA-led segmented manufacturing regulatory reform after more than seven years of operation (Source: pharmasource.global). Boehringer Ingelheim's contract manufacturing segment reported approximately 1.02 billion euros in net sales in 2022 (Source: themedicinemaker.com).

Strengths and Limitations

BioXcellence's strength is more than 40 years of experience with the segmented (drug substance and drug product separated) manufacturing model, now being extended into China (Source: pharmasource.global). A transparency limitation for prospective sponsors is that Boehringer Ingelheim's own corporate site restricts automated access to detailed BioXcellence capability pages, so site-level fill-finish specifications (line counts, container formats) are less publicly documented than for several peers on this list.

CordenPharma



Capabilities

CordenPharma, founded in 2006 (Source: cordenpharma.com) with more than 3,500 employees across facilities in seven countries (Source: cordenpharma.com), concentrates its sterile injectables platform at an integrated facility in Caponago, Italy, 20 kilometers outside Milan, combining 30 years of injectable drug product experience (Source: cordenpharma.com) with more than 25 years of sterile injectable manufacturing overall (Source: cordenpharma.com). The Caponago site offers aseptic fill and finish for prefilled syringes (1 to 10 mL, fill volumes from 0.5 mL), vials (standard 2R to 20R sizes), and 3 mL cartridges, specializing in complex modalities including peptides, oligonucleotides, biologics (mAbs), and lipid nanoparticles (LNPs) (Source: cordenpharma.com) (Source: cordenpharma.com). CordenPharma states its injectables platform delivers commercial products to more than 110 markets worldwide (Source: cordenpharma.com).

Adoption

CordenPharma achieved 960 million euros in net sales in 2025, delivering 11% constant-exchange-rate growth year over year, and completed 10 health authority audits and 80 customer audits across its network during the year (Source: cordenpharma.com) (Source: cordenpharma.com). The company is investing to nearly double injectable capacity by 2028 through two new isolator filling lines at Caponago: a high-speed Syntegon prefilled-syringe and cartridge line rated to fill more than 500,000 units a day with batch sizes up to 500 L, targeted operational mid-2027, and a flexible Bausch and Stroebel combination line for vials, PFS, and cartridges targeted for 2028 (Source: cordenpharma.com) (Source: cordenpharma.com). CordenPharma is also acquiring an adjacent 11,000-square-meter property at Caponago, finalized by January 2026, to expand fill-finish, inspection, and packaging space (Source: cordenpharma.com).

Strengths and Limitations

CordenPharma's strength is deep specialization in complex, high-growth modalities, peptides, oligonucleotides, and LNPs, aligned with GLP-1 and nucleic-acid drug demand. Because its sterile injectables platform is concentrated primarily at one integrated Italian site pending the 2027 to 2028 expansion (Source: cordenpharma.com), sponsors requiring immediate multi-region redundancy may need to weigh that concentration against CordenPharma's modality expertise.

Recipharm

Capabilities

Recipharm, founded in 1995 through a management buyout of a solid-dose facility in Stockholm and now describing itself as the fourth-largest global CDMO (Source: recipharm.com), operates 16 facilities in eight countries (Source: recipharm.com) and, as of a 2022 capabilities summary, more than fifty sterile fill-finish lines across eight facilities (Source: recipharm.com). Its sterile fill-finish offering spans vials, ampoules, cartridges, prefilled syringes, and blow-fill-seal, with ampoule filling using RABS/isolator technology and high-voltage non-destructive inspection (Source: recipharm.com), and vial filling supporting cold-chain storage down to minus 70 degrees Celsius (Source: recipharm.com). Recipharm's Wasserburg, Germany site is positioned as a European center of excellence for sterile manufacturing, aseptic filling, and lyophilization supporting biologics, vaccines, and nanoparticle-based therapies (Source: recipharm.com).

Adoption

Recipharm reported record 2024 revenue of 827 million euros, up 7% year over year, and employed more than 5,000 people worldwide as of March 2025 (Source: recipharm.com). During 2024 the company expanded Wasserburg to more than 60 million combined PFS and vial capacity and added more than 100 million ready-to-use sterile units in the United States (Source: recipharm.com). A new high-speed line at Monts, France can fill 400 vials a minute with capacity exceeding 100 million vials annually (Source: recipharm.com).

Strengths and Limitations

Recipharm's strength is geographic and format breadth across more than fifty fill-finish lines, giving sponsors multiple site options within one CDMO group. Because several of its published unit-capacity figures date to a 2022 capabilities summary rather than a single current consolidated figure, sponsors should confirm current line-by-line capacity directly with the company for time-sensitive capacity planning.

Fareva

Capabilities

Fareva, operating since 1981 and describing itself as a world leader in industrial subcontracting with more than 40 sites globally (Source: fareva.com), maintains an industrial network of five sterile sites as of mid-2025 (Source: fareva.com). In June 2025 the company opened a new GMP sterile pilot unit at its Pau, France site dedicated to liquid and lyophilized injectable forms, with an isolator supporting monoclonal antibodies, mRNA in lipid nanoparticle form, proteins, peptides, and ADCs, at flexible batch sizes from 200 to 8,000 vials (Source: fareva.com) (Source: fareva.com). Its nearby Idron, France site has more than 200 employees and more than 20 years of experience manufacturing prefilled syringes and lyophilized and liquid-filled vials across 10 manufacturing workshops (Source: fareva.com).

Adoption

Fareva has invested more than 30 million euros to modernize its sterile facilities in line with revised EU GMP guidelines and expanded its Valdepharm site with a new automated aseptic filling line (Source: fareva.com). In April 2021 the company acquired a Novartis site in Unterach, Austria specializing in injectable, high-potency drug products packaged in vials and prefilled syringes (Source: fareva.com). Fareva's pharmaceutical sector reported 1.2 billion euros in sales in 2023, serving more than 300 customers across 16 manufacturing sites (Source: fareva.com).

Strengths and Limitations

Fareva's strength is a diversified pharmaceutical manufacturing base that gives it capacity flexibility, and its Pau investment shows active Annex 1 modernization. Its sterile fill-finish footprint, five dedicated sites, is comparatively smaller than the largest specialists on this list, and detailed line-speed disclosures for several individual sterile sites beyond Pau are not yet public.

Feature Comparison

Table 1 below summarizes container formats, core fill-finish technology, and a representative scale indicator for each of the ten CDMOs profiled in this report, drawn from each company's own capability disclosures gathered in August 2026.

COMPANY	HQ / OWNERSHIP	CONTAINER FORMATS	FILL TECHNOLOGY	KEY SCALE INDICATOR
Lonza	Switzerland (public)	Vials, PFS, cartridges, ampoules	Isolator, Annex 1 aligned	CHF 500M Stein expansion opening Q4 2027 (Source: lonza.com)
Thermo Fisher Scientific (Patheon)	USA (public)	Vials, PFS, cartridges	Isolator/RABS across 6-site global network	130M+ vials/year (Source: patheon.com)
Catalent (Novo Holdings)	USA (private)	Vials 2R-20R, PFS 0.5-20mL, cartridges	Isolator/RABS	Assisted 50% of FDA approvals in past decade (Source: novoholdings.dk)
Samsung Biologics	South Korea (public)	Vials, PFS	Aseptic, integrated lyophilization	Up to 350,000 vials/day (Source: samsungbiologics.com)
WuXi Biologics	China (public)	Vials 2R-50R, PFS	Isolator-based; oRABS at DP1	17-20M PFS units/year at DP5 (Source: wuxibiologics.com)
Vetter Pharma	Germany (private)	Vials, PFS, cartridges	Isolator, RABS, proprietary V-CRT hybrid	238M units filled in 2025 (Source: vetter-pharma.com)
Boehringer Ingelheim (BioXcellence)	Germany (private)	Vials	Isolator (Shanghai line)	~430,000L bioreactor capacity across 4 sites (Source: bioprocessonline.com)
CordenPharma	Italy-centered, multi-country (private)	Vials 2R-20R, PFS 1-10mL, 3mL cartridges	Isolator (Robotized Open RABS legacy)	Delivers to 110+ markets (Source: cordenpharma.com)
Recipharm	Sweden-founded, multi-country (private)	Vials, ampoules, cartridges, PFS, blow-fill-seal	RABS/isolator	50+ lines across 8 facilities (Source: recipharm.com)
Fareva	France (private)	Vials, PFS	Isolator (new Pau line)	5 dedicated sterile sites (Source: fareva.com)

Table 1 follows the editorial ranking order established in the methodology. Its scale indicators are not standardized across companies, and a missing public throughput figure should not be interpreted as evidence of lower capacity. Sponsors should obtain current, site-specific line, format, batch-range, and inspection information before making a comparison.

Performance and Benchmarks

Disclosed line-speed and throughput figures provide a partial, but useful, performance benchmark across the ten CDMOs. On raw daily throughput, CordenPharma's new Syntegon-built prefilled-syringe and cartridge isolator line is rated to fill more than 500,000 units per day once operational in 2027 (Source: cordenpharma.com), comparable to Samsung Biologics' stated capacity for up to 350,000 vials per day (Source: samsungbiologics.com). On a per-minute basis, WuXi Biologics' Leverkusen PFS line runs at up to 400 syringes per minute (Source: wuxibiologics.com) and Recipharm's Monts, France line fills 400 vials a minute with capacity for more than 100 million vials annually (Source: recipharm.com), a similar order of magnitude despite the different container type. On the smaller end of published batch flexibility, Fareva's new Pau pilot unit and WuXi Biologics' oRABS-based DP1 facility both emphasize flexible, smaller-batch runs, Pau from 200 to 8,000 vials (Source: fareva.com) and Vetter's three German commercial sites spanning under 10,000 to 500,000 units per batch (Source: vetter-pharma.com), useful indicators for early-phase and orphan-indication sponsors that do not need commercial-scale runs.

Regulatory approval density offers a second benchmark. Samsung Biologics discloses more than 460 cumulative global regulatory approvals (Source: samsungbiologics.com), while WuXi Biologics reports a 99% success rate across more than 2,530 clinical drug product batches (Source: wuxibiologics.com). CordenPharma reports completing 10 health authority audits and 80 customer audits in 2025 alone (Source: cordenpharma.com). None of these figures are directly comparable on a like-for-like basis, since each company defines its own reporting period and audit scope, underscoring that prospective sponsors should request current, site-specific inspection histories rather than relying on aggregate marketing statistics alone.

Data Analysis and Evidence

Table 2 below compiles market-sizing figures published by Grand View Research that are relevant to sterile fill-finish outsourcing as of 2026.

MARKET SEGMENT	BASE YEAR VALUE	PROJECTED VALUE	TARGET YEAR	CAGR
Sterile injectables CDMO market	$37.82B (2025)	$87.34B	2033	11.2% (Source: grandviewresearch.com)
Sterile injectable contract manufacturing market	$15,997.7M (2024)	$31,884.4M	2030	12.3% (Source: grandviewresearch.com)
Fill-finish pharmaceutical contract manufacturing market	$17.95B (2024)	$29.06B	2030	8.3% (Source: grandviewresearch.com)
Pre-filled syringes market	$8.72B (2025)	$18.12B	2033	9.7% (Source: grandviewresearch.com)
Biologics CDMO market	$47.84B (2025)	$84.91B	2033	7.4% (Source: grandviewresearch.com)

These five estimates diverge because each measures a differently scoped segment (fill-finish services alone versus the broader sterile injectable or biologics CDMO market), so readers should treat them as complementary rather than substitutable. A separate industry analysis from Alira Health puts the global biologics CDMO market at $20.7 billion in 2024 in actual (not projected) terms, with advanced therapies the fastest-growing segment, up 37% year over year to $3.3 billion, or 18% of total CDMO value (Source: alirahealth.com), and finds the top eight biologics CDMOs captured 51% of total market revenue, $10.6 billion of the $20.7 billion total, in 2024 (Source: alirahealth.com).

Regional and segment data help explain where investment is concentrating. North America held the largest regional share of the sterile injectables CDMO market at 33.7% in 2025 (Source: grandviewresearch.com), while Europe held the largest share of the global prefilled syringes market at 37.1% the same year (Source: grandviewresearch.com). Outsourcing itself continues to rise: BioPlan Associates survey data show 82.6% of cell and gene therapy companies now outsourcing at least some biologics manufacturing (Source: biopharminternational.com), and its annual biomanufacturing report data have shown a consistent 5% annual reduction in the number of facilities doing all their manufacturing in-house (Source: contractpharma.com). Despite the capacity investment cataloged in this report, L.E.K. Consulting assesses that aseptic fill-finish demand growth will continue to outpace capacity for the next five to ten years (Source: lek.com).

Regulatory structure underpins all of this activity. The European Commission's revised Annex 1 was adopted August 22, 2022 and took effect August 25, 2023, one year after publication in Eudralex Volume 4 (Source: health.ec.europa.eu), and its guidance document explicitly identifies contamination control strategy, design of premises, and cleanroom classification as core principles CDMOs must address (Source: health.ec.europa.eu). In the U.S., FDA's September 2004 aseptic-processing guidance replaced the 1987 Aseptic Processing Guideline and explains FDA's current thinking on helping manufacturers meet the CGMP requirements in 21 CFR parts 210 and 211; the regulations, rather than the guidance, are binding (Source: fda.gov).

Case Studies and Real-World Examples

GLP-1 demand has helped drive substantial new manufacturing investment since 2024. *Table 3* distinguishes disclosed fill-finish investments from a CordenPharma drug-substance investment; both affect the broader injectable-drug supply chain, but only the former directly expand fill-finish capacity.

COMPANY	ANNOUNCED INVESTMENT	LOCATION	PRIMARY DRIVER
Novo Nordisk	$4.1 billion (approx. 27 billion Danish kroner)	Clayton, North Carolina, USA	Second fill-and-finish facility, adding 1.4 million square feet of aseptic space (Source: globenewswire.com)
CordenPharma	$981 million (900 million euros) over three years	Europe and U.S.	GLP-1 peptide drug-substance manufacturing expansion; not a disclosed sterile fill-finish expansion (Source: fiercepharma.com)
Simtra BioPharma Solutions	$250 million	Bloomington, Indiana, USA	150,000-square-foot dedicated fill/finish building, citing GLP-1 demand (Source: bioprocessintl.com)
National Resilience	At least $225 million	Cincinnati, Ohio, USA	Drug product/fill-finish capacity expansion citing GLP-1 demand (Source: bioprocessintl.com)
Eli Lilly	$3 billion	Pleasant Prairie, Wisconsin, USA	Expansion of injectable product manufacturing site (Source: bioprocessintl.com)
Vetter Pharma	$574.3 million (480 million euros, phase one)	Saarlouis, Germany	New commercial fill-finish production facility on a 40-hectare site, targeted 2031 (Source: fiercepharma.com)

The Novo Nordisk and Vetter examples in Table 3 also illustrate two distinct capacity-response strategies. Novo Nordisk, an originator, is internalizing fill-finish capacity for its own GLP-1 pipeline rather than relying solely on CDMOs, a strategy reinforced by its parent Novo Holdings' $16.5 billion acquisition of Catalent and the subsequent transfer of three Catalent fill-finish sites into the Novo Nordisk network (Source: catalent.com) (Source: globenewswire.com). Vetter, by contrast, is a pure-play CDMO expanding third-party capacity to absorb overflow demand from originators that either lack in-house fill-finish capability or choose to diversify supply across multiple partners. Both strategies point to the same underlying pressure documented throughout this report: sterile fill-finish capacity has become a strategic bottleneck that both drugmakers and dedicated CDMOs are racing to relieve.

Implications and Future Directions

Several structural shifts documented in this report will shape sterile fill-finish sourcing decisions through the remainder of the decade. Annex 1 requires risk-based contamination control and recognizes both RABS and isolators as beneficial barrier technologies. Sponsors should assess the site-specific CCS, intervention strategy, qualification, and inspection history rather than infer that one technology is categorically compliant or superior. This is visible in Lonza's October 2025 Stein line (Source: lonza.com), Fareva's June 2025 Pau pilot unit (Source: fareva.com), and CordenPharma's planned 2027 to 2028 Caponago lines (Source: cordenpharma.com). Because much of this new capacity does not come online until 2027 through 2031, per Lonza's Q4 2027 target (Source: lonza.com), Vetter's 2029 Illinois and 2031 Saarlouis targets (Source: vetter-pharma.com), and CordenPharma's mid-2027 and 2028 targets, sponsors negotiating capacity today should expect continued tightness in the near term, consistent with L.E.K. Consulting's five-to-ten-year demand-outpacing-capacity assessment cited earlier in this report.

Consolidation is a second durable trend. Novo Holdings' $16.5 billion Catalent acquisition, and the accompanying transfer of three fill-finish sites to Novo Nordisk (Source: catalent.com), illustrates originators internalizing fill-finish capacity even as overall industry outsourcing continues to rise per BioPlan Associates data cited in the Data Analysis section. For sponsors, this means the CDMO landscape is not static: a facility contracted today may change ownership, as Bloomington, Indiana did in December 2024 (Source: catalent.com).

This complexity is prompting sponsors to formalize CDMO evaluation the same way they formalize other high-stakes vendor decisions. Life-sciences advisory practices that support sponsors' data and digital infrastructure, including IntuitionLabs, which states it specializes exclusively in the pharmaceutical and life sciences industries, including biotech, medical devices, diagnostics, and CROs (Source: intuitionlabs.ai), report that AI-enhanced approaches to drug discovery and development can accelerate timelines by up to 60%, citing Deloitte research (Source: intuitionlabs.ai). Applied to manufacturing partner selection rather than discovery, the same underlying discipline, treating vendor evaluation as a structured data problem rather than a relationship-driven one, is increasingly how sponsors compare disclosed capacity, regulatory approval counts, and investment trajectories across candidate fill-finish CDMOs before committing to multi-year supply contracts.

Frequently Asked Questions (FAQs)

What is a sterile fill-finish CDMO? A sterile fill-finish CDMO is a contract development and manufacturing organization that specializes in aseptically transferring a finished sterile drug product, typically a biologic, vaccine, or other injectable, into its final container: a vial, prefilled syringe, cartridge, or ampoule, under conditions that prevent microbial, particulate, and endotoxin contamination (Source: health.ec.europa.eu).

Which sterile fill-finish CDMOs does this article rank in 2026? This article ranks Lonza, Thermo Fisher Scientific (Patheon), Catalent, Samsung Biologics, WuXi Biologics, Vetter Pharma, Boehringer Ingelheim (BioXcellence), CordenPharma, Recipharm, and Fareva using the disclosed-factor methodology above. Sponsors should still assess current, site-specific capabilities for their product.

What is the difference between isolator and restricted access barrier system (RABS) technology? Both are cleanroom barrier technologies used in aseptic fill-finish, but isolators provide a more fully enclosed, higher-sterility-assurance environment, while RABS offer more operational flexibility at a lower capital cost; Vetter Pharma notes the industry typically relies on one or the other, and developed a patented hybrid, V-CRT, intended to combine isolator-like quality with RABS flexibility (Source: vetter-pharma.com). Revised EU Annex 1, effective since August 25, 2023, has generally favored isolator adoption (Source: health.ec.europa.eu).

Why is prefilled syringe capacity growing faster than vial capacity? Prefilled syringes are the fastest-growing container format in the fill-finish contract manufacturing market, at a 9.3% CAGR through 2030 according to Grand View Research (Source: grandviewresearch.com), driven by patient self-administration trends in biologics and GLP-1 therapies and by the broader global prefilled syringes market, sized at $8.72 billion in 2025 and projected to reach $18.12 billion by 2033 (Source: grandviewresearch.com).

What is EU Annex 1 and why does it matter when selecting a fill-finish partner? EU Annex 1 is the European Commission's GMP guidance for the manufacture of sterile medicinal products, revised and effective since August 25, 2023, requiring every sterile manufacturer to maintain a documented Contamination Control Strategy addressing microbial, particulate, and endotoxin risk across the entire production process (Source: health.ec.europa.eu) (Source: pda.org). CDMOs supplying the EU market must demonstrate compliance. Sponsors should confirm the candidate site's CCS, intervention strategy, qualification, and inspection history; Annex 1 recognizes both isolators and RABS as beneficial technologies.

Is sterile drug product manufacturing outsourcing increasing? Yes. BioPlan Associates survey data show 82.6% of cell and gene therapy companies now outsource at least some biologics manufacturing (Source: biopharminternational.com), and its annual report data show a consistent 5% annual reduction in facilities performing all manufacturing in-house (Source: contractpharma.com).

How is GLP-1 demand affecting fill-finish capacity for parenteral drug manufacturing? GLP-1 therapies have triggered several of the largest capacity investments cataloged in this report, including Novo Nordisk's $4.1 billion Clayton, North Carolina facility (Source: globenewswire.com), CordenPharma's $981 million peptide expansion (Source: fiercepharma.com), and Eli Lilly's $3 billion Pleasant Prairie, Wisconsin expansion (Source: bioprocessintl.com).

Conclusion

Sterile fill-finish has moved from a back-office manufacturing step to a strategic bottleneck shaping how injectable drugs, especially biologics and GLP-1 therapies, reach patients. The ten CDMOs profiled in this report, Lonza, Thermo Fisher Scientific (Patheon), Catalent, Samsung Biologics, WuXi Biologics, Vetter Pharma, Boehringer Ingelheim (BioXcellence), CordenPharma, Recipharm, and Fareva, represent a spectrum from diversified, multi-billion-dollar life-sciences conglomerates to focused, family-owned aseptic filling specialists. Each combines a distinct mix of container-format range, modality specialization, regulatory footprint, and capital investment trajectory, and no single company leads on every dimension simultaneously.

Selecting among them requires matching a sponsor's specific format (vial, PFS, cartridge, or ampoule), modality (small molecule, monoclonal antibody, mRNA, or complex conjugate), volume requirement, and regulatory market against each CDMO's documented capabilities rather than relying on brand reputation alone. The market context reinforces the urgency of that exercise: demand for outsourced sterile fill-finish capacity continues to outpace supply, EU Annex 1 requires risk-based contamination control supported by an effective CCS, and GLP-1-driven investment is redrawing capacity maps on a multi-year timeline. Sponsors that begin capacity conversations early, and evaluate candidates against verifiable, sourced data rather than marketing claims alone, will be best positioned to secure the aseptic manufacturing capacity their injectable pipelines require through the remainder of the decade.

Tags: sterile fill-finish cdmo, aseptic fill finish, injectable manufacturing, cdmo comparison, biologics cdmo, prefilled syringe manufacturing, parenteral drug manufacturing, annex 1 compliance, cdmo companies 2026

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