Vetter Pharma Recognized for

2021

Customer Value Leadership

Global Biopharmaceutical Aseptic Fill-Finish Contract Development and Manufacturing Organization Industry

Excellence in Best Practices

FROST & SULLIVAN

Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Vetter excels in many of the criteria in the biopharmaceutical aseptic fill-finish contract development and manufacturing organization space.

Need for CDMO Partners with High-end Expertise in Innovative Fill-finish Solutions

Biopharmaceuticals are one of the considerable growth areas globally. Biologics finished dosage formulations (FDF) are predominantly sterile injectable, pre-filled syringes, or cartridges. Innovation in drug delivery and the increasing demand for patient-centric targeted therapies propel FDF outsourcing to contract development and manufacturing organizations (CDMOs), offering advanced technology in aseptic drug development and injectable manufacturing.

The global biologics contract manufacturing market will grow from $11.38 billion in 2020 to $20.31 billion in 2026 at a 10.1% compound annual growth rate (CAGR).[1] Similarly, within the small molecule CDMO market, the injectable segment is valued at $4.39 billion, growing at a 7.8% CAGR from 2020 to 2026 driven by the rising demand for specialty products and injectable cytotoxic drugs.[2] Manufacturing challenges include highly sensitive processes affected by environmental changes and difficult-to-establish reproducibility. A single manufacturer deals with all product manufacturing stages, with decentralization possible in only fill-finish activities. Oncology, orphan diseases, and anti-infectives remain the main contributors to the injectable segment. Specifically, there is a high unmet medical need in the orphan drug market, with therapies available for less than 8% of the identified diseases.

[1] *Global Biologics Contract Development and Manufacturing Organizations Growth Opportunities*, *(*Frost & Sullivan, September 2021*)*
[2] *Global Small Molecule Contract Development and Manufacturing Organization (CDMO) Growth* Opportunities,(Frost & Sullivan, September 2021)

Due to the coronavirus (COVID-19) pandemic, CDMOs face additional challenges regarding raw material availability due to supply chain delays. A steady supply of primary raw materials (buffers and resins), consumables (single-use bags and sterile filters), and fill-finish items (vials and stoppers) must be in place to ensure continuous manufacturing operations.

Pharmaceutical and biopharmaceutical companies focus on improving parenteral formulations and combination products, such as pens and auto-injectors with complex solutions such as messenger ribonucleic acid viral vectors, monoclonal antibodies, and nucleotides. Hence, drug sponsors increasingly prefer outsourcing to experienced CDMO partners to meet this growing need for specialized therapeutics, complex fill-finish solutions, and smaller batch sizes. Additionally, drug sponsors require partners who offer end-to-end clinical manufacturing, product-specific support, and innovative delivery technologies for the easy administration of high-viscosity and large-volume drugs.

Sterile Injectable Fill-finish Services: From Clinical to Commercial Manufacturing

Founded in 1950 and headquartered in Ravensburg, Germany, Vetter Pharma-Fertigung GmbH & Co KG (Vetter) is an expert in producing aseptically pre-filled syringe systems, cartridges, and vials. With over 70 years of experience, the globally recognized, family-owned CDMO employs 5,500 employees across three continents. It has international expertise in providing highly skilled support and state-of-the-art development and manufacturing resources to its customers, filling the active pharmaceutical ingredient (API).

Vetter handles clinical projects, stability studies, fill-finish, secondary packaging, and delivery. The company split into two interlinked branches: the Vetter Commercial Manufacturing arm and Vetter Development Service. The Development Service group facilitates product management from preclinical to clinical development (phases I, II, and III) to market launch, reportedly accounting for 20% of the company's revenue.

> *"The company offers end-to-end development services for variable batch sizes and injection systems. Backed by flexible, scalable, and reproducible processes, its high-quality services cover clinical phase material development, commercial manufacturing, regulatory approval process management, product launch, and subsequent product life cycle management."*
>
> ***- Supriya Lala, Best Practices Research Analyst***

Vetter's robust product pipeline has currently 250 projects, with 80% of those involving new molecular entities and complex biologics. The company offers end-to-end development services for variable batch sizes and injection systems. Backed by flexible, scalable, and reproducible processes, its high-quality services cover clinical phase material development, commercial manufacturing, regulatory approval process management, product launch, and subsequent product life cycle management.

Vetter partners with the customer's development team to optimize formulation candidates for clinical trials and recognizes the most clinically suitable drug candidate formulations for successful validation.

An expert in variable process designing, the company employs single-use or multi-use equipment, handles different pump systems (rotary piston, peristaltic, and membrane pumps), and uses various sterile filtration techniques.

Expertise in Lyophilized Products

As an expert in lyophilized products, Vetter develops customers' lyophilization cycle for economically and technologically scalable commercial manufacturing. The well-known dual chamber technology for complex compounds requiring lyophilization provides competitive differentiation.

> *"With a focus on process excellence, it applies Production Excellence (ProdEx), its company-wide process optimization system, to develop a highly regulated, customer-transparent, and knowledge-intensive production process and recognize and eliminate waste."*
>
> ***- Supriya Lala, Best Practices Research Analyst***

The company works on different types of lyophilized vials, dual chamber systems for sensitive products. Notably, it works on a children's drug product requiring deep freeze (minus 70˚Centigrade) while ensuring the non-vial breakage. With over 70 Food and Drug Administration-approved products, Vetter demonstrates market-leading CDMO capabilities globally.

Operational Excellence System and Digitization: Improved Process and Production Efficiency

Vetter successfully handled the pandemic-related challenges, fulfilled two-thirds of its "Vetter Excellence 2025" goals, its current strategy, and is progressing with "Vetter Next 2029". With a focus on process excellence, it applies Production Excellence (ProdEx), its company-wide process optimization system, to develop a highly regulated, customer-transparent, and knowledge-intensive production process and recognize and eliminate waste. ProdEx implements Lean Management, Six Sigma, Statistics, and Kanban, for continuous process improvement, leading to systematic waste disposal and terminating redundant processes. Indeed, the operational excellence system:

- Implemented the digital micro-malfunction management method that increased performance and technical availability in aseptic filling, packaging, and automated visual inspection by 12%.
- Process, organization, and human factor focused, it limited the human error rate by 15% within three years.[3]

Furthermore, Vetter's advanced technologies reduced cycle times by 30% over the years. The company applies hydrogen peroxide in every cleanroom after every batch through its holistic concept, Vetter Cleanroom Technology (V-CRT®), which allows decontamination within three hours compared to the 24 hours required by solely applying an isolator. The unique V-CRT® solution combines the advantages of an isolator and restricted-access barrier system. It follows comprehensive aseptic filling working steps (decontamination, set-up and filling, monitoring, and analytics), heightening safety and mitigating microbe carry-over risks while enabling rapid product changeover.

[3] .(https://www.vetter-pharma.com/en/news/detail/production-excellence/)

Digitization and Quality Improvements

Vetter's digitization focus leads to quality, safety, and process improvement in predictive maintenance, visual remote services, and intelligent worker assistance systems, limiting downtimes and troubleshooting. The company applies machine learning to complex forecasting projects and robotic automation of recurring activities.

The Vetter 4.0 initiative includes digital strategies to simulate optimal man-machine processes and improve transparency and reliability in automated visual inspection, electronic batch recording, and potentially extend to secondary packaging and cleanrooms. Vetter also applies Quality-by-Design (QbD). QbD monitors critical quality issues during manufacturing, long-term process improvements, and custom designs 'Continued Process Verification program' (based on agreed-upon parameters), vital for formal validation for drug's market registration and submission.

Product Life Cycle Management and Innovations: Enhanced Customer Value

Vetter has one of the broadest fill-finish packaging container portfolios from a product lifecycle management perspective. Apart from vials, its pre-filled syringes offer market-disruptive innovations.

The company offers bulk and pre-sterilized single chamber syringes in multiple volume formats and dual chambers cartridges and syringes. Vetter´s unique tamper-evident syringe closure system V-OVS® ensure enhanced security and protect the drug's integrity before administration.

The company provides matchless customer service, with the best consult choice on delivery technology. It partners with auto-injector system manufacturers and engages its interdisciplinary team and project management techniques to understand customer requirements, integrating relevant technologies to manage the product life cycle.

The company engages with customers at several stages. Its key performance indicators (KPIs) tracking system, proactive demand planning, and sales and operations meetings with customers enable it to deliver optimal customer services, prevent supply chain disruptions and address unforeseen issues. Notably, Vetter's complete delivery rate of 95% on make-to-order projects during the pandemic ensured robust supply security to customers.

The company's global customer project management comprises a dedicated interdisciplinary team of certified project managers who interact with the client on pipeline and timelines concerns, supporting new launch and life cycle improvements. Vetter conducts business review meetings to assess KPIs and customer feedback. It runs an end-of-project evaluation and customer satisfaction surveys to determine gaps and improve its strategic direction and customer focus.

Future Focus: Capacity Building and Customer-centric Initiatives

Over the last five years, Vetter experienced an organic CAGR of almost 11%.[4] Its investment strategy aims to sustain consistent growth. The company built a new corporate headquarters in Germany and is increasing its capacity with approximately €500 million invested in four new cleanrooms, warehouse, and visual inspection capabilities. Vetter continues to invest in existing and new sites; its ten-year-old

[4] Company Source

Chicago site (focused on early phase clinical materials) demonstrates an exceptionally successful run to date.

In Austria, Vetter recently acquired a new clinical manufacturing site (for Phase I and II clinical development), expanding its European footprint, and well-stationed to integrate into Vetter's existing clinical operations.

The company aims to replicate the Chicago site's rapid operational procedures, delivering first field batches within a few months of project start. Vetter is a two-times recipient of the 'Facility the Year Award' by The International Society for Pharmaceutical Engineering, validating its heightened focus on operational excellence and best-in-class infrastructure, i.e.., unique combination of location, design, state-of-the-art technologies, and processes. The company also partners with Rentschler Biopharma, an API manufacturing CDMO, to enhance services and know-how and offer complementary skills and experience along the biopharmaceutical value chain.

Owing to its sustainability, climate, and environmental protection focus, Vetter has used carbon-di-oxide-neutral electricity from verifiable renewable energy sources to power its German sites since 2014. Since 2021 all Vetter sites are climate-neutral and no longer have a CO2 footprint. Furthermore, it invests in human capital through its newly opened training Center, providing specific education to prospective employees.

With an impressive growth curve, Vetter has come a long way, winning accolades for its expertise, quality, and reliability, and emerged as a leading player in the sterile fill-finish CDMO space.

Conclusion

Vetter Pharma-Fertigung GmbH & Co KG (Vetter) is a leading aseptic fill and finish contract development and manufacturing organization (CDMO) with extensive expertise in supporting small, mid-size, and large biopharmaceutical customers. Vetter's end-to-end services comprise early phase development, including clinical to commercial manufacturing, providing multiple secondary packaging solutions (for vials, syringes, and cartridges), managing regulatory approval process to successful product launch, and life cycle management.

The company focuses on operational excellence by implementing production systems, digitization, cleanroom technology, and quality improvement initiatives. Furthermore, constant product innovation in packaging and drug delivery technologies allows Vetter to supports customers' varying requirements for patient-centric, safe, and convenient-to-use solutions. An extensive product portfolio for efficient product life cycle management, high customer service levels, regular key performance indicators' evaluation, and consistent client interaction strategies allow Vetter to deliver matchless customer value and emerge as the partner of choice in the industry.

For its strong overall performance, Vetter is recognized with Frost & Sullivan's 2021 Global Customer Value Leadership Award in the biopharmaceutical aseptic fill-finish CDMO industry.

What You Need to Know about the Customer Value Leadership Recognition

Frost & Sullivan's Customer Value Leadership Award recognizes the company that offers products or services customers find superior for the overall price, performance, and quality.

Best Practices Award Analysis

For the Customer Value Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Business Impact

Financial Performance: Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

About Frost & Sullivan

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The Growth Pipeline Engine™

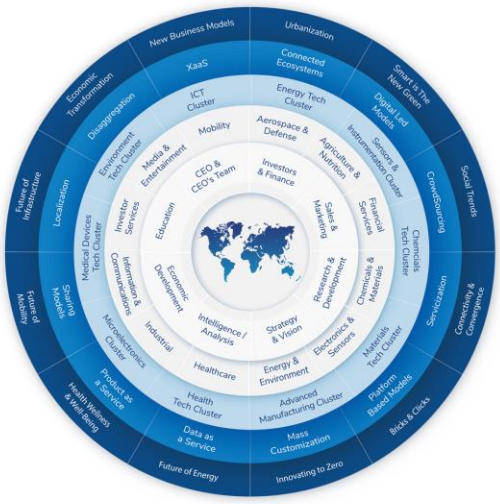
Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.
Learn more.

Key Impacts:

- **Growth Pipeline:** *Continuous Flow of Growth Opportunities*
- **Growth Strategies:** *Proven Best Practices*
- **Innovation Culture:** *Optimized Customer Experience*
- **ROI & Margin:** *Implementation Excellence*
- **Transformational Growth:** *Industry Leadership*

The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.



Analytical Perspectives:

- Mega Trend (MT)
- Business Model (BM)
- Technology (TE)
- Industries (IN)
- Customer (CU)
- Geographies (GE)