

A unique blend of capabilities
for aseptic fill and finish



Vetter Commercial Manufacturing

Delivering results
across the production chain



Answers that work

Manufacturing quality is just the beginning.

What matters most to your product's success? There may be several answers, from costs and competitive pressures to regulatory challenges. Commercial manufacturing of pharmaceutical and biotech drug substances has become increasingly complex, requiring close integration of sophisticated resources and technologies – as well as a clear understanding of both present and future market needs.

Vetter Commercial Manufacturing can help you address these challenges with confidence.

Commercial manufacturing expertise is at Vetter's core, with decades of experience identifying and solving quality and supply chain challenges. Discover how we can deliver results for Phase III clinical manufacturing through global market supply.



Vetter
Development Service

- Formulation support
- Process development
- Clinical trial manufacturing
- Analytical service
- Regulatory support



Vetter
Commercial Manufacturing

- Fill and finish
- Analytical service
- Regulatory support
- Product life cycle management



Vetter
Packaging Solutions

- Customized packaging development
- Specialized technologies
- Proven platform technologies
- Packaging services
- Logistic services

About Vetter Commercial Manufacturing

Vetter Commercial Manufacturing is the contract fill and finish service of Vetter, an independent, family-owned company with more than 25 years of experience in aseptic, high-quality manufacturing of injectable products. Recognized as one of the world's leading CDMOs, Vetter is proud to work with many of today's top global pharmaceutical and biotech companies.

People: Hands-on knowledge builds confident results.

From the moment commercial filling of your product begins, Vetter's highly trained teams of scientific and engineering specialists work closely together to guide its success.

Their exceptional skills and project management capabilities span a wide range of complex pharmaceutical and biotech compounds that often require finely tuned approaches to deliver efficient, precise filling results. Vetter's specialists support you and your product throughout the entire manufacturing process.



Seamless expertise across the production chain. With comprehensive know-how in all common packaging systems and related components, Vetter supports your product with industry-leading expertise in

- analytical services
- aseptic pharmaceutical production
- dedicated customer service
- regulatory support
- supply chain management
- Quality Control/Quality Assurance

Continual investment in specialized expertise including Lean Management and Six Sigma training for process optimization and dedicated departments focused on meeting changing market and regulatory requirements for product quality.

Quality Management expertise is critical to the process

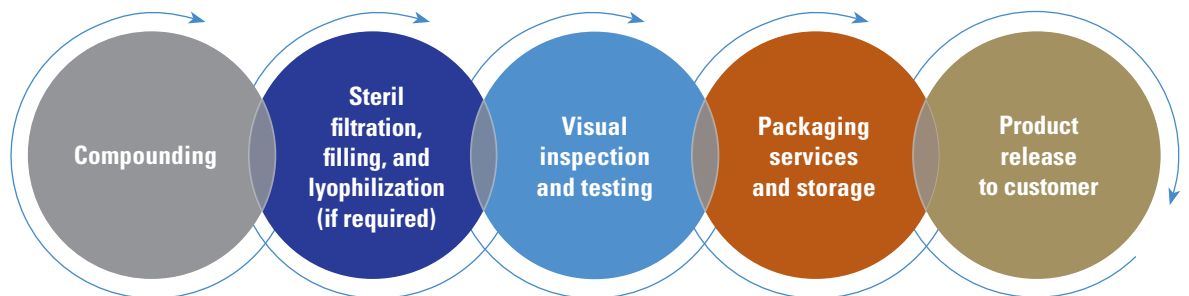
In aseptic fill and finish, meeting the highest quality and safety standards is essential. That's why the Vetter teams of Quality Assurance, Quality Control, and Regulatory Affairs/Quality Compliance combined are more than 400 strong, with Quality Oversight at each manufacturing site and a commitment to ongoing quality improvement initiatives at every step of the process.

Process: Attention to detail keeps your product on target.

From patient safety to security of supply, the smallest details can impact your product's success in the market. With intensifying competition and cost pressure, commercial manufacturing of complex, sensitive compounds demands the delivery of consistent results day after day, batch after batch. This is why Vetter combines precise planning that identifies critical and technical manufacturing requirements with a standardized process that builds in flexible, responsive solutions to anticipated challenges at every stage.

Reliable, long-term market supply is the ultimate goal of our tightly coordinated processes, which are also designed to help your product meet the highest possible safety and quality standards.

Vetter commercial manufacturing processes

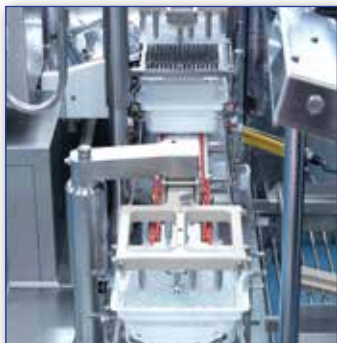


Trending Program spots potential problems

In response to increased regulatory requests for evidence of company-wide quality improvement systems, Vetter established a Trending Program focused on early detection of negative trend developments. Vetter continuously tracks and monitors all process and quality steps, anticipates specific issues, and proactively implements corrective measures.

Measuring success. Vetter's multifaceted programs focus on both quality and supply chain metrics for our high manufacturing standards and provide a clear window into all aspects of your product's performance.

- Upstream and downstream monitoring – to maintain the integrity of the supply chain through regular quality assessments of all suppliers as well as cross-linked IT systems (eg, TrackWise®) to monitor processes
- Analysis of process steps – to determine potential production changes that can improve yields, reduce batch cycle times, and reduce errors
- Key Performance Indicators reporting – including Right-First-Time (RFT) batch quality and On-Time-in-Full (OTIF) supply performance
- Company-wide Permanent-Process-Optimization Program



Global regulatory expertise

Vetter supports you through all phases of regulatory submission. We have an excellent track record with global regulatory agencies, including FDA, EMA, PMDA (Japan), and RP (Germany). Even after approval, the process is continually monitored through customer audits and ongoing review meetings on KPI results.

Technology: Maximizing your market potential.

Over the past decade, Vetter has made significant strategic investments in both facilities and commercial production systems to meet both regulatory and customer needs for quality, capacity, and efficiency smoothly and reliably.

Production sites. With the Ravensburg Vetter South (RVS), Vetter Langenargen (VLA), and Vetter Schuetzenstrasse (SST) facilities, Vetter offers 3 independent commercial manufacturing sites for flexibility and safety. Each site includes:

- redundant, independent power supply
- multiple cleanrooms with Restricted Access Barrier Systems (RABS)
- material preparation and compounding areas
- state-of-the-art microbiology and analytical labs



RVS



SST



VLA

Packaging services. The increased demand for patient-friendly delivery systems has made secondary packaging an important part of the commercial manufacturing process. Vetter packaging specialists work closely with you to identify and develop customized solutions – from assembly to cartoning – that support your product's success at all stages of its life cycle.

Logistic services. With extensive expertise in storing, packaging, and worldwide cold chain shipment, Vetter offers comprehensive support in compliance management, import/export customs management, transportation, and logistics. Our state-of-the-art storage facility features a high-bay, climate-controlled warehouse for cold storage and room-temperature products, plus freezer storage capacity for frozen active ingredients.

Vetter Aseptic Commercial Production Facilities

	RVS	SST	VLA
Batch size range			
Up to 50,000 units	■	■	■
50,000 to 250,000 units	■	■	■
Over 250,000 units	■	■	
Process			
Bulk	■	■	■
Presterilized	■	■	
Systems			
Single-chamber syringe	■	■	■
Single-chamber cartridge	■	■	
Dual-chamber syringe	■	■	■
Dual-chamber cartridge	■	■	■
Vial (liquid, lyophilized)	■		■

Resources and Capabilities

<ul style="list-style-type: none"> ■ Purified water systems ■ Clean steam ■ Disposable equipment and reusable stainless steel ■ Glass barrel sterilization <ul style="list-style-type: none"> –Dry heat tunnel –Autoclave –Presterilized 	<ul style="list-style-type: none"> ■ Siliconization technology ■ RABS ■ Inline weight control ■ Pump systems <ul style="list-style-type: none"> –Rotary piston pump –Rotary vane pump –Peristaltic pump –Diaphragm pump ■ Stability storage 	<ul style="list-style-type: none"> ■ Filtration <ul style="list-style-type: none"> –Bulk filtration –Inline filtration ■ Lyophilization <ul style="list-style-type: none"> –Clean-in-place (CIP) –Steam-in-place (SIP) ■ 100% visual inspection <ul style="list-style-type: none"> –manual –automated
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For further information, please get in touch with us

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