



Comprehensive
support for your
injectables

From clinical development to commercial production



Answers that work

Vetter Development Service

Vetter Commercial Manufacturing

Vetter Packaging Solutions



There are
many sides to
your product's
success.

Build them together with Vetter.

Succeeding in today's global pharmaceutical and biotech markets requires flexible thinking and precise manufacturing. No matter what phase of development your injectable product is in, we have solutions that can open new doors, shorten lead times, and solve complex challenges.

At Vetter, we look at your project from every angle to help you find answers that work – answers that support your goals for quality, reliability, innovation, safety, and efficiency. When you partner with us, we integrate with your team to design and implement a personalized plan for success in a shifting global marketplace.

Who is Vetter?

We are a global leader in aseptic development and manufacturing of complex drug products. With over 35 years of experience, our services range from early stage development support including clinical manufacturing, commercial supply, and packaging solutions for vials, syringes, and cartridges.

As a family-owned, independent company, we do not manufacture our own drugs. Our focus is on developing solutions for our customers' needs.



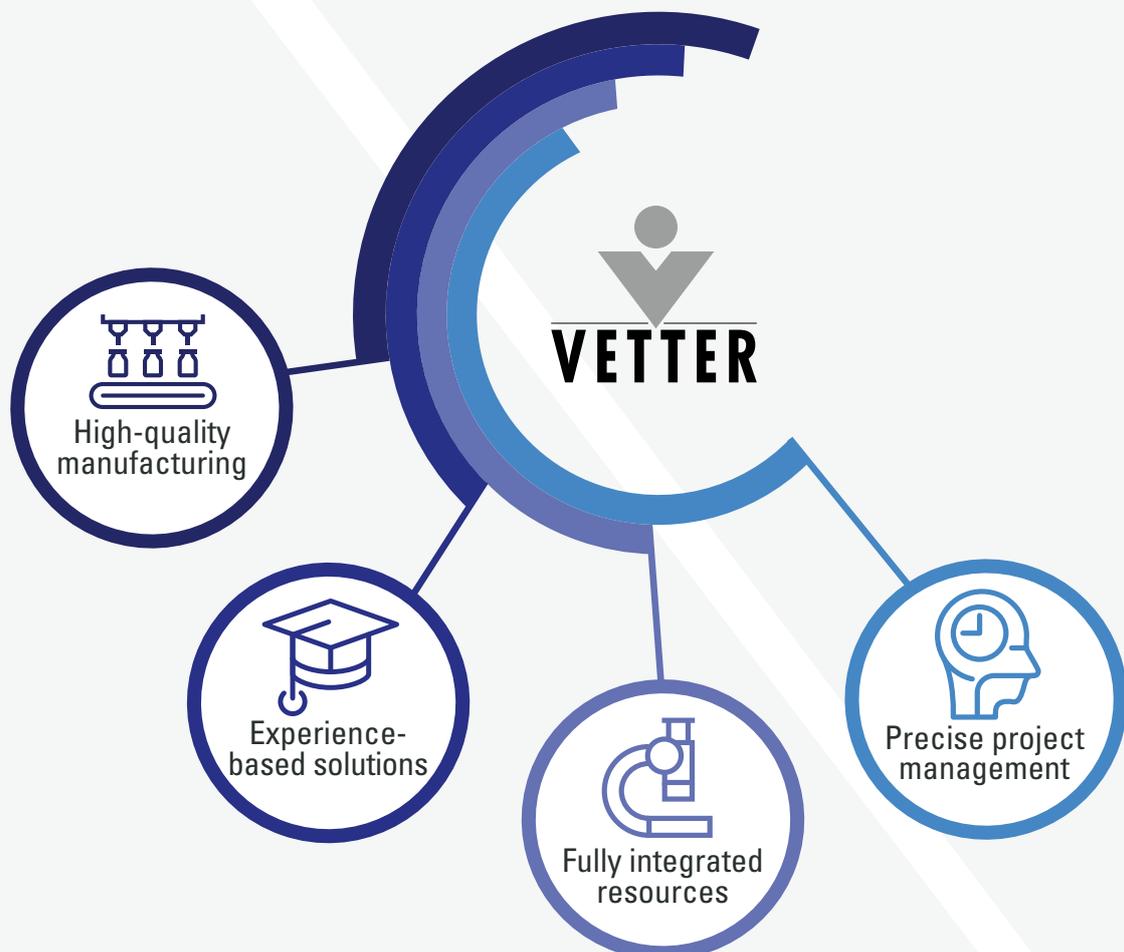
Be confident your product is on target.

Vetter offers a unique blend of expertise that helps launch and grow successful products.

- Customized clinical and commercial manufacturing services
- Comprehensive technical, analytical, and regulatory subject matter expertise
- Proven manufacturing processes that are flexible, efficient, and scalable
- Filling and packaging capabilities that meet international market demands

Stay ahead of the curve

We continually invest in high-quality, specialized resources and leading-edge technologies to support our customers.



Your partner for every stage of growth.



Development Service

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

Preclinic | IND | Phase I and II | Phase III



Commercial Manufacturing

- Fill and finish
- Analytical services
- Regulatory support
- Product lifecycle management

NDA | Approval | Launch



Packaging Solutions

- Customized packaging development
- Proven and innovative platform technologies
- Packaging services
- Logistic services

Integrated through all stages of development and manufacturing



We can grow
your success.

Vetter Development Service helps streamline your product's path to clinic.

Every new compound has high expectations – and highly specialized requirements that are pivotal for clinical trials. We bring together a variety of people, processes, and technology to guide your molecule from preclinical development through successful market launch.

Resources where you need them

We offer two state-of-the-art clinical production locations strategically located in Ravensburg, Germany, and Chicago, US. Each facility provides a wealth of expertise and manufacturing resources to support the successful development of new compounds, including peptides, monoclonal antibodies, and DNA/RNA-based therapeutics.





The right solutions deliver the right results.

Vetter offers decades of experience solving complex development challenges.

We work with you to establish a well-defined project plan to meet critical goals and guide the development of key implementation details, such as material compatibility, pump, and filtration studies. In addition, we'll partner with you to create processes that are flexible, scalable, reproducible, and efficient.



Quality for the long run

*The smallest details can
determine long-term success.
That's why from the initial
planning meetings and
beyond, we put quality first
and foremost.*

Inside Vetter Development Service

People

Advanced expertise

- Feasibility studies
- Compounding, pump, and filtration design
- Chemical and microbiology analysis
- Lyophilization
- Siliconization
- Regulatory compliance
- Packaging material development

Process

Integrated steps

- Peer-to-peer project management
- Implementation of process design
- Method transfer
- Regulatory support for streamlined approval
- Transfer to commercial manufacturing

Technology

Preclinical and Phase I – Phase III manufacturing

- Laminar-flow manual filling
- cGMP automated filling
- Liquids and lyophilized products in vials, syringes, and cartridges
- Clinical supply
- Primary and secondary packaging capabilities



Every detail
counts.

Vetter Commercial Manufacturing delivers expertise across the production chain.

Our experience as a contract manufacturer providing fill and finish for injectable drugs helps deliver the right results for pharmaceutical and biotechnology companies both large and small.

The high-quality support we provide our partners includes:

- State-of-the-art equipment and facilities designed to deliver products with efficient precision
- Integrated software to monitor quality and track regulatory data across all production sites
- Process optimization program staffed by Six Sigma team members certified as black, green, and yellow belts

Meeting your individual needs

Our state-of-the-art fill and finish services cover a wide range of injectable compounds, including analytical testing, lifecycle management, and regulatory support.





Creative thinking. End-to-end quality.

It takes both to manufacture injectables that set a higher standard.

Finding new ways to deliver added value is fundamental to our partnership with you. So is meeting the highest possible safety and quality standards.

- Our production sites include three independent commercial facilities, each with its own analytical testing
- Industry-leading Restricted Access Barrier (RABS) and Vetter CleanRoom Technology (V-CRT®) for a high level of sterility
- High-quality results are maintained by tightly integrated Quality Assurance and Quality Control programs as well as ongoing quality improvement initiatives

Locking in security of supply

Vetter takes active steps to maintain the integrity of the supply chain. We regularly review the quality of all suppliers, use cross-linked IT systems to monitor our manufacturing processes, and inspect cold chain logistics and storage resources.



Inside Vetter Commercial Manufacturing

People

Expertise through all stages of production

- Analytical service
- Engineering and pharmaceutical production
- Dedicated customer service
- Quality Control/Quality Assurance

Process

Finely tuned systems and procedures

- Enhance transparency and production monitoring
- Optimize yields and reduce batch cycle times
- Provide precise supply chain management
- Streamline regulatory approvals
- Guide innovative lifecycle management

Technology

Ongoing investment in state-of-the-art resources

- Redundant power supply at each site
- Both high-value dedicated equipment and disposable equipment
- A broad menu of drug delivery systems and packaging solutions
- Integrated TrackWise® system for quality management



Reshape your
product's potential.

Vetter Packaging Solutions build in safety, quality, and opportunity.

In today's parenteral market, packaging matters. Growing demand for innovative and user-friendly injection devices necessitate specialized packaging solutions. We work with you to determine the best options for your primary and secondary packaging design and materials.

Our packaging experts can help you identify and develop the right solutions at key stages in your product's lifecycle.

Safety first

At Vetter, we plan the safety and integrity of our packaging solutions carefully right from the start. Our manufacturing facilities meet strict hygiene and environmental controls, and comply with global cGMP guidelines and design control regulations for combination products.





Packaging strategies that work.

Find the best packaging solution for your compound.

Vetter offers you a wide range of packaging services and injectable delivery systems that can be tailored to your product's specific needs and optimize end-user convenience.

Customized packaging development

- Selects the ideal injection system and materials for your compound's specific characteristics
- Provides in-depth advice on important considerations in primary and secondary packaging
- Supports your product differentiation throughout its lifecycle



Proven and innovative platform technologies

- Vetter-Ject[®], a tamper-evident closure system for prefilled syringes, allows baked-in siliconization of an integrated needle syringe
- Dual-chamber systems Vetter Lyo-Ject[®] (syringe) and V-LK[®] (cartridge) for lyophilized compounds
- V-OVS[®] tamper-evident closure systems promote your product's safety and integrity
- Service for sterile, prefilled water for injection (sWFI) syringes for reconstituting lyophilized compounds
- Versatile technologies for specialized manufacturing or compound needs also include
 - Bulk/pre-sterilized syringes
 - Safety devices
 - Combination products
 - Autoinjectors, pens, and pump systems

Packaging services

We offer a comprehensive menu of services, including:

- Packaging services for smaller batch sizes, from assembly through storage
- Full market supply services for commercial production
 - Assembly
 - Printing
 - Labeling
 - Blister packing
 - Cartoning
 - Serialization
 - Storage
 - Cold chain logistics

Customized packaging solutions

Vetter supports you with patient-friendly packaging design and development, along with process development, validation, implementation, and transfer to commercial packaging.





Knowledge
that goes above
and beyond.

How specialized expertise gives you an inside edge.

Vetter is more than just a single-source partner for contract development manufacturing. We're a company of integrated specialists dedicated to your project's success from initial planning through full market supply and beyond.

Our solutions-focused approach is built on decades of hands-on problem-solving and innovation in key areas, including:

- Siliconization
- Lyophilization
- Analytical methods transfer
- Process optimization
- Strategic lifecycle planning

Global regulatory expertise

We support you with your regulatory submission.

Our excellent track record with global regulatory agencies, including FDA, EMA, PMDA (Japan), and RP (Germany), ensures confidence.

Over the years, we have successfully completed numerous FDA client product approvals.





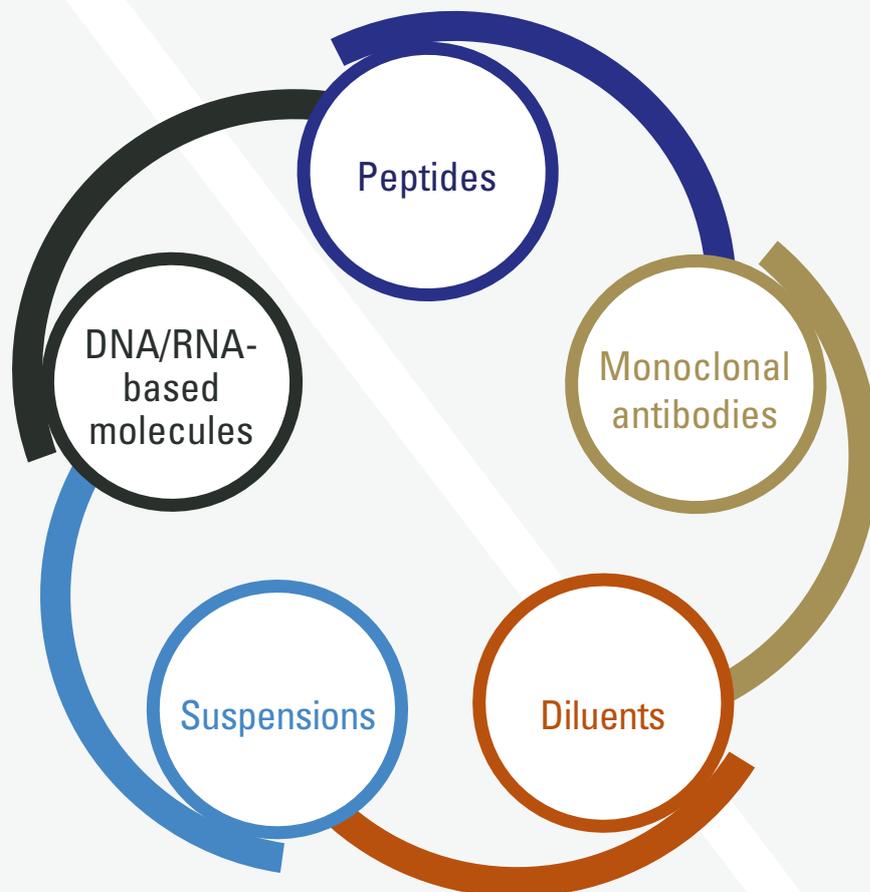
Exceptional solutions for everyday challenges.

Bring us your challenges.

Imagine a sensitive biologic product with tremendous potential suddenly sidelined during development by excessive reactivity to silicone oil. It's a roadblock that can be difficult to predict in early planning, yet can significantly impact time to market.

At Vetter, we anticipate complex technical challenges in the project planning process. Scientists and manufacturing specialists then focus on developing novel, efficient solutions tailored to your product's specific needs.

Your team will include experts with in-depth experience in many technical disciplines and classes of products.



Lyophilization

A significant number of injectable drugs now require lyophilization to protect biological activity, increase dosing precision, and extend shelf life.

Vetter offers decades of expertise and innovation in lyophilization. Recognized industry specialists work closely with your team to design a lyophilization cycle that optimizes efficiency and yields. They also conduct comprehensive feasibility analyses to help ensure your active substance is perfectly matched to its method of administration.



Method transfer

Vetter's analytical team is regularly involved in highly customized, intensive work to guide the critical transfer of microbiologic and chemical analytical methods.

Their experience and skill streamline the many complex issues involved in a successful transfer, including starting material testing, new method validation, instrument validation, process qualification, stability testing, and clinical testing.



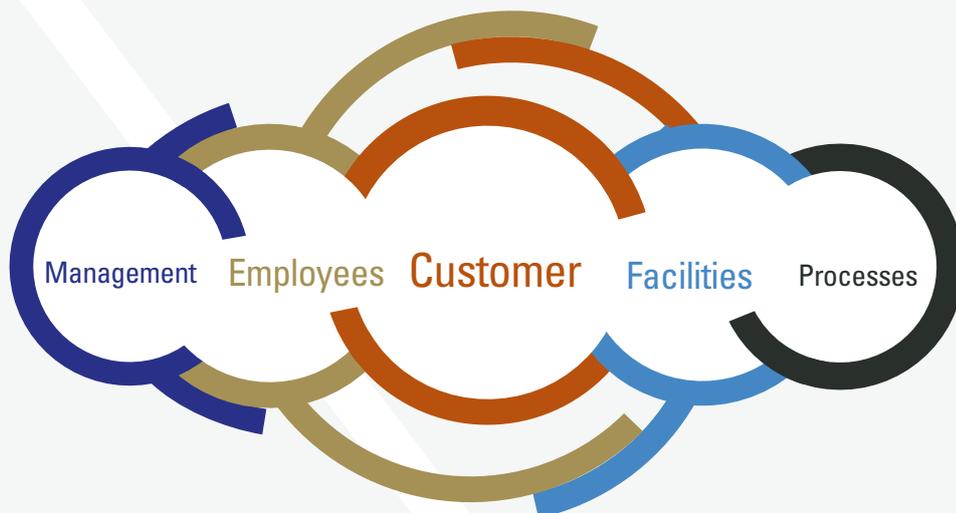


Partnership that prioritizes your needs.

A collaborative partnership with Vetter keeps you at the center of success.

We value your vision and keep it aligned with everything we do. We see you as equal partners in a collaborative process built on trust and clear communication.

Just as importantly, everything we do is centered around quality and with the end user in mind. We take pride in our ability to generate innovative ideas, and to implement them systematically and cost-effectively.



Class A operational performance

Vetter is recognized for excellence in operational performance and end-to-end supply chain management.

Strategic approach

Our strategic approach can be defined in a single word: alignment. All decisions, both within the company and with our partners, are aligned to clear, specific goals. From corporate planning and forecasting to creative, proactive lifecycle strategies for our customers, we know the best results come from never losing focus on the results you want to achieve.

Project management and product planning

We strive to provide a clear dialogue and a thoughtful project management process with our partners.

- Structured peer-to-peer communication
- Dedicated project managers
- Transparency in all aspects of project workflow
- Proactive lifecycle management strategies

Quality systems

Our quality and performance measures set a high bar for your product's success. Quality management consists of multiple elements, including:

- Ongoing quality reviews and trending initiatives
- Analysis of all process steps to determine potential production changes
- Close monitoring of key performance indicators

Corporate social responsibility (CSR)

Our commitment to corporate social responsibility extends beyond regulation. We believe good corporate citizens have a positive impact on the environment, our partners, and our working conditions. Our CSR pillars focus on:

- Corporate compliance
- Sustainability
- Health and family support
- Educational support
- Social projects

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