A unique blend of expertise for clinical manufacturing

Vetter Development Service

Supporting your compound's success

VETTER

Answers that work

Your molecule's future starts here.

By the time your new injectable compound enters clinical development, you have already invested years of painstaking work. Yet the next stage of growth is still unpredictable. And even the smallest details can influence your project's timing, costs, and long-term success.

Vetter Development Service can help you navigate this critical phase with confidence.

As your strategic partner, we provide a wide range of services tailored to your molecule's technical and scientific needs. Discover how we can support your clinical trial goals – and help you build a seamless pathway to the future.

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 Development Service

Vetter Development Service is a specialized area within 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 pharmaceutical and biotech companies.

People: Decades of experience help shape a solid future.

Planning and executing the steps that take your active pharmaceutical ingredient to stable drug formulation and into scale-up require a partner with strong expertise.

At Vetter, your product's development is guided by specialists with decades of experience. Their in-depth, firsthand knowledge spans many classes of products, including

- peptides
- monoclonal antibodies
- fusion proteins
- suspensions
- diluents
- vaccines (nonlive)
- oligonucleotides
- microparticle formulations

Teamwork multiplies success. An interdisciplinary team approach aligns your product's specific needs with experts trained to identify and solve complex, time-sensitive problems in

- feasibility studies
- compounding, pump, and filtration design
- chemical and microbiology analysis
- lyophilization
- siliconization
- regulatory compliance
- clinical manufacturing
- risk analysis

All teams work closely together to keep your product moving smoothly through each key development area and share a clear focus on your goals, such as optimizing use of API and expediting time-to-market.

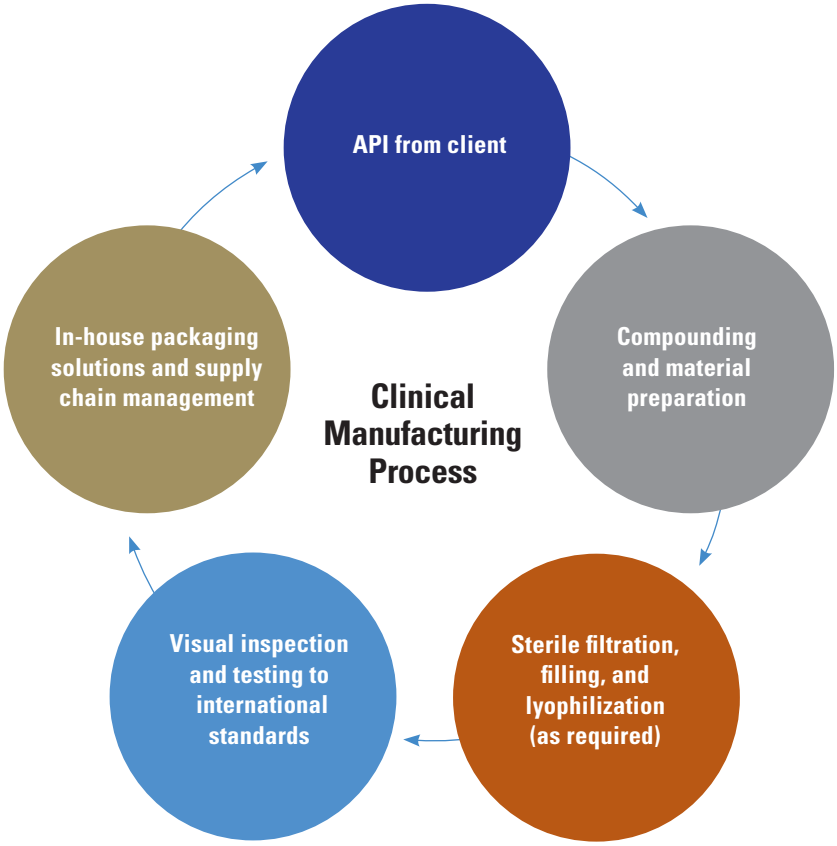
Method transfer: streamlining success

Vetter's dedicated Chemical Analytics team guides the transfer of your microbiologic and chemical analytical methods. Their experience streamlines the many complex issues involved in a successful transfer, including starting material testing, new method validation, process qualification, stability and clinical testing.

Process: Where strategic precision meets creative solutions.

The foundation of your project is a comprehensive project blueprint, which not only guides the timeline for your molecule's development but anticipates and plans for challenges along the way. What is the optimum lyophilization cycle? Which container closure is the most compatible? How will the filtration system affect your compound's bioactivity?

The process of consulting unlocks multiple paths that ultimately tie together into a streamlined, efficient road to clinical trial.



Starting with the end in mind

The initial planning stage of development is a prime opportunity for identifying future needs. Vetter looks at your product's short- and long-term goals to design strategies that can help save time and costs as you move from clinical development into full commercial production.

End-to-end support. Clinical development spans a complex series of technical processes, quality assessments, and regulatory requirements. Vetter helps keep your compound moving through each phase with integrated services that include

- expert, peer-to-peer project management
- selection of primary and secondary packaging materials
- compounding studies
- formulation support
- implementation of the final process design
- scale-up and clinical batch production
- quality validation for materials, solutions, and finished product
- support for registration documents
- seamless transfer to commercial manufacturing

Regulatory: clearing a critical hurdle

The regulatory submission process can be complicated and difficult, particularly for a new molecule. Working side by side with your team, we provide expert technical writing and dossier preparation, drawing on our extensive knowledge of global regulatory requirements, including FDA, EMA, PMDA (Japan), and RP (Germany).

Technology: The key to consistent quality and cost-efficient results.

Staying at leading edge of technology is a fundamental part of our approach to clinical manufacturing. From the moment your compound begins development, it is supported by state-of-the-art production capabilities and resources – designed to deliver your product to clinical trial accurately and efficiently.

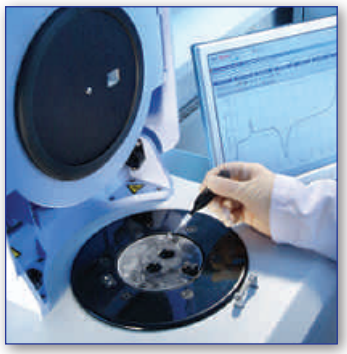
Vetter provides a wealth of expertise and manufacturing capabilities for preclinical and Phase I to Phase III manufacturing, with clinical production in 2 strategic locations: Ravensburg, Germany and Chicago, US.

Resources overview

- Chemical analysis
- Microbiology laboratories
- In-process and release testing including
  - Chromatography
  - Spectroscopy
  - Electrophoresis
  - Opalescence
  - Oxygen analysis
- Sterilization technology
  - Autoclave
  - Dry-heat tunnel
- Siliconization technology
- Visual inspection
- GMP storage for API and final product
  - Room temperature 15°– 25° C
  - Cold controlled storage 2°– 8° C
  - Frozen storage down to -80° C

Capabilities

- Inline weight control
- Aseptic compounding processes for unique requirements
  - Sub-liter to 500 l
  - Disposable equipment and reusable stainless steel
  - Modular system based on different component options
- Restricted access barrier system (RABS) consistently operated with closed doors
- Lyophilizer with
  - Clean-in-place (CIP)
  - Steam-in-place (SIP)
- Multiple pump systems
  - Peristaltic pumps
  - Diaphragm pumps
  - Rotary piston pumps
- Packaging service
- Transfer and scale-up for commercial manufacturing



Drug delivery systems: Ravensburg

Multiple automated cGMP filling options

Vials (liquid/lyophilized)

Fill volume: 0.1 – 50 ml

Single-chamber syringes with V-OVS® tamper-evident closure system

Fill volume: 0.1 – 10 ml

Single-chamber glass and polymer syringes with RNS staked needle

Fill volume: 0.1 – 1.1 ml

Up to 3 ml for presterilized systems

Single-chamber cartridges

Fill volume: 0.1 – 5 ml

V-LK® dual-chamber cartridge (lyophilized/liquid or liquid/liquid)

Dosage volume: up to 1 ml

Vetter Lyo-Ject® dual-chamber syringe (lyophilized/liquid or liquid/liquid)

Dosage volume: up to 5.6 ml

Fill volumes beyond the ranges listed above will be evaluated upon request.

Batch sizes vary depending on format and filling line.

Drug delivery systems: Chicago

Semi-automated cGMP filling options

Vials (liquid)

Fill volume: 0.3 – 50 ml

Single-chamber syringes

Fill volume: 0.3 – 10 ml

Cartridges (liquid)

Fill volume: 0.5 – 5 ml

Batch sizes, all formats: up to 500 units

Automated cGMP filling options

Vials (liquid/lyophilized)

Fill volume: 0.3 – 23 ml

Batch sizes:

– Max filling speed: 1,800 units/hr

– Liquid products: Up to 10,000 units/batch

– Lyophilized products: Up to 6,200 units/batch, depending on format

For further information, please get in touch with us

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VETTER

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