Vetter Pharma International GmbH · POB 23 80 · 88193 Ravensburg · Germany

Company profile

Meet Vetter

For more than 35 years, the Vetter name has stood for quality, innovation and strategic partnership. Vetter is a leading contract development and manufacturing organization (CDMO) that specializes in the aseptic filling of syringes, cartridges and vials. In collaboration with our customers, we support pharmaceutical and biotech products from preclinical development through global market supply. Our clients include the top 10 pharma/biotech companies worldwide, along with mid-sized firms and emerging startups.

Extensive experience with biologics

Working with biologics and other complex compounds requires special expertise. Biologics are often highly sensitive to the very containers – syringes, cartridges and vials – they are filled into**.** Type of stopper, container material, and degree of siliconization[1] can all interact with a product's active ingredient, or API. That interaction may contaminate the drug or affect its activity. Even the act of filling a drug can shear the molecule if not done properly.

Vetter has extensive experience with complex compounds, including monoclonal antibodies, peptides, interferons and vaccines. We know how to design a manufacturing process that promotes a product's integrity from the time it enters our facilities as bulk drug to when we deliver it in final form. Our scientists work closely with clients to determine the appropriate drug-delivery system, components and methodology for successfully producing their unique product.

Advanced technology and processes…

- **Safeguard quality.** Vetter's state-of-the-art facilities are designed to meet or exceed stringent cGMP requirements. We are a leader in the use of Restricted Access Barrier Systems (RABS)[2] in cleanrooms, which mitigates risk of contamination by minimizing human contact with products during manufacture. Our commercial filling operations are highly automated. We are increasing use of disposable components (e.g., tanks, pumps, tubing), which also reduces risk of contamination. The expertise of our staff is just as critical as our technology to maintaining the quality standards for which Vetter is known. Vetter's many scientists stand shoulder-to-shoulder with clients on each project, and we invest more than $2M annually in training our staff in the latest procedures and industry developments.

- **Maximize API yield.** Biologics are enormously expensive to manufacture. The amount of bulk drug that would fit into the size of a soda can could be worth more than a million dollars. Vetter's leading-edge technology reduces loss of API during the filling process. Filling units have minimal tubing lengths, so less API will be left coating tube walls. Disposable components also eliminate the need for cleaning validation, which may require API for test runs.

[1] Most syringe barrels require a coating of silicone oil to enable the piston to glide during drug administration
[2] High-tech combination of walling with built-in gloves and airflow control

Rigorous quality and key performance measures

Vetter's quality management includes:

- Ongoing quality reviews and trending initiatives
- Analysis of all process steps to determine potential production changes that can improve yields, reduce batch cycle times, and reduce errors
- Close monitoring of Key Performance Indicators, such as Right-First-Time (RFT) batch quality and On-Time-in-Full (OTIF) supply performance

An industry innovator

Holding numerous patents, Vetter has always strived to provide its clients with market-leading services and products as the pharma/biotech industry evolves.

First CDMO to use first-of-its-kind Bosch fully automated vial filler (Chicago site)
- Designed specifically for early-stage, high-value biologics
- RABS and high degree of automation reduce risk of contamination
- Minimum tubing lengths reduce API loss

Innovator of dual-chamber technology: Vetter Lyo-Ject® syringe and V-LK® cartridge
- Easy reconstitution and administration of lyophilized (freeze-dried) drugs in a single, all-in-one system
- Simple for patients and caregivers to use at home – increasingly relevant as home healthcare grows
- Provides safe, accurate dosing, because drug is premeasured and sealed within the syringe or cartridge

First CDMO to fill silicone-free polymer syringes
- Syringe barrel is free of silicone oil, adhesives and tungsten
- Reduces risk of protein aggregation
- Break resistance protects drug sterility during manufacture, shipping and administration

International production facilities

Vetter's manufacturing facilities include:

- **Europe:** Three commercial aseptic filling facilities and state-of-the-art secondary packaging facility
- **U.S.:** Small-batch clinical manufacturing facility in Chicago. Supports preclinical through Phase II products. At Phase III, products are transferred to Vetter's commercial manufacturing facilities.

Vetter's facilities work independently of each other and have nearly identical production processes. If contracted, they can serve as backup reserves, providing clients security of supply. Vetter's Chicago site, an expansion of Vetter Development Service, meets the need for early-stage product support in North America, where approximately two-thirds of global Phase I and II parenteral drug development takes place.

The crucial role of project management

Vetter employs a rigorous project-management approach throughout drug development to steer the effort to successful completion.

- Dedicated project managers follow projects from conception through launch, providing continuity at all stages
- Structured peer-to-peer communication streamlines information flow between customers and key staff
- Early, proactive lifecycle management strategies strengthen market success

Regulatory support

Vetter's international regulatory experience spans continents. We support our clients from early-stage development through regulatory approval. Approved as a foreign manufacturer by the government of Japan, Vetter has helped clients achieve product approvals by Japanese, U.S. (FDA) and European (EMA) regulatory bodies. We have also worked with other agencies around the world, including Canada, Russia, Brazil, Mexico, Saudi Arabia, Algeria, South Korea, Taiwan and Iran.

Partnership

At the center of our work is partnership with our clients. Without collaboration, and without a sense that "we're in this together," success would be elusive. Drug development is a process that takes years and an enormous amount of capital. A trusting, open relationship and the willingness to solve problems together are necessary to success – for us and for our clients.

For more information, visit **www.vetter-pharma.com**.
Or contact Oskar Gold, Senior Vice President Key Account Management, Marketing / Corporate Communications · **PRNews@vetter-pharma.com** phone +49-(0)751-3700-3729 (Germany)