



Vetter Pharma-Fertigung GmbH & Co. KG · Postfach 23 80 · 88193 Ravensburg

Vetter Services & Solutions

Vetter Development Service (VDS)

In view of the characteristics of modern pharmaceuticals, it is increasingly essential that a product's active ingredient and mode of delivery are optimally attuned to each other. Only such an approach can make the product ready for the market efficiently. Biotechnologically produced pharmaceuticals, in particular, contain highly sensitive active ingredients that can interact with the application system or with a packaging component. These interactions are some of the challenges that need to be mastered when filling sensitive substances.

The Vetter Development Service division specializes in managing products from the clinical development stage through to market launch. In close cooperation with its customers, Vetter selects an appropriate application system and corresponding components that are optimally suited to the relevant active ingredient. Vetter Development Service is also in a position to advise customers on packaging components such as rubber formulations or secondary packaging components, and to develop transport magazines, special inspection devices and methods.

In the process development stage, a suitable method for commercial production is selected. As an expert in lyophilization, Vetter develops specific lyophilization cycles and, as part of product lifecycle management, also offers the transfer of vial applications into innovative syringe and cartridge systems. Vetter carries out all analyses related with this process.

Before clinical production commences, samples from different process steps are analyzed in order to verify that the new drug can be produced. The documents required for international approvals are compiled in parallel with the clinical production stage. After conclusion of the clinical phases, the products are transferred directly to the Commercial Manufacturing division, where they enter the implementation stage. Commercial filling conditions are taken into account right from the development process phase. As soon as there is a change to the process, for example due to new requirements stipulated by the approval authorities, the active ingredients are returned to VDS where they are processed accordingly.

Vetter Development Service comprises:

- Primary Packaging Development
- Process Development
- Clinical Manufacturing
- Pharmaceutical Analysis
- Regulatory Affairs Services
- Transfer to Vetter Commercial Manufacturing



Vetter Commercial Manufacturing

The Vetter Commercial Manufacturing division provides the basis for the Ravensburg-based company's many years of experience and know-how in the production of aseptic prefilled injection systems. In serving a global customer base, Vetter fills products to the highest quality levels and in accordance with international standards. All products and processes are designed and tested according to the highest international quality standards (cGMP, FDA, EMEA, etc.). Vetter currently fills 19 customer pharmaceuticals that enjoy FDA approval. The experts at Vetter Commercial Manufacturing assume responsibility for the entire process of pharmaceuticals production, from aseptic filling up to the final packaging stage.

Highly developed technologies in all areas, such as the RABS (Restricted Access Barrier System) barrier technology, ensure an aseptic production process. RABS, which has been implemented by Vetter since 1996, combines the functionality and stability of an insulator with the flexibility of a classical cleanroom: in this process, laminar airflows in the cleanrooms establish barriers between staff and machinery. All devices in direct contact with the product are sterilized. Sterile gloves that are integrated in the machine cover are always used for working on the machines. Man, machine and environment are clearly separated. All products and processes are monitored by a quality control system that enables to meet the agreed specifications as notified by the customer.

Vetter Commercial Manufacturing comprises:

- Fill and Finish
- Packaging Service
- Pharmaceutical Analysis
- Regulatory Affairs Services

Vetter Solutions

The Vetter Solutions division uses its many years of experience in the field of aseptic filling to develop proprietary, patented innovations that are distinguished by efficient manufacturing processes, high quality and patient-friendly design. Besides the dual-chamber technology developed by Vetter, Vetter Solutions also devises anti-counterfeiting solutions. Vetter's innovative systems can create genuine added value for partners and customers and represent a competitive advantage on the market.

The Vetter Lyo-Ject[®] dual-chamber ready-to-use syringe was designed especially for sensitive pharmaceuticals that are preserved by freeze-drying. One chamber contains the lyophilized active ingredient, the other the solution. The active ingredient and the solution are not mixed until immediately before application. This all-in-one concept not only means the product can be stored for longer but also makes it easier to use. The high accuracy of dosage translates into lower active ingredient losses, which represents an additional advantage. In this way, the Vetter Lyo-Ject[®] dual-chamber technology enables the product to be reconstituted in a particularly careful manner.



Vetter also offers the V-LK[®] dual-chamber cartridge, which enables multiple dosages of lyophilized active ingredients and is suitable for use in pen and auto injection systems.

At present, pharmaceutical safety is a hot topic in product development. Vetter has responded to this challenge with the development of the V-OVS[®] tamper-evident closure system, which can be installed on conventional ready-to-use syringes. The patient can establish whether the product is intact by inspecting the closure. In the case of syringes with stacked needles, Vetter's patented tamper-evident closure system with needle protection (V-OVS NS[®]) provides added security.

Vetter Solutions comprises:

- Dual-chamber technology: Vetter Lyo-Ject[®], V-LK[®] (lyophilized/liquid; liquid/liquid; powder/liquid)
- Anti-counterfeiting solutions: V-OVS[®], V-OVS NS[®]

Further information is available at www.vetter-pharma.com.

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