A unique blend of resources for filling and packaging

Vetter Packaging Solutions
Delivering your product’s potential

Answers that work
Think outside the vial.

Vetter packaging experts help you optimize your product’s safety, quality, and potential.

How should your injectable drug be delivered and packaged? At every stage of growth, there are many questions to consider – from ensuring material compatibility and compound stability to meeting the growing demand for user-friendly systems.

As a dedicated strategic partner, Vetter Packaging Solutions can help you identify and develop the right strategies for your compound throughout its life cycle. Discover how we can support your success – from clinical development through full market supply.

Vetter Packaging Solutions is a service of Vetter, an independent, family-owned company with more than 35 years of experience in aseptic, high-quality manufacturing of injectable products. Recognized as one of the world’s leading CDMOs, Vetter is proud to support biotechnology and pharmaceutical customers both large and small.
Customized packaging development

The right place to start for long-term results.

For many products, packaging decisions require careful planning and in-depth knowledge of complex issues that can affect clinical performance and market success. Vetter works closely with your team to create packaging solutions that reflect your compound’s specific challenges and opportunities.

Whether your product is a fragile new compound or an established injectable in a challenging market, our specialists can help you

- select the ideal injection system and materials for your compound’s characteristics
- get in-depth advice on important considerations in primary and secondary packaging
- develop custom packaging solutions that help optimize end-user convenience and production efficiencies

Packaging confidence

With the rapid growth of advanced treatments for chronic illnesses and increased demand for user-friendly systems, injectable packaging is now under tighter regulatory scrutiny to ensure patient safety. At Vetter, you can be sure that the safety and integrity of your packaging will be carefully planned from the start – and in full compliance with cGMP guidelines for the US, Europe, and Japan.
Solutions that set you apart.

Following launch, your product can face a variety of clinical, economic, and competitive challenges. Vetter can help you reshape its potential with a unique portfolio of specialized packaging solutions as part of a life cycle management program.

Dual-chamber systems: one-of-a-kind convenience

Vetter’s patented dual-chamber technology allows different ingredients and solvents to be prefilled and stored separately, then easily mixed and administered as needed. Dual-chamber systems can be used for lyophilized/solvent drugs, and liquid/liquid drugs and offer your sensitive compound many advantages.

- Simple administration – fewer components required vs traditional vial/syringe combinations
- Increased patient safety – allows precise dosing and helps minimize reconstitution errors
- High product security – systems are closed inside the lyophilizer
- Versatility – dual-chamber cartridges can be used for single- and multidose pen applications
- Low residual volume – closure system and stopper geometry design reduce overfill and minimize packaging waste

Example: Vetter Lyo-Ject® dual-chamber syringe 1.0 ml
Vetter-Ject® syringe closure system: designed for today’s compounds

The Vetter-Ject closure system offers the convenience of a syringe in a design that addresses the unique requirements of highly sensitive compounds.

- Combination of an integrated staked needle with a baked-in siliconization process for standard glass barrels
- Heat tunnel sterilization for endotoxin-free glass barrels
- Tamper-evident closure supports product integrity
- Prefilled syringe offers convenient administration for patients and clinicians
- Flexibility across the process, components, and packaging

V-OVS® tamper-evident closures: streamlined security

The V-OVS closure includes a tamper-evident seal that provides additional protection for your glass-barrel syringe and is suitable for syringe formats with a Luer cone and groove.

- Efficient production – on existing aseptic equipment means minimal change to process flow
- Easy handling – 3 simple elements include a tamper-evident seal, tip cap, and Luer lock
- Versatility – compatible with multiple autoinjector systems, vial adapters, needle lengths, and Luer connectors

Safety devices: simplifying needle stick protection

To help protect patients and clinicians from injuries such as needle sticks, single-chamber syringes with staked needles are available assembled within a safety device.

Bulk glass syringes: optimized flexibility

Bulk glass syringes allow specific siliconization and sterilization processes to be tailored to your compound’s unique requirements, with added flexibility in primary component assembly. Manufacturing is processed in place to minimize contamination risks, with no transfer out of sterilized grade A units.
Vetter combination products: expanding your versatility

Vetter’s combination systems help you deliver your drug in a variety of formats that are particularly useful in the home health care setting.

- Single-chamber cartridges for pens and pump systems
- Dual-chamber cartridges for pen systems
- Single-chamber syringes for autoinjectors

Polymer syringes for sensitive molecules

For biologics and other complex substances that are highly sensitive to glues and tungsten, ask Vetter about polymer systems.

- Ideal for use with autoinjectors – tight dimensional specifications help achieve consistent glide-force behavior, providing precise, consistent drug delivery from dose to dose
- Break-resistant material increases patient safety and minimizes product loss during handling and application
Proven platform technologies

Simple solutions, high-quality results.

When conventional delivery systems are best suited to your product needs, Vetter offers high-quality aseptic filling of both standard vials and presterilized/nested glass syringes.

- Vials for liquids and lyophilized products are available in filling volumes up to 50 ml
- Single-chamber glass syringes for liquid products are available with
  – Staked needles and filling volumes from 0.1 ml to 3 ml
  – Luer lock caps and filling volumes from 0.1 ml to 20 ml

Sterile Water for injection (sWFI) syringes: built-in convenience

sWFI syringes for reconstituting lyophilized products offer unique advantages at all stages of your product’s life cycle.

- **Fast time-to-market** – Vetter offers ready-to-submit documentation for Europe, US and Japan as well as stability data to streamline registration
- **Turnkey simplicity** – flexible filling ranges from 0.5 ml to 3 ml (1.5 ml and 3 ml formats) and premium-quality packaging materials, including customized convenience kits
- **Market-differentiating convenience** – All-in-one sWFI syringes can simplify the reconstitution process and help to improve patient compliance
Packaging services

Broad flexibility, precise quality standards.
Secondary packaging has become a critical part of parenteral manufacturing. Vetter’s integrated packaging services help you meet increased safety and quality requirements with a broad menu of well-designed, efficient solutions.

All of our packaging services are housed within a state-of-the-art facility with separate production and utility areas on each floor.

- **Assembly** – A comprehensive menu of services includes
  - complete assembly of all syringe components
  - assembly of safety devices, pens, and autoinjectors

- **Printing and labeling** – Choose from a broad range of options, such as
  - variable data printing for packaging and cartons
  - component labeling
  - special services, such as vignettes
  - serialization and aggregation services

Customized convenience

*Vetter supports your product with both single-source efficiency and exceptional flexibility. All of our packaging services can be tailored to meet your specific needs, from clinical trials through full commercial production.*
Blister packing and cartoning – In addition to packing blisters in cartons, we offer
- thermoforming in various formats
- tamper-evident carton labels
- layout design services

- customized carton assembly
  (including insertion of leaflets and other materials with your product)

Serialization Services – We offer a comprehensive portfolio of serialization services, including aggregation with various customized and flexible options that allow you to meet regulatory requirements. Through our service offerings, you have the basis for the implementation of track-and-trace systems that can achieve greater security and efficiency of your supply chain.

Shipping packaging and storage – Final product can be packed for shipment per your specifications or stored under precise GMP conditions, including
- room temperature storage (15° – 25° C)
- cold controlled storage (2° – 8° C)

Integrated safety, quality, and hygiene protocols

Vetter’s packaging and filling operations comply with cGMP guidelines for the US, Europe, and Japan. Our facilities include control systems for each process step to help ensure consistency and accuracy. We also offer specialized production technology for products with high cosmetic requirements.
An overview of filling and packaging options.

Vetter’s injectable delivery systems are available in a wide array of configurations to meet your product- and patient-specific needs.

<table>
<thead>
<tr>
<th>Device</th>
<th>Type</th>
<th>Closure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-chamber syringe</td>
<td>Bulk</td>
<td>Staked needle</td>
</tr>
<tr>
<td></td>
<td>Presterilized</td>
<td>Staked needle</td>
</tr>
<tr>
<td></td>
<td>sWFI</td>
<td>Luer lock</td>
</tr>
<tr>
<td></td>
<td>Bulk</td>
<td>V-OVS®</td>
</tr>
<tr>
<td>Dual-chamber syringe</td>
<td>Bulk</td>
<td>V-OVS®</td>
</tr>
<tr>
<td>Single-chamber cartridge</td>
<td>Bulk</td>
<td>Crimp cap</td>
</tr>
<tr>
<td>Dual-chamber cartridge</td>
<td>Bulk</td>
<td>V-LK®</td>
</tr>
<tr>
<td>Vial</td>
<td>Bulk</td>
<td>Crimp cap Flip-off cap</td>
</tr>
<tr>
<td>Possible filling volume</td>
<td>Dosage form</td>
<td>Dosage format</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------</td>
<td>---------------</td>
</tr>
<tr>
<td>0.1 ml – 1.1 ml</td>
<td>Liquid</td>
<td>Multiple ml formats</td>
</tr>
<tr>
<td>0.1 ml – 10 ml</td>
<td>Liquid</td>
<td>1.5 ml/1 ml long</td>
</tr>
<tr>
<td>0.1 ml – 3 ml</td>
<td>Liquid</td>
<td>1.5 ml/1 ml long</td>
</tr>
<tr>
<td>0.1 ml – 20 ml</td>
<td>Liquid</td>
<td>Multiple ml formats</td>
</tr>
<tr>
<td>0.5 ml – 3 ml</td>
<td>Liquid</td>
<td>1.5 ml/1 ml long</td>
</tr>
<tr>
<td>0.1 ml – 1.5 ml</td>
<td>Liquid</td>
<td>1.5 ml/1 ml long</td>
</tr>
<tr>
<td>Diluent Chamber: 0.5 – 5 ml</td>
<td>Lyophilized/liquid</td>
<td>1 ml</td>
</tr>
<tr>
<td>Dosage volume 5 ml max (depending on dosage format)</td>
<td>Lyophilized/liquid</td>
<td>1 ml</td>
</tr>
<tr>
<td>Dosage volume (both chambers): 5.6 ml max (depending on dosage format)</td>
<td>Lyophilized/liquid</td>
<td>1 ml</td>
</tr>
<tr>
<td>0.1 ml – 5 ml</td>
<td>Liquid</td>
<td>Multiple ml formats</td>
</tr>
<tr>
<td>Diluent Chamber: 0.3 – 1.1 ml</td>
<td>Lyophilized/liquid</td>
<td>1 ml</td>
</tr>
<tr>
<td>Dosage volume 1 ml max (depending on dosage format)</td>
<td>Lyophilized/liquid</td>
<td>1 ml</td>
</tr>
<tr>
<td>Dosage volume (both chambers): 1 ml max (depending on dosage format)</td>
<td>Lyophilized/liquid</td>
<td>1 ml</td>
</tr>
<tr>
<td>0.1 ml – 50 ml</td>
<td>Lyophilized Liquid</td>
<td>Multiple ml, R, and other formats</td>
</tr>
</tbody>
</table>

**All devices** Kit packaging, printing, labeling, blistering, cartoning, shipping, packaging, serialization, aggregation and cold/room temperature storage
For further information, please get in touch with us

**Vetter Pharma International GmbH**
Eywiesenstrasse 5
88212 Ravensburg
Germany
phone: +49-(0)751-3700-0
fax: +49-(0)751-3700-4000
e-mail: info@vetter-pharma.com

**Vetter Pharma International USA Inc.**
10 W. Algonquin Road
Des Plaines, IL 60016
USA
phone: +1-847-581-6888
fax: +1-847-581-6880
e-mail: infoUS@vetter-pharma.com

**Vetter Pharma International GmbH**
Singapore Branch
The Metropolis, Tower 2
Level 8 Unit-09, North Buona Vista Drive
Singapore 138589
phone: +65-6808-7766
e-mail: infoAsiaPacific@vetter-pharma.com

**Vetter Pharma International Japan K.K.**
Level 28 Shinagawa Intercity Tower A
2-15-1 Konan Minato-Ku
Tokyo 108-6028
Japan
phone: +81-3-6717-2740
e-mail: infoJapan@vetter-pharma.com

**Vetter Pharma International GmbH**
South Korea Branch
#1106 Get-Pearl Tower, 12 Gaetbeol-ro
Yeonsu-gu, Incheon
Korea 21999
phone: +82-32-831-7039
e-mail: infoAsiaPacific@vetter-pharma.com