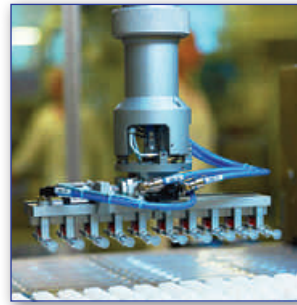


A unique blend of resources  
for filling and packaging



## 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 so 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  
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 Packaging Solutions

*Vetter Packaging Solutions is a service of 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.*

# Customized packaging development

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## 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.*

# Specialized packaging technologies

## 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, liquid/liquid drugs, and powder/liquid drugs, and offer your sensitive compound many advantages.



*Example: Vetter Lyo-Ject® dual-chamber syringe 1.0 ml*

- **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

#### Dual-chamber options include

- Vetter Lyo-Ject® dual-chamber syringe – 1.0, 2.5, and 5.0 ml formats
- Vetter V-LK® dual-chamber cartridge – 1.0 ml format

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## V-OVS<sup>®</sup> 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.



*Example: Safety Syringe, UltraSafe Passive<sup>®</sup> Needle Guard*

## 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



*Example: Ypsomed, LyoTwist™ Trio*

## Polymer syringes: a breakthrough for sensitive molecules

For biologics and other complex substances that are highly sensitive to silicone oil, glues, and tungsten, Vetter now offers 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



*Example: West, Daikyo Crystal Zenith® syringe*

# 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



*Example: Blistered WFI-Syringe 3.0 ml*

## Water for injection (WFI) syringes: built-in convenience

WFI 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 and the US as well as stability data to streamline registration
- **Turnkey simplicity** – Customize your WFI product's volume with flexible filling ranges from 0.5 ml to 3 ml (1.5 ml and 3 ml formats) and incorporate premium-quality packaging materials, including customized convenience kits
- **Market-differentiating convenience** – All-in-one WFI syringes can simplify the reconstitution process and help to improve patient compliance



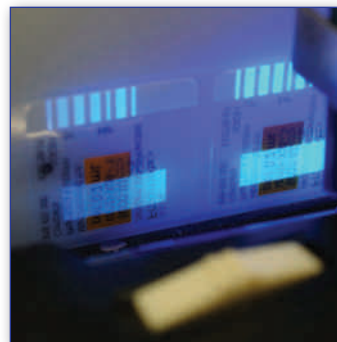
# Packaging services

## **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

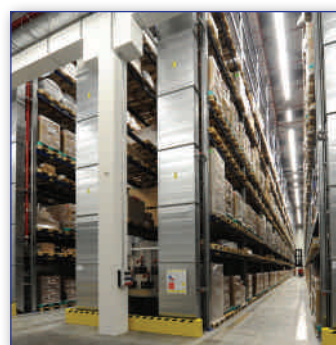


## **Customized convenience**

*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.*



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- **Blister packing and cartoning** – In addition to packing blisters in cartons, we offer
    - thermoforming in various formats
    - customized carton assembly (including insertion of leaflets and other materials with your product)
    - tamper-evident carton labels
    - layout design services



- **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.*

# Vetter Packaging Solutions

## 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.

Device	Type	Closure
<b>Single-chamber syringe</b>	Bulk	Staked needle V-OVS®/tip cap
	Presterilized	Staked needle Luer lock
	WFI	V-OVS®
<b>Dual-chamber syringe</b>	Bulk	V-OVS®
<b>Single-chamber cartridge</b>	Bulk	Crimp cap
<b>Dual-chamber cartridge</b>	Bulk	V-LK®
<b>Vial</b>	Bulk	Crimp cap Flip-off cap
<b>All devices</b>	Kit packaging Printing, labeling, blistering, cartoning, shipping packaging, cold/room temperature storage	



Possible filling volume	Dosage form	Dosage format	Packaging and assembly services: System and component options			
			Syringe options	Auto-injector	Safety device	Pen system
0.1 ml – 1.1 ml	Liquid	Multiple ml formats	Plunger rods	■	■	
0.1 ml – 10 ml				■		
0.1 ml – 3 ml				■	■	
0.1 ml – 20 ml						
0.5 ml – 3 ml	Water for injection	1.5 ml 3 ml	Back-stops			
Diluent Chamber: 0.5 – 5 ml Dosage volume 5 ml max (depending on dosage format)	Lyophilized/ liquid	1 ml 2.5 ml 5 ml	Plunger rods			
Dosage volume (both chambers): 5.6 ml max (depending on dosage format)	Liquid/liquid					
0.1 ml – 5 ml	Liquid	Multiple ml formats				■
Diluent Chamber: 0.3 – 1.1 ml Dosage volume 1 ml max (depending on dosage format)	Lyophilized/ liquid	1 ml				■
Dosage volume (both chambers): 1 ml max (depending on dosage format)	Liquid/liquid					■
0.1 ml – 50 ml	Lyophilized Liquid	Multiple ml, R, and other formats				

For further information, please get in touch with us

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Answers that work

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