



Delivering Excellence in Assembly & Packaging

Insights & Solutions from Vetter

Today's
presenters are



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Today's agenda

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Introduction

Secondary packaging at Vetter

2

Key considerations

Packaging & assembly strategy

3

The Vetter portfolio

Our packaging & assembly services

4

Working with Vetter

Quality, flexibility & experience



Introduction

Secondary packaging at Vetter



About Vetter

**World-class manufacturing services
for the biopharma industry**

- Clinical & commercial filling
- Assembly & packaging

238M

units filled
2025

\$1.3B

revenue
annually

>7300

employees
worldwide



Schützenstraße 87
88212 Ravensburg

Vetter Pharma-Fertigung
GmbH & Co.KG



Comprehensive support for your parenteral product



Clinical development



Packaging
dev & process
design



Method
transfer & lab
qualification



Clinical filling
& scale-up



Commercial filling



Commercial
fill-finish



Visual
inspection



Market
supply



Assembly & packaging



DP Delivery
devices



Packaging

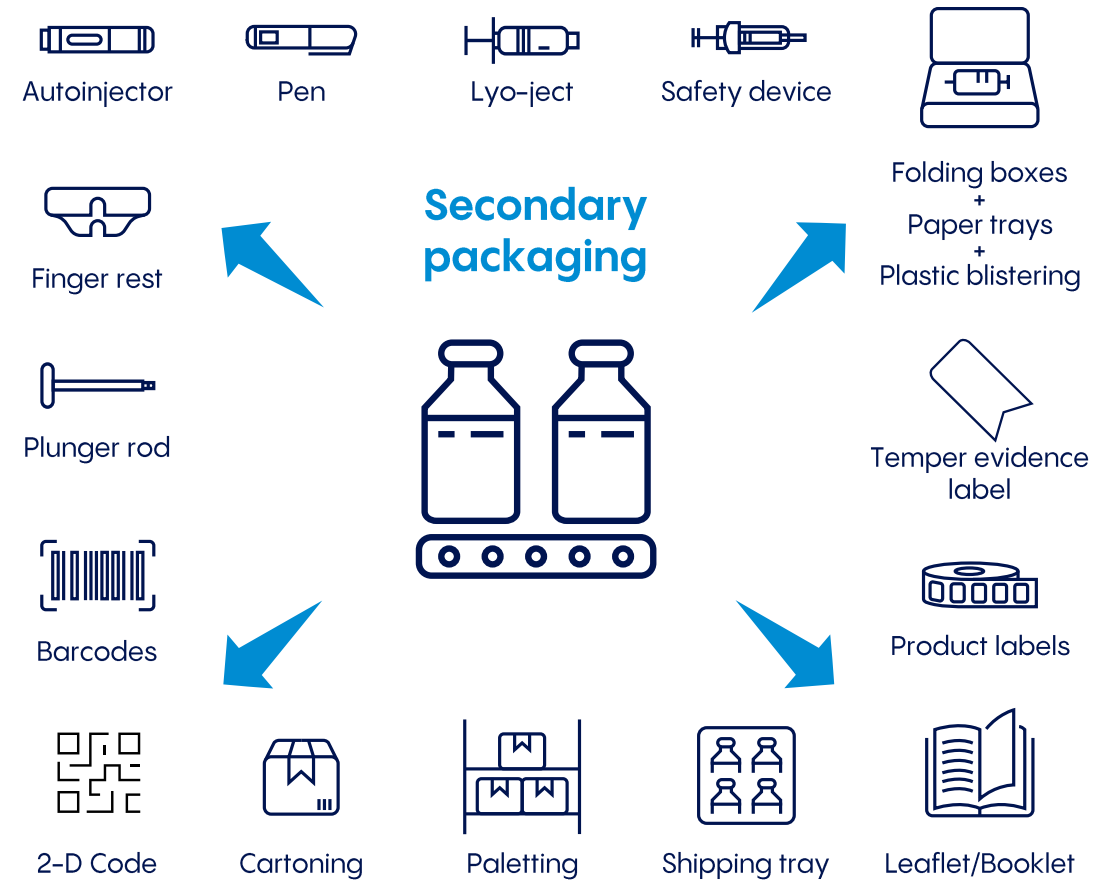
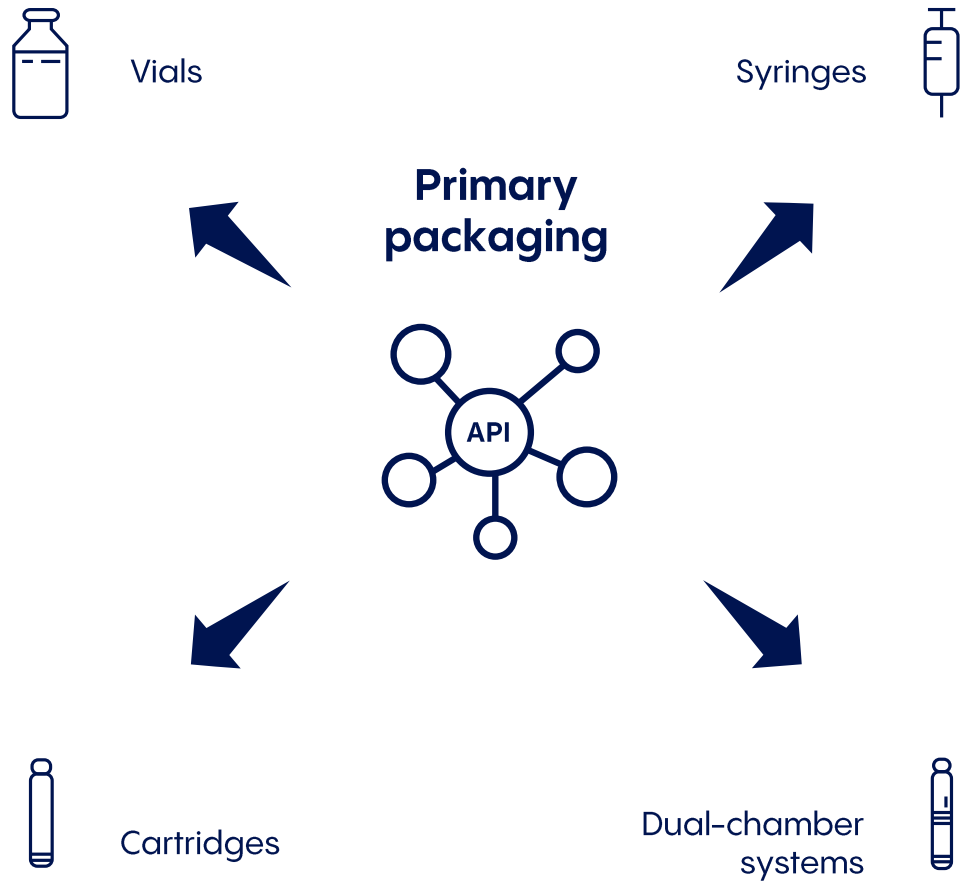


Storage
& logistics

Analytical services • Regulatory support • Logistic services



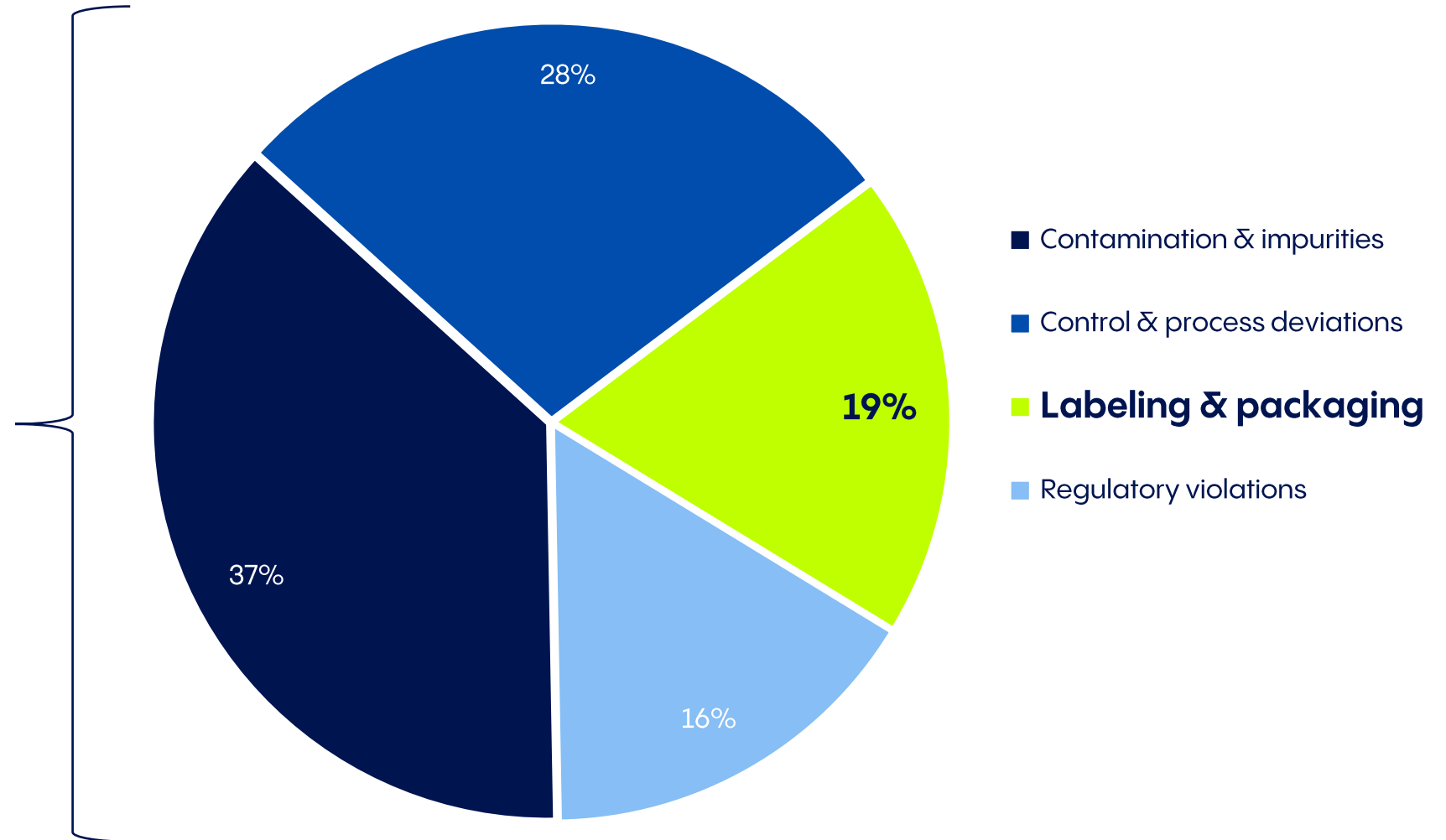
What do we mean by secondary packaging?



Why high-quality secondary packaging is important

Top reasons of FDA drug recalls

2012-2023



Assembly & packaging unlock products' full potential



Key considerations

Packaging & assembly strategy



A holistic strategy is essential to success



Timing

Start early with your device strategy.

Your primary container selection impacts your device options.



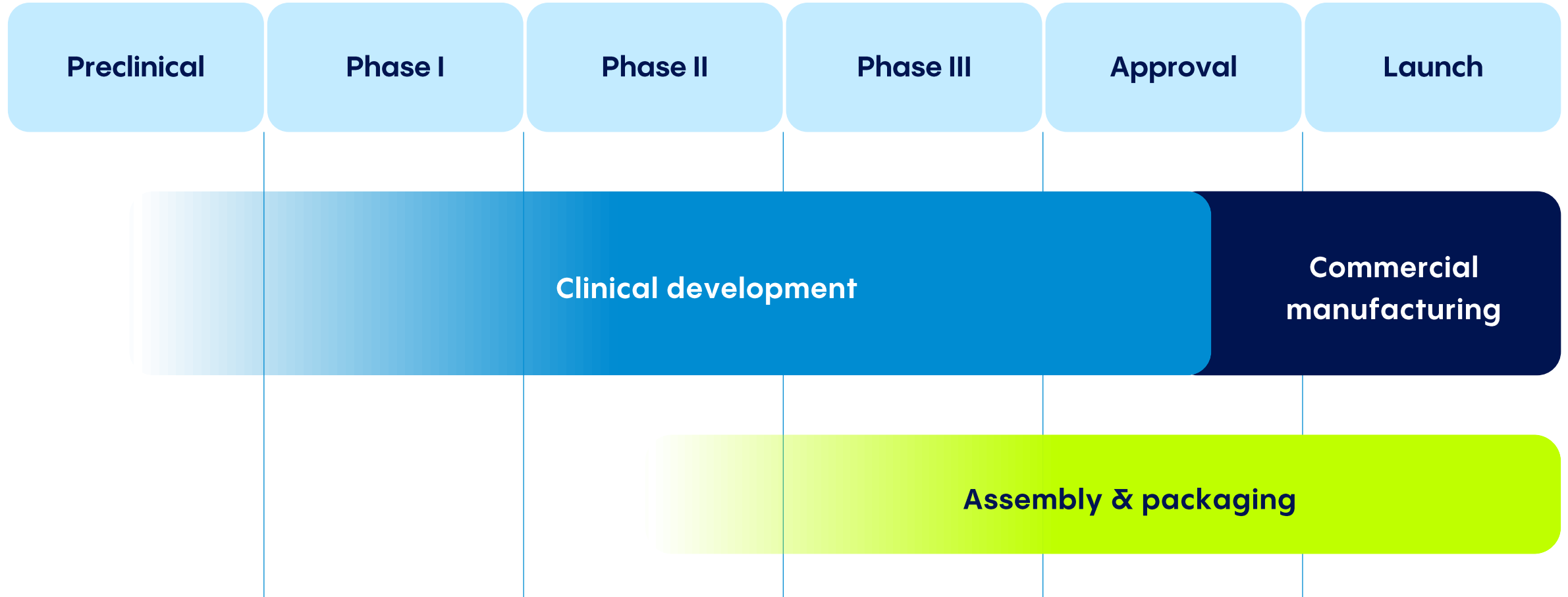
Patient & product profile



Technical considerations



When to start planning assembly & packaging



What's next once you've mapped a timeline



Timing



Patient & product profile

Consider health system requirements, disease attributes, patient demographics, and injection site (self-administration or HCP), as well as drug product attributes.



Technical considerations

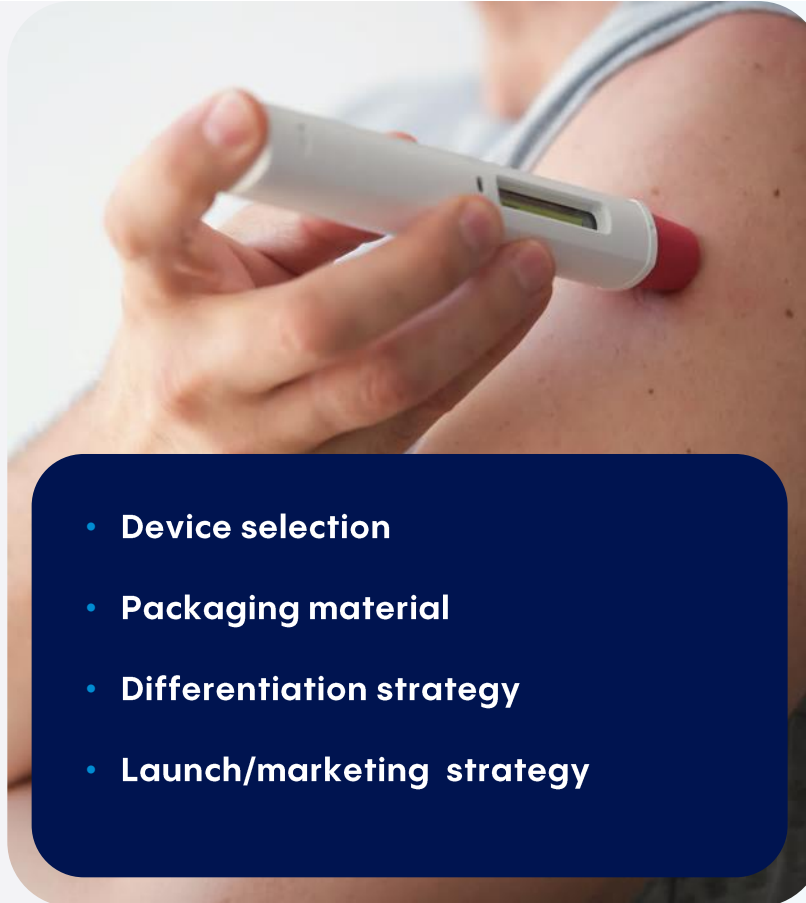


Example > Planning for an autoinjector



Product profile

- Drug characteristics
- Fluidic properties
- Regulatory considerations
- Budget & timeline



Patient profile



- Health system requirements
- Disease attributes
- Demographics
- Injection site(s)
- Indication

Key factors your strategy should focus on



Timing



**Patient &
product profile**



**Technical
considerations**

Consider technical and manufacturing-related aspects when selecting the most suitable injection device.

Key considerations for launching in an autoinjector to reduce risk of re-design and delayed timelines

Assembly process

Fill volume & stopper position

Size varies for different filling volume and impacts the assembly process

1

Type of platform customization

Design, color, cap, body can be customized and impact the assembly process

2



Window size

Size varies for different filling volume and impacts the assembly process

3

Compatibility of PPM and device

Type of finger flange

The autoinjector's design defines the fixation points of the primary packaging, influencing the forces on it, which must be considered when selecting the syringe.

4



Compatibility of autoinjector cap vs. syringe needle shield

Consider the forces required for device cap removal and the protection provided by the needle shield to ensure ease of use and safety during handling.

5





Start early to align



Vetter's portfolio

Assembly & packaging services



A wide variety of formats to suit your injectable product*



Model	Ypsomed UnoPen™	BD UltraSafe Plus™	Nemera Safe'n'Sound®
Device	Pen	Safety device	Safety device
PPM	Cartridge	Syringe	Syringe
Formats	1.5 mL 3 mL	1 mL 2.25 mL	1 mL 2.25 mL
Status at Vetter	Implemented	Implemented	Implementation via customer project possible



* Processable devices according to Vetter's platform strategy. Customized devices based on these platforms can be evaluated.

A range of autoinjector assembly capabilities too*

	Standard		High viscosity	Large volume injection ($\leq 5.5\text{mL}$)	
					
Model	Ypsomed YpsoMate®	SHL Molly®	Owen Mumford Aidaptus®	Ypsomed YpsoMate® Pro	Ypsomed YpsoMate®
PPM	Syringe	Syringe	Syringe	Syringe	Syringe
Formats	1 mL 2.25 mL	1 mL 2.25 mL	1 mL 2.25 mL	2.25 mL	5.5 mL
Status at Vetter	Implemented (small to large scale)	Implemented (small scale)	Implementation via customer project possible		



* Processable devices according to Vetter's platform strategy. Customized devices based on these platforms can be evaluated.

Device release testing capabilities



Ensuring safety & compliance of medical devices

- Devices are tested to ISO standards (e.g., 11608)
- Automated and manual testing ensures functionality, safety, and reliability

Standard devices & test capabilities*

	  		
Test parameter	Autoinjector	Safety device	Pen
Delivered injection volume	●	●	●
Cap/RNS removal force	●	●	
Activation force	●	●	
Override force	●	●	
Click detection	●		
Plunger rod detection	●		
Injection time	●		
Needle extension	●		
Break loose & glide force		●	
Torque for dosing			●
Injection force			●

Implementation of product-specific testing requires:

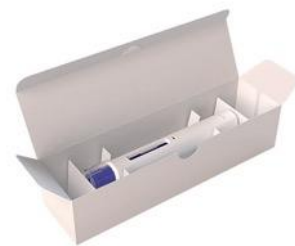
- Defined testing strategy
- Format implementation
- Method validation
- Sample availability for validations
- Timeline for method development

Discuss your release testing strategy as early as possible



*Final test parameter and methods to be aligned in customer project

Versatile product packaging formats



Packaging formats



**Mono-material >
All-paper packaging**

Blister tray packaging

Material	Inlay/tray	Paper	PET (Tray) + Optional: <i>Paper (Lid)</i>
	Folding carton	Paper	 NEW: PP (tray) + optional: PP (Lid)*
Optional tamper-evident sealing		Plastic based sealing and carrier	
Status at Vetter		Implemented	Implemented



Serialization & aggregation > Parent/child relationships

Folding box serialization



Each saleable unit is assigned a unique identifier.

Sample code



GTIN: 04012345000344
Serial #: 100000000234
Lot #: 987654321G
EXP: 30-05-2015

Shipping case aggregation



Saleable units packed into cases. Each case is assigned a unique identifier, while each unit (child) is associated with the case (parent).

Sample code



GTIN: 0405060708090
Serial #: 11111111111
Lot #: 987654321G
EXP: 30-05-2015
QTY: 50

Pallet aggregation



Cases packed onto pallets. Each pallet is assigned a unique identifier, while each case (child) is associated with the pallet (parent).

Sample code



(00)340123451234567895



Working with Vetter

Quality, flexibility
& experience

Facility overview: Vetter Secondary Packaging (VSP)

Flexible, state-of-the art site offering a wide range of expertise & services

- 8,900 m² (95,799 ft²)
- 9 automated production lines + 5 production rooms for manual assembly
- 7 standalone labeling & assembly machines
- Hygienic area E
- Modern testing & analytics
- cGMP compliant (e.g., USA, Europe & Japan)
- ~77.2 MM units processed in 2025 (~2,300 orders)

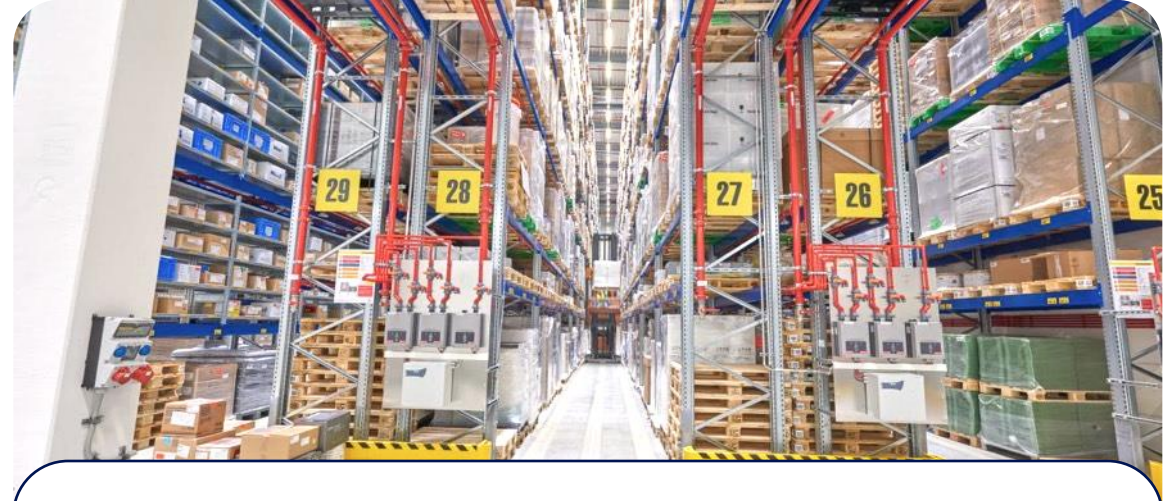


Infrastructure designed to deliver quality



Syringe assembly & packaging

- One-way linear material flow
- Separate production lines
- Dedicated access controls



On-site cold & room temperature storage

- State-of-the-art climate control & ventilation tech
- Control systems for each process step
- Monitoring for temperature-sensitive substances

Support from samples to commercial batches

Small-scale

Large-scale



Non-GMP samples

Tabletop assembly machines



Clinical batches

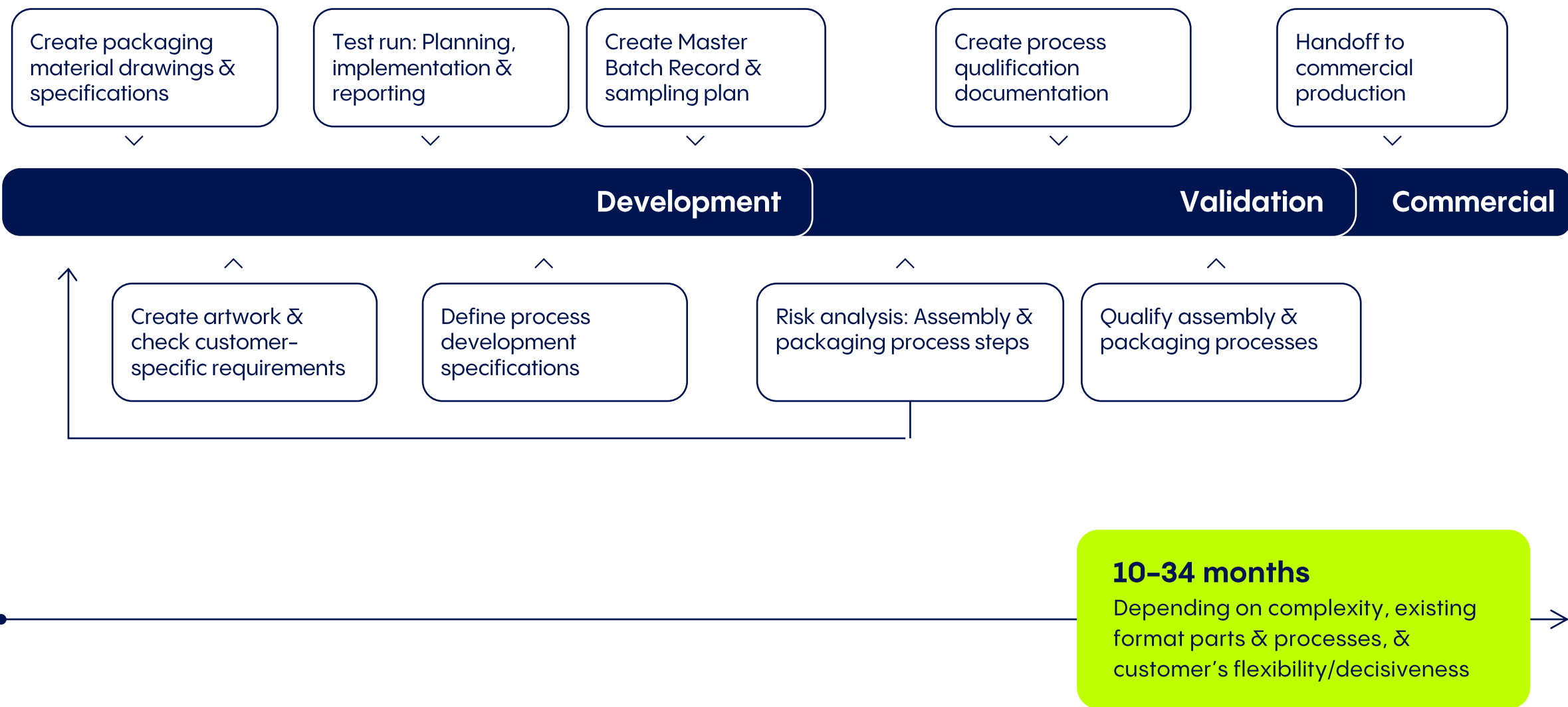
Tabletop & semi-automated machines



Commercial batches

Semi- & fully automated production lines

Example > Secondary packaging project



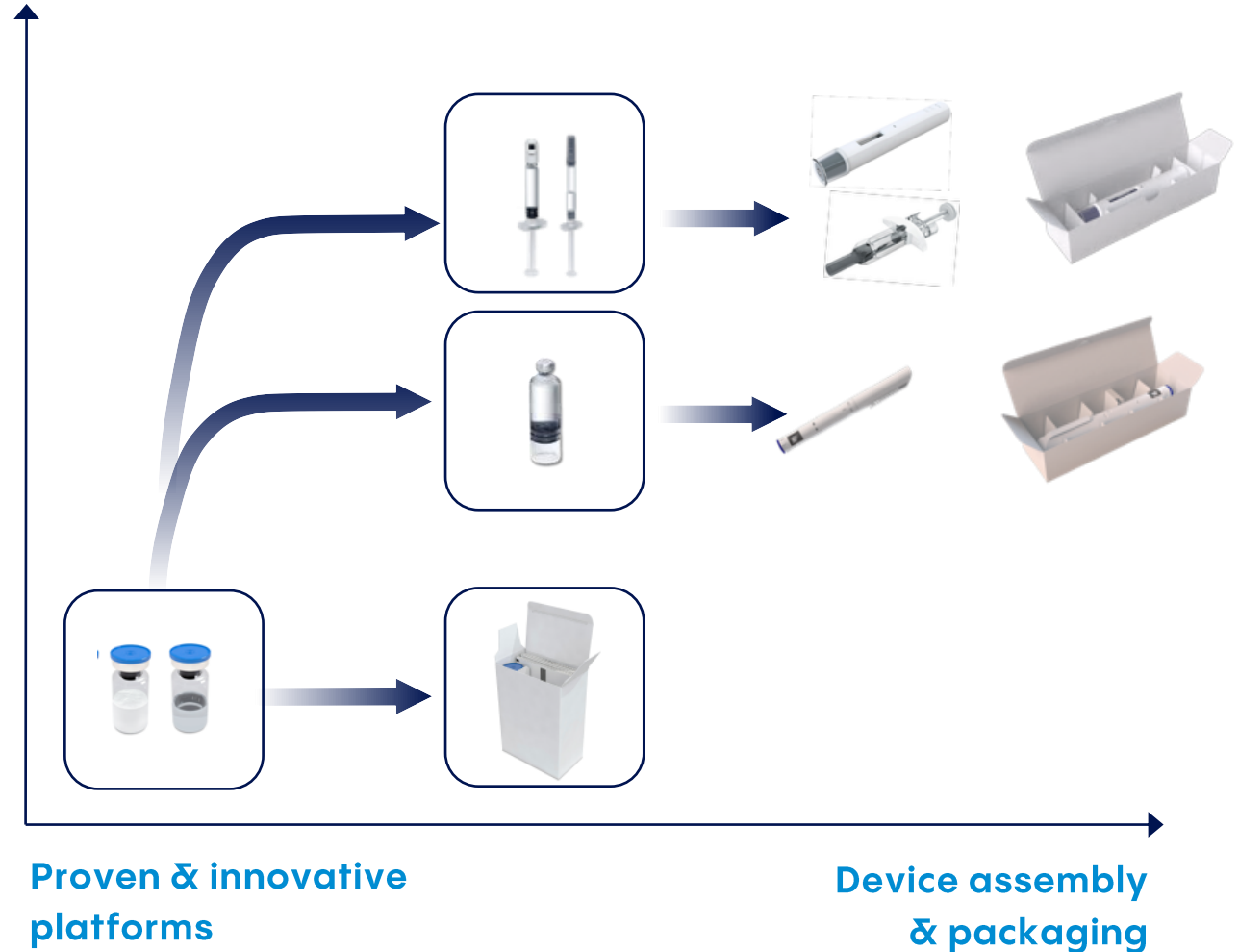
Your packaging journey with Vetter

As market needs shift, we help you continually evolve your product to meet them.

As your CDMO, we'll host regular business review meetings to exchange information on current and future drug product(s), with the potential for process adjustments if product strategy updates are needed.

Examples

- Up- & downscaling commercial volumes
- Adapting primary & secondary packaging, and/or processes
- Launching in additional countries



Proven Track Record in Device Assembly & Packaging



Experience

25+ years
20+ products with device assembly



Scale

~77M manufactured units (2025)
~40M autoinjectors



Quality

21 successful inspections/audits in 2025



Flexibility

Small to large batch sizes
Fully automated lines



Thank you!