Going to market in an autoinjector

How to prepare for the device assembly & packaging process

VETTER

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It’s the format powering a global trend

Across the healthcare market, the shift to at-home care is driving a surge in demand for self-administered therapies. For many drug owners, launching in a patient-friendly format has shifted from an aspirational goal to a life-cycle “must.”

As that trend accelerates, **autoinjectors** have become one of the market’s most popular and successful formats. But while demand for these devices may be hot, they pose an important challenge for drug owners: complex, technically demanding manufacturing processes.

If you’re planning to launch your product in this format, keep reading. This eBook will cover some of the key product, packaging, and process considerations you need to consider.

Table of contents

Key takeaways

What you'll learn in this eBook

A patient-centric approach is key

Ultimately, the "right" autoinjector for your product is the device that's best for your target patient. The first step toward launching in this format: understanding your users' needs, expectations, and priorities when it comes to a therapy self-administered with an autoinjector.

Your product and container are crucial factors

Every autoinjector-based product is a medication, inside a syringe, inside a delivery device. Each of these components can have a major influence on how the others are selected, configured, and assembled. To develop a successful assembly process, you need to look closely at key details of each component.

Always start with your end goals in mind

Going to market in an autoinjector is a technically, operationally, and strategically complex process – one where smart long-term thinking is essential. Don't be distracted by simple, incremental steps: clearly defined goals and proactive planning are vital to this intricate launch.

Pull in the right experts as early as possible

When you're considering an autoinjector, it's important to partner with a CDMO who has mastered both aseptic fill-and-finish and delivery device assembly. Each of these processes takes specialized expertise. Minimize your risks by choosing a partner with expertise in both.

Overview

Why make the leap to an autoinjector?

While launching in this format is a complex process, there are a number of growth-driving reasons why drug owners are adding this step to their products' life cycle. The right autoinjector can add substantial value in many different ways, with benefits for patients, prescribers, and drug owners alike.

To capture those benefits, though, you'll need to look closely at many different dimensions of your product, target patients, and packaging – and how they can shape your approach to launching in an autoinjector.

Adherence support

Ease of use promotes consistent compliance with therapy

Intuitive functionality

Simplified self-administration wherever it's needed

Reimbursement support

Added functionality helps drug owners secure premium pricing

Market differentiation

Competitive edge for patient-friendly products

Going to market in an autoinjector

Overview

A holistic strategy is essential for this launch

Every autoinjector-based therapy is a technically precise combination of medicinal product, primary container, and delivery device, all designed with a specific target patient in mind. Each of these components has important variables that can influence related manufacturing processes.

The following sections will look closer at these factors, how they can impact key device assembly steps, and how integrating those steps can shift the entire manufacturing process for your combination product.

Critical factors to consider

Patient profile	Product characteristics	Container considerations	Point of care	Partner selection
• Demographics • Indication • Disease attributes	• Concentration • Viscosity	• Syringe design • Filling volume • Fixation points	• At-home • Hospital/clinic	CDMO with expertise in aseptic filling & device assembly

Overview

5 key steps from product to delivery system

To launch in an autoinjector, there are several major shifts you'll need to make in your product's manufacturing process. New, device-related steps will need to be integrated from start to finish. You'll also need to reassess multiple key factors in the familiar fill-and-finish process.

Consider the requirements for each step, and you can see why proactive planning is critical to a successful launch — and why it's essential to allow ample time for every step in a comprehensive strategy.

Additional:

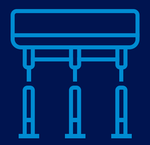
Device selection

Identifying the right autoinjector for your product's intended use & users

Reassess:

Primary packaging

Selecting a container that fits your long-term combination product strategy



Reassess:

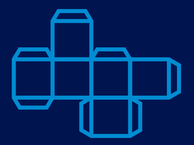
Aseptic fill-finish

Designing a robust, customized filling process with an autoinjector in mind

Additional:

Device assembly

Defining the requirements & control strategy for your combination product



Reassess:

Final packaging

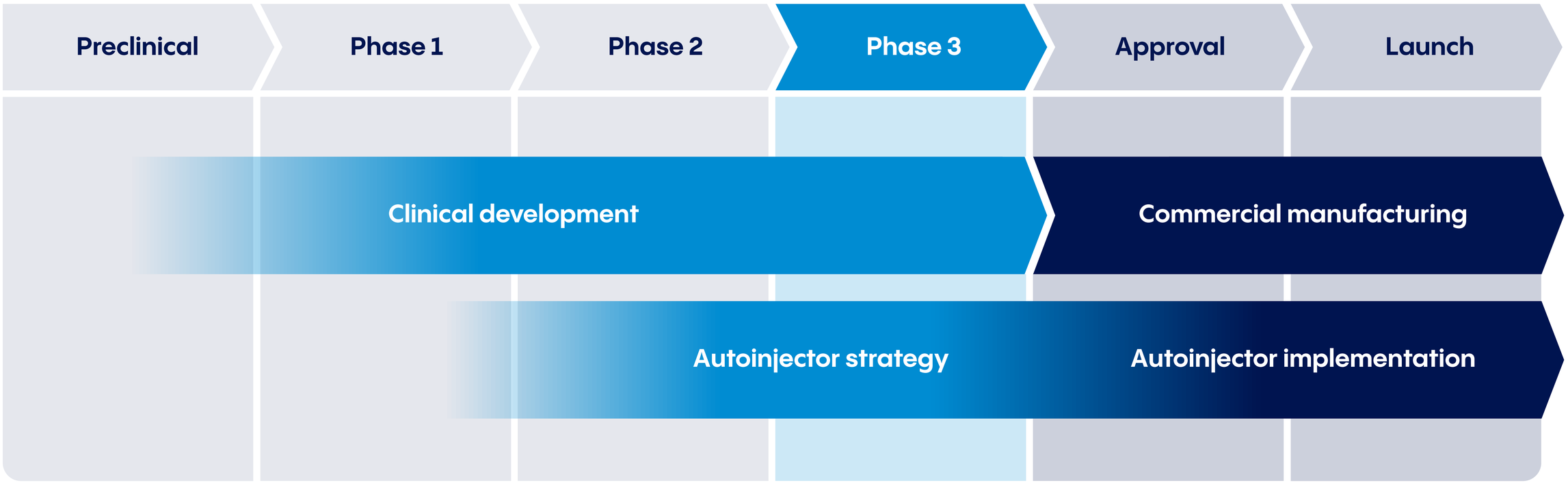
Configuring, aggregating, and serializing autoinjector-based product units

Overview

The path to success starts early

When you're going to market in an autoinjector, developing and executing a comprehensive launch plan takes time. You should ideally start developing that strategy in parallel with in-human testing, and be ready to execute by the time your combination product is ready for regulators.

Of course, that complex journey has to begin somewhere. With an autoinjector in mind, the right place is with **your target patients.**



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Device selection

Start with your patients and their needs

While many different patients have benefitted from autoinjector-based therapies, each group of users needs something different from this device format.

A critical first step for your launch: Understanding your target patient profile and how it can define the “right” autoinjector for your product. Selecting a device that meets users’ unique needs – and factors in their physical capabilities – is a key step toward a successful new therapy.

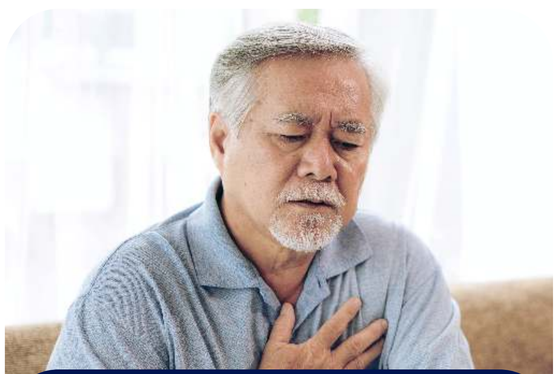
Rheumatology

Autoimmune

Weight management

Neurology

Anti-infectives



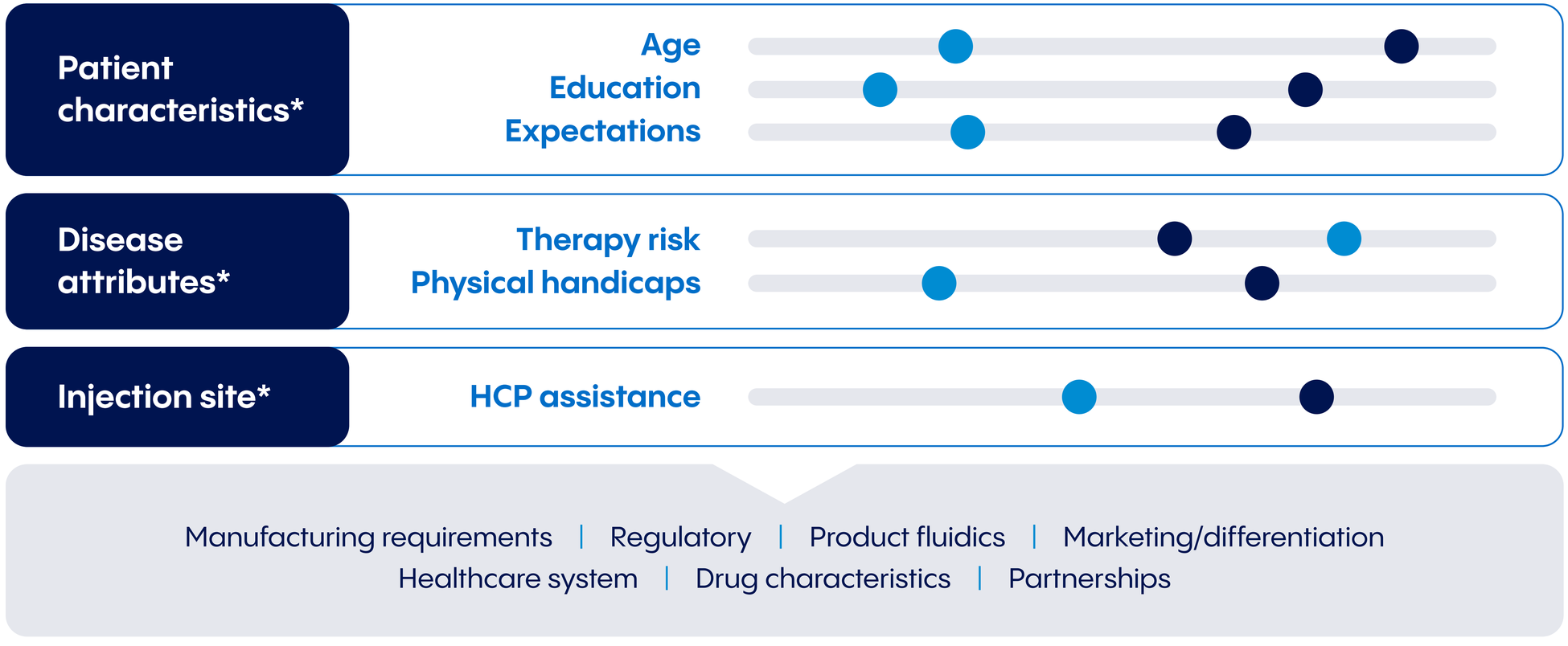
Cardiology

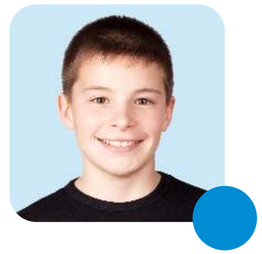
Device selection

Multiple patient factors can influence your choice*

When it comes to an autoinjector, patient needs can vary widely. A pediatric therapy may be administered by a healthy adult with few physical limitations. An elderly high-risk patient with poor manual dexterity may still be able to self-administer – so long as she can remove the cap.

Taking characteristics like these into account, the "right" autoinjector can be as different as the patient populations shown here. To steer your search toward an optimal choice, work closely with a CDMO partner who can help you understand how each device will perform for different users.





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*Examples ONLY. Not a complete patient profile.

Device selection

Example: Syringe shield & autoinjector cap

With an autoinjector, patient needs and product configuration can often connect in subtle but important ways. Consider the interaction between an autoinjector's remover cap and the rigid needle shield (RNS) on your product's syringe — and how it can determine whether your product meets users' needs.

The cap must exert target removal force on RNS.

To access the syringe and deliver your therapy, target patients need to be physically capable of that force too.

RNS designs vary among syringe suppliers.

Don't wait to find out if the RNS on your syringe requires a removal force that's excessive for your users — or you may be at risk of costly delays.

Primary container

Syringe design can be an important factor too

In addition to the RNS, other characteristics of your selected syringe can also impact your device assembly processes. One of the most important: the finger flange.

This key component can come in several different designs, each of which has different mechanical attributes. If you're planning to launch in an autoinjector, it's important to understand how this variable can influence the way your device is assembled.

Standard round flange

Cut flange

Small round flange

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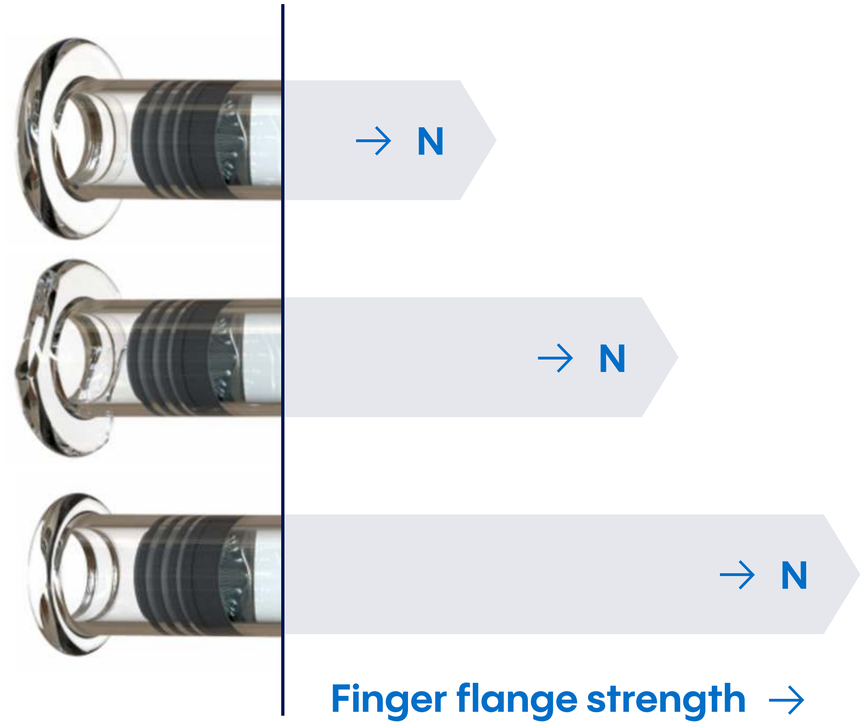
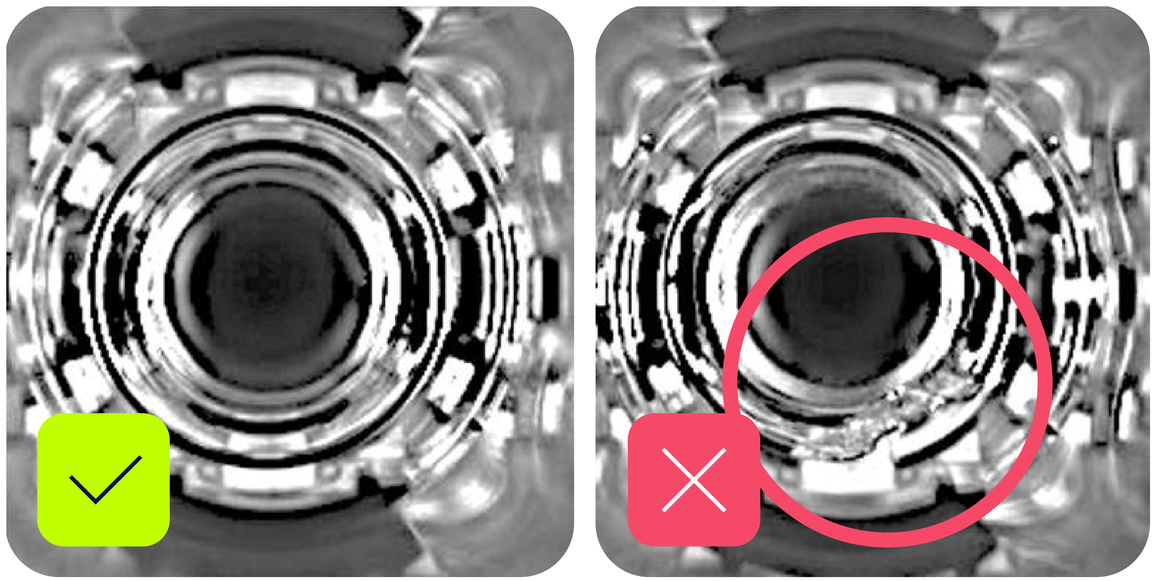
Primary container

Flange strength can influence control strategy

Syringe flanges vary in more than shape. Each flange design supports a different amount of mechanical force during device actuation. The strength of the individual flange types may also vary from supplier to supplier.

Keep this in mind both when selecting a syringe and developing a control strategy for your manufacturing processes. If there's a possibility that a flange may be damaged during assembly or testing, you may need to integrate a camera control to identify quality deviations.





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Aseptic fill–finish

Product characteristics to focus on

The fluid that goes into your primary container — your product itself — can also have a substantial impact on your autoinjector assembly processes. Several key fluidic attributes of your product are important to consider, as they can influence multiple downstream decisions and processability factors.

Product viscosity

Determines the break-loose and glide force the autoinjector must deliver and the syringe must sustain

High-viscosity products may require a wider-gauge needle with higher cap-removal force (or an electro-mechanical device).

Product concentration

Determines the fluid volume required for each dose, which influences the position of the syringe stopper

Stopper position can then impact syringe insertion process.

Device assembly

Fill volume & stopper position are key variables

Several key assembly processes can be influenced by a single factor: how much of the syringe barrel remains empty and accessible once your product, a protective air bubble, and the syringe stopper are accounted for. If that small but critical space isn't taken into account upstream, it can lead to some challenging procedural issues.

Interior: Grip point for insertion

The remaining hollow just inside the flange is ideally where the syringe is held during insertion into the syringe.

If the stopper position doesn't leave enough interior gripping room, the syringe may need to be held from the outside.

Exterior: Potential assembly issues

If a syringe has to be held from the outside, there must be enough room between the syringe and autoinjector to do so.

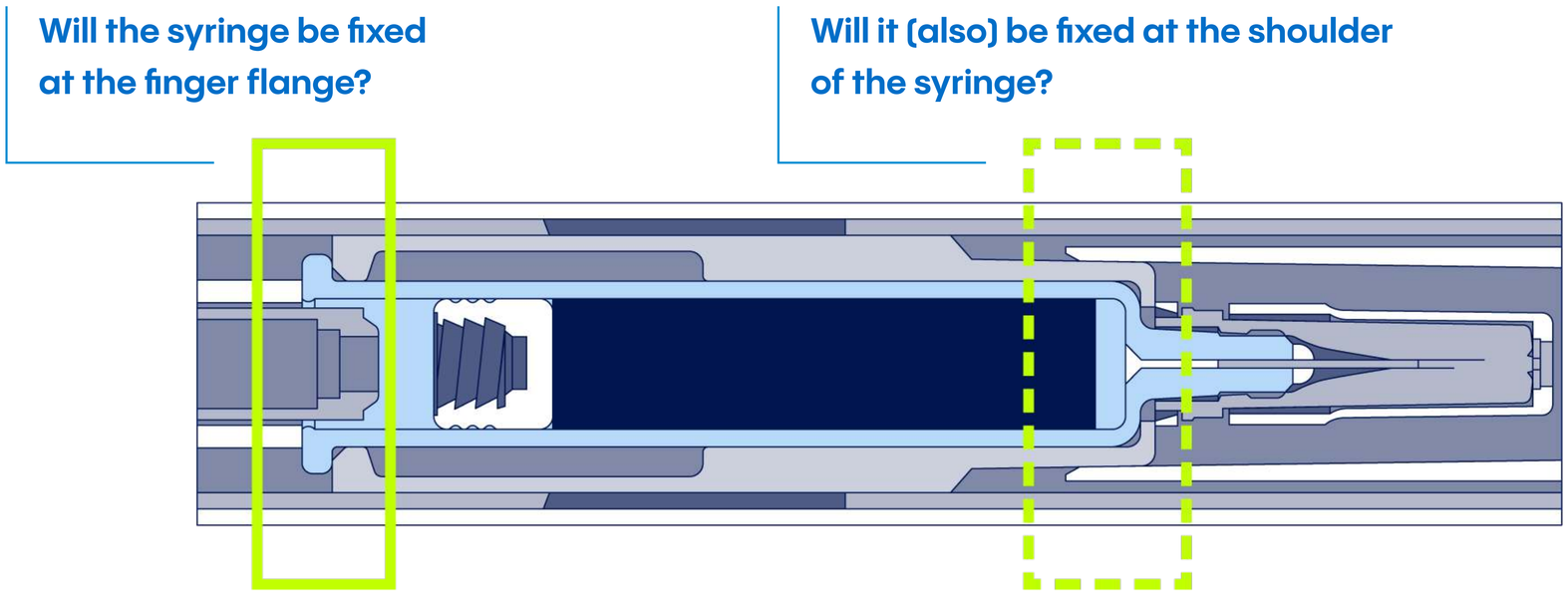
Insufficient space may lead to costly delays or a need to exchange syringes.

Device assembly

Device design can influence safety features & control strategy

During delivery, the mechanical force from the autoinjector isn't the only one the syringe needs to withstand. The barrel of the syringe will also come under pressure from break-loose and glide force.

The syringe needs to be secured in the device in a way that enables it to manage all these forces. Depending on your autoinjector, that may require fixing the syringe at the flange, at the shoulder, or both. Your assembly process needs to factor in the appropriate camera control strategy to ensure that the syringe remains undamaged and can withstand these forces.



Device assembly

Procedural priorities: Process development

In addition to these product and packaging considerations, it's also critical to define and implement a comprehensive manufacturing process. During this stage, the focus is on component selection, process design, and early technical steps — all with the goal of defining, verifying, and documenting the processability of your autoinjector-based units.

Packaging: Component selection & specifications

- Drawings w/ dimensions
- Material, delivery & assembly specs

Machinability

- Ensure machine functionality & availability
- Test runs: Packaging material & machine processability

Technical runs & sampling

- Train operators on production process
- First samples
- Establish master batch record
- Conduct risk assessment

Development | **Validation** | **Commercial handoff**

Artwork

- Colors
- Logo
- Technical production parameters (code, text-free areas)

Process definition & testing

- Process development & specification
- In-process-control
- Release test

Production documentation

- Master batch control
- Sampling plan
- Text on shipping labels
- Pallet packaging scheme

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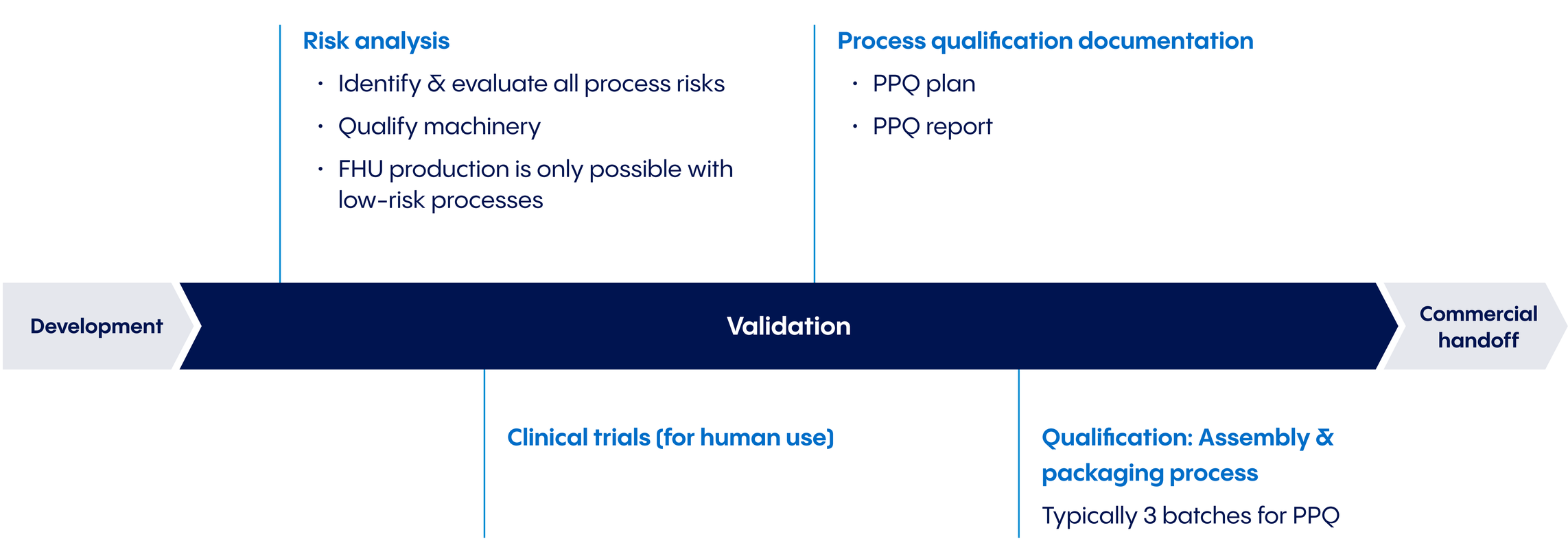
Device assembly

Procedural priorities: Validation

Once the foundational features of your process have been established, you can shift your focus to maximally de-risking that process and executing a plan to fully qualify it. To ensure your assembly processes are ready for commercial scale-up, these steps should ideally be taken in parallel with in-human evaluation of your product.



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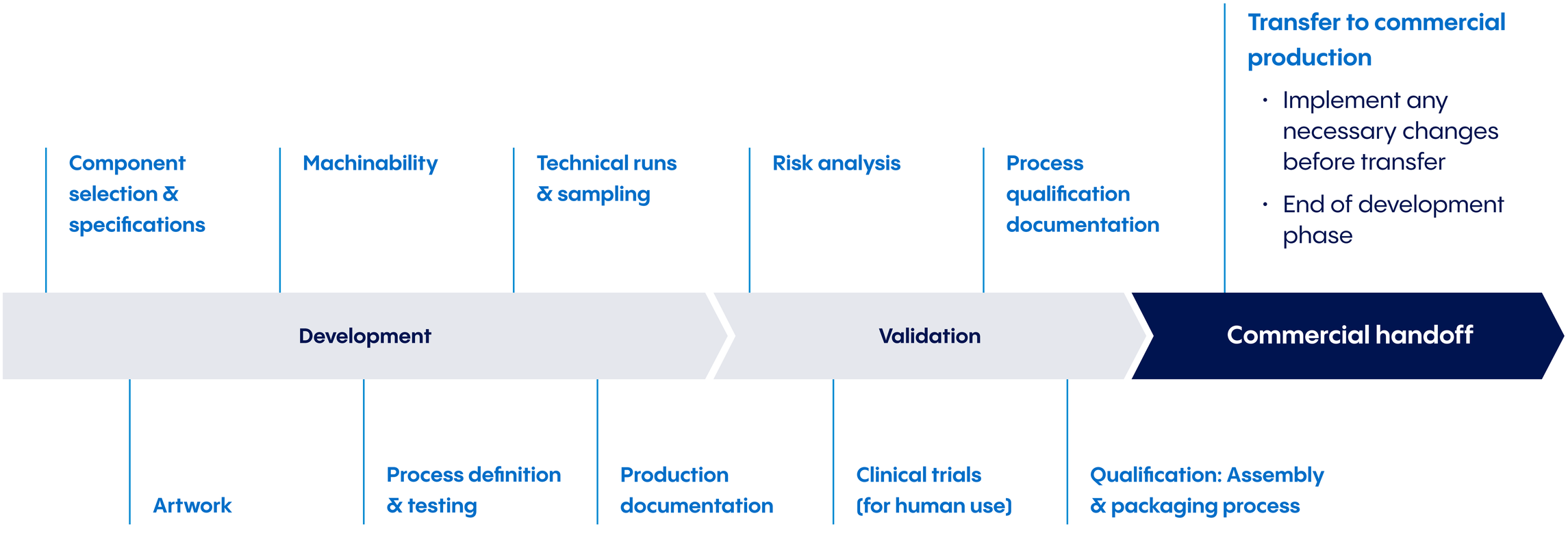
Device assembly

Procedural priorities: Commercial handoff

After successful, documented qualification, your device assembly and aseptic filling processes should be fully integrated and ready for transfer to commercial fill-and-finish. At that point, your launch can be called a success — and it's time to start thinking about the next evolution of your product.



Transfer to commercial production

- Implement any necessary changes before transfer
- End of development phase

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Thinking ahead

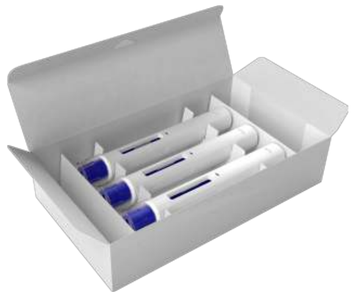
Evolving your product's final configuration

During your combination product launch, don't forget to consider how your product arrives in patients' hands. The right secondary packaging format can help further enhance their experience with your autoinjector-based therapy.

High-quality cartoning, sustainable materials, and multi-dose packs are just a few ways your packaging configuration can amplify the premium value and user convenience of a delivery device.

Sustainability

All-paper packaging can help showcase your environmental stewardship.



Multi-dose pack

Single dose unit

Protection

Blister packaging can help further protect the integrity of your valuable product.

Top-opening unit

Expert support

What to look for in the right launch partner

Launching in an autoinjector is a complex, technically demanding process — one that adds many new dimensions to your product's market profile and manufacturing processes. It's a launch that requires experienced, skilled support from step one.

An outsourced manufacturing partner can be a vital resource — especially one with expertise in both fill finish and device assembly. The right CDMO can help simplify the steps, navigate inherent challenges, and support your product's success. Here's what to look for in that critical partner.

Extensive experience

Do they have in-depth technical know-how and a range of solutions for products like yours?

Commitment to quality

Do they have a proven track record and extensive experience with international authorities?

Flexible approach

Can they readily customize their device assembly solutions to meet your product and launch goals?

Comprehensive services

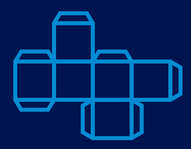
Can they serve as a single-source partner from filling to final packaging and storage?

Expert support

Vetter: Full-service flexibility to meet your needs

As a leading global CDMO, Vetter offers comprehensive services from clinical development, to commercialization, and device assembly and packaging.

Our deep expertise and specialized know-how support your product's success through every step of the launch process. We can provide a wide range of secondary packaging and delivery device options to help differentiate your product and improve your users' experience.



Customized packaging development

Device assembly process development & service

Secondary packaging solutions

Aggregation and serialization

Onsite storage and cooling

Going to market in an autoinjector

Formats & solutions

From primary containers to global distribution

Our expertise goes far beyond autoinjector assembly. We can support every step of your product's packaging evolution, from transitioning to a delivery device, to multi-unit SKU development, to track-and-trace systems for your worldwide supply chain.

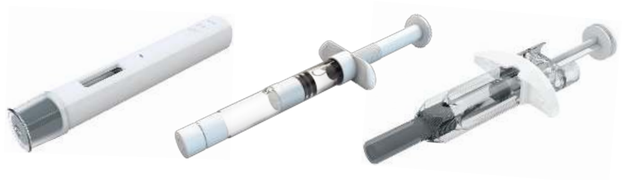
Primary containers

Vials

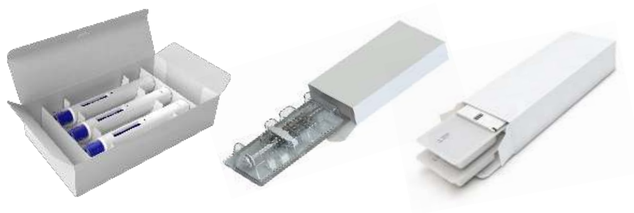
Syringes

Cartridges

Assembly options



Packaging & labeling options



Serialization services

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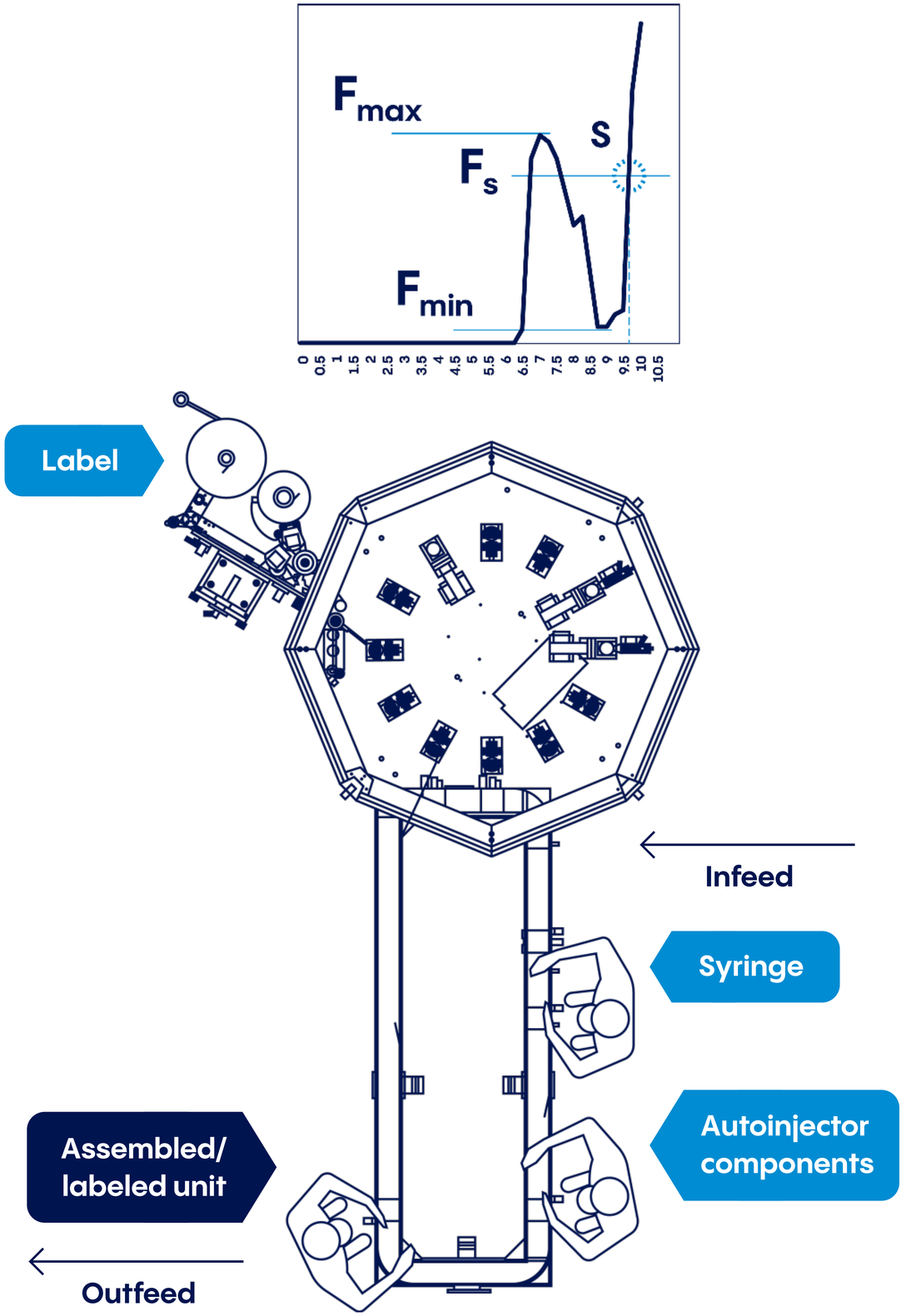
Device assembly

Process & in-line controls

We assemble our customers' autoinjector-based products using a state-of-the-art workflow designed to enable 100% control of all produced units. Operated by expertly trained packaging specialists, the entire process is a direct extension of our standard-setting aseptic filling facilities — and held to the same level of globally renowned quality standards.

In-line controls include:

- Force-distance control
- Control of label accuracy & variable data
- Control of assembly steps & crack detection
- Direct transfer to fully automated assembly lines



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Our Facility

Vetter's world-class secondary packaging center

Our dedicated packaging services are based in Ravensburg, Germany. This state-of-the-art facility offers cGMP compliant services for key markets like the USA, Europe, and Japan, as well as the technology and capacity to support the global market supply of your product.

Co-located with our global commercial manufacturing hub, our secondary packaging center can serve as a single point of contact and release for your product. Our comprehensive services can simplify your supply chain, reduce transportation effects, and mitigate the risks of transferring your product between filling and packaging partners.

209 Mio
injectable drug product units filled in 2022

8900 m²
space dedicated to secondary packaging

8 fully automated packaging lines

5 dedicated manual packaging rooms

7 standalone labeling and assembly machines

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Take the next step with us

Contact Vetter at **info@vetter-pharma.com** to learn more about how we can support you, your product, and your market success.

For more insights like these, follow us on LinkedIn.

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V1 | 2023