

7 steps to a smart secondary packaging strategy

How to build a packaging plan that starts with the end in mind — and helps put your product on a path to success.



@VetterPharma **in**



Start smart. Start now.

Today's parenteral drug products face a complex and rapidly shifting market landscape, with fast-changing patient needs, increasing clinical competition, and growing regulatory challenges. Securing a successful future in this market requires more foresight, agility, and proactivity than ever, especially when it comes to one critical, continually evolving feature of every injectable drug product: **secondary packaging**.

In this eBook, you'll see why proactively planning in this area can be a critical step toward key lifecycle goals, including sustainable product differentiation, streamlined market entry, and efficient adaptation to changing market needs. It all starts with a proven 7-point checklist: a valuable tool designed to help you build a secondary packaging strategy that supports your product's long term success.

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Overview

The secondary packaging checklist

Developed by Vetter's team of dedicated secondary packaging experts, this strategic framework has been applied across a wide range of therapeutic areas, substance classes, and product configurations.

With a plan based on these 7 steps, you and your team will know how to:

- Avoid costly delays and roadblocks across your product's lifecycle
- Create and secure competitive advantages for your product
- Make proactive decisions to support sustainable product success



7 steps to a smart secondary packaging strategy

Key takeaways →

Key takeaways

What you'll learn in this eBook

Start with the end in mind

The secret to a successful secondary packaging strategy: Clearly identifying your end goal first. Whether that goal is launching in a patient-centric delivery device or streamlining your labelling and serialization process, working back from your target can help you identify key decisions, inputs, and other factors that pave the way to success — or put roadblocks in your path.

Factor in different market landscapes

Think ahead to not only where and how you want to launch, but also how varying regulatory frameworks, patient needs, and reimbursement schemes may impact your strategy from market to market. Planning for these factors in advance can help avoid delays, build realistic schedules, and capture production efficiencies.

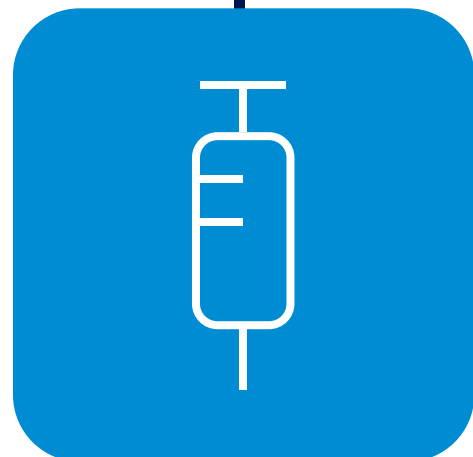
Be prepared to adapt

In today's rapidly changing market, agility and flexibility should be at the heart of every product life cycle strategy. When it comes to secondary packaging, that means having the technical expertise, production infrastructure, and market foresight you need to readily adapt your approach at any point in your product's evolution.

The right expertise is critical

Whether this is your first parenteral product launch or your tenth, the right partnerships can be a vital asset. Bringing in experts with deep expertise and a proven track record can help you navigate the secondary packaging process, avoid unforeseen challenges, and protect your product's quality. Find them early in the process and engage them at every step.





Checkpoint 1

Choose the right primary packaging

Goal: Your choice of primary packaging can have a big impact on your future secondary packaging options. Make sure your chosen packaging option is a fit for your future plans.

Factors to consider

Does your primary packaging have any processability limits that may affect production?

A product's primary packaging helps determine the speed and volume at which the product can be produced in its final packaging presentation. Find out if your preferred primary packaging will limit how efficiently your product can be packed.

Is your primary packaging compatible with your target packaging presentation?

Naked syringes and syringes assembled in an autoinjector encounter very different sets of mechanical forces during production. To avoid costly transition steps, select a primary packaging option that's compatible with your long-term secondary packaging goals.

Will your primary packaging affect blistering or kit packaging?

A product's primary packaging format can also affect how easily it can be placed in different forms of secondary packaging. For example, if you plan to pack lyophilized vials in a carton kit, the vials will need to be packed upright for safety and stability during distribution.

Will your primary packaging meet your product's future needs?

Does your product roadmap include delivery devices, wearable formats, or other complex packaging configurations? Make sure you choose primary packaging that's suitable for those future goals. Identify up-featuring steps now to ensure that your decision doesn't lead to roadblocks in the future.



Checkpoint 2

Prepare for volume scale-up

Goal: Know that your packaging infrastructure is built to grow with your production needs, and supported by experienced, flexible partners who can meet stringent quality requirements.

Factors to consider

Are your production processes and supply chain optimized for scalability, agility, and automation?

From Phase 3 scale-up to market maturity, your production volumes will change significantly at multiple points in our product's lifecycle. Make sure your team, partners, and suppliers have the technical skills and process agility you need to adapt to shifting production volumes. Have answers to questions like:

- Does your team have the engineering/tooling skills needed to adapt your production lines?
- How can you minimize the number of technical and qualification runs needed to scale production?
- Have you minimized the potential for glass-to-glass contact that can spike high-volume production lines?
- Do your partners have experience managing large regional and global production scale-ups?

What intermediate packaging configurations will you need before you reach your product's final configuration?

Your ultimate goal may be to launch in a patient-friendly device like an autoinjector. But will that require an in-between step like transitioning to a new syringe configuration or switching from a syringe to a cartridge? Plan ahead for all the interstitial steps to ensure your timelines and budgets are realistic.



Checkpoint 3

Know the different regulatory demands you need to meet

Goal: Be aware of how necessary reviews and approvals will change as your product shifts from one packaging format to the next.

Factors to consider

What kinds of regulatory evidence will each packaging configuration require?

Different secondary packaging configurations often follow different regulatory pathways. Avoid costly setbacks by mapping out exactly what evidence, reviews, and approvals you'll need for each packaging presentation in your product roadmap.

What additional studies/tests will you need to generate that evidence?

Regulatory authorities increasingly expect combination products (device/medical product combos) to demonstrate their effectiveness in both clinical and real-world settings. If you expect to move your product to a delivery device, plan to develop evidence for each specific use case.

How will additional regulatory demands impact workload and timelines?

Proactively engaging regulators can help your team efficiently manage immediate and future compliance needs. Work with relevant authorities in advance to map out key regulatory milestones, resource appropriately, and keep everything on schedule.

Are there any market-specific regulatory requirements you'll need to meet?

Avoid costly market entry delays by building a proactive plan to meet and address regional regulatory requirements. For example, products launching into the Italian market need "bollini" drug-tracking stickers, while the US has specific requirements for needle device safety in clinical trials.



Checkpoint 4

Consider market- and country-specific needs

Goal: Identify when and why you may need to meet specific regional packaging demands that can affect your production timelines and budgets.

Factors to consider

Do you need to version artwork by country?

Evaluate local market requirements to determine what regionally customized artwork or content you may need for your labelling and packaging. To keep your production schedule on track, make sure your timelines factor in the expertise and capacity needed to create multiple versions of your product presentation.

Will users have different needs in different markets?

Reimbursement landscapes and patient needs can vary significantly between regions. Know how these variations will impact your product's use cases and user preferences: for instance, regional focus on in-clinic vs at-home care, patients' typical education level, and prevalence of reimbursed public vs private vs cash pay.



Checkpoint 5

Consider indication-specific factors

Goal: Determine when your drug substance or end-users may have unique needs that should be considered in your packaging configuration.

Example: Ophthalmic products

Sterility

Injectables launching into the ophthalmology market have to meet stringent sterility requirements, typically including sterilization of the entire product kit.

Particulates

Packaging for ophthalmic products must show near-zero particle levels to meet many requirements for eye care applications around the world.

Precision delivery

Ophthalmic injections also require intense hand-eye coordination by users. Your delivery device needs to facilitate exceptional manual control.

Example: High-viscosity products

If your product is viscous, your injection device will need specific mechanical properties required to handle high glide force. Plan for an option that can handle higher levels of fluid resistance within the device without damaging the device during delivery.



Checkpoint 6

Maximize potential for competitive differentiation

Goal: Grow your product's advantage in an increasingly competitive market by enhancing your product's safety, convenience, and usability.

User experience factors to consider

In today's crowded injectables market, devices stand out when their design shows a deep understanding of users' needs, habits, and preferences. Carefully evaluating these user-centricity factors can help you sharpen your product's competitive edge:

Safety

What new features or different components can reduce the risk of needle sticks, both in professional and at-home settings?

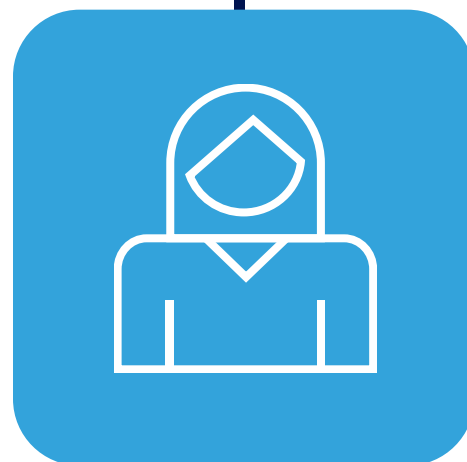
Convenience

How can your packaging be adapted or streamlined to make the delivery process quicker, more painless, or both?

Usability

Where can your packaging be optimized for specific professional or patient needs (e.g., reduced dexterity, low vision, or precision administration)?

Keep in mind that device simplicity and user-centricity often move in opposite directions during the production process. Producing an easy-to-use device can often require considerably more complex production and assembly methods. Factor in this increasing complexity as you plan your product's differentiation strategy.



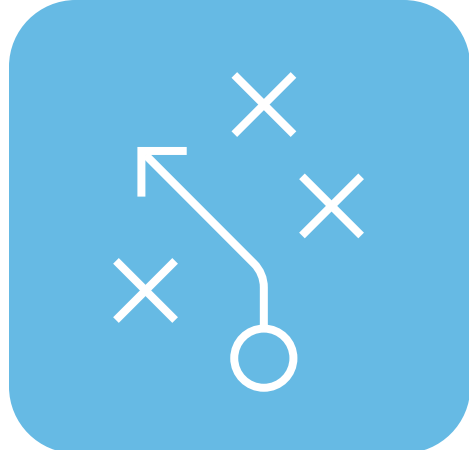
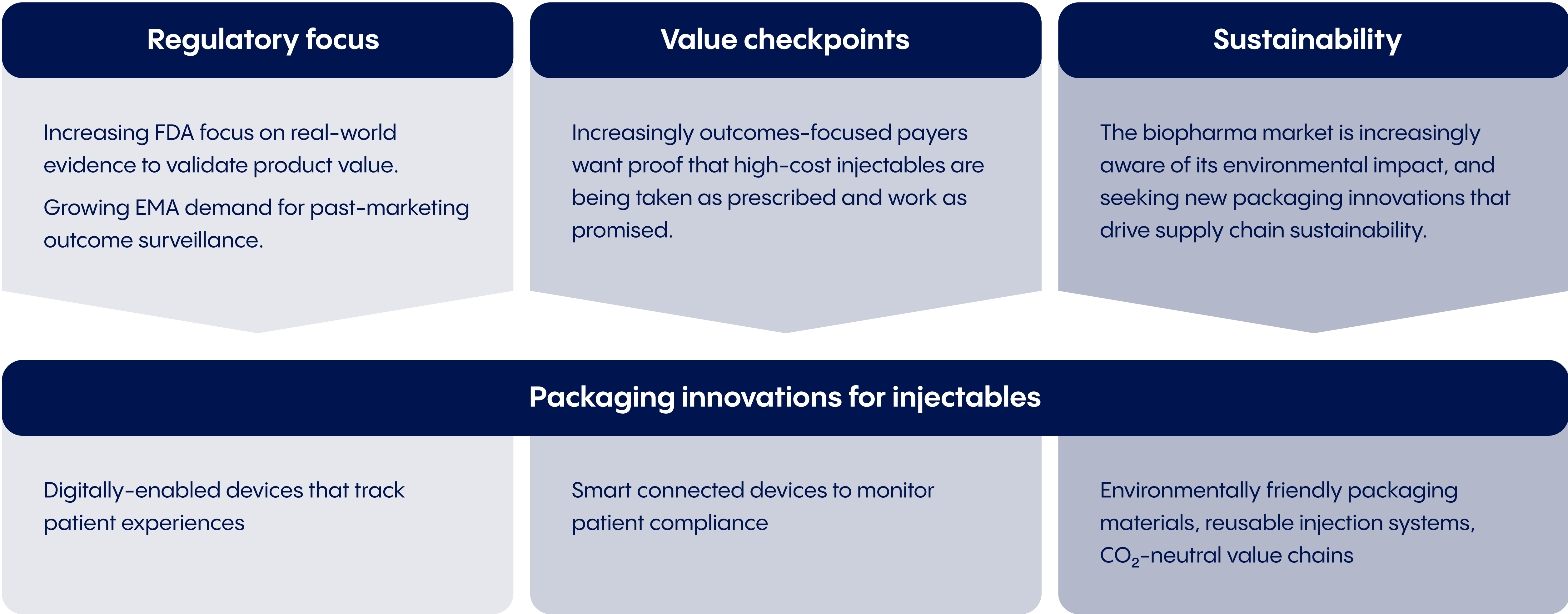
Checkpoint 7

Prepare for future needs

Goal: Start thinking ahead about how today’s regulatory and market pressures may shift your strategy for future product configurations.

In the coming years, a confluence of regulatory trends and market pressures will likely continue to drive demand for a new generation of digitally enhanced injection systems. Start considering which of these innovations may be the best fit for your product, and why – and plan ahead for the additional testing, validation, and production steps they may require.

Market forces driving innovation



Summary

Why start your strategy now

Planning your product's lifecycle is a complex and ever-evolving process. A strong secondary packaging strategy is a critical component of this plan, one you can complete with confidence through proactive planning, smart guidance, and the right manufacturing partner. These 7 proven steps will help you streamline that process from start to finish, while protecting your product's quality, value, and competitive differentiation from launch to maturity.

With decades of strategic and technical expertise in packaging injectable products, Vetter is ready to help you take these steps confidently and effectively from the start. Our global team, state-of-the-art resources, and innovative, customizable solutions are ready for you to leverage them as you map your product's path to success.



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[About Vetter →](#)

About Vetter

Customized solutions across the product life cycle

At Vetter, we offer a wide range of secondary packaging and device assembly options to differentiate your product and improve your user's experience. With 40+ of experience as a CDMO partner to parenteral product owners, we are confident we can help put you on a path to success at every step of your product's evolution.



Why choose Vetter for your secondary packaging?

Quality

We care for your product's purity and integrity throughout the packaging process.

Complex packaging

Trust our decades of experience developing technically challenging production processes.

Flexibility

We offer a wide range of capabilities and services that can be customized to specific product needs.



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Our Services: Device Assembly →

Our Services

Device assembly

We have an extensive proven track record with technically challenging packaging solutions, including pen and autoinjectors. Our dedicated engineering department specializes in developing the novel packaging processes, machinery, and testing methods these devices require.



Pens

Assembled around either a single or dual-chamber cartridge, pens provide your patients with a user-friendly way to administer your injectable product.



Autoinjectors

Convenient, compact, and easy to handle, autoinjectors can be a useful way to facilitate long-term patient self-administration of products delivered from a syringe.



Safety devices

This assembly option simplifies needle stick protection by combining a single-chamber syringe and staked needle.



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Our Services: Secondary Packaging →

Our Services

Secondary packaging

Vetter packages a wide variety of drug delivery systems and formats. At every step, we apply the same rigorous focus on quality to our packaging operations as we do to our filling services — enabling us to meet stringent, customer-specific quality requirements at a broad range of production scales.



Testing

Rigorously monitoring product packaging for compliance.



Blistering

Purpose-built protective shells that help safeguard product integrity.



Cartoning

Kitting options customized for specific products, patient needs, and regulatory demands.



Labelling

Flexible, adaptable solutions for artwork, printing, and label position control.



Serialization/ Aggregation

IT and packaging expertise to support your product's "track and trace" system.



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Our Secondary Packaging Facility →

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

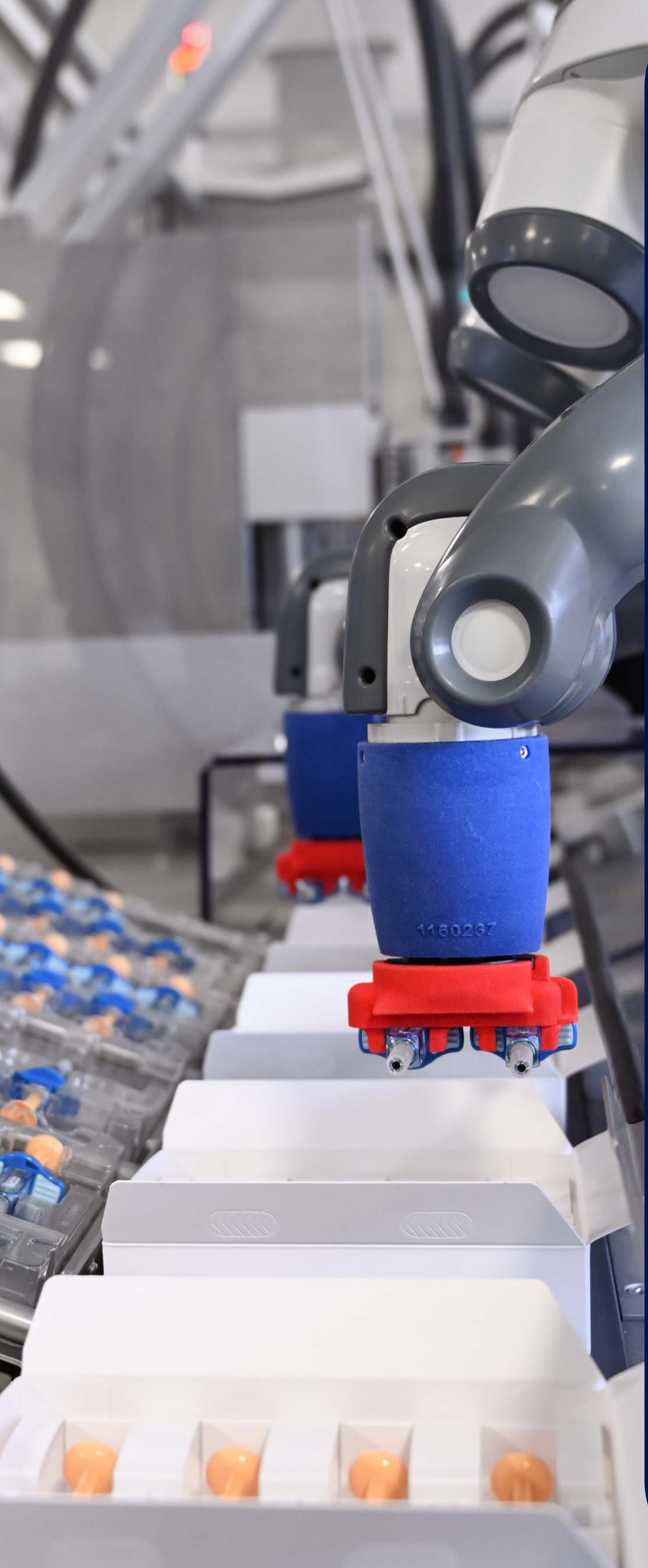
5 dedicated manual
packaging rooms

5 standalone labeling and
assembly machines



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Take the next step →



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. And follow us on LinkedIn for more insights like these.

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