

Launching in a Delivery Device

**5 key success factors for your injectable
drug product**



@VetterPharma **in**



Plan for a product that truly delivers.

Across the biopharma market, multiple major trends are both driving demand for injectable medications and increasing competitive pressure on the drug developers supplying those products.

To meet this growing demand with differentiated offerings, more and more biopharma businesses are adding another complex step to their product's life cycle: **launching in a drug delivery device**.

This eBook is a valuable resource for any drug development team that's looking ahead to this technically and operationally demanding task. Keep reading to explore 5 key factors you should consider as you build your launch strategy.

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Parenteral drug market

The injectable product life cycle is shifting.

Launching in a delivery device — like an autoinjector, pen, or wearable — is often significantly more demanding and cost-intensive than standard delivery formats. So why are more and more drug developers considering it?

The market is growing rapidly, producing ever more options for patients and their HCPs to choose from. Care models continue to shift away from clinics and into patients' homes — where safe, convenient, user-friendly delivery formats are critical to both compliance and differentiation.

Together, these trends are redefining success for injectable drug products. Let's look closer at how — and what that shift may mean for your team and product.



Launching in a delivery device

The global pipeline is rapidly filling with injectable innovations.

2019

3000+

injectable technologies in development¹

The forecast for the injectable sector is stronger than ever.

2019 → 2027

12.5%

CAGR for parenteral medications²

(vs. 10.2% for oral meds)

Global demand continues to shift toward injectable medications.

2020 → 2027

+7%

share of global biopharma market²

The trend toward at-home care is changing patient needs.

2016 → 2021

12.3%

CAGR for self-administered therapies³

(vs. 7.5% for hospital-based therapies)

Key takeaways

Start with the final results in mind.

Factor in market-specific requirements ahead of time.

Consider patient needs, regulatory frameworks, and production requirements in each market you plan to launch in.

Know how your product profile will impact your device options.

Think ahead to primary and secondary packaging, as well as how unique features of your drug substance may impact your choice of delivery device.

Plan for increasingly ambitious sustainability standards.

As the industry sharpens its focus on environmental responsibility, prepare to meet higher sustainability benchmarks for your product and processes.

Source the right expert support as early as possible.

Engage an experienced launch partner to help you navigate the many technical and operational complexities of launching in a delivery device.

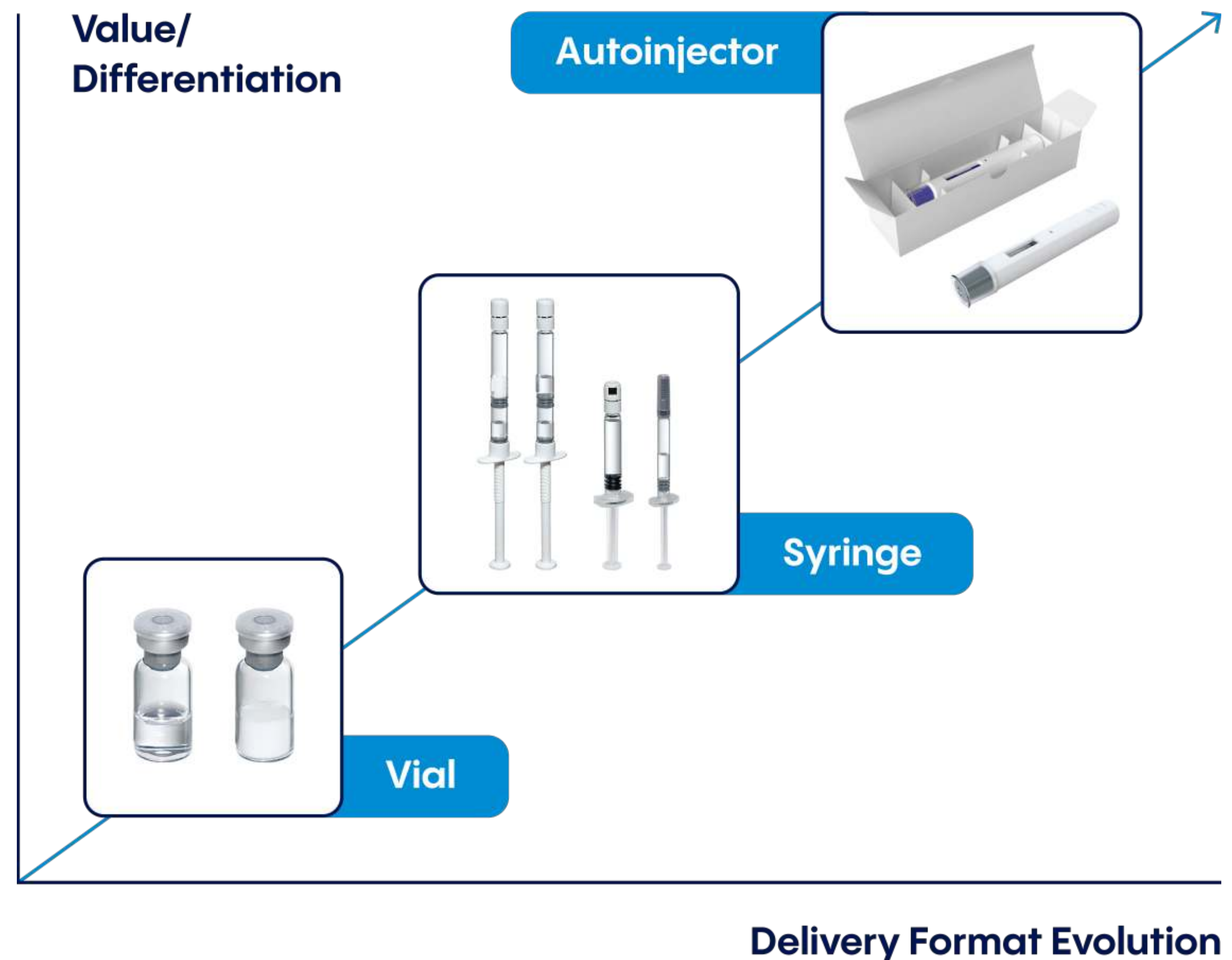


Market dynamics

Competitive pressure is pushing the product life cycle further than ever.

With a wide range of injectable products on the market and in development, competitive differentiation is an ongoing battle for biopharma businesses. Drug developers across the industry are rethinking how they plan to continually set their brands apart from the competition.

One of the leading strategies: evolving a product's delivery format over time, both to enhance a product's market profile and better align with patient needs. This type of evolution is an effective way to add value to your product's market profile across its commercial life cycle.



Launching in a delivery device

Market dynamics

Patient-centricity is critical for today's injectable drug products.

Shifts in patients' needs are driving many of the changes in today's rapidly evolving market. To achieve sustainable success, drug developers need a clear long-term strategy for how they'll meet those needs in a meaningful and differentiation way.

Moving to a delivery device with a patient-centric design is an increasingly critical step in that strategy. While autoinjectors, pens, and wearable delivery devices may be more technically demanding, they offer a range of desirable advantages for users.

Delivery Devices: Advantages for Patients



Safety

Autoinjectors, pens, and other drug delivery devices can help protect patients from fingersticks, dosing errors, and other potential risks of basic injection systems.



Ease of use

The intuitive functionality of most drug delivery devices helps simplify the dosing process, and eliminates the learning curve that typically comes with legacy injection systems.



Convenience

In many therapeutic areas, patients are both trading clinic-centric care for at-home therapy. Drug delivery devices can make that shift feasible for treatment regimens that once required a clinic visit.



Launching in a delivery device

Market dynamics

As products evolve, so do their manufacturing needs.

Launching in a delivery device adds multiple new dimensions to an injectable product's market profile, especially when that launch targets multiple use cases at a global scale. Once you factor in launch countries and their requirements, alternate device formats, and the secondary packaging those devices may require, a single product can easily require 100+ different production configurations.

Also, as you enter new markets and drive demand for your product, your production needs will scale with that product's market performance. Success means that the size and focus of your production batches will inevitably change, particularly when your strategy includes multiple delivery formats.

When planning your launch, consider the support you will need to make these pivots as efficiently and effectively as possible — especially when they may require changes to your filling and assembly processes.

Key Resources for Agile Device Assembly

Scalable, automatable production equipment

Versatile packaging and assembly configurations

An established, secure supply chain

Engineering/tooling expertise

Support for technical and qualification runs

Minimal to no glass contact on assembly lines



Market dynamics

Regional requirements can be highly variable.

From region to region, drug-device combinations often face a wide range of different patient needs, regulatory frameworks, and production requirements. Individual markets may require variations in your device format, separate packaging concepts, and even different printed artwork.

As you create your launch plan, make sure you factor in these key variables. They can have a major impact on your costs, launch cadence, and production needs.



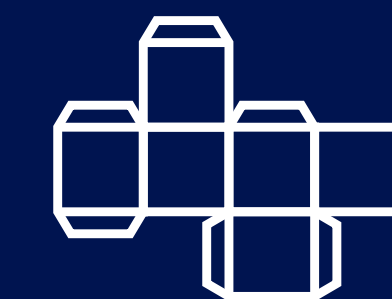
Healthcare system

Map the reimbursement landscape in your target markets, and the extent of its support for at-home care. It may vary considerably in markets at different levels of development.



Patient population

Know target patients' average age and level of education. These variables can have a big impact on their ability to manage self-administered therapies.



Packaging artwork

Plan for the time it takes to produce and approve, as well as its impact on production processes. Meeting different countries' language and regulatory requirements can have a big impact on production time, batch size, and related costs.



Launching in a delivery device

Factor 2 →

Regulatory frameworks

Navigating device system regulations in key markets.

In most major markets, regulatory authorities have specific frameworks for the many combinations of drug products and medical devices available today. If you plan to launch your product in a delivery device, it's vitally important to know which of these frameworks applies – and make sure you consider the time and expertise you'll need to manage these requirements successfully.

The US and EU provide good examples of how different major markets regulate injectable medications delivered with a device. Let's look closer at each region's regulatory framework.

Example: Varying Regional Regulatory Frameworks

US Regulations



21 CFR 4: Combination products

Govern any combination of a medicinal drug product and medical device.

EU Regulations



Medical Device Regulations (MDR) 2017/745: Drug-device combinations

Focus on medical devices, but bridge to products that combine a medicine and a device.



Launching in a delivery device

Regulatory frameworks

US: Regulation of combination products.



For combination products in the US, the key regulation to consider is 21 CFR 4, which integrates components of drug product and medical device regulations. 21 CFR 4 stipulates that both drug product cGMP regulations (21 CFR Parts 210–211) and medical device quality system regulations (21 CFR Part 820) should be applied to combination products.

Drug developers can choose from two different ways to comply—comprehensive or streamlined. For common devices like single use autoinjectors or pens, most companies choose the “streamlined” approach.

Two ways to comply with 21 CFR 4

Comprehensive

Demonstrate compliance with **both** 21 CFR Parts 210–211 (drug product cGMP) **and** 21 CFR Part 820 (quality system regulations for medical devices).

Streamlined

Select a quality system that complies with **either** 21 CFR Parts 210–211 **or** 21 CFR Part 820, then supplement with any additional requirements from the other quality system.



Launching in a delivery device

Regulatory frameworks

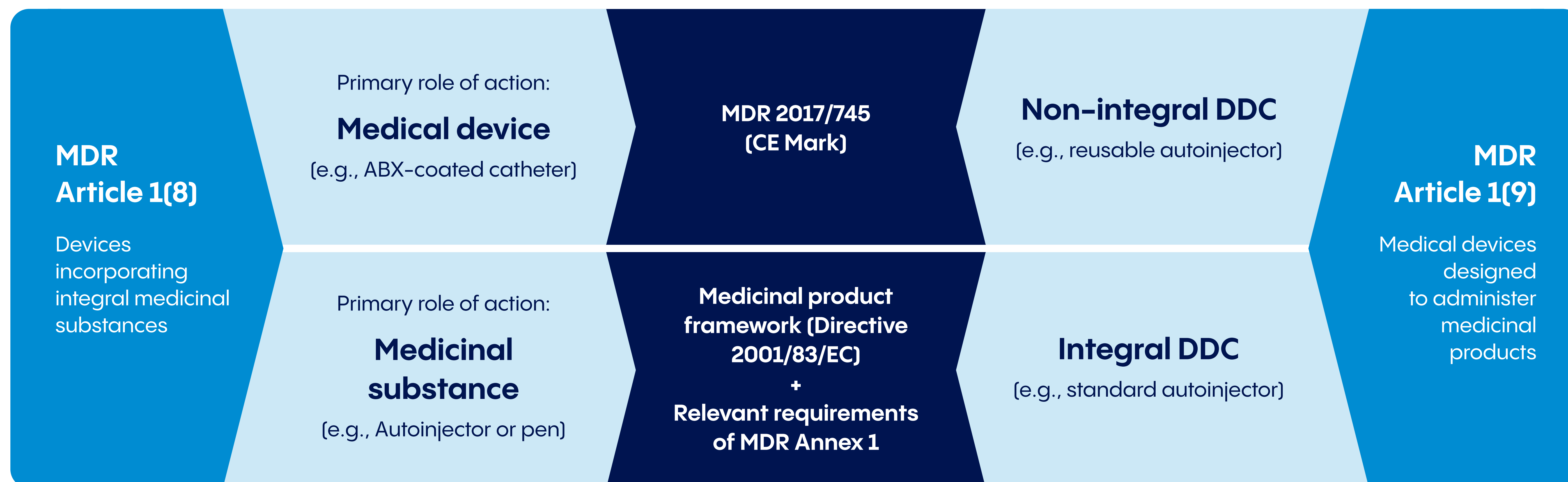
EU: Regulation of drug-device combinations (DDCs).



The EU's regulatory framework for drug-device combination describes a continuum of integration between the device and the medicinal substance it's paired with.

For devices with an integrally incorporated medication, MDR Article 1(8) stipulates a different quality system depending on whether the product's primary role of action is performed by the medicine or by the device.

For devices designed to deliver a medication, MDR Article 1(9) stipulates one regulatory framework for drugs and devices that are co-packaged or obtained separately (non-integral DDCs), and another for drugs and devices designed to exclusively work together (integral DDCs).



Launching in a delivery device

Factor 3 →

Technical considerations

Know how your primary packaging can affect your launch.

As you prepare to launch your delivery device, you'll want to carefully assess how your primary packaging will impact your strategy. Whether your chosen device requires a syringe or a cartridge, the format, design, and size of your primary packaging can have a significant downstream impact on your device assembly options.

Part of your launch plan should include thinking ahead down the whole value chain to ensure your choices align with your goals. Engaging packaging experts early can help you understand your options and decide which make the most strategic sense.

Syringes & autoinjectors



Stock vs. platform

Save time and money by leveraging an existing device. Tailoring an off-the-shelf platform to specific product requirements can be costly and time-consuming.

Syringe compatibility

Multiple different specifications of your syringe can influence its readiness for autoinjector manufacturing processes.

Cartridges & pens



Cap compatibility

Crimp cap must be a fit for the internal functionality of the pen.

Mechanical stability

Cartridge must hold up to forces on shoulder and/or crimp cap.

Assembly variables

Compression of rubber septum can impact the force needed to apply the needle.



Technical considerations

Features of your drug substance can have an impact, too.

The unique features of your product can also affect the choices you make when launching in a delivery device. Different fluid characteristics, formulations, and dosages can all have an impact on your device options, and on how your product is assembled.

Two good examples: your drug substance's **filling volume** and its **viscosity**.



Filling volume

Autoinjectors

- Maximum filling volume limited by syringe-handling process during insertion into device
- Filling volume influences device mechanics (e.g., different filling volumes require different mechanical versions)

Pens

Filling volume determines pre-priming process

Safety devices

Filling volume can impact device design (e.g., plunger rod length)

Viscosity

- Device and primary packaging need to handle high glide force
- Consider electromechanical device
- Long injection time
- Match needle size/diameter to injection needs



Technical considerations

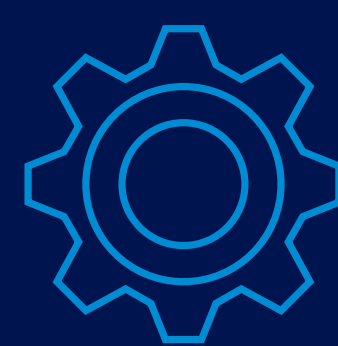
Establish your processes as early as possible.

Significant challenges can arise if you don't map out your final target device/device process early in your launch. Here's where to focus during the early planning process.



Materials and parts

Find a supplier who can not only develop a delivery device that meets your specifications, but also readily source required components. When you build your timelines, make sure both you and your supplier factor in the time needed for incoming goods inspection.



Assembly process

Work closely with your supplier on the assembly specifications for your device. By reviewing these specs together, you can both verify that the process meets your requirements and potentially identify opportunities to streamline. Make time to review all technical drawings as well, to ensure that all machine parts are appropriately selected and implemented.



Packaging specifications

Make sure that you plan for the many factors that can influence your assembly process, volume, and costs, including:

- How the filled units are delivered (bulk vs. tray)
- Load carrier volume, required feeding machine design and speed, and processing steps (especially where there is the potential for glass-to-glass contact)
- Any sustainable packaging requirements (e.g., plastic-free packaging, paper trays)



Testing

Evaluate what kind of IPC tests are right for your assembly process, including both visual inspection to verify product quality and functional testing directly at the manufacturing line.

Consider which release tests your product may require, including injection time, dose accuracy, activation force, cap removal force, needle length, injection depth, needle cover override force, or separation force.



Launching in a delivery device

Technical considerations

Secondary packaging formats



Safety devices

A common option for products intended to enable one-handed passive activation while also protecting users from accidental needlesticks.

Key considerations

- Limited labeling space can make label placement tricky.
- Devices must be fixed in final packaging configuration to avoid damage in transit.
- If needed, reworking assembled units can be challenging and expensive.
- Typically require functional tests for factors such as activation force and break loose/glide force during insertion.



Autoinjectors

A popular choice for injectable products meant to enable safe, convenient, long-term administration at home.

Key considerations

- Device shape (round vs. angular) may dictate label placement.
- Depending on assembly steps, benchtop assembly may be best for clinical/technical batches, followed by automated assembly lines for commercial manufacturing.
- Packaging concepts often require multiple configurations (e.g., a carton, a shipping box, and pallets) and robust material that lead to heavy final transport units.
- Typically require selection and implementation of a testing method to verify the functionality of assembled devices.



Injection pens

Another common option for injectable products designed to offer enhanced user convenience.

Key considerations

- Needles can be packed multiple different ways and require proactive planning for how they'll be integrated into your assembly process.
- Depending on patient preferences and market requirements, needles can either be co-packed or distributed through pharmacies.
- A strategy for ensuring correct cartridge insertion is critical to the integrity of the final assembled units.
- Different filling volumes may require adjustments to certain key assembly steps.

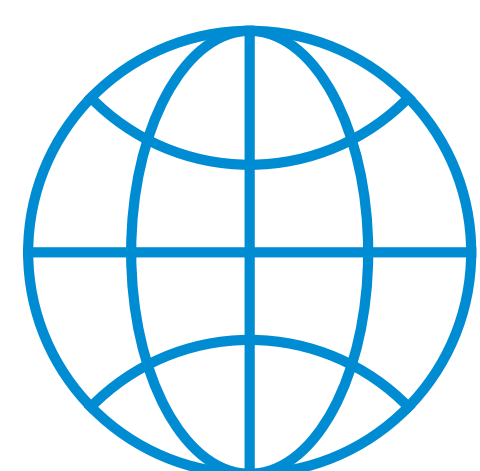


Sustainability

Prepare for increasing focus on environmental responsibility.

The biopharmaceutical sector is notorious for generating more carbon emissions than the automotive industry.⁴

As injectable drug developers become increasingly aware of their environmental impact, they are taking steps toward improving operations to promote sustainability. Given this reality, tomorrow's delivery device launches may need to hit significantly higher sustainability benchmarks for their **drug product** and **production processes**.



Pharma's impact

5% of the global carbon footprint⁴



Launching in a delivery device

Sustainability

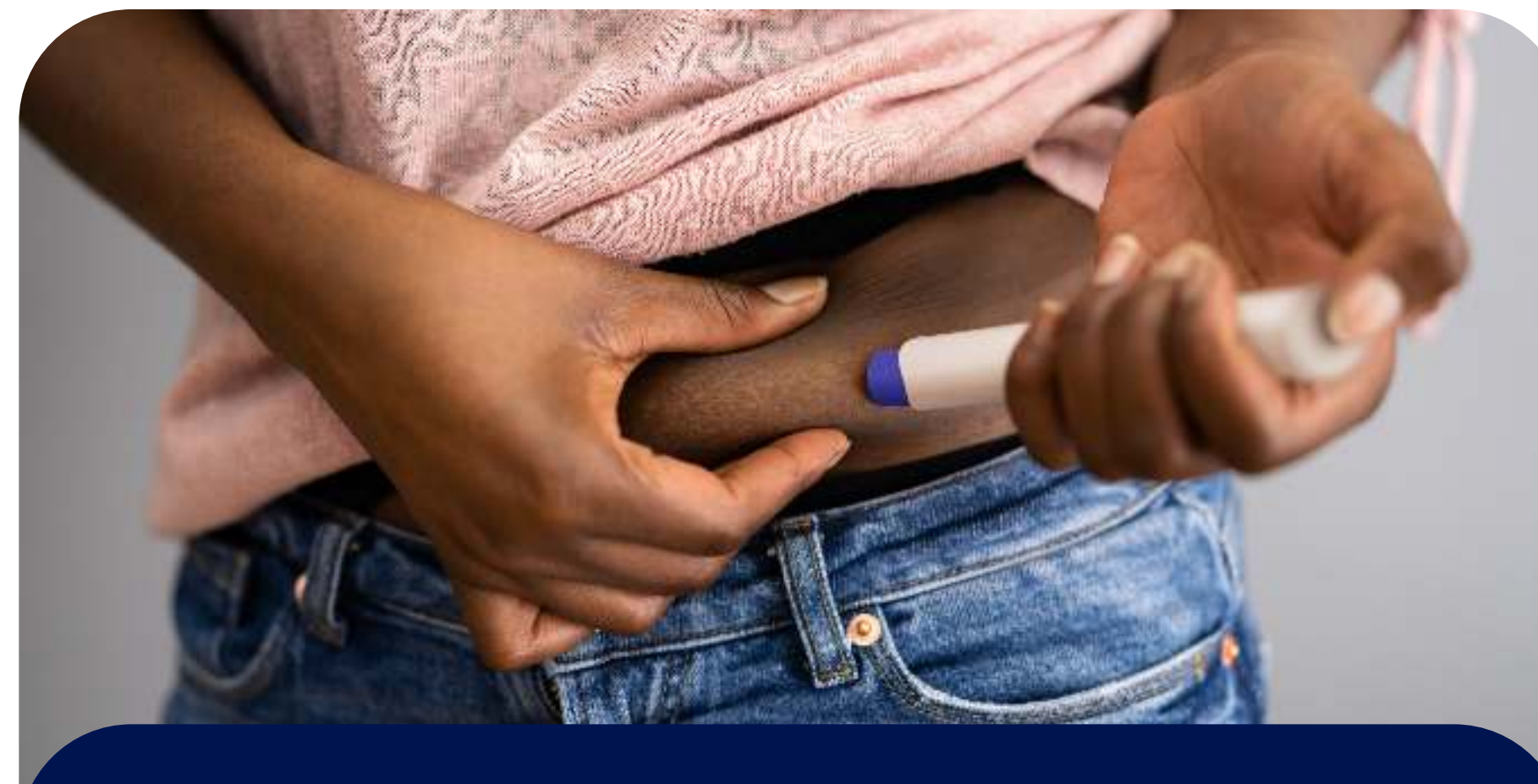
Three promising areas for green solutions.

Innovation in key domains like these is already creating promising new opportunities for those looking to hit ambitious sustainability targets for their next launch. To stay ahead of tightening global standards, be prepared to consider these approaches in your product strategy.



Sustainable materials

Shift from conventional plastics and production methods to recyclable, eco-friendly materials that can easily enter the waste stream.



Reusable devices

New advances in reusable injection technology may soon help reduce waste associated with disposable devices and delivery systems.



Carbon neutrality

Increase focus on minimizing resource use and carbon footprint across manufacturers' operations.



Launching in a delivery device

Factor 5 →

Expert support

What to look for in the right launch partner.

Launching in a delivery device 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 packaging solutions to meet your product and launch goals?

Comprehensive services

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

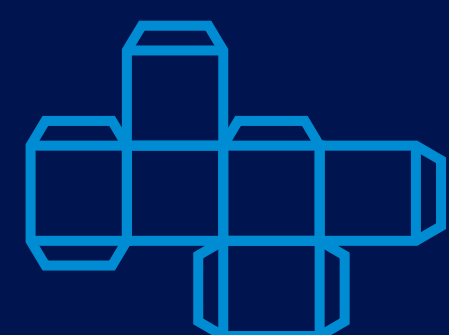


Expert support

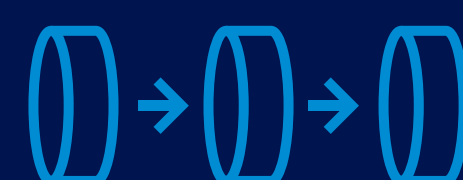
Vetter: Full-service flexibility to meet your needs.

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

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 injection device options to help differentiate your product and improve your user's experience.



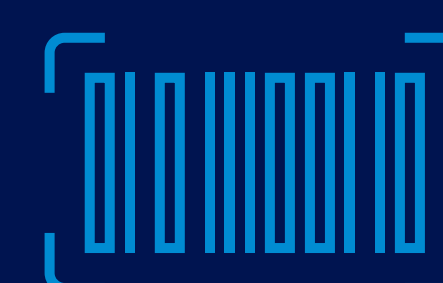
**Customized
packaging
development**



**Device assembly
services**



**Secondary
packaging
solutions**



**Aggregation and
serialization**



**Onsite storage
and cooling**



Launching in a delivery device

Our 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



7 steps to a smart secondary packaging strategy

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.

 www.vetter-pharma.com

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