Beyond compliance:

Optimizing user-centric device development through iterative human factors, industrial design, and cross-functional collaboration

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In this whitepaper we discuss how applying human-centred design goes beyond fulfilling minimum regulatory expectations when developing devices for self-injection. Taking the Gx Inbeneo® autoinjector as an example, the authors illustrate how human factors studies, stakeholder consultation, and cross-functional collaboration support development of a mature, user-centric product for home-use.

As self-administration becomes an increasingly popular route of administration for high-volume and high-viscosity biologics[1], the expectations placed on drug delivery devices also continue to increase. Devices for subcutaneous injection in home settings must function technically, but they also need to be safe and intuitive to users with different levels of experience, confidence, and dexterity. At the same time, pharmaceutical companies need development partners and platform technologies that can respond efficiently to product-specific requirements without compromising on device performance, time to market, or supply security and reliability.

The Gx Inbeneo® autoinjector platform, developed by Gerresheimer, in partnership with Midas Pharma, meets these demands through an iterative, human-centered design process combining user feedback, human factors expertise, industrial design, engineering, and stakeholder input across functions. This approach enabled the development team to identify usage challenges early, implement targeted risk mitigation measures, and refine the design to optimize safety and user experience.

The development challenge

Biologic drugs, including monoclonal antibodies and other advanced formulations, place demanding requirements on self-injection systems. Longer injection times are increasingly required due to dose, volume and viscosities.

These technical demands shaped the architecture of the Gx Inbeneo® autoinjector. To support reliable delivery of such formulations, the device combines several design features intended to enable robust injection performance. Unlike most autoinjectors, the Gx Inbeneo® employs a pre-pressurized 3 mL cartridge. Push-on-skin activation cause the narrow end of the unique double-ended needle to pierce the patient's skin while the larger end of the needle pierces the cartridge.

This novel technology overcomes technical challenges of biologic drugs, enabling realiable administration of larger volume and very high viscosity in acceptable delivery times[2]. However technical performance needs to be balanced with simple usage to support correct, safe, and adherent self-injection, and a design that can be produced consistently at scale.

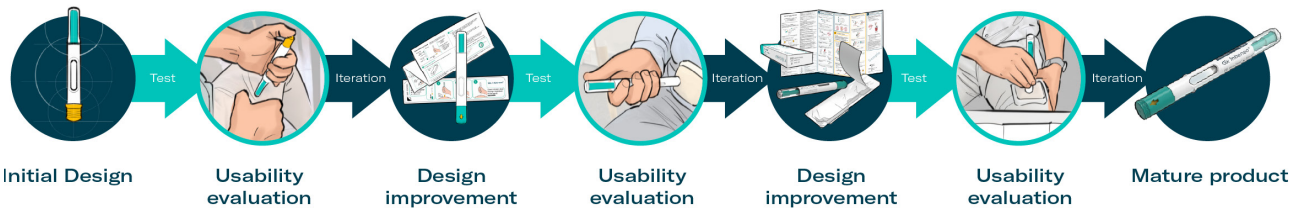


Figure 1: Repeated cycles of design, evalutation, and improvement from concept to mature product design

A human-centred approach

A traditional product development approach typically requires only a formative study and a summative study at the end of development, rather than multiple formative tests throughout the process. As a result, usability issues could be identified too late, in the worst-case only after development has been completed. This can lead to suboptimal solutions, costly development loops, or delayed market launch.

Human-centred design is characterized by a strong, systematic focus on the user and an iterative process that utilizes prototypes from the very beginning[3]. This allows potential use errors or difficulties to be identified and corrected early on in the development process and at a lower cost. The goal is to identify both explicit and unspoken needs and to determine how these translate into new areas of innovation, which are then examined from economic and organizational perspectives (figure 1).

The development of the Gx Inbeneo® autoinjector followed an iterative, human-centred design approach in line with ISO 9241[4], incorporating input from usability engineering, industrial design, marketing, sales, system and mechanical engineering, packaging development, and other stakeholders. Meeting regulatory requirements for safe and effective use is critical, but the Gerresheimer team also incorporated broader human-centred design principles that considered subjective user feedback, customer expectations, and the overall experience of interacting with the product.

The outcome is an autoinjector that is simple to administer by a patient, lay caregiver or health care professional from clinical to home environments. It doesn't require assembly, has a straightforward push-on-skin activation without an activation button and supports visual tracking of injection process in real time

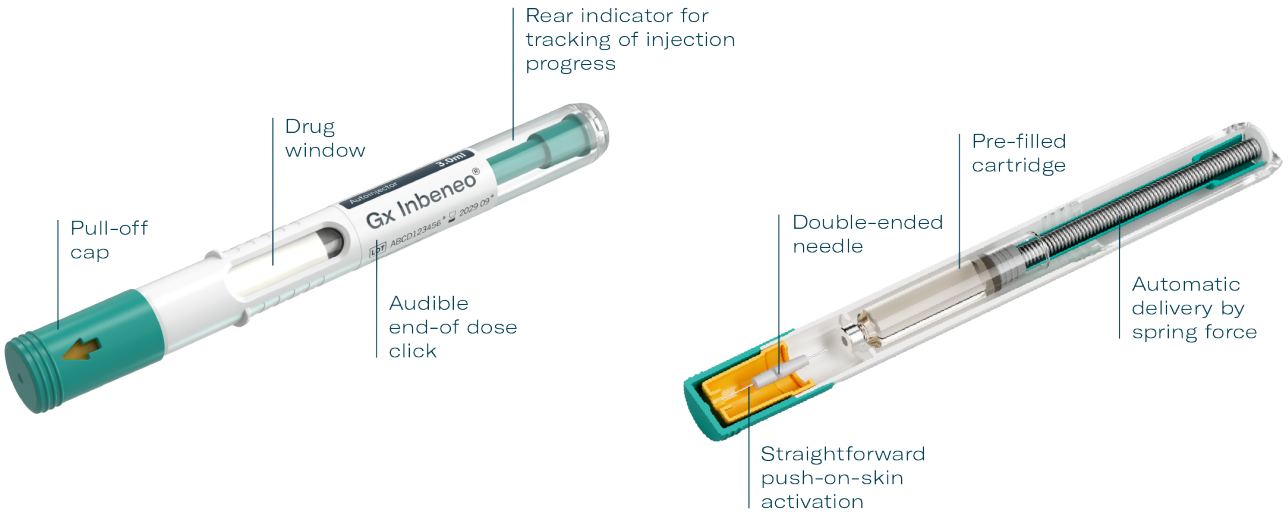


Figure 2: The technology of the Gx Inbeneo, designed for user-friendly biologic drug delivery

thanks to the unique transparent top casing and standard drug window. In addition to the visual end-of dose indication, the device provides an audible signal to assist the user in recognizing a successful injection. This simple self-administration reduces the risk of use errors, reinforces confidence and therefore supports therapy adherence (Figure 2).

Crucial learnings from early usability testing

The development journey with the Gx Inbeneo® autoinjector began with an early design concept incorporating patented technology in a prototype design. At this early stage a handling study was conducted with eleven naïve participants to ensure that the design was on the correct path. The initial design had a tapered top which was found to be misleading and led to incorrect orientation by study participants. This highlighted how strongly users rely on semantic cues and existing mental models when first encountering a device.

Usability testing at such an early development stage delivered some critical usage insights and reinforced the key development principle that safe and effective use depends on the combined performance of product form, information design, and contextual cues[5]. The Gerresheimer product management, industrial design, and mechanical engineering teams took the learnings and implemented them into the next iteration of the device to ensure close alignment with user requirements and mitigate previously unforeseen risks.

Formative evaluation confirms concept optimization

The next formative evaluation tested revised shape, color cues, labels, blister, and preliminary Instructions for Use (IFU) together in simulated use. The population of n=34 was broken down into 8 naïve patients with mild to moderate dexterity limitations, 8 patients with self-injection experience, 9 naïve lay caregivers and 9 health care professionals with injection experience.

Orientation improved significantly: 97% of participants oriented the device correctly without instructions. 82% rated the device as intuitive or very intuitive. Moreover, 94% rated the ease of use of the autoinjector as easy or very easy and the rear indicator was seen as very useful feature for denoting the start (n=14), progress (n=19) and end of injection (n=17). Additionally, it was favourable to hold the device closer to the body therefore covering the drug window. The study also generated useful evidence regarding injection monitoring and dose completion. Across use conditions, participants relied on visual cues to understand injection start and progress. In particular, the transparent rear indicator proved to be a meaningful guidance feature. This unique secondary indi-

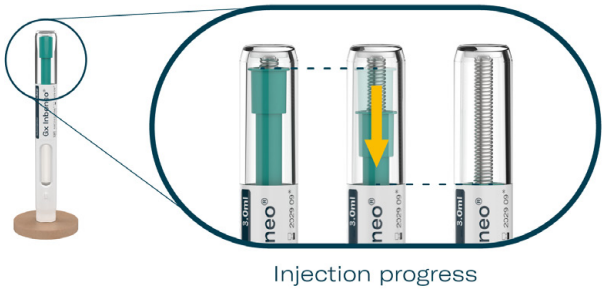


Figure 3: The rear visual indicator clearly indicates injection progress

cator is visible to the user even if the central drug window is obscured by the hand. It communicates not just that the injection is happening, but also how far the injection has progressed, managing the user's injection expectations, a particularly important feature with longer injection times (Figure 3).

Nevertheless, some issues were observed. During simulated use, some study participants did not press the autoinjector down for long enough. The root causes were traced to negative transfer from prior injection experience and by misreading the "hold for another 5 seconds" instruction. That result was significant as it pointed to a specific design response: improve not just the device, but also the wording and hierarchy of packaging and IFU.[6]

91% of the participants stated that it would be acceptable to complete two 30 second injections every day. Cap removal is straight-pull, with usability closely resembling PFS-based devices. This straightforward design was perceived as neutral to very easy, with the majority rating cap removal as very easy.

Human factors evaluation of mature design

To assess the maturity of the updated design, a further formative human factors evaluation was conducted with 16 autoinjector naïve participants across two study procedures. The study assessed both the autoinjector, and the full user interface system, including optimized IFU, blister tray, carton, and labels. Different simulated-use conditions were applied to compare intuitive handling without supporting materials, to use with a full set of information.

The results confirmed the efficacy of iterative design adjustments. All participants oriented the device correctly, and no use errors related to device orientation were observed. The on-device labelling was positively received, with participants highlighting the clarity and usefulness of the visual guidance.

The packaging results were similarly positive as all participants were able to open the original sealed blister tray and remove the autoinjector successfully. Handling of the blister tray lid was overwhelmingly perceived as very easy or easy (93%), with a strong majority (80%) rating the required force to remove the lid as very low or low indicating good overall acceptance and ergonomics.

How did you monitor injection progress?

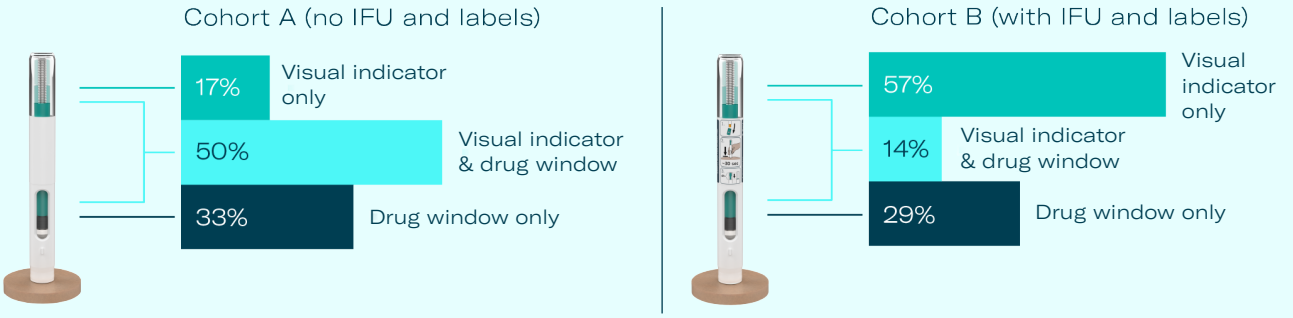
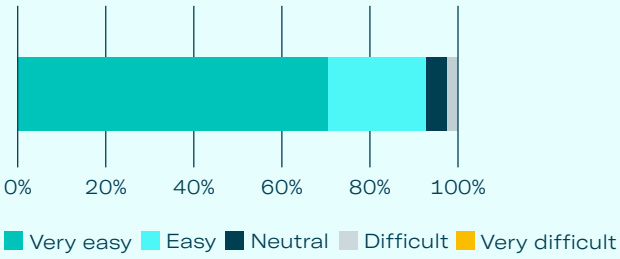


Figure 4: Comparison of use of visual indicator between two cohorts during human factors evaluation, n=16

How easy was it to activate the autoinjector?



How acceptable would you rate the duration of this injection (24-26 secs)?

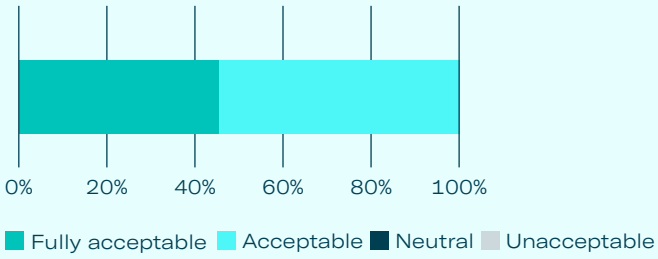


Figure 5: Responses from participants in the human factors evaluation, n=16

When supporting materials including labels and IFU were available, participants were more consistently guided toward the intended monitoring cue and unique feature of the rear visual indicator. This suggests that the indicator supports confidence, especially during injections of a longer duration.

Supporting materials also proved their value in risk mitigation. Premature removal of the autoinjector occurred only in the condition without IFU or on-device labelling, confirming the determined root cause of negative transfer of prior injection experience or lack of familiarity. Once the full information set was provided, no premature removals occurred. This indicated that the revised instructions and labels were effective in addressing this previously identified risk and that packaging and information design were functioning as intended.

Overall performance of the autoinjector was also positively received with 93% of participants stating that activation of the autoinjector was very easy or easy. All participants felt that duration of the simulated injection was fully acceptable or acceptable (Figure 5).

From findings to design action

Human factors evaluations identify where users struggle, what assumptions they make, and which parts of a user interface cause ambiguity. Industrial design then plays a central role in translating observations into tangible solution concepts.

Exploratory industrial design was essential in the development of the Gx Inbeneo. Findings from the early handling study and formative evaluation were brought into cross-functional brainstorming sessions, translated into sketches and concepts, and then developed into selected design proposals. Through early rapid prototyping, the proposals could be made tangible in order to clearly communicate design intent. Internal and external stakeholders were able to quickly assess handling logic and feasibility which enabled efficient progression from observation, to interpretation, to implementation in several iterations.

In such an autoinjector design, cartridge size, spring architecture, needle wall thicknesses, moulding requirements, and other engineering factors place limits on what is possible.

Through close interaction between human factors, industrial design, and mechanical engineering, exploratory thinking remained grounded in feasibility while still responding meaningfully to user and stakeholder needs. The collaborative approached also helped ensure that no nuance was lost and solution concepts could be developed more rapidly.

As a result, the design changes not only mitigated risk but also contributed to an enhanced user experience. The optimization of the overall form resolved early orientation issues, while updates to the labels, carton elements, and instructions for use addressed misunderstandings that contributed to premature removal. In addition, feedback beyond use error was integrated into the device with the inclusion of a grip structure and adjustment of the anti-roll feature. The anti-roll feature now serves an additional purpose as a finger rest and ensures the central viewing window and arrow on the cap face upwards when the injector is placed on a surface (Figure 6).

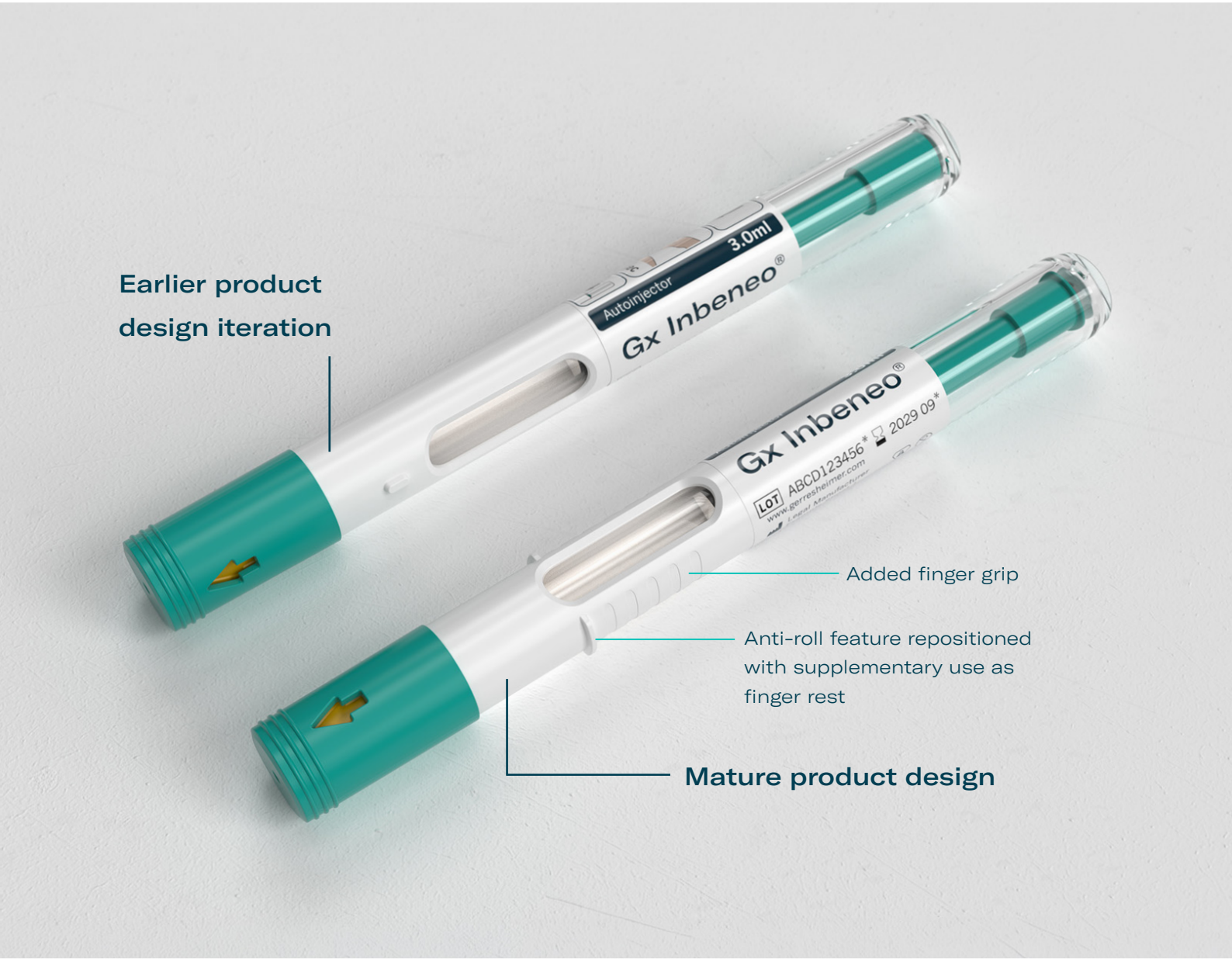


Figure 6: Optimized design features following feedback from users and stakeholders

Mature platform, strong development partner

The Gx Inbeneo® project illustrates a broader development mindset at Gerresheimer as human factors activities were not treated as isolated checkpoints, but as decision-enabling milestones within a process of continuous product development. Positive results were used to confirm direction, while residual findings were used to optimize design iterations. These improvements not only aimed at reducing use-related risk, but also at strengthening confidence, clarity, and overall user experience.

The project relied not only on close collaboration across Gerresheimer sites and with Midas Pharma, but also greatly benefited from collaboration with pharmaceutical customers. Usability and formulation teams from several companies provided valuable perspectives that supplemented the direct user feedback.

Pharmaceutical companies seeking an autoinjector for their next biologic drug can be confident that the mature design of the Gx Inbeneo has successcully addressed usability, technical feasibility, and stakeholder expectations. The project also demonstrates the development mindset, expertise and collaborative approach of the Gerresheimer team. Together these two crucial aspects ensure the autoinjector can be efficiently and effectively tailored to the requirements of a specific formulation, helping accelerate time-to-market of the final combination product.

Conclusion

The development of Gx Inbeneo® shows how human-centred design goes beyond regulatory compliance. It illustrates how an evidence-based, iterative approach can translate user insight, stakeholder input, and cross-functional expertise into comprehensive product improvements across the device and supporting materials. The result is a mature autoinjector platform with demonstrated usability performance.

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About the authors

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About Gerresheimer

Gerresheimer is an innovative systems and solutions provider and a global partner for the pharma, biotech and cosmetic industries. The Group offers a comprehensive portfolio of drug containment solutions including closures and accessories, as well as drug delivery systems, medical devices and solutions for the health industry. The product range includes infusion, dropper and syrup bottles, tablet containers, vials, syringes, pens, auto-injectors, inhalers, ampoules, cartridges, on-body devices as well as digital solutions for therapy support. Gerresheimer ensures the safe delivery and reliable administration of drugs to the patient. Gerresheimer supports its customers with comprehensive services along the value chain and in addressing the growing demand for enhanced sustainability. With 39 production sites in Europe, America and Asia, Gerresheimer has a global presence and produces locally for regional markets. Together with Bormioli Pharma, the Group generated revenues of around EUR 2.4bn in 2024 and employs over 13,000 people. Gerresheimer AG is listed on the Frankfurt Stock Exchange (ISIN: DE000A0LD6E6).

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Transparent casing for injection progress tracking

Cartridge-based, pre-pressurized system

Double-ended needle remains dry in storage

Gx Inbeneo®

Patient-friendly design

— Push-on-skin activation for ease of use
— Double-ended needle shortens injection time

Created for biologic drugs

— Dry needle prevents clogging in storage
— Accommodates cartridges with baked-on siliconization to minimize aggregation risk

Quick customization

— Platform concept reduces time-to-market
— Adaptable to volumes up to 3 mL and very high viscosity

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