

# Interview: Celebrating 10 Years of Molly Enabling Patients' Independence

In this interview, **Nicholas Heaton** of **SHL Medical** looks back on the decade since Molly – the company's signature two-step autoinjector platform – received its first approval, reviewing what made the device platform a success, where Molly is positioned in the market today and how it will continue to evolve to meet the demands of the future.

**Q** What was the original vision behind the Molly autoinjector?

**A** Molly, as we know it today, is the culmination of more than 35 years of extensive, hands-on device engineering expertise that SHL Medical has built as a pioneer in the autoinjector space. It draws directly on the insights and learnings from its predecessor, the button-activated Disposable Autoinjector, which is widely regarded as a trailblazer for modern autoinjectors, helping to transition self-injection technology from its origins in military applications to patient-centric, at-home care – achieving this at a scale never seen before.



Figure 1: SHL Medical's Molly autoinjector platform.

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At Molly's inception, SHL Medical's two decades of understanding on how autoinjectors perform in real-world settings provided the groundwork to develop a reliable platform engineered to support emerging drug modalities and deliver consistent, high quality performance at scale. At the same time, Molly's creation was driven by a clear ambition: to bring an autoinjector to market that effectively balanced reliability with user-centric design.

To achieve this ambition, proven technologies were combined with new IP, yielding a result greater than the sum of its parts. The introduction of a novel two-step injection mechanism was the outcome of that vision, delivering simplicity for patients while ensuring robustness for pharmaceutical applications. Together, this blend of legacy expertise and an eye for innovation have defined Molly's versatility and have underpinned the platform's success to date (Figure 1).

**Q** How did early customer needs shape the development of Molly, and how did those needs manifest in the evolution of the technology across different device formats?

**A** Customer requirements have played a central role in shaping Molly's evolution. Early on, we collaborated with our

pharma partners on highly specific use cases for the technology, ranging from metabolic emergency use applications to distinctive industrial design presentations. Over the years, these customer needs have taken many forms, from branding and indication-specific usability affordances to manufacturability and operations-driven optimisations; Molly has consistently proved capable of meeting them.

Those demands pushed us beyond conventional boundaries, both in terms of device engineering and industrialisation. Rather than viewing those requirements as challenges, we used them as opportunities to expand what an end-to-end device offering could deliver, ultimately strengthening Molly's versatility.

Once it was established, interest in leveraging the Molly autoinjector technology grew rapidly, and it quickly became clear that it was a compelling choice for pharmaceutical companies developing combination products. A strong example of this came when one of our longstanding partners presented us with a higher-dose biologic formulation requiring a 2 mL fill volume, creating a clear case for the Molly 2.25 mL format.

The resulting combination product was launched in 2020 for atopic disorders and marked the first autoinjector with a  $\geq 2$  mL label volume, enabling patients to access a higher-dose biologic in a convenient,



## Nicholas Heaton

Global Head of Sales

T: +41 41 368 00 31

E: nicholas.heaton@shl-medical.com

Nicholas Heaton is the Global Head of Sales at SHL Medical, based at the company's headquarters in Zug. He leads the company's commercial teams, overseeing account management, business development and customer success teams across the United States, Europe and Asia. With more than three decades of experience in the life sciences industry, Mr Heaton brings deep commercial and strategic expertise to the organisation. He holds an MA (Hons) in Chemistry from the University of Oxford (UK).

at-home format. This paved the way for the next generation of high-dose self-administered injectables. It was a critical progression for the technology, and we look back on it as an important demonstration of how Molly has played a part in advancing the state of the art in drug delivery.

**Q** Can you expand on SHL Medical's operational approach to scaling Molly?

**A** As demand grew, it became clear that Molly needed to scale beyond individual project needs. This shift prompted deliberate investment in transforming it into a true platform from a design and development perspective, as well as across our operations. From an industrial design and IP viewpoint, the underlying technology was always consistent, effectively making it a platform from the outset. Therefore, the focus was on driving efficiency, ensuring consistent reliability and making it easier for both new and existing customers to adopt Molly.

A key part of this was the development of SHL Medical's own toolsets and equipment, which helped reduce the overall cost of ownership for customers while improving standardisation and scalability. SHL Medical's legacy of vertically integrated toolmaking, equipment development and manufacturing infrastructure was a big part of pulling that off (Figure 2). That platform mindset has since been a major enabler of Molly's success.

**Q** As Molly marks its 10th anniversary, what does this celebration actually represent in terms of Molly's presence and impact in the market today?

**A** Unsurprisingly, the benefits that Molly offered on the reliability and usability fronts would only find success if deployed in a way that also prioritised development simplicity and speed-to-market. Its market introduction, originally as a "preconfigured" solution, resonated well with what our customers were looking

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for – bear in mind that they would have spent the previous decade developing their precious, novel drug, only to arrive at this long-awaited final stage of combination product development. In 2016, we celebrated Molly's first approval in collaboration with one of our trusted pharmaceutical partners.

Today, 10 years later, Molly is a well-established global platform that has enabled the regulatory approval of more



Figure 2: SHL Medical's vertically integrated approach to development helps to reduce total cost of ownership for customers and improve both scalability and reliability.

than 20 combination products, covering nearly 30 therapeutic indications and still growing. It supports some of the industry's most prominent self-injection therapies, including blockbusters in the dermatologic, autoimmune and cardiometabolic spaces. In terms of scale, 90 million Molly devices reached patients in 2025, which places it as a leader in the marketplace.

**Q** Scale doesn't come without its challenges – how does SHL Medical ensure quality and reliability at such volumes?

**A** Reliability is a priority for SHL Medical and one of Molly's defining strengths. Over the years, we've developed a world-class quality organisation that tirelessly focuses on the quality of both our processes and outgoing products. With Molly's market-leading low complaint rate, performance is also consistently validated in real-world use, as devices leave our facilities and end up in the hands of patients. This reflects the robustness of Molly's design, the rigour of our process development and the maturity of our manufacturing operations. For pharmaceutical companies, that level of performance translates directly into reduced risk and greater confidence throughout the product lifecycle.

**Q** How do you collaborate with customers who may have unique needs outside of the design envelope?

**A** That's an important question, as customer needs vary significantly based on a wide variety of factors. We've developed a flexible platform approach that combines a high degree of standardisation with the ability to introduce targeted customisation within the Molly platform on pre-defined axes (Figure 3).

When a customer is interested in more bespoke developments, the core Molly technology can be leveraged to ensure that even a necessarily unique autoinjector solution benefits from what Molly brings to the table. This allows customers to profit from the efficiencies, speed and reliability of a proven platform, while still achieving meaningful differentiation where it matters most. Ultimately, it's about providing

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the right level of adaptability without compromising performance, regulatory robustness or development timelines.

**Q** SHL Medical has historically prided itself on its vertical integration – where does that play a role in Molly, and do you find yourselves collaborating with other industry leaders?

**A** A significant differentiator with SHL Medical is our ownership of key toolsets and manufacturing equipment. By controlling these critical elements, we're able to reduce the total cost of ownership for our customers while enabling scalability. In a highly competitive and resource-intensive environment, our investment in unifying toolsets and equipment secures the market launch and lifecycle needs of our customers' combination products.

But to your point, we can't do it alone. We've built a strong alliance network with leading partners across the value chain. These include de-risked primary container providers and pre-validated final assembly services, to name a few. Together, we've worked to create a plug-and-play ecosystem that simplifies development and accelerates time to market.

**Q** Sustainability in drug delivery is becoming increasingly important – how is Molly evolving in this area?

**A** Like many of our customers, sustainability has been a key focus for us in recent years and will continue to be going forwards. We now offer a bio-based version of Molly that can reduce associated carbon emissions by up to 49%. This is a significant step in supporting our customers' environmental goals while maintaining the same performance in our products and robustness in our supply chain. This approach positions Molly as a leading choice for companies that are prioritising sustainability in their drug-device development strategies, while also looking for the benefits that a market-proven device has to offer.



Figure 3: Molly is highly customisable to suit customer requirements.

**Q** As it looks to support future growth, where is SHL Medical making investments today?

**A** We're continuing to invest in both subassembly and final assembly capabilities, which represent two distinct and strategically important areas of our offering and footprint. Regarding subassembly manufacturing, by the end of this year, we will be the only autoinjector platform manufacturer with operational sites across three continents. Our presence in North America, Europe and Asia enables a unique level of not only scale, but resilience and proximity to key markets as global demand grows. In parallel, we are strengthening our final assembly offering through the continued investment in SHL Medical Assembly & Services, bringing together our end-to-end service offerings,

which are a significant lever when looking to reduce our customers' time to clinic as well as to market.

**Q** After 10 years, what do you think defines Molly's success, and what comes next?

**A** Molly's success is grounded in its modular design and a strong focus on incremental, effective innovation. Combined with SHL Medical's entrepreneurial spirit and commitment to going above and beyond customer and patient needs, we have created a solid foundation for the platform's continued advancement.

We are perpetually pushing the boundaries of the platform through improvements in functionality, reliability and development efficiency. Drawing on

a decade of real-world insights across a wide range of therapies, use cases and customer programmes, we are uniquely positioned to advance Molly in ways that are currently unparalleled in the industry. We strive to continue the legacy of Molly, enabling our customers to bring therapies to market quickly and efficiently without compromising on quality.

Molly's success comes down to a combination of innovation, adaptability and execution. We've developed a platform that meets today's needs alongside both the vision and infrastructure to evolve with the future of self-administered drug delivery. Looking ahead, our focus is on scaling sustainably, expanding globally and continuing to push the boundaries of what an autoinjector platform can achieve.



**SHL MEDICAL**

**SHL Medical AG**

Gubelstrasse 22  
6302 Zug  
Switzerland  
[www.shl-medical.com](http://www.shl-medical.com)

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# A proven platform

Marking 10 years of enabling patients' independence with SHL Medical's Molly modular platform technology.

Over **210M**

Molly devices reached patients since launch in 2016\*

Over **35** years

SHL Medical pioneering the industry

**22**

Molly commercial approvals\*\*

