

STEVEN KAUFMAN, STEVANATO GROUP & URI BARUCH, CAMBRIDGE DESIGN PARTNERSHIP



Steven Kaufman is Vice-President, Drug Delivery Systems at Stevanato Group, responsible for managing business development, proposal management and project management as well as strategic initiatives in the group's drug delivery systems business. He has been active in the drug delivery device field for more than 15 years, working with leading multinational biopharmaceutical companies to provide pen injectors, autoinjectors and wearable injection systems, as well as test equipment, assembly equipment and final device assembly services.

Uri Baruch is Head of Drug Delivery at Cambridge Design Partnership (CDP), where he has led a large variety of design projects including an award-winning needle safety device, an emergency autoinjector, a pen injector packaging design for delivery devices, and inhalation products. He is presently heading the collaboration with Stevanato Group on pen injector projects.

In this interview, Mr Kaufman and Mr Baruch discuss the recently announced collaboration between their two companies to accelerate the development of a new variable-dose, cartridge-based pen injector platform for diabetes care based on the Axis-D technology licensed from Haselmeier.

Q Congratulations on the recent announcement on the collaboration for the development of a new diabetes pen injector. Please could you give us a brief rundown of what this agreement is about, its objectives?

SK We are excited about this collaboration. It has a powerful objective to bring together different capabilities and services from Stevanato Group, within our existing collaboration with Haselmeier, and now in particular with CDP, to bring this SG pen – a new pen injector platform based on Haselmeier's variable-dose pen injection technology, Axis-D (Figure 1) – into the diabetes space for the delivery of, for example, insulin/insulin analogue products and GLP-1s.

Haselmeier has over 100 years of tradition and a history in bringing complex pen injectors to market. We talked extensively with them about Axis-D and, in October 2019, we were able to secure a licencing agreement for the technology, covering the diabetes therapeutic area. Haselmeier has done a terrific job. It's a proven technology in that a version is currently on the market

today having been launched by a major pharmaceutical company and approved by both the FDA and EMA.

In the crowded diabetes space, we are seeing some pharmaceutical companies struggling to find a device solution that's a good fit. Factors such as intellectual

property and freedom to operate are given a lot of attention of course, but pharmaceutical companies are also looking at which companies can provide a more complete solution based on expertise and track-record. So, Axis-D, as the basis of our SG pen, has significant potential.

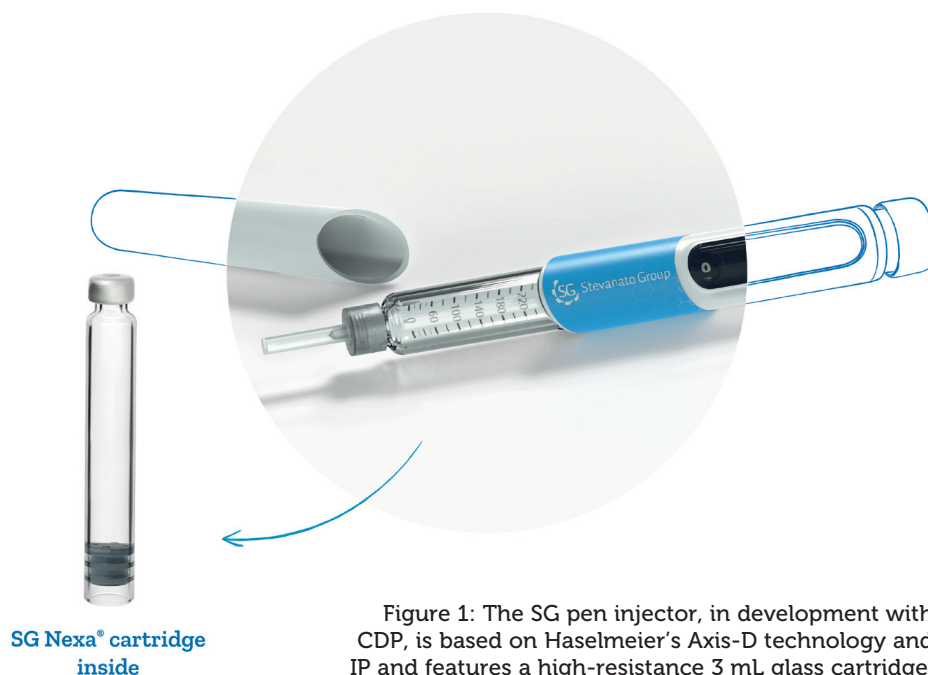


Figure 1: The SG pen injector, in development with CDP, is based on Haselmeier's Axis-D technology and IP and features a high-resistance 3 mL glass cartridge.

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There are terrific companies that make pen injectors in the market today. We hold them with very high regard, both pharmaceutical companies and device companies. But it would appear that in the diabetes area, demand for insulin and GLP-1 products is continuing to grow. It’s simple supply and demand – there are too many companies seeking pen injector solutions from a limited number of players in the market.

With this unmet need in mind, we realised that we should look to a partner to support in the development of the SG pen based on Axis-D, and that’s where CDP came in. Stevanato Group had already been working with CDP for some time, and we’d had the opportunity to see the quality of service that CDP can provide. On an individual level, Uri and I have known each other for more than a decade. By collaborating with CDP on this SG pen injector project, we will be able to customise and bring our offering to market at a greater speed as well as be more in tune with customer and patient needs.

When I think of Haselmeier and CDP, I see two great companies with the industry pedigree, that legacy, pharma is looking for in its device partners. Combined with Stevanato Group’s own 70-year heritage in glass containers, and our complementary skills in manufacturing, laboratory services, and equipment – it’s the total package.

UB CDP has extensive experience in the variable-dose injection pen space, we’ve worked with market leaders, and there is intellectual property relating to injection pens with our name on it. We’re aware of how dense this space is.

Likewise, CDP and Stevanato Group have known each other for a long time and have had several previous successful working relationships, which were similar to this current SG pen injector project in many respects. CDP has worked with Haselmeier in the past too. Clearly these two companies have the ability to bring this pen injector to the diabetes market. Where we can help them is with accelerating time to market.

When you’re working with a large number of clients as Stevanato Group does, on multiple projects, you spend large amounts of time and resources, recruiting, training, equipping manpower to meet those demands. But inevitably demand fluctuates – sometimes it tails off, sometimes it peaks. Where we see the fit between CDP and Stevanato Group is that we can help in those surges. We can come in and get moving quickly, to meet the demand and help augment the existing staff, the existing design team. It’s very much a supporting role.

In terms of the objective of this collaboration, it is to take the existing Axis-D offering, which is actually a very

successful launched product in another therapeutic area, and adapt it to the needs of the diabetes market. We want to create a world-class offering in a short timeframe for existing and newly developed therapeutics that are coming onto the market.

Q How does this collaboration fit with your companies’ wider offerings and strategies in the drug delivery devices space?

SK Over the past few years, Stevanato Group has strategically expanded its drug delivery systems team and broadened its offering to include capabilities and services as an integrated solutions provider. In the past our Ompi brand, specialised in glass primary packaging, was the most familiar to people. Now, under the Stevanato Group brand, we’re offering a broader range of solutions to our pharmaceutical partners such as contract manufacturing of devices, which is key, to produce their autoinjectors, pen injectors, wearables and inhalers. It also enables us to collaborate in a more meaningful way on a greater number and variety of programmes.

Primary containers, cartridges and prefilled syringes are at the heart of our offering. We’re the largest supplier of cartridges to the pen injector market for insulin in the world today.

We brought SVM on board, a Danish company, which has been producing high-speed and intermediate-speed equipment for sub-assembly and final assembly of pen injectors for decades. And in 2016 we acquired Balda, a contract development and manufacturing organisation (CDMO) with facilities in Germany and the USA, specialising in plastics, with strong expertise in tooling and manufacturing of diagnostic components as well and pharmaceutical and medical devices. Balda too have been involved in the diabetes space with experience supporting the manufacturing of lancing devices and blood glucose meters. Pulling it all together, with our laboratory services, we have a very strong truly integrated offering – providing a multi-dimensional approach.

Thanks to Stevanato Group’s integrated approach and capabilities, pharma companies, instead of having to speak to many different suppliers to bring a product to market, need only speak to one or two. The total one-stop-shop approach is not viable for every project, companies can look for a provider only for the primary container, or for the device and primary container.

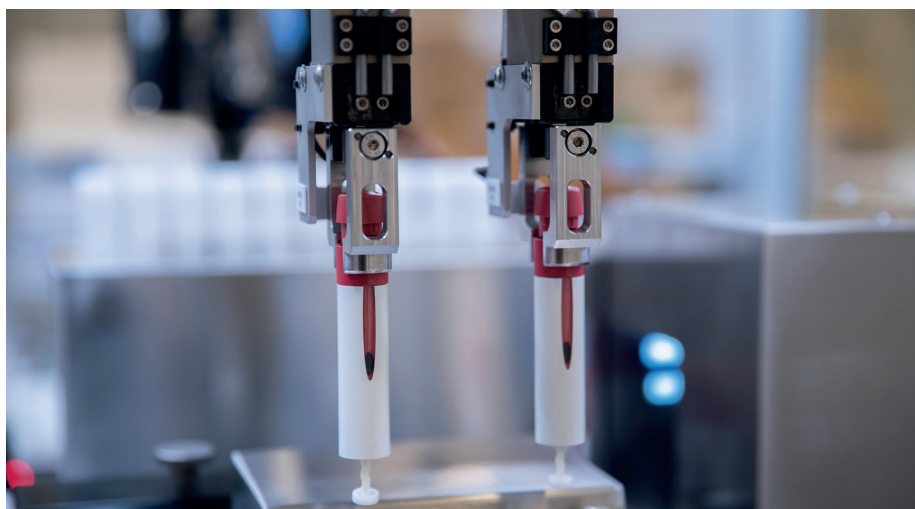


Figure 2: Stevanato Group provides advanced equipment for the final assembly of a pen injector, based on Haselmeier’s Axis-D technology.

And if you can provide both of those, with laboratory services, characterisation of drug product, and equipment, then you have a package. Stevanato Group's offering covers a range of competences and capabilities that can be applied according to different project needs and that's the value proposition we are taking to the market for a range of drug delivery systems. The SG pen based on Axis-D, for which Stevanato Group provides advanced assembly equipment (Figure 2) is a key part of that strategy.

One important point I want to make though is that our strategy of offering integrated solutions does not limit us from collaborating with others as well. We don't want people to assume that. While the company is currently investing in integration, Stevanato Group has always built relationships with other players, and we will continue to collaborate and develop key partnerships in the future. As these agreements with CDP and Haselmeier demonstrate.

UB CDP has been involved in many projects where there's a need to align with external suppliers, for example an external assembly equipment manufacturer or an external container closure manufacturer, which is possible of course, it is common, and it is what we do. As Steven said, there is rarely a complete one-stop-shop, but when as much as possible is under one roof as is the case with Stevanato Group's broad integrated offering, with other aspects being brought in by partners talking to each other very, very closely, then you can really present a united business case, the project as a whole is stronger, everything is much easier. With separate companies, you can achieve alignment of course but there is no single business case – they all have their own business cases. This project with Stevanato Group achieves that united business case. It is a collaboration between the two teams and we all bring our insights. Like every type of relationship that we enter into, every contract we sign, we view this as a long-term relationship. We learn from our partners as well, so we can strengthen each other. This is our role with many of our partners. Gone are the days where we would just take a project on, work on it in isolation, and then at some point hand it over complete. We've done this in the past but such projects were always few and far between. And today the model is increasingly collaborative.

At the same time we recognise that our partners, device companies and also

pharma companies, naturally want to retain the knowledge, and want to retain control internally. They do not want to feel like we've stepped in to the point where they're losing control of the project. That's an important factor. It must be a supportive collaboration.

Q **Finalising and signing this agreement under the restrictions arising from the novel coronavirus outbreak must have been difficult. Can you talk about that a little, and also perhaps comment on how the pandemic is affecting your companies?**

UB Our overarching concern regarding the pandemic, as a company that does a lot of hands-on work, has been to maintain our staff's safety while still delivering projects. We moved everyone who didn't need to be in the office, home, leaving key people in the office who had to be there. These people could spread out to a much larger extent, taking over all the meeting rooms and offices. A lot of the meeting rooms have been converted to labs. A member of the senior management team goes into the office every day to make sure people are supported, looked after and they're all safe.

In terms of the impact of the pandemic on the current collaboration with Stevanato Group, we were all working on this for a while beforehand and I think some of those initial meetings would have been difficult if we couldn't have travelled and met face-to-face. But actually, perhaps counterintuitively, contract negotiations themselves and negotiating the agreements became easier in a lot of ways in my view as the pandemic unfolded, rather than harder. For example, I found that people were more available for phone calls, they had more time, were more focused, not in as many meetings, and there were fewer distractions working from home. So of course the pandemic did have an impact but it was not all negative by any means.

We've seen a lot more activity, definitely, since coronavirus hit. Again, probably

counterintuitive to what many would think, but remember we work in healthcare, and so activity has increased across pharma, diagnostics, and medical technology. There are more resources and more capital being made available to fight the outbreak. And we need to make sure this doesn't happen again too, so there's investment in preparedness for possible future pandemics. CDP is currently working on a number of projects related to the pandemic including a major project to expand COVID-19 testing, as well as supporting the NHS Visors project to manufacture emergency personal protective equipment (PPE). Healthcare in general is much more of a focus for governments, for society, for everyone, and we are seeing an increase everywhere, not just with projects that are directly related to the virus.

SK Truly we are living in unusual times. Everyone has been impacted by COVID-19 on some level but in our collaboration with CDP, and working with Haselmeier, we found that there was minimal impact from having to finalise the negotiation and sign the agreement under these circumstances. I think probably the simple reason for this is, both as companies and individuals, we already knew each other well and had a history of successful collaboration.

Our CTO, Paolo Patri, who led the programme with his R&D team, has highlighted in recent presentations how Stevanato Group continues to grow its R&D organisation internally with ongoing recruitment and several key hires this year to better meet the needs of our clients that want to work with us for their devices, or for one of ours. Working with a range of consultants, such as CDP, allows us to conduct more projects, offer a range of expertise and expand the bandwidth of our R&D resources.

There was of course due diligence, working with our facility in Germany as well as our facilities in Italy and Denmark. If anything, as Uri has said, not having the extensive travel allowed everyone to be

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laser-focused in reviewing agreements and getting them signed. The fact of the matter is that we had potential clients already in active talks with us for quite a while starting from when we were doing our market evaluations and market sounding to understand client needs related to pen injectors. We knew that timing was a key element to these discussions, as was having the right resources.

Now, just as important is how are we working with CDP and going forward with the lockdown restrictions still in place. We’ve had a strong kick-off meeting, we’ve had great alignment, and a number of the key engineers and other staff have been put in place on our side and theirs and are already working well with our executive leadership. We have a steering committee tasked with making sure that not only the development programme goes well but also that we’re addressing immediately some of the needs of the customers we think are going to sign up or have signed up for the SG pen injector.

Turning to the pandemic and its impact on our organisation, Stevanato Group has 14 facilities throughout the world and we’re one of the largest suppliers of primary containers to the global pharmaceutical market, meaning that we have a strong connection to any vaccines or any drug product that are going to be used to potentially fight the virus.

I’ve only been in the company for about a year and a half, and I’m prouder than ever to work with this team in this organisation. In the early days when we first saw there was something happening, Stevanato Group had the foresight to set up two teams, one led by HSE, responsible to ensure the health and safety of our staff, while guaranteeing the business continuity. The second, an *ad hoc* task-force composed of the commercial, supply chain, technical and quality support teams responsible for proactively responding to the needs of our pharma clients, and continuously committed to quickly and effectively secure products, technologies and services for use in potential vaccine development and treatment. The company has made that one of our highest priorities, with daily meetings.

Within the device team, drug delivery

systems, we have quite a few partner and client companies who have accelerated some of their requests, some of their programmes or devices. There has been no pullback since the outbreak, quite the opposite.

Society in general is prioritising healthcare more, and people are now seeing the real value of being able to take medication at home. Drug delivery systems are what make self-administration at home possible. How do you achieve it? What technology are you using? Are the instructions for use clear? Can the patient see the viewing window well? Can someone with limited dexterity use this? These considerations are always front and centre within the world of drug delivery device development. And whereas these things were previously not priorities for a lot of people, now they’ve become more important questions because so many patients are isolated in their homes less able to go and visit their doctor. More stakeholders are paying closer attention to these aspects.

Q Returning to the details of the agreement, why was Haselmeier’s Axis-D chosen as the most suitable technology for this collaboration? And also, can you provide some detail on the terms of the licence agreement for Axis-D?

SK Stevanato Group has explored the combination product space extensively; in particular, drug delivery systems in four categories: pen injectors, autoinjectors, wearables and inhalers. On inhalers we’re working with Iconovo with their capsule-based inhaler system. For wearables we have a cartridge-based wearable pod device, through the ownership of a company called Medirio. In autoinjectors we’ve announced collaborations with companies like Duoject Medical Systems for an emergency use autoinjector, and we will make further announcements on autoinjectors in the future.

For pen injectors there were several strategies we could have adopted. One example was to acquire the technology through a design house who would develop intellectual property workarounds and so on. There is a number of other possible approaches. But the most straightforward approach was to find a company with a proven track-record that has several pen injectors on the market and that was willing

to collaborate. That was Haselmeier with its Axis-D technology, which has already been launched on the market with a very large pharma company for a major therapeutic area.

One of the key reasons Axis-D was a good fit relates to intellectual property and the designers of the technology. We wanted to utilise a pen injector technology where the core IP was well established, covered by a number of patents, and already on the market. We had the opportunity to speak to the original designers of the technology and that meant a lot. The passion they had for the device and the confidence they had on how it could help more patients. More broadly, Haselmeier as a company ticked all the boxes with its 100 years of history, strong family-owned business, great board leadership, excellent sales and marketing, and a portfolio of other device platforms. Our collaboration with Haselmeier allows both companies to benefit and, crucially, it allows Stevanato Group to provide an integrated solution in the pen injector space, a key part of its overall ability to provide integrated solutions for combination products.

Q Thinking forward to the point where the device is developed and ready, what is your estimate on the timeline for that, and what is your strategy regards the resulting device’s incorporation into pharma products?

SK We have been working behind the scenes for well over a year, engaging with some very well-known biopharmaceutical companies who’ve approached us. We’re in active talks with those companies about providing solutions in the diabetes space. The teams are already set up, people are working daily on this, speaking to those pharma companies and finding out exactly what their requirements are to meet their needs.

In some cases we are working towards aggressive timelines, in others we see companies looking to have a pen injector that can be used as a platform for drugs beyond diabetes. If you know the market, you know the timelines regarding generic GLP-1 agonists and insulins/analogues, then you have a pretty good indication of what we’re working towards – there is absolutely time pressure but, with CDP working with our internal R&D team and with the support of our partner Haselmeier, we believe we can meet client needs.

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UB The Axis-D platform has been launched with a product already, which is a huge advantage, but every new application, and every new client, requires some customisation and modification. It is not ever as easy as just plug and play, never. I think all the players in the market know that, they understand that there is more work to be done. The timelines Stevanato Group is going for are challenging and that’s exciting! We’re really looking forward to delivering this. Both companies welcome the opportunity to show the capability to move very, very quickly after committing to a goal. We’re glad for the opportunity to do this together and to show that it’s possible.

Q Finally, as always, this is ultimately about patients. Can you explain how this collaboration and the resulting delivery device will benefit patients?

SK Our responsibility to our clients is always a priority, but even more important than that is the responsibility we have to patients – the people carrying these products with them in their briefcases, their purses and their backpacks. These are people living with different challenges and they need reliable products that help them get through their lives, especially now during the COVID-19 pandemic.

However, the fact is, a lot of people still don’t know enough about these devices. We know because it’s our industry and we’ve been lucky enough to be part of it for many years, but patient populations need better education, more videos, clearer IFUs, training devices, greater support from marketing, not about selling the device but about educating people. We need more white papers that talk about how patients can benefit from these devices and what learnings different companies have had with the range of pen injectors on the market today.

Having worked with some of the biggest biopharma companies in the world and having had the chance to work in three

great companies now during my career, I am really pleased by the direction we are taking at Stevanato Group and what it means for patients. I see pharma now engaging device companies or pharma solution providers as true partners, as collaborators, because they see the benefit that drug delivery devices can bring to patients.

On an industry level, the key to successfully delivering products to patients when they need them is being open to collaborations and partnerships. This is exactly what we’re doing here.

UB CDP is honoured to have this opportunity to work on a platform that can touch so many patients’ lives. With some of the potential therapies in the future that this will address, beyond insulin and GLP-1 agonists, it has huge potential. So there is need in the market both in the nearer term with insulins/insulin analogues and GLP-1 agonists, and beyond in the longer term, working with biopharma companies’ generics. There is need in the market for new devices, for new offerings like this SG pen that will allow access for a larger patient population to improved therapies, helping them manage their disease.

ABOUT THE COMPANIES

Established in 1949, **Stevanato Group** is the world’s largest, privately owned designer and producer of glass primary packaging for the pharmaceutical industry. From its outset, Stevanato has developed its own glass converting technology to ensure the highest standards of quality. The group comprises a wide set of capabilities dedicated to serving the biopharmaceutical and diagnostic industries: from glass containers with its historical brand Ompi, to high-precision plastic diagnostic and medical components, to contract manufacturing for drug delivery devices, to vision inspection systems, assembly, and packaging equipment. Stevanato also provides analytical and testing services

to study container closure integrity and integration into drug delivery devices, streamlining the drug development process. Thanks to its unique approach as a one-stop-shop, Stevanato Group can offer an unprecedented set of solutions to biopharma companies for a faster time to market and a reduced total cost of ownership.

Cambridge Design Partnership is an employee-owned technology and product design partner, located in Cambridge (UK) and Raleigh, North Carolina (US). CDP provides an integrated and holistic product development capability through a highly qualified team, well equipped development labs and ISO 13485/9001 approved methods. This encompasses research and strategy, design, technology and digital innovation, product development and regulatory and manufacturing support. CDP experts are able to take combination products through a full design cycle and submission, enabling customers to launch products that are user-centric and commercially effective.



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Cambridge Design Partnership provides an end-to-end design and development service, assisting pharmaceutical companies and device manufacturers taking new delivery systems to market.

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