

STEVEN R KAUFMAN, BESPAK

Steven Kaufman is Global Business Development Lead at Bepak Europe Ltd, responsible for business development activities related to injectable devices such as auto-injectors and wearable injection systems. As a member of the commercial team, he works actively with the Bepak Innovation team in Cambridge, UK, which designs and develops advanced drug delivery devices. He is an active member of the Bepak Senior Leadership Team and the Bepak Growth Team.

Mr Kaufman has a biopharma background, broad experience in bringing drug delivery devices to market, and is also involved with strategic alliances with related suppliers and consultants. He has extensive presentation and workshop experience at industry conferences, and has authored several articles related to the drug delivery device field.

Speaking with ONdrugDelivery Magazine here, Kaufman discusses his role at Bepak, the company' activities and capabilities in the injection devices space, and how Bepak meets the current demands from the biopharma industry, in particular in terms of the technology and, crucially, manufacturing and final assembly.



Q Before we delve into the details of Bepak's offering in the injectable delivery space, could you give us a brief update on the wider business – its structure, recent history, broad business strategies and objectives?

A Bepak is well known for its manufacturing and design expertise and over the last 10-15 years we've spent a great deal of time and effort addressing challenges in injectable drug delivery. We acquired The Medical House in 2009 and soon afterwards set up an Innovation Centre in Cambridge (UK). With those two actions, combined with our prior experience with other types of drug delivery system and in manufacturing, we enabled the development of a substantial amount of intellectual property to resolve some of those challenges. What we focused on some time ago was a niche that has now in fact become very "hot" – viscous and high volume drug delivery. We are quite fortunate to be one of the first companies to have really focused on this area.

Our spring-based auto-injectors are arguably one of the two designs that can allow for highly viscous drug delivery. We are pleased to have worked with great companies and to have addressed challenges that other spring-based technologies have not been able to. One of our devices is probably the only 1 mL single-use disposable injector able to deliver its particularly viscous drug

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payload. This is a testament to the ability of our technology to deliver such formulations.

Coupled with that it seems that most people in this space are aware of Bepak thanks to our VapourSoft® technology, where we're using a liquefied gas to facilitate with viscosity issues and also higher volumes, using small canisters as the power-pack to allow for the delivery of as low as 2 mL to as high as 10 mL. The canisters are all the exact the same size but use different types of liquefied gas and different volumes. We found that this resonated really well with the market, and so we've focused on this.

We feel there is an unmet need that we are able to address by being able to offer spring-based and VapourSoft®-based single-use auto-injectors that allow for the delivery

of highly viscous, high volume formulations. We have also spent time recently looking at the delivery of even higher volumes via wearable devices powered by VapourSoft®.

Q How do the respiratory side of Bepak and the CDMO API/finished dosage form business, Aesica interact with the injectables side of Bepak? How does the presence of this broader organisation benefit customers and patients?

A The VapourSoft® technology has its origins in our respiratory business and so this is a very tangible way, in terms of our injection technology, that the broader business has brought benefits.

Also, the company has hired many high calibre people over the years including in the commercial-scale manufacturing part of the business. With experience comes knowledge and with knowledge comes better designs and better devices. The presence of such extensive capabilities, and with them know-how and expertise, at the manufacturing and assembly end of the process feeds back to our device design and development activity so we are always taking manufacturing and assembly into account, right from the beginning and throughout (Figure 1).

Additionally, there is our industry track-record, and goodwill. What we are seeing now are opportunities to work in the injectables space for clients we've had for



Figure 1: Bepak is known for its extensive world-class manufacturing and assembly capabilities.

“Bepak auto-injector technology and IP is in multiple single-use disposable auto-injectors launched on the US and European markets and we have a number of others now coming through the pipeline using our novel VapourSoft® technology.”

many years in other areas. Bepak has had the opportunity to work with the biggest and the best biopharmaceutical companies in the world. By leveraging that past experience and trust having worked with them, we feel that it’s an excellent connection with the injectables side of the business.

At the same time, we’ve had instances where we’re working on the injectable side and that has also sparked other opportunities. As I said before, we’re looking increasingly at our final assembly offering in the injectables space and this really is

an excellent way for us to differentiate. Bepak is one of the few – possibly only two – companies that have a launched device and final manufacturing and assembly capabilities, whereas in other instances it would have to be the pharma company themselves or a contract filler who would have to perform this role.

Q Tell us about Bepak’s injectable delivery device portfolio in a little more detail?

A So in terms of auto-injectors, we’re divided up into spring-based and VapourSoft®-based. Within spring-based we have simple aqueous auto-injectors. For example, Dr Reddy’s Laboratories use our technology in their Sumatriptan device. And then there are the spring-based devices for higher viscosities.

With VapourSoft® we have the Syrina range (see Figure 2) which includes the micro, the mini and the three versions of auto-injector – the S, the AS,

and the AR. So Syrina S has manual needle-insertion, needle shield extension; Syrina AS has automatic insertion and needle-shield extension; and the Syrina AR has automatic needle insertion and automatic retraction.

Then in addition to the auto-injectors we have the wearable injector, Lapas® which uses our VapourSoft® technology. We have lots of exciting work to do in that area – some of that is driven by customers and some of it is internal.

Finally, we have Lila®, which uses our stopper-valve technology and enables sequential injections. We can place this stopper-valve in between two different liquids – ie two drugs – and then we can inject those. This is great for companies with products that have co-formulation issues, and several companies are interested in that technology.

Bepak technology is in multiple single-use disposable auto-injectors that are launched on the market and we have a number of others now coming through the pipeline using VapourSoft® technology. What we’re really trying to focus on though is keeping up the quality, delivering on our promises to meet expectations, and also anticipating what’s next.

I would like to talk a little about what I think could be next. You know, everyone keeps talking about platform devices. I keep hearing this everywhere but there a few true platform devices. One of our devices though could be the solution to that challenge – and that’s the Syrina S.

The Syrina S (shown in Figure 3) is the smallest 2.25 mL auto-injector available in the market today using a standard primary container. Also, with minimal change it becomes a 1 mL device. So now we have the potential to use Syrina as a platform for both 1 mL and 2.25 mL with only one changed component, and all assembly processes will be exactly the same.



Figure 2: The Syrina range comprises, left to right, the micro, the mini and the three versions of auto-injector – the S, the AS, and the AR.

We know that the Syrina S is being looked at more and more now by industry as a platform. Some companies, because of the type of formulation work they're doing now, don't know whether it's ultimately going to be a 1 mL or 2 mL injection. So it's great to have one device good to go where, depending on the final dose volume, they can just swap out one component depending on whether they need a 1 mL "long" or 2.25 mL device. The benefit can translate into two years of time saved.

Q You joined the company relatively recently and at an exciting time in its evolution. Would you be able to tell us more about that? What about Bepak interested you? What is your role within the organisation? What are your aims?

A I've been at Bepak for more than two and a half years now. I've relocated back to North America and I work in a truly global role for Bepak, spending a fair amount of time in the UK

but with a focus on the US, Europe and at times APAC too.

Previously I had the opportunity to work with the market leader SHL and I loved that experience. I worked with a lot of terrific people there and had some exceptional mentors. It was at PDA 2013 in Basel that I first saw the technology that Bepak was bringing into play. When I saw that technology, and the mindset of introducing a disruptive technology that was really out of the box, I realised right away what it could achieve. The second I saw it demonstrated to me, a lightbulb came on and "boom"! It was exciting. I always kept that in mind and then when they offered me the opportunity to relocate to North America to work and to lead business development in the area of injectables globally, I agreed.

So my job title now is Global Business Development Lead and what that means is that any programme that we have that involves an auto-injector or any kind of injectable device, I'll be involved whether the company we're talking with is somewhere in the US, in Europe or in Asia or anywhere in the world. I've always wanted this kind of global role. I had something similar when I was working in marketing but I hadn't previously had it in business development where I focused primarily on the Asian market with some work in Europe and the US.

What I gained and continue to gain from having had this transition over to this new role is experience of another way of doing things. On one hand I have the benefit of working in a company that has 60 years of experience being very well regarded in their industry, and on the other I have the freedom to work with new people and build up new relationships.

As for my goal, I want to ensure that Bepak is recognised as a key player in the injectable devices field. With two launched devices using our technology, we can comfortably claim to be a player of course, but I want more. Additionally, I want Bepak to be viewed by the global industry as among the most innovative companies

in the area of injection devices for highly viscous drugs and high volumes.

I spend much more of my time building relationships, helping to find solutions and negotiating now rather than promoting, and within those negotiations I'm talking a lot about freedom to operate and IP, and really finding the right solution for our clients rather than selling to them. It's kind of nice. We're creating deals that really deliver for our partners, based on timelines we can all keep to.

Q Both today and into the future, what do you see as the most significant demands from the industry on injection device companies like Bepak, what drivers are behind those demands, and how does Bepak meet those demands?

A I've already mentioned high viscosity and high volume. I think the key demand is for a technology that can deliver these kinds of formulations but at the same time coming from a company that can offer solutions in terms of manufacturing infrastructure. Reducing time to market is another major demand and, as always, cost is a critical consideration.

I think we're there as far as having the technology and the infrastructure but we will continue to build up our infrastructure. We have a facility in Milton Keynes (UK) that we're going to expand. It's going to house some of our injectable programmes in the future. We also have our facility in King's Lynn (UK). What we're doing to prepare for all of the different programmes that will be coming through is to put more of the right people in place.

Bepak is really good at producing billions of components and assembling them into hundreds of millions of devices. We can do that. Now we are looking at ensuring we are able to produce just millions of devices comprising tens-to-hundreds of millions of components. So it's a bit of a shift. Companies like Bepak know how to scale – as we produce at these smaller volumes and then, should the market change, ramp up rapidly. Our unparalleled tooling, moulding and assembly experience are critical – we don't talk about this enough. You have to get the tooling right because this impacts on your ability to supply the market. To me the subassembly line and the tooling with moulding are the most significant elements determining cost and



Figure 3: The Syrina S, pictured here with the AR, is the smallest 2.25 mL auto-injector available in the market today using a standard primary container.

investments in any of these programmes, and pricing is an important consideration of course. There is huge pressure on pharma companies to keep costs at affordable levels.

With some of the other companies' solutions we've seen for highly viscous formulations, the costs appear to be rather high – really premium prices. But if you look at the price-points of the systems we're offering they are still within the range that pharma companies feel comfortable with.

Q What are the major technical challenges injection device manufacturers are facing and, in a highly competitive environment, how does Bepak differentiate itself in the way it approaches these challenges?

A We typically work with partners who have experience with drug delivery devices, but their spring-based systems are now coming up against major challenges. These companies are now saying, "Hey, you know what, we can't get the formulation down below 1 mL so it's going to be a 2 mL formulation or more. And we can't get the viscosity down below 30 cP, and we're having real big issues with stalling and injection time. What solutions are there?"

I'd like to think our VapourSoft® technology is unique. We have strong IP behind it. We were one of the first companies that put forward a technical solution to the major challenges of delivering high volumes and viscous formulations that we were confident would work.

Another aspect is the technology challenges around the equipment. Some companies when they need to develop subassembly systems, they usually throw people at it. We don't. We work with the best subassembly line suppliers in the world and the best toolmakers in the world. We've got people that could build everything on-site, but we prefer to work with companies that specialise, and we oversee the work they do on behalf of our clients. We're not looking to make money from our clients on their tooling and their subassembly equipment. What we're looking to do is to put a good system in place that allows them to have an optimised production process set up within Bepak.

We have that technical expertise for setting up all these different programmes – whether it's for an inhaler, or a medical check valve or a 2.25 mL auto-injector. We run our systems at a higher level; not only Six Sigma but we're also running the majority of our programmes in clean-room

environments. Most other companies will be doing this in a GMP room or white room. We try to raise the bar as far as standards go for the production of our devices. We know the value of the drugs is high and we know that any challenges with the devices can lead to really serious issues for pharma companies, so they have to have confidence in the systems we're producing. Being able to troubleshoot, having this deep technical expertise and an excellent reputation, the Six Sigma quality system and regulatory affairs, having clean-room environments – all of these sorts of things combine to give a solid and valuable proposition.

Q In addition to unique technical characteristics of its devices how, in a broader sense, does Bepak set itself and its offering apart in the injection devices space?

A This industry is booming and the market is showing an extraordinarily strong demand for devices like ours. Now, the fact is that one or two companies can't make all of these devices. We need five, maybe up to ten companies.

Bepak is not trying to dominate the auto-injector space in the manner that other companies do. We have great regard for the market leaders and key players in the device field. What Bepak offers is simply world-class, excellent design, development and manufacture for customers see value in our IP and a fit with the unique technology that we have.

There is disappointment out there in the industry from biotech and pharma companies who have not been able to achieve what they expected, when they expected it, from their device programs. We are not interested in raising expectations beyond what is possible and are absolutely clear about telling our partners and customers what we can do and what we cannot. We care about making sure that the solution that we're offering is a fit, and the best solution possible, and that we can work to the timelines specified.

We are a well-established organisation. I don't know that there are many other companies that are 60 years old in this industry. It's a company that's publicly listed, under our parent company, we are well vetted, and transparent. I think it's great that Bepak is open about challenges that we face with clients, and works together to find solutions. We're very much a European company, but the irony is we work with so many American companies

right now and the question becomes, why is that? I guess this is because some of the US firms are early adopters of new technology. This is the reason so many of them have quickly approached us. So despite being a European company, we have a truly global mind-set and work very well with our US biopharma company partners who represent a lot of what we're doing right now. Clearly we will look to expand our footprint to the US in the near future with the response we have received.

We are eager about the next year or so when the names of some of the companies – US and otherwise – we are currently working with become public as more products begin to enter the clinic and to be launched. These are exciting times.

ABOUT THE COMPANY

Bepak is a full-service drug delivery partner, specialising in innovative patient-centric medical devices. Bepak partners with its customers to design and develop innovative world-class drug delivery solutions, as well as providing "off-the-shelf" proprietary products and contract device manufacturing services from pilot to commercial scale. With more than 50 years' experience in drug delivery we apply our proven know-how and technologies to address the ever-changing needs of the pharmaceutical industry, across multiple applications.

Bepak's portfolio of proprietary products includes devices for injectable devices, inhalation, nasal and ocular technologies, as well as point-of-care diagnostics know-how. Working in conjunction with many of the world's pharmaceutical companies, the company consistently provides regulatory-compliant devices critical to the delivery of therapeutics for treating a variety of medical needs.



BESPAK
A Consort Medical Company

Mr Steven R Kaufmann

Global Business Development Lead

T: +1 519 878 8866 (EST)

E: steven.kaufman@bepak.com

Bepak Europe Ltd

Bergen Way

King's Lynn

Norfolk, PE30 2JJ

United Kingdom

www.bepak.com



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