GLOBAL EXPANSION AND A DEEP COMMITMENT TO PRECISION DRUG DELIVERY DEVICE COMPONENT MANUFACTURE

– AN INTERVIEW WITH JULIEN MARTINS & DAVID PHILBRICK OF PARAGON MEDICAL

In this exclusive interview, Julien Martins and David Philbrick talk with ONdrugDelivery about Paragon Medical's recent expansion. They discuss a wide range of topics, including the services Paragon Medical can provide the drug delivery industry, its wider business operations, the company's expanded facilities in the US and Europe, and its new Advanced Surgical Innovation Center.

Julien Martins is Director of Business Development – Europe at Paragon Medical. With an Engineering degree he joined Paragon Medical 15 years ago, and has held various roles in engineering, operations and business development. He is responsible for developing the drug delivery market in Europe for Paragon Medical.

David Philbrick is the New Business Development Manager for Paragon Medical. Mr Philbrick supports various Paragon Medical engineering and commercial team members with new product development tasks. He also interfaces directly with customer teams through early-stage project development. His experience of over 43 years in engineering management and product development, including disposable medical devices, has led to numerous manufacturing innovations that have earned him many shared patents with Paragon Medical's customers and partners.

Q To begin with, please could you provide an overview of Paragon Medical as an organisation? What does the company offer and who are its partners and clients both more broadly and specifically in the drug delivery device space?

JM In summary, Paragon Medical is a contract manufacturing organisation (CMO) that works in the life science industry, including drug delivery systems (Figure 1). We are a large, international company with a global footprint, with facilities in the US, Europe and in China; we have 15 campuses in total. All these facilities come from organic and inorganic growth. We have over a century of combined expertise in high-precision manufacturing, advanced engineering, and design support. With facilities across the globe, we can lean on the varying expertise within each of our locations in order to provide an integrated, end-to-end supply chain solution for our customers.

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We have experience working with Top Five OEM companies in each of the medical industries we operate in.

DP Our work with drug delivery is interesting. We find that a lot of design and engineering for drug delivery devices, such as wearables and autoinjectors, is based in Europe, but the production manufacturing is more global. For example, for a North American launch, we would have to have direct manufacturing in the US to support American production. On the other hand, if the products are going to launch in Europe or Asia, then we would want to target launching production there.

JM It's worth mentioning that part of the reason for this is to align with local regulatory standards, as well as proximity to our customers and the target market. So far, Paragon Medical has been pretty successful in the drug delivery devices market, but we did that primarily from the US. However, we've seen that, as a global contract manufacturer, best results require proximity to our customers, which is what we do in the other segments we operate in. So, with drug delivery being one of our most important segments, we want to be able to support our customers locally the same way we have been doing in the US.

We have also seen that having local operations is key to sustainability objectives. This is becoming an increasingly important consideration for our customers in the industry, so we need to be able to provide local manufacturing – Europe for Europe, US for US, Asia for Asia. This is the direction we're steering in today.

Q What sectors does Paragon Medical operate in outside drug delivery?

JM Paragon Medical initially started in the orthopaedic industry, where we make implantable

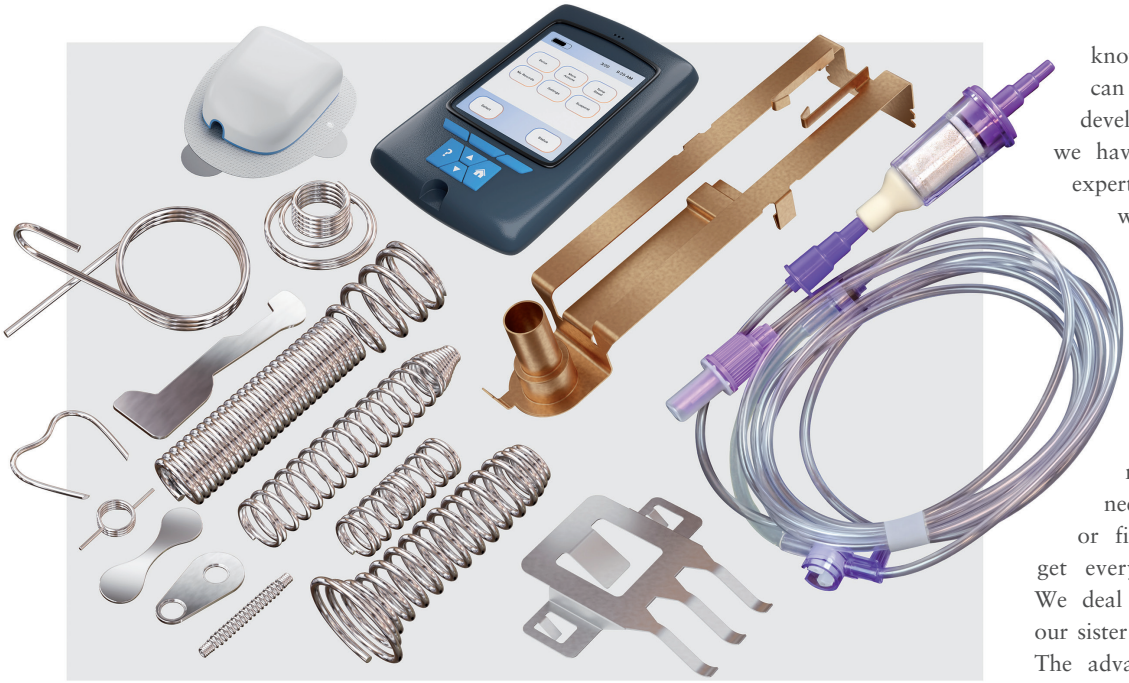

Figure 1: Paragon Medical serves a broad market crossing multiple anatomical, technological, and procedural segments.

components, instruments and cases & trays. Since the acquisition by MW Industries, we are also active in other life science segments, such as robotics, cardiovascular and dental. We now have a much larger portfolio of capabilities and services that we can offer across the different life sciences.

DP Not only are we a contract manufacturer ourselves, but we also support some of the very largest contract manufacturers in the world in the drug delivery space – we work for everyone. We own the relationships. Even when we're supporting a project with a CMO and we're not the engineering firm, we end up owning a relationship with the original equipment manufacturer as an outcome of the relationship.

Q Can you give us some examples of the metal components Paragon Medical provides to the drug delivery industry?

JM We produce a wide variety of components. For example, our facility in Southington (CT, US) has extensive expertise in making springs and stamped metal parts and components of different complexities and sizes. However, we also make other types of components, such as hypodermic needles, and we have support for connected devices that require electronic components. We have also a facility in Bridgeport (CT, US) that works together with Southington when there is a need to do assemblies in a cleanroom environment, or when there is a need to do some moulding.

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We have the advantage that we have a lot of sister facilities that have different capabilities. For example, Southington is the expert for wire forming, coiling and metal stamping, but we also have facilities that are expert in moulding or expert in computerised numerical control (CNC) machining, such as turning, grinding or milling. This means that we can use the expertise of the sister facilities as necessary to support the needs of each individual project.

Q How would you say Paragon Medical is uniquely positioned to serve the requirements of its drug delivery device partners and clients?

JM In large part it's thanks to our global footprint and the different life science segments that we cover. We have a large portfolio of capability and knowledge at Paragon Medical that we can use to support drug delivery system developers. We have CNC knowledge, we have moulding knowledge, we are experts in coiling and stamping, and we can use all that knowledge and expertise together under the same roof, which is the key to how we can help our customers to reduce their supply chains. If you have a project that needs spring stamping parts, CNC parts, moulding parts and hypodermic needles, rather than going to four or five different suppliers, you can get everything from Paragon Medical. We deal with the supply chain because our sister facilities can simplify everything. The advantage is that Paragon Medical only operates in the medical and life science industries, so we are ISO 13485 certified for every single facility and we have embedded knowledge about the requirements and the regulations required for life science manufacturing.

DP One of the key drivers that really brought a lot of our success is the engineering support that we provide up front. For a lot of products or projects we get involved in, we're usually providing engineering support for one to two years before we even get to run our first validation. We provide all of our customers with this direct engineering support up front as the project progresses through design verification. Our customers ask us, "Are you in it for the long haul? Are you going to stick with us and help us until we get this thing commercialised?" We provide that service directly for our entire global network of companies in addition to regulatory support.

JM We also understand our customers' need to have trusted partners that can help them in developing their projects from ideation. We understand that there is a lot of validation to run, there is a lot of complexity, there will be a lot of changes, etc. To support this, we can take the expertise that we've gained across the different industries we work with and draw out the best of each and use those lessons to inform current projects.

For example, we have an innovation centre in Warsaw (IN, US), initially focused on the orthopaedic market – that has been so successful and so in demand by our customers

Figure 2: In Spring 2023, Paragon Medical opened its 65,000 square foot manufacturing facility in Siechnice, Poland, as part of its ongoing effort to serve the European and worldwide markets.

that we have decided to open a second innovation centre focused on drug delivery. We started to build that last year. Now, it is up and running and is a perfect example of the benefits Paragon Medical can offer – helping our customers to develop processes, undertake rapid prototyping and launch their products to market as soon as possible, all while reducing costs. We want to accompany our customers from the very beginning up to the launch of the product.

Q Could you give us a rundown of Paragon Medical's expansion programme and the benefits it offers to drug delivery device partners and customers?

DP We expanded our Southington facility about three years ago. We had to expand because we outgrew our footprint and there wasn't enough physical space to build out a building big enough to double or triple the size, which was the scale we required. Instead, we ended up selling our building and moved about a mile away into an approximately 24,000 square metre building, which essentially tripled our capacity for manufacturing there. Our company invested in additional machinery as well as moving our existing equipment. It's been pretty exciting to see a modern, state-of-the-art facility doing the precision work that we do.

A lot of the drug delivery projects that we work on also demanded that we increase capacity on very popular products. Before we moved to our new building, we had around 10% of our overall equipment dedicated to specific drug delivery products; now, we have approximately 45% of our equipment dedicated to this market segment, even in an environment where we added 30 or 40 more machines. They're all dedicated machines for certain product lines. It's pretty exciting to see.

As this market continues to grow, even our competitors have to invest because the global manufacturing footprint doesn't have enough equipment to meet the expanding demand in the drug delivery segment. We all have to continue to invest to meet the current growth.

JM Alongside moving into the new building in Southington, another thing that we've done is to put presence in Europe for our European customers. The first thing that we've done is to add the team that we have here in Lausanne, Switzerland, which is a sales and business development team. That's where I'm based, with a focus on developing our drug delivery market in Europe.

We've also decided to expand our existing facility in Poland, which was primarily working on orthopaedics. We've bought the building next to our current building, which is 6,000 square meters, and we completed the building work earlier this year – we had a grand opening back in March of this year (Figure 2). This new facility is going to be dedicated to serve the surgical and drug delivery sectors as needed. We've already received the first coiling and wire forming machines to make springs for drug delivery devices.

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The goal is to continue expanding our capacity for drug delivery projects; we're listening to our customers in Europe to see what they're looking for, what they're missing and how we can help them from there. Our plan is to use the same strategy that we have in the orthopaedic industry, which is having a local presence in the EU to help our customers in Europe, having a local point of contact and a local contract manufacturer that is just a one- or two-hour flight from them. It makes everything easier – they can visit our facilities, while our team is working in the same time zone, and a number of other benefits.

DP It's going to be very easy to grow our European footprint in Poland. Poland is just getting started, but the equipment is all state-of-the-art manufacturing equipment that's a good fit for the work that we're going to do

"The ASIC's objective is to help customers develop new products, provide rapid prototyping and facilitate a smooth transition from ideation to prototype and from prototype to launch."

there. So, it's going to be very easy for our European sales team to provide manufacturing services on products that are going to launch in Europe. We're going to have the capability to launch in the Americas or in Europe, depending on what market the customer wants to serve first.

Q Can you tell us about recent advances with Paragon Medical's Advanced Surgical Innovation Center (ASIC)?

JM The ASIC is a new product development centre we've built at our Southington facility. We have something similar for our advanced orthopaedic industry operation in Indiana, so we decided to do the same for our advanced surgical and drug delivery business because we see the intrinsic value to our customers (Figure 3). The ASIC's objective is to help customers develop new products, provide rapid prototyping and faciliate a smooth transition from ideation to prototype and from prototype to launch. We're going to have state-of-the-art machines there. It's going to be completely independent from the production facility, but will have the same type of machines; this is where the advantage comes from because we build the prototype on the ASIC machines and then, when the process is created, easily transfer it to the machines and processes in the main production facility during scale-up.

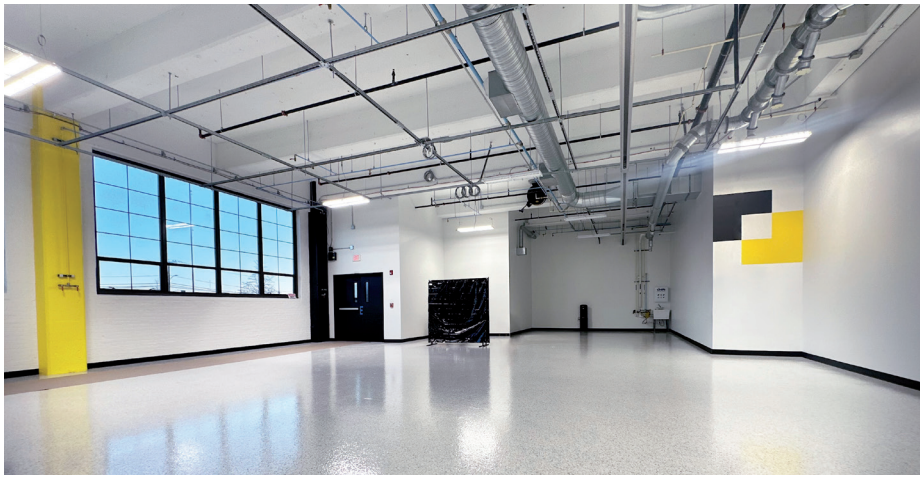

Figure 3: With an expected grand opening in late Summer 2023, Paragon Medical's ASIC offers 4,000 square feet of space dedicated to new enterprise innovation, rapid prototyping, process and equipment development, production and assembly.

The ASIC has some of our most knowledgeable people in terms of skills – the best designers, engineers, etc. These are the people who are going to create the concept, create the process and then deliver to the other facilities. So, this centre is going to support not only Southington but also our facilities in Bridgeport, Mansfield and Poland with the same service.

DP The equipment that we've brought in so far includes wire machines, CNC hole popper machining centres and three axis machining centres, and we've got another dozen pieces of equipment that we'll be moving in over the next two weeks. The ASIC is going to be a completely built-out facility. Their entire project board is already completely full for the next month and a half on projects with all types of customers. It's really fascinating to watch how quickly this is happening.

Customers come to us when they know they want to get high-precision products that can be commercialised through the DFM process. We help them make the process acceptable for the required robustness of their device. We're the ones that can run the design verification tests or pre-production to verify the process is accurate. You can't get that in a prototype house. You'd have to go to the source where you're going to do your manufacturing.

Thanks to our experience, we know what it takes to commercialise a product – it requires investment, and a CMO has to be prepared for that growth cycle. One of the strengths of our entire organisation is our SIOP process where we manage a customer's forecast. We even help the customer build

a forecast even if they don't have one themselves, which helps us predict when we have to buy equipment and machinery at any given point in the growth cycle, which is a really important factor that you have to pay attention to.

Q Can you elaborate on who at Paragon Medical is driving your European expansion in the drug delivery market?

JM Regarding our European operations, I've worked for Paragon Medical for 15 years in different roles. I started as an engineer, then I moved to project management and business development. I'm located in Lausanne, together with Kees De Louw, who is our sales director for Europe. He has extensive experience in the orthopaedic and life science industry. Both of us report to Greg Hall, who is our Director for International Business Development, meaning that he's responsible for all business development activities outside the US. Greg has worked for Paragon Medical for over 30 years; he was one of the first employees and, again, has extensive experience in the industry. That's our core business development team.

Then we have Dave, who probably has the most experience in the drug delivery space. We all have experience in the life science industry, but when it comes to drug delivery specifically, Dave is probably the one who has the most, coming from a very technical background. Dave brings several things to the table; he knows a lot of people in the drug delivery industry, he has a thorough understanding of industry trends and his technical background is very helpful. His support is key when it comes to helping customers with developing new products. That's the core team. There are a lot of others who are helping to develop our European presence, but if I had to name the core team for the development of drug delivery outside United States, it's the four of us.

> "It's pretty amazing to watch our global reach continue to grow. We've got a very, very strong team."

DP Naturally, our customers are global in nature too. So, if they choose to source in America, that's fine, but we're getting very established and able to support projects anywhere in the world. We also export a great deal of products to Asia. It's a very exciting time for us; we have both Japanese and Canadian customers coming on board. In Latin America we already have a strong relationship with several facilities in Mexico, the Baja Peninsula and the Caribbean. It's pretty amazing to watch our global reach continue to grow. We've got a very, very strong team.

Q Any final thoughts you'd like to share with our readers?

JM I'd like to elaborate a little on our expansion at our Poland facility. A major driver behind the increase in capacity is to provide local manufacturing for our European customers, but that doesn't mean that the Poland facility is solely going to serve the European market. It can also serve the US and global market and act as an extension of Paragon Medical's Southington operations. Say, for example, we have customer with an insulin product that's growing with a big ramp-up. With the Poland expansion, we're going to be in a position to provide that customer with a mitigation plan by dual sourcing the product using both the Poland and Southington facilities.

DP We currently have 15 business locations, including some that have multiple buildings on a campus, and we're continuing to expand and invest. This month we are celebrating the grand opening of a new building on our Pierceton (IN, US) campus where we have an additive manufacturing facility offering 34,000 square feet of manufacturing and operational space dedicated to 3D printing.

I'd also like to mention our Automation Equipment Services (AES) briefly – one of our locations has a team with dedicated engineers building automation equipment for our plants, including sub-assembly of components for drug delivery. A lot of our AES work is around drug delivery assemblies and specialised packaging to help our customers be efficient with how they want to introduce our products to their automation lines. It gives us the ability to support all of our locations with an automation team that builds specialised equipment.

At Paragon Medical, we are in a good spot right now and we have great customers. Our customers don't just come to us once; they come to us over and over again for their next development project. It's a constant cycle of new things. It's a very exciting time for us.

ABOUT THE COMPANY

In today's challenging healthcare environment, the right contract manufacturer can help simplify the complexities of supply chain management and expedite product commercialisation. Paragon Medical is a trusted partner for the drug delivery industry, serving as an extension of development teams by delivering world class operational excellence and sales, inventory and operations planning with over a century of combined expertise in high-precision manufacturing, advanced engineering and design support.

Paragon Medical is a strategic partner for medical device manufacturing, offering an end-to-end supply chain solution from initial concept and product development to verification and validation testing, final production, assembly and ongoing strategic demand planning, with differentiated and personalised solutions designed to exceed expectations every time.

Paragon Medical

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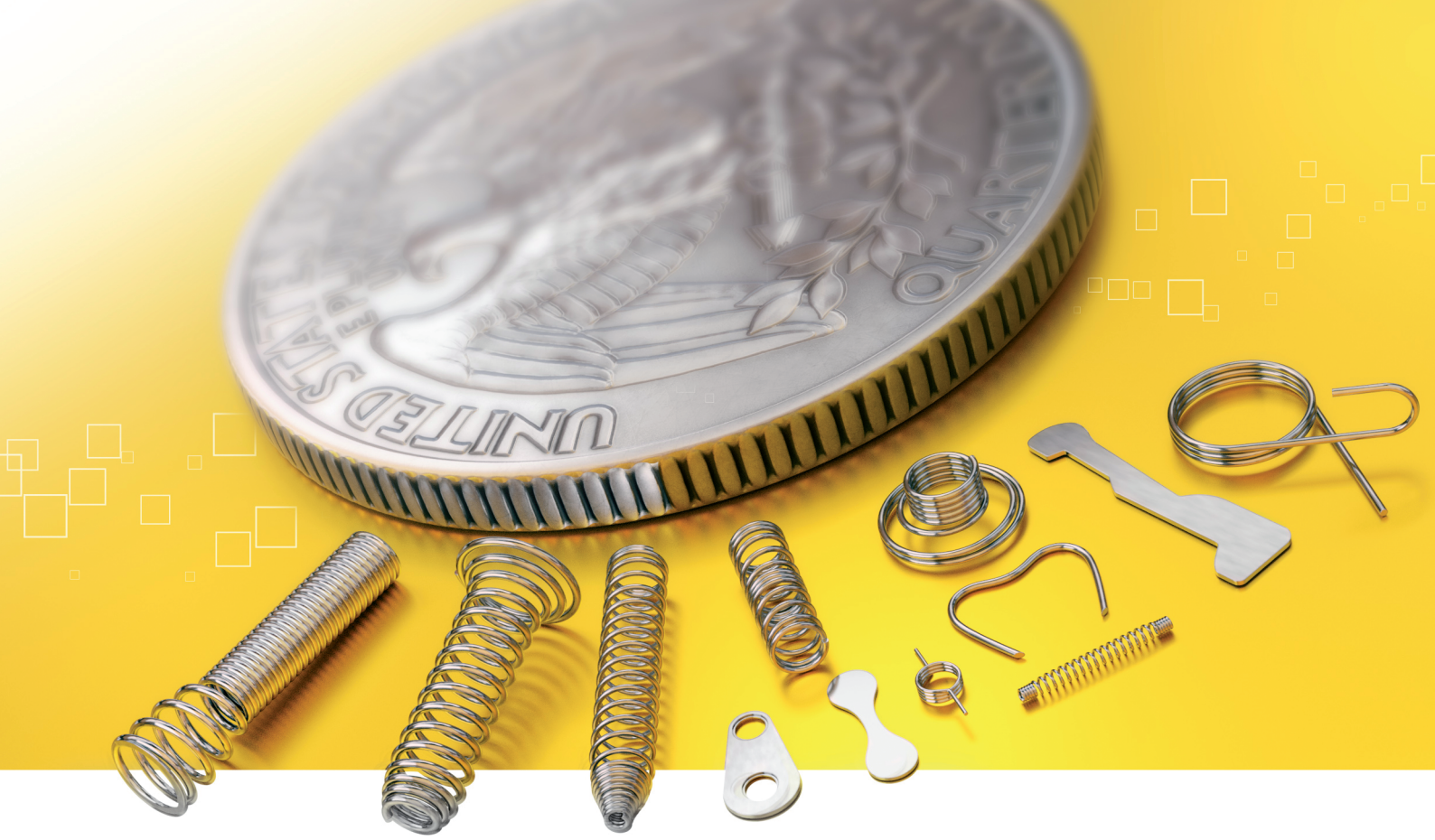

Our passion for service enables your team to design the next **breakthrough innovation.**

As your trusted partner with a shared commitment to quality, you will feel confident as we come alongside to serve as an extension of your team by delivering world class operational excellence through over a century of combined expertise in high-precision manufacturing, advanced engineering, and design support. Discover how you can experience a consistently remarkable partnership through Paragon Medical's differentiated and personalized solutions designed to exceed your expectations every time.

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