INTERVIEW

In this exclusive interview, Scott Ariagno talks with ONdrugDelivery's Guy Furness about the role that contract development organisations play in the drug delivery industry ecosystem and how independent expertise can enable companies like EdgeOne Medical to troubleshoot and accelerate product development by bringing fresh eyes, an unbiased perspective and extensive expertise to bear on a development project. Furthermore, Mr Ariagno goes into detail on the unique advantages that EdgeOne can offer over others in the field.

SCOTT ARIAGNO,
EDGEONE MEDICAL

Scott Ariagno is Vice-President of Engineering and Development Services at EdgeOne Medical and has over 25 years' experience in medical device and combination product design, development and manufacturing. His expertise includes development and global launch of various single-use, disposable medical devices, infusion systems and combination products, strategic/technical development of device platforms and intellectual property development. Throughout his career, he has held management roles in engineering, including heading device development at Baxalta (a subsidiary of Shire, now Takeda). Mr Ariagno is a named inventor on over 20 patents and applications. He has a Bachelor of Science degree in Mechanical Engineering from Bradley University (Peoria, IL, US) and a Master in Engineering Management from Northwestern University (IL, US).

Q Many of our readers will be familiar with EdgeOne Medical already but, for those who aren't, please could you begin by providing an overview of the company and its culture?

A EdgeOne Medical is an ISO 13485-certified medical device contract development organisation, or CDO. What that means is that we're in the business of supporting medical devices and combination products at any stage of their lifecycle. Customers come to us in the early concept design stages, and other times they're looking for support in the planning and verification stages. We've even been brought in much later, such as during manufacturing transfers or resolving design or manufacturing flaws for marketed products.

EdgeOne has deep knowledge across a wide variety of drug delivery platforms and across all stages of their development, including autoinjectors, pen injectors, prefilled syringes, on-body injectors and inhalers. We also work on complex systems consisting of electromechanical hardware, software and disposables that are used to deliver cutting-edge gene therapies across the blood-brain barrier to systems that are designed to replace organs.

Since the company's founding in 2012, we've worked with many, many pharma companies, from small biotech start-ups to big pharma. That variety really keeps us on our toes and our skills sharp, especially when working with biotech firms that are developing bleeding-edge technologies.

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Regarding our culture, I would say that it's rooted in our core company values. The thing that we really hold near and dear is making sure we're a tight-knit team – we're really focused on building trusting relationships, both within our team and with our clients. Second, we strive to be humorously serious, meaning that we're both passionate about what we do and that we always let our humour shine through in the work that we do.

Another key thing we do at EdgeOne is ensure that what we say is grounded in data – right at the heart of our culture is our engineering laboratory and all the testing we do there. We understand that it's always critical to demonstrate and back up our conclusions and recommendations with data. This is especially important when we're delivering bad news, such as a client having picked the wrong delivery system for their specific drug, or one that's incapable of meeting a design requirement. We make sure to communicate with a human element that covers the logical thought process with data, but also remains respectful and straightforward.

Q And how about your own career, what's your background in the drug delivery sector and current role at EdgeOne?

A My educational background is mechanical engineering. I spent the early years of my career deeply engrossed in computer-aided design. Working at a top medical device company, I took several medical devices all the way from a back-of-a-napkin sketch idea through to a commercially launched product. I'm especially proud of my work in the field of vial-access devices; I've spent a lot of time trying to figure out optimal ways to access drug products from vials. I've come up with some really clever systems that have been successfully commercialised and improved the patient experience over many years on market. To this day, that design aspect remains my true passion, and I find ways to reconnect with that as often as I can.

Another really valuable aspect of the middle of my career was gaining deep and meaningful experience with manufacturing. I learned the arts of moulding, machining, bonding, automated assembly – all the nuances of how to design robust manufacturing processes and how to debug them.

Today, I take all those foundational experiences in design, testing and manufacturing and apply them to my current role as Vice-President of Engineering at EdgeOne, working closely with a talented team of engineers. While I've always preferred a hands-on approach, which means I gravitate to the laboratory and the high-tech tools, I now combine that with leading and mentoring the team, ensuring that the team make the breakthroughs we need together. That can mean anything from working with high-speed video or computer tomography scanning through to 3D printing or implementing some unique sensors into a laboratory experiment. I really get a kick out of learning through that hands-on approach and putting a device through its paces. The depth and breadth of my background enables me to lead the team to solve EdgeOne's clients' most difficult challenges.

Q Could you outline the fundamental rationale for engaging an independent expert for drug delivery product development and describe the solutions that EdgeOne offers?

A One of the fundamental things to keep in mind is that drug delivery product development is, at its core, a risky endeavour. That applies whether you're going from scratch or trying to put your latest drug into a popular prefilled syringe platform. It all comes with some level of risk. It's your job and duty as the product development team to systematically retire those risks. The stakes are high and the rewards are high. The expertise of a company like EdgeOne can make all the difference – we're a secret weapon to help our clients reveal blind spots that they may not even be aware of themselves and eliminate risks they can't on their own.

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Being independent enables us to give each device a fair and objective look. Being free of burdens like sunk cost is hugely important, which, coupled with our expert knowledge, puts us in an excellent position to identify problems and move a project forward. There are always multiple ways to test a device and multiple ways to solve problems, so it's important to have the expertise needed to recognise and act on those options.

At EdgeOne, we've got a proven track record where we've taken years off development cycles by helping our clients avoid pitfalls and make swift corrections. It's all about having that expertise, recognising what the pitfalls are early on. When we're not responsible for the design, we can approach problems with a fresh outlook and fresh eyes, without as any biases and preconceived notions that can colour our thinking.

Q You mentioned experience as a key aspect of EdgeOne's offering – can you talk about the experience at hand within the EdgeOne team?

A We take great pride in the fact that EdgeOne is made up of a strong, cross-functional team, led by a team of leaders with over 100 years of combined experience in combination product development. Many of us have taken multiple products to market – we've successfully developed products from idea to marketed product. Having been through that process earlier in our careers, we've learned many things that are important to our clients and combination products. One such learning is knowing how to effectively communicate with drug and biologic experts to ensure that a delivery device is going to work seamlessly with a drug.

Another key differentiator is that our team has worn many hats across the pharmaceutical and medical device industries. We've not only held leadership and engineering roles but have also executed highly successful programmes in the same environments that our clients operate in today. It's important for our clients to know that we've walked in their shoes – we recognise the pressures they're under and the challenges the industry faces. This gives us a distinct ability to bring different perspectives together and adapt to the dynamic demands of our clients' projects. For instance, I lead a team of experts in design and laboratory testing, leveraging our collective product development and manufacturing expertise to improve our clients' products. And we work side by side with other EdgeOne resources – best-in-class project management and regulatory experts and quality professionals. Bringing all these interwoven disciplines under one roof is what makes us special.

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Q Can you elaborate on how EdgeOne enables a way of working that is uniquely valuable for its clients and partners?

A EdgeOne is both cross-functional and largely co-located. We place strong value on all having a common place that we come to every day to get our work done. A key hub for us is our on-site laboratory, something truly unique in our industry. All the company's functions are connected to that, and the magic of what we do often happens because of that proximity.

Having a diverse, and highly technical interdisciplinary team working together in the same place as often as we do makes us really agile and enables us to take a seamless approach to our work. It speeds up the whole process of gathering the information we need and delivering it right back to our clients – speed and time to market are the key currencies these days. So whatever EdgeOne can do to speed up our own processes and our own discoveries, that's inherently to the benefit of our clients.

Most importantly, we do not view ourselves as a transactional organisation. An example of what I mean by that is, say we're executing a test for a client, they don't pick a test off a menu then have us execute it, hand them some data back and walk away. We always undertake our work in the context of understanding exactly what it is that the client is trying to achieve, which gives us an edge in being able to offer advice or recommend approaches that our clients might have missed. We've lived and breathed drug delivery systems for our entire careers and they're what we're passionate about – it's a topic that we're excited to talk about and work we're excited to do.

Q At what stage in drug delivery product development should industry clients engage EdgeOne?

A There isn't a "gold standard" for the ideal time to engage with a device development organisation like EdgeOne. That said, based on our experience with clients over the years, I believe that the best time to start talking to us is as early as possible in the process. This is where EdgeOne's value truly multiplies. A great example is during the process of selecting a delivery device platform. When clients involve us at this stage, we can actively facilitate discussions with device suppliers and contract manufacturing organisations. The earlier we collaborate, the more opportunities we have to anticipate challenges and streamline the process.

On top of that, we're able to provide a significant amount of help with developing foundational programme documents, such as design input requirements, development plans and risk assessments. We can also co-ordinate very early characterisation testing at that stage to help the pharma companies have confidence that they're picking the right device and that they're on the right path to achieving regulatory success.

Another common engagement point for us is when clients run into a roadblock. For example, their device may be struggling to meet a specific requirement, or their current partners aren't making enough progress on a solution, leading to frustration within their teams. In one case, the client's device was experiencing high activation forces and we had to work with the existing internal design and manufacturing teams to solve the problem in firefighting mode. In other cases, we have actively engaged with clients that are dealing with persistent issues with devices already on the market, and then helped those clients to resolve these challenges successfully. The key for us there was coming in with fresh eyes and a clean slate, letting us discover overlooked factors that got those teams unstuck and the project progressing again.

Q Can you provide some examples of common missteps that you've seen clients make and how EdgeOne can help to head these off before they happen?

A The most common misstep that I see clients make is underestimating the complexity of the challenges ahead of them. I hear frequently that clients are looking for an off-the-shelf device but, in my experience, there's no such thing when it comes to regulated combination products – they all have a certain level of complexity and nuance to them. You have to pay attention during development as there's no one-size-fits-all solution. Hearing things like: "My combination product is just a syringe", or, "Others have used this syringe platform before so it'll be fine", always sets alarm bells ringing for me.

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At EdgeOne, it's common for us to head this off by applying inverse thinking. This concept has been seen at work everywhere from scientific to financial communities, from Albert Einstein through to Warren Buffett. The idea of inverse thinking is to look at something from the opposite point of view to envision what can or may go wrong in the most complete way possible. Then, with that in mind, you systematically take proactive steps to retire your risks. That is the true fastest path to getting a product to market, in my opinion.

Q The drug delivery industry is constantly evolving, so, with the experience you've built up over your career, can you highlight some recent or upcoming developments in the industry that you think will have a significant impact on how combination product evaluations are conducted?

A You're exactly right that it's a constantly evolving industry, especially with regards to regulatory expectations. I think one thing that has just come out over the summer is the US FDA Guidance on essential drug delivery outputs for devices and drugs. Through the regulatory expertise that we have at EdgeOne, the ability to decipher that and anticipate the implications for our clients' combination product development programmes is right at the heart of what we do.

Even to this day, clients are still reacting to changes to the ISO 11608 series of standards that was updated a couple of years ago for autoinjectors and on-body injectors. One key that I have come to appreciate about regulatory standards over time is that, while they continually strive to add more clarity, there are often some grey areas and room for interpretation. That means the choices you make as a team to follow one path or the other can still comply with the ISO standards. So being open-minded to the variety of possible approaches is important.

Another trend is increased pressure to execute faster development cycles. Multiple pharma companies are often competing across the same target indications, so getting to market faster and combining novel drugs with the best available delivery devices is critical. From EdgeOne's position, whether we're supporting small biotechs or medium or big pharma clients, it's all about getting it right on the first try and getting them on that path to success.

ABOUT THE COMPANY

EdgeOne Medical is a global contract device development organisation that supports the compliant device development and testing of combination products. Since 2012, EdgeOne Medical has been elevating medical device and combination product development teams, including in over half of the global top 20 biopharma companies. EdgeOne Medical has a unique combination of multidisciplinary product development experts combined with in-house ISO 13485 certified testing labs. These capabilities provide clients with the peace of mind that they have complemented their teams with a partner that has a successful track record of de-risking, navigating and accelerating device development programmes.

EdgeOne medical

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