INTERVIEW

Stephen Perry and Nicholas Ciccarelli discuss the August 2021 acquisition of Neuma by Kymanox, highlighting how the acquisition has positioned Kymanox to lead the development of particularly complex drug delivery systems and cutting-edge medical device technologies, providing additional services to progress combination products to market.

STEPHEN M PERRY

Kymanox
Your Life Science Solutions Partner

Stephen M Perry, Chief Executive Officer and Founder of Kymanox, has more than two decades of experience in biopharmaceutical manufacturing with an emphasis on design engineering, scale-up, start-up and regulatory approval. Mr Perry has participated in the US FDA commercial approval of over two dozen unique drugs, devices, biologics and combination products. In 2004, he created Kymanox, a professional services firm specialising in the commercialisation of modern medicines. Prior to this, he held leadership roles at M+W Group (Stuttgart, Germany), Abbott Laboratories (IL, US), FujiFilm Diosynth Biotechnologies (TX, US) and Human Genome Sciences (MD, US). He holds a Bachelor's degree in chemical engineering from the University of Notre Dame (IN, US) and studied at graduate level at Purdue University (IN, US).

NICHOLAS CICCARELLI

NEUMA by Kymanox

Nicholas Ciccarelli, PE, President and Co-Founder of Neuma, an engineering services company, is a principal product development engineer with 12 years of experience in the fields of medical devices and drug delivery. He focuses on analytical design and the development of devices for high-volume manufacture while prioritising design for manufacturing and design for assembly. He has worked extensively on cross-functional teams that span the US, Europe and China. His experience includes individual component design (including plastic injection moulding, stamping, machining, glass, rubber), sub-assembly layout and top-level system integration. He has been heavily involved in design verification activities, *in vivo* study design and execution, and the preparation of premarket notification submissions.

Q How did Kymanox and Neuma team up to work on product development prior to the merger?

NC We have been working together since early 2019, and our teams have established a good rapport. Early on, Neuma was supporting Kymanox on the quality engineering side and, when Neuma engineers were exposed to Kymanox projects, we saw opportunities for educating the Kymanox team on what we do while also learning more ourselves.

Kymanox was uncovering issues with products, documentation, testing and product design and we saw the possibility to bring in more of what we work on – prototyping, building and testing. It's a complimentary set of activities, so this partnership was just building on the strong projects and work that Kymanox was already doing.

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SP Michael Denzer, our Vice-President of Technical Solutions and a member of the Kymanox Executive Leadership Team, made the Neuma introduction shortly after he joined Kymanox. Right away, the two companies were heavily engaged on a post-market programme – the products were already approved, on the market and being used at relatively high volumes. A high-volume product can easily show why it is successful, but problems also come to light. The Neuma engineers got to see something they normally do not get to see: commercial products where the design was being used in the real world every day and generating problems.

That feedback from real-world use then informs Neuma's design approach for next-generation products. Also, the Neuma team

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can provide feasible product updates to improve the design without fundamentally changing a product.

The collaboration between Kymanox and Neuma provides tremendous value to the marketplace. Kymanox is tuned to support commercialisation initiatives while Neuma excels in early stage prototyping and development of that base design. Bringing these two worlds together – having a design and early development team exposed to products that are being prepped for and used on the market every day – makes for better designs and better outcomes for both our clients and their patients. It is a closed loop, and one of the main premises for putting the two organisations together.

Q At what point did this acquisition become a clear path and why?

NC As we gained more familiarity with each other while working together, it became clearer and clearer that the teams were complementary, and that our capabilities could be used on the commercial and post-market side as well as in the earliest stage of development. That both teams could leverage one another in all those areas became more and more apparent.

SP We also validated that the company cultures, including core values, were similar. We both take care of the project and customer, and how we deliver the work is similar in almost every aspect. We felt bringing our teams together would be synergistic.

Plus, while we knew that we did not need each other – we could continue to both be successful on our own – we also knew that we could be more successful together! A lot of our discussion centred on the idea that, together, we can get more done in a shorter amount of time and with better results. We like to characterise the merger of the companies as "one plus one equals three".

External validation came from private equity firm WestView Capital Partners (MA, US) and lender Abacus Finance (NY, US). They looked at the potential merger from both a business and financial lens. They also brought in industry advisers to examine it. Their investment validated the equation, and we have been together for over a month now. We are already seeing the synergies play out and both teams are very energised. We can do "more, better, faster" – one plus one really does equal three.

Q What trends do you see in the prefilled syringe and injection devices space?

NC One is the desire to move some medicine administration to self-administration and at-home care getting people out of doctors' offices and giving them a little bit of their lives back. Many see a specialist or physician multiple times a week, particularly when dealing with chronic illness. Most would rather be at home on their own schedules. Our goal is to help commercialise those injection technologies that allow people to administer medication on their own or with the help of a family member.

There are also connectivity and data analytics aspects, which can be a double-edged sword. People want simplicity – one press of a button – along with detailed insight into how healthy or unhealthy they are. It is a delicate balance for engineers to design the fewest number of steps possible to use a device, but with an extensive ecosystem, underlying data, data analysis and feedback.

With self-administration, reliability becomes even more important. A device needs to work every time, so if you are going to let people self-administer, you need the utmost confidence in the device's reliability to get the job done.

Another growing trend is sustainability. With millions of products made from glass, plastic or other materials going into landfills, we do not have all the answers we need for a greener industry just yet. But we are cautiously optimistic that those problems can be solved in the near future, whether through materials that are more biodegradable or through recycling and reuse. Companies want their products to be more sustainable and more environmentally friendly.

SP The ramifications of medicine administration matter. Getting family members to the doctor is a strain, and home-based medication eliminates a lot of the logistical problems and potential health hazards.

It can also be part of the solution for making existing therapies better. For example, I have data on one product showing that if you switch a monthly intramuscular injection done at the doctor's office to a weekly one done at home, you get better efficacy, reduced side effects and improved efficiency. In this one case, you reduce the delivered dose by a factor of six and introduce it subcutaneously; the patient needs more injections, but the needle is significantly smaller and the injection is less painful. We are able to improve the performance of existing drugs just by altering the prescribed regimen with the support of optimised delivery systems (e.g. mini prefilled syringes, multidose autoinjectors). This is a game changer.

Both Kymanox and Neuma can more fully support their customers with the wealth of resources and expertise the other brings

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to the table. With fully integrated teams, we have multiple people working together, providing significant horsepower to push projects and products along no matter where they are in the product lifecycle.

NC We are not waiting for an outside external expert to help us. All the expertise, the know-how and the doer mentality is right here. We can execute on it. We can do it. We can rely on our internal expertise and proven past performance. It is all here and can be deployed for our customers when it comes to new or existing products.

The cross-functional collaborative work between the teams is where true blending occurs, which is a solid win for clients and for the industry to get more done.

ABOUT THE COMPANIES

Kymanox is a life science professional services organisation that offers engineering, scientific and compliance support to companies exclusively in the biotechnology, pharmaceutical, medical device and combination product industries. With its diverse team of experts, Kymanox helps clients navigate commercialisation challenges that arise throughout a product's lifecycle – from early development to post-market – with optimised safety, quality, efficacy and accessibility. Kymanox was founded in 2004 and is headquartered in Morrisville, NC, US.

Neuma is an engineering services company focused on the development of robust, verifiable, reliable and manufacturable drug delivery devices. The company's experience includes work on novel, custom and platform device adaptations across prefillable syringes, autoinjectors, reconstitution devices and wearable injectors.

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