INTERVIEW

In this exclusive interview, Mathias Romacker, Fran DeGrazio and Paul Jansen, all Kymanox Executive Advisors, sit down with ONdrugDelivery's Publisher, Guy Furness, to discuss what has driven Kymanox's rapid rise in the drug delivery space and what makes the consulting company's model so successful, as well as to share their expertise on a variety of topics in an illuminating discussion, including connectivity, how large and small drug developers engage with consultancies, 5 mL autoinjectors and the interface between drug primary packaging and delivery devices.

MATHIAS ROMACKER

Mathias Romacker is a Kymanox Executive Advisor with more than 30 years of experience in the field of injectable drug delivery devices. He brings a deep understanding of prefilled syringes, handheld injection devices and on-body wearable devices, having been involved in multiple successful combination product launches. Mr Romacker was a co-chair for the PDA Universe of Pre-filled Syringes and Injection Devices in 2013, 2017, 2019 and 2022, and received the PDA Edward Smith Packaging Science Award in 2018 for his contributions over the years.

FRAN DEGRAZIO

Fran DeGrazio is a Kymanox Executive Advisor with over 35 years of experience in the life sciences industry. She has extensive expertise in sterile drug product systems, including vial container closure systems and prefillable syringes for combination products. Ms DeGrazio has published numerous technical articles and book chapters, and was a recipient of the PDA Packaging Science Award in 2021, the Philadelphia Business Journal 2018 Healthcare Innovators of the Greater Philadelphia Region Award and the Healthcare Businesswoman's Association Luminary Award for West Pharmaceutical Services in 2017.

PAUL JANSEN

Paul Jansen is a Kymanox Executive Advisor with over 35 years of experience as a professional engineer in drug device development. He has extensive experience in the design, development, manufacturing and lifecycle management of medical devices and has successfully led teams that have launched several award-winning devices, including Sanofi's Lantus SoloStar, the world's most popular insulin pen injector. Mr Jansen is a longstanding member of the International Organization for Standardization (ISO), serving as Working Group Convenor and Expert on many working groups responsible for standards related to injection devices.

Q Can you please tell our readers what first attracted you to Kymanox – your route to joining as a KEA and what you bring forward from your previous roles and experiences?

MR I spent the first half of my career on the supplier side with BD and Gerresheimer, and the second half with pharma, working for Amgen and Pfizer. After I left Pfizer, I did a little bit of freelancing, after which I joined Kymanox in 2022.

I've been in touch with Kymanox for a long time now and, as someone whose career 'grew up' alongside combination products, I couldn't help but be intrigued by Kymanox's success. Before I joined, I also heard about them from their clients, who consistently told me how their co-operation with Kymanox was really beneficial. As one of my colleagues put it, Kymanox is almost like a pharma company without a product – it's a fully end-to-end service provider. I find it a very interesting model, so I was keen to be a part of it, both to see the business grow and, obviously, to provide my expertise.

I can provide assistance and insights on a variety of topics relevant to my experience. My expertise is mostly focused on the front-end, particularly around combination products – I can look at a device and drug portfolios and see how to really maximise the impact of actually bringing them together as a combination product.

FDG Initially, Kymanox was just a company that I had seen start to grow and flourish in the

"You get real solutions and real experts – highly talented, highly competent individuals across a wide range of areas that can really dig down into problems and come up with solutions."

combination product space over the last few years. However, after I retired in 2022, they reached out to me and asked if there was potential for me to bring my experience and expertise to their customers, to see if we could reach a balance that would satisfy both my needs and theirs. That's essentially what I see the KEA as – a group of highly seasoned experts with a wealth of knowledge and experience with a lot still to offer the industry. I enjoy taking opportunities to share my knowledge, so was pleased to accept Kymanox's offer.

As for what I specifically bring to the table, I was at West Pharmaceutical Services for close to 39 years in a myriad of technical and R&D roles, as well as working in the quality and regulatory departments. I've had a hand in a lot of different areas, which means that I've developed a significant understanding of the market and pharma customers and their needs. Sharing that knowledge with Kymanox as a KEA is a great fit for me.

PJ My current relationship with Kymanox started with a request during the early days of the covid-19 pandemic. They reached out to me looking for specific information to help one of their clients. This was a really good way to get to know Kymanox better; I had interacted with them previously, but there's nothing better than actually working together – I realised then that they were in a unique space.

If you wanted to, you could make a long list of competitors but, as Mathias said, the fully end-to-end nature of the business, combined with with really high-quality talent, isn't something easy to find anywhere else. There are a lot of agencies out there that claim to be able to do everything Kymanox does but, truthfully, in my experience from when I worked at Sanofi and Lilly, such organisations often come in and they ask you, as the client, what's wrong? They ask you, what you would do to fix it? Then they package up your answers, and that's what you pay for.

That's not the case with Kymanox. Here you get real solutions and real experts – highly talented, highly competent individuals across a wide range of areas that can really dig down into problems and come up with solutions. That's what makes Kymanox unique to me.

Regarding my background, I retired from Sanofi in 2017, which meant that I'd had a few years of retirement before covid-19 hit. What I was looking for were unique experiences; both opportunities where I could grow and where I could help other people learn and benefit from what I've picked up over the years. That's what Kymanox offered me.

I've had a long tenure; I've been very fortunate in that I've been able to work with two large pharma companies and, at the same time, I've interacted with a lot of people through my work at the ISO. Many of the standards that come out of Technical Committee 84 are those relating to drug-device combination products, from autoinjectors to pens to on-body wearable injectors. I've been able to meet not only the people in the companies I've worked with and their suppliers, but with a wide variety of people from across the industry. This experience has given me a somewhat unique perspective that allows me to add real value and help solve problems.

Q **Kymanox has seen rapid growth over the past few years. Why does its unique model work so well, and what advantages does Kymanox offer that pharma companies couldn't get if they kept everything in-house? Are factors in the current state of the market also driving this growth?**

PJ There are a lot of factors but, to really get to the heart of the matter, I think the key factor at play is that, in reality, when an employee at a big pharma company, for example, tells their leadership the certain way a thing should be done, they often just aren't listened to. Instead, the leadership decides to hire a consulting company but, as I said before, those companies are often just repackaging the ideas and concepts that weren't being listened to in the first place.

What you're missing with some traditional consulting companies is any real innovation, any new ideas. They might offer a new set of eyes, but if they are only repackaging ideas that are already there – the only difference is that they're coming from someone who the CEO listens to better, for whatever reason. It's a bizarre syndrome, but I've seen it play out over and over again, and I'm sure that Fran and Mathias have too. It's just how the big corporate world works.

So it all comes back to what I said before; Kymanox can listen to what the customer's problems are and then turn to their own group of talented people who aren't afraid to give their own ideas and perspectives, building and expanding on what employees are saying rather than just repackaging it. That's what makes the model unique.

KYMANOX EXECUTIVE ADVISORS

A key part of Kymanox's model is the employment of the Kymanox Executive Advisors (KEAs) – a group of prestigious, seasoned and well-respected industry professionals with a wealth of diverse experience from across the pharmaceutical industry. Together, the KEAs have over a century of experience in building businesses, enhancing capabilities and bringing products from inception through commercialisation in the pharmaceutical, biotechnology, and medical device industries. With their collective knowledge and expertise, the KEAs are able to provide guidance and strategic thinking, foster valuable relationships and identify additional resources to help your project be successful, particularly in the areas of combination products, connected devices and pharmaceutical manufacturing.

Kymanox currently has five KEAs. In addition to Fran DeGrazio, Mathias Romacker and Paul Jansen, interviewed here, Kymanox Founder and Chief Executive Officer Stephen Perry, and the company's Chief Innovation officer, Evan Edwards, are both also KEAs.

The other part of it is demonstrated by the three of us that you're talking to right now – we all have a unique set of experiences, and we have a lot of them, and that provides credibility, which is what the customer really wants. Kymanox has been so successful because they can say, "We've got people who have done this before and who know how this is done."

FDG I concur one hundred percent with what Paul just said. I think there's a unique benefit to the Kymanox model.

To answer the part of the question about market factors, it's the growth of combination products, which is clearly the direction that the industry is going. This is driven by the need for more at-home administration, more self-administration. With biologics in particular, there are additional challenges in delivering those types of products.

Kymanox has a wealth of experience in these areas, as well as talented people they can leverage or reach out to. So, if there's a certain type of specialised talent that's needed, which there often is, we as KEAs, as well as Kymanox staff more broadly, may know certain people with that specific expertise. They know who to reach out to, who they can then bring in and gain access to that certain specialised talent as needed.

MR Firstly, I'd like to say that what Paul was saying about the big pharma experience made me smile because it sounded all too familiar. I think Paul and Fran have answered the question very well, but maybe one aspect we haven't discussed yet is that, when you look at smaller biotech organisations, they usually have a really good, innovative molecule but, at best, they have maybe one or two people who have any real knowledge when it comes to combination products. That means that there's a huge void in their understanding regarding topics like quality management systems, design history files, design controls – all the detail that you have to get right to successfully bring a product to market.

I understand that, for many of them, the business model is essentially to get the molecule ready and then get bought-up by one of the big pharma companies who will then go on to commercialise it. Yet, with current trends, I think it's a mistake to neglect the device side of the puzzle. Smaller biotech companies can really benefit from bringing in the expertise to develop their molecule as a combination product.

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Kymanox can really offer a lot of value here because, to be serious about developing a combination product, a company must bring in a lot of expertise – which traditionally meant a lot of new employees. However, these companies often want to stay lean and mean, and bringing all that expertise in-house would be a huge expense.

Furthermore, when you're talking about combination product development, you don't need all of that expertise all the way through the process – there are going to be peaks and valleys where such people spend some time incredibly busy but at other times they'll have very little to do. Based on conversations I've had over the years, my feeling is that there's a genuine need within that class of company to outsource this type of expertise, which is where Kymanox comes in.

PJ Another aspect with small companies is that they don't know what they don't know, and Kymanox can add a lot of value there. There is a real benefit for companies from engaging with the combination product conversation sooner rather than later – many of them still come to the conversation far too late. One of the benefits of working with some of the smaller companies is that you tend – not always, but often – to be able to get involved a little bit earlier.

As Mathias said, smaller companies aren't in a position to hire all the necessary people – they're running with limited cash and they need to be able to move quickly if something goes wrong in their clinical trials; they don't want to have to lay off a whole bunch of people. Kymanox knows how to work from end-to-end, so we can be brought in when needed, for any part of the development programme, or even the whole thing.

Q **What value and insights can you deliver to Kymanox clients, both existing and prospective, as a KEA?**

FDG Part of our role is to understand and think more strategically – Kymanox's clients, both current and future, know that they need to get the strategy right and to understand what's actually going on out in the market, including from a regulatory and a technical standpoint. That's what the KEAs can bring to the party. Certainly, my specific expertise includes strategy, planning and execution in a lot of different areas, including quality and regulatory coupled with technical aspects. So, I can bring some unique experiences to bear.

One of the things that I'm most proud of, personally, is that I've always tried to look at everything from the pharmaceutical side – even looking from the outside in, you need to understand what challenges the pharmaceutical client needs to meet and how to get their product to the end patient. From that perspective, I think that there's a unique combination of experience, knowledge and outlook that I can bring to the table.

When I started at West, it was a much smaller organisation. Being a part of growing the company and able to influence the industry has been a great learning experience for sure. And now it's something that I can bring to others as a KEA.

MR A key to success when developing a combination product is understanding that you need to answer important questions early. For example, if you pick your concentration and your injectable volume, it could be the difference between a handheld injector or a wearable injector. However, doing so has proven to be difficult for the industry, as the internal structure at pharma companies is often complicated. So, while I wouldn't say it's treated as an afterthought, making these decisions is definitely not seen as core activity within drug companies.

With that in mind, I think what we can do from the consultant side is to help these companies to better understand their drug portfolios and what device technology they may need. We don't live in an insulated world – there's so much innovation

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happening right now and it should be of interest to anyone who really wants to understand their drug portfolio.

Let's take an example, maybe you have some blockbusters that are on the decline but still delivering good value. You need to ask yourself how you can make sure that, five to ten years down the road, you have the right device technologies in-house to maximise the value of those assets. Obviously, this can be a very difficult conversation. Sometimes there may be an easy business case for a single asset that's likely to be high value down the road, which means that there's a temptation to grab some innovative technology and focus on that single asset. However, it should be the needs of the whole portfolio that drive such decisions.

Kymanox has a very thorough understanding of the novel and emerging technologies, and I think it would be very beneficial for our pharma clients to make use of it, combined with a full picture of their drug portfolios. I remember from my pharma years that conversations between the drug development and commercial teams can be difficult. However, if you have a structured approach across the full portfolio, which, realistically, you probably need an outside partner to facilitate, it can yield results in the way you categorise and look at new technologies in the device area.

PJ I completely agree that strategic thinking is the critical element that we, as senior leaders and former senior executives of our organisations, can provide for any existing or prospective customers. If you total it up, we've got more than 100 years of experience between us, which is a lot of years in this business.

Reflecting on my early days in the industry, I had the good fortune of working in the diabetes sector. I was involved with the very first pen injectors way back in the in the mid-1990s. We were like a maverick band of engineers from Eli Lilly, Novo Nordisk and, in those days, Hooks – which is now Sanofi – that were putting these ideas together. Looking at how the industry has evolved in regard to injections since then, I feel both incredibly old, because I've been there since the beginning, and incredibly lucky, because I've been part of that evolution all the way through, including the establishment of the standard.

I remember when ISO 11608 was first – and finally – published, we all looked at each other from those three companies and, while we knew that we'd use it, we wondered if anyone else would. Today, it's the document that's been adopted by regulatory agencies around the world. I still get phone calls from people who, because I was part of writing it, want to ask me what this or that part really means. So, I think my perspective on the standards side of things is somewhere I can add true value.

Another thing to mention, aside from the understanding of the strategy and technical side of things you get from actually having been in the thick of development projects from the beginning to the end, I've learned a lot of lessons from hard experience. In fact, there's a lecture I give at Northeastern University as part of a bioengineering course there, which is entirely focused on what mistakes I made and what I learned from them – the things that didn't work out. You don't often learn a lot from the things that went well; you learn a lot more from the things that went badly, and so those are what I tend to reflect on. Importantly, I can share those lessons with other people so that they don't make the same mistakes.

The last thing to mention is that I had the good fortune of being able to develop and commercialise the SoloStar pen, which has been widely successful and for many years was, and probably still is, considered to be the gold standard for pen injectors. Along with that came my desire to get involved in managing patents and intellectual property, which led me to create and oversee a patent department at Sanofi that started with seven patent families and, 10 years later, had more than 1,300. We were a patenting machine! And that's an experience that I learned a lot from. Not just about patents themselves, but also about the litigation aspects and strategic elements of how to manage patent portfolios. In my experience, companies both big and small still don't fully appreciate the value such an understanding can bring them.

Q **Something that I find interesting about expertise is that you can instinctively know that something will or won't work with certainty before you necessarily have the words to explain why. In your roles as KEAs, is this something you experience often and how do you handle it when dealing with clients?**

PJ Our opinions aren't entirely black or white and I think that we're generally very good at justifying why we feel the way we do. We might know it first in our gut, but I think if we sit back and think about it, we've had enough of these things go wrong or go right that we know what's going to work and what's likely not to work.

I'll give you a real example. I often have people come to me with a new pen injector, on-body wearable injector or other kind of device who say, "We've got this new device and we want to go into diabetes". My advice to them is almost one hundred percent consistent: don't. Don't go after diabetes with a new device, there's far too much competition there so go somewhere else. And nearly every time I have to take them through the very laborious rationale, but they just don't want to hear it, because diabetes is such a huge market. I understand where they're coming from, but it's the wrong approach and I have to convince them to trust me.

MR One thing I want to point out is that, of course, you're not always right. For instance, 10 years ago I predicted that on-body wearable injectors would be a major thing by 2023. I expected a lot of product launches by now. But, while this class is clearly emerging,

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we only have a few out there, nowhere near as many as I predicted. The point being, you're not always going be right with your gut feeling.

FDG Although you have a gut instinct, there's always a reason why. Being able to always put your instinct and the reason behind it into words so that someone else can understand it effectively is a skill, and I think we've all got that.

PJ Another example is connectivity. I couldn't count the number of times that the three of us collectively have been asked, "Should we go with a connected solution, yes, or no?" My view is always yes, you should be making provision for connectivity. You may not want to put it into your device right away, but you do need to make sure you can accommodate it.

That said, before you do anything, you should figure out what you're going to do with all the data you plan to generate. We've got all kinds of people making connected devices and it's still a mystery to me how patients are really benefiting. We're increasing the cost of the device and we're generating a whole bunch of numbers, but what's the real added value? There are a few who really benefit but, for most of these solutions, most people don't just yet, primarily because the devices we're making are far too complicated. We're not making it easy enough for patients yet, there are too many steps added and there's too much going on.

That's my view on connectivity – it's emerging and it's going to be important, but as an industry we're not getting it right just yet. I think it's a sector where the three of us can give good insights and good advice, and somewhere Kymanox can add a lot of value. We have experts who know the software and the hardware, the ins-and-outs of whether you use Bluetooth or NFC or other types of solutions.

Q **As you mentioned before, a big part of the value the Kymanox model can offer is the variety of your experience. Therefore, I've got a question for each of you individually that focuses on your particular areas of expertise. Starting with you, Mathias, what is the right time for pharma companies to look at selecting a drug delivery technology during the lifecycle of a drug product? Additionally, how can drug delivery technology be adapted to maximise the value of such assets?**

MR For pipeline projects the answer is as early as possible in development – there's no such thing as "too soon". Drug developers are beginning to take this advice on board and consider delivery technologies sooner. Big pharma have definitely changed their game in this respect over the past few years, by which I mean delivery device technology is no longer an afterthought. In some cases, it means they've adopted a single device platform and stick to it for everything, even as drug delivery technology evolves.

After a product is an inline product, once it's launched, it's a different story. Then you're getting into lifecycle management strategies.

As we discussed earlier, it's difficult for smaller companies who don't have any device expertise in-house. They know the properties of their molecule, they know the target indication and, at some point, they may figure out that self-injection is the way to go. Once they've figured that out, they need to consider the details, including injection frequency, therapy duration and several others. You can imagine that they may be inclined to kick that can down the road, but they shouldn't.

In fact, if you wait too long to consider the device, you can jeopardise the filing date. You can't launch as a combination product if the device isn't ready. Many smaller companies want to partner with or be bought by one of the big players to commercialise their drug. Imagine you're in talks with a big pharma company and everything's looking good, the molecule is good, the clinical work is good, but then it comes out that you've not done any work on the device part of the combination product – that could really harm the conversation.

This is one of the sweet spots where Kymanox can really help, especially for those companies that only have one or two employees that are device savvy. We can help to get their projects moving ahead – put the quality management system in place, the device design controls, you name it.

Q **To follow on from that, is there ever a time where you would advise a smaller company not to go too far with looking into the combination of their molecule with the device? My thinking is that, when it comes to being incorporated into a large pharma company, they might have a particular way of doing things or their own preferred suppliers.**

> "Every company, whether they're big pharma, small biotech or a start-up – whatever size they are – the number one priority is always to get the product to market."

MR My take is, if you're a small biotech, you probably don't want to go with a device that's at all experimental. For example, if your molecule is designed to be a single fixed dose in a handheld device, go with a prefilled syringe – go with what's established, reliable and accepted.

Following on with that example, you're filling your product in a prefilled syringe, you're generating stability data, etc. You probably want to partner with a company on the device side that has done this before, one that has several customers and products on the market. Then let's say you're having talks further down the road with a big pharma partner and that partner has a different take on it. That's when you want to have a conversation about potentially taking the molecule in a different direction, but up until that point I would strongly recommend to move forward with something that's proven, potentially with an established device partner.

PJ I agree with Mathias. It's really a risk question; every company, whether they're big pharma, small biotech or a start-up – whatever size they are – the number one priority is always to get the product to market. As Mathias said, if you introduce a new, unproven technology, you'll increase the risk.

Take Sanofi as an example with Dupixent (dupilumab). It was launched in a prefilled syringe because a prefilled syringe was the fastest way to get to market. Now, the autoinjector is following behind it. That's a much more convenient way for users to take it, particularly in some of the newer indications that are coming along. It's a great example of prioritising speed to market. Enbrel (etanercept) from Amgen did exactly the same thing – prefilled syringe then an autoinjector. So, I think I'd expand on your point about using proven technology by saying

what you want is always the fastest way to market with the lowest risk. That's what I'd advise.

Q My next question is for Paul, on the topic of the recent emergence of 5 mL autoinjectors. What are your thoughts about these larger volume devices?

PJ At a PDA conference last year, a speaker in the closing session said that the delineation between an autoinjector and an on-body wearable was now 5 mL. When I heard that, I thought to myself, this can't be true. 5 mL of liquid in the subcutaneous cavity is a huge volume.

The response to that is usually that the people trying to inject these large volumes say that they're going to use a Halozyme-type solution [Enhanze, recombinant human hyaluronidase PH20 enzyme, rHuPH20, which locally degrades hyaluronan in the subcutaneous space temporarily removing a barrier to fluid flow] and it's going to dissipate into the subcutaneous cavity quicker. That is a solution, and there may be some others. And Halozyme loses its patent soon, so others will be able to copy it. But you're still trying to get 5 mL of liquid out through a fairly thin needle into the subcutaneous space. The injection doesn't go any faster even if you increase the speed at which it dissipates into the subcutaneous tissue – it still has to get out of the container in your autoinjector and into the patient. And that means that the user has to hold this autoinjector against their skin for a long period.

Some of the companies developing 5 mL devices say they can do the full injection 30 seconds, others say 60 seconds, and a couple have said that it's probably going to be more than a minute. Try holding something against your skin for a minute and then just imagine putting a needle on the end of it; I promise you that you're going to get a lot of incomplete injections – the problem with an autoinjector is that once you start it, you can't stop it, although some do claim ability to pause it.

I'm told that there are pharma companies demanding 5 mL, but that doesn't include any I've spoken to about it. I think 2 mL is about the right volume and, maybe, under the right circumstances, you can stretch to 3 mL.

FDG I really see this as a case of technology-driven thinking. People ask, "Can we do it?" first and then develop it from a technical standpoint. Once they've developed the product, they need to find a place for it, so they've targeted it as an alternative to on-body wearables.

> "People don't commonly think about stoppers and vials as a potential part of a combination product, but many of those are packaged in kits with reconstitution systems or vial adapters. Well, that's a combination product and the vial is a part of it."

PJ That's a really good way of putting it, Fran – it's technology-driven rather than patient-driven. I think that's probably what's actually happening. I did some of the studies in this area myself when I was at Sanofi, and we found that people do tell you that, given the choice of holding something against their skin versus sticking something on, they prefer to hold. But what isn't clear in those studies, at least in the ones I've seen and was involved with, is the amount of time they're willing to hold. They aren't comparing sticking on against holding for a full minute or more.

MR Talking of the voice of the customer, I also recall market research where the choice was between sticking the device on and getting two injections, say two of 2.5 mL each. The result was consistently 50-50. So, there's already an autoinjector-based alternative to on-body wearables.

One argument you could possibly make for 5 mL is, if the system is cartridge based, which I believe one is. In that case, it's just your maximum fill volume that's 5 mL, which means you can fit all the fill volumes that you have in your portfolio into this single device platform. You'd have to accept having a larger, and therefore less favourable device as a trade-off.

PJ That's an interesting thought, Mathias, especially from a sustainability perspective. Once, we never imagined that a cartridge-based autoinjector platform would be possible because of potential mix-ups and creating extra steps for the patient. But now that sustainability and climate change are really taking root in the industry, I think the sustainability angle of a single cartridge-based system for a whole portfolio will become increasingly relevant. And there's a very elegant programme that Novo Nordisk has put in place for recovering pens in Europe and the UK, which could also play into this idea. For certain, sustainability is going to become a bigger topic as time goes on.

Q Lastly, a question for you, Fran – can you tell us your thoughts about the risks and issues involved with companies thinking about the device without putting much thought into the packaging?

FDG This is actually a favourite topic of mine because, as you know, when you talk about a combination product, you're bringing together the device and the drug – in its primary packaging. And, as Mathias emphasised, you want to bring those two pieces together as early as possible. However, in large companies, the delivery device and drug packaging side are frequently treated as almost separate organisations. You have engineers in delivery, and you have scientists in drug formulation, so it's critical that those aspects be brought together as early as possible.

When you talk about packaging, it's not only the chemical side of it that's a concern – how the container interacts with the drug – but also how that package is going to work with whatever delivery device it is going to be paired with it. People don't commonly think about stoppers and vials as a potential part of a combination product, but many of those are packaged in kits with reconstitution systems or vial adapters. Well, that's a combination product and the vial is a part of it.

All these pieces very much marry together, and they each need to be thoroughly considered – the drug, the package and the delivery device – because the whole combination product is only as strong as its weakest link. You really need to understand these things both as individual elements and as part of the system as a whole. In my experience, most challenges occur where these things interface with each other, so that's one of the primary things that you need to be aware of.

Q To wrap up, I want to look to the year ahead. What do you think 2023 will bring and what will you be doing as a KEA in the coming year?

PJ I'm going to continue to spread the word about Kymanox. That will include at conferences, now that they are back to being in-person events – you can't do this kind of work virtually, you have to do it face-to-face.

There is going to be a lot of activity in the combination product space. My prediction for 2023 is there will be noteworthy advances made in three areas: on-body wearable injectors, connectivity and sustainability.

FDG I concur with Paul, and I think he picked out the right three areas. I think on-body will continue to grow, and digital and sustainability certainly will.

Sustainability really started in and has been driven by Europe more than anywhere else so far. But these things go global, and sustainability is becoming a real hot topic globally.

MR On sustainability, I learned recently that some fund managers are now putting together their portfolios according to sustainability goals, which could have a significant effect on the industry in 2023 and beyond.

As for what I'll be doing, as Paul already said, face-to-face events are back, so I'll be on the conference circuit. Another thing that I'll be doing is serving on the board of directors with PDA for another year. Many of us will get together at the PDA Universe of Prefilled Syringes & Injection Devices in Gothenburg in October.

It's going to be a great year, there are many positive developments happening, and I'm looking forward to it.

ABOUT THE COMPANY

Kymanox is a life sciences professional services organisation that offers engineering, scientific and compliance support to companies exclusively in the biotechnology, pharmaceutical, medical device and combination product industries throughout the product lifecycle from early development to postmarket.

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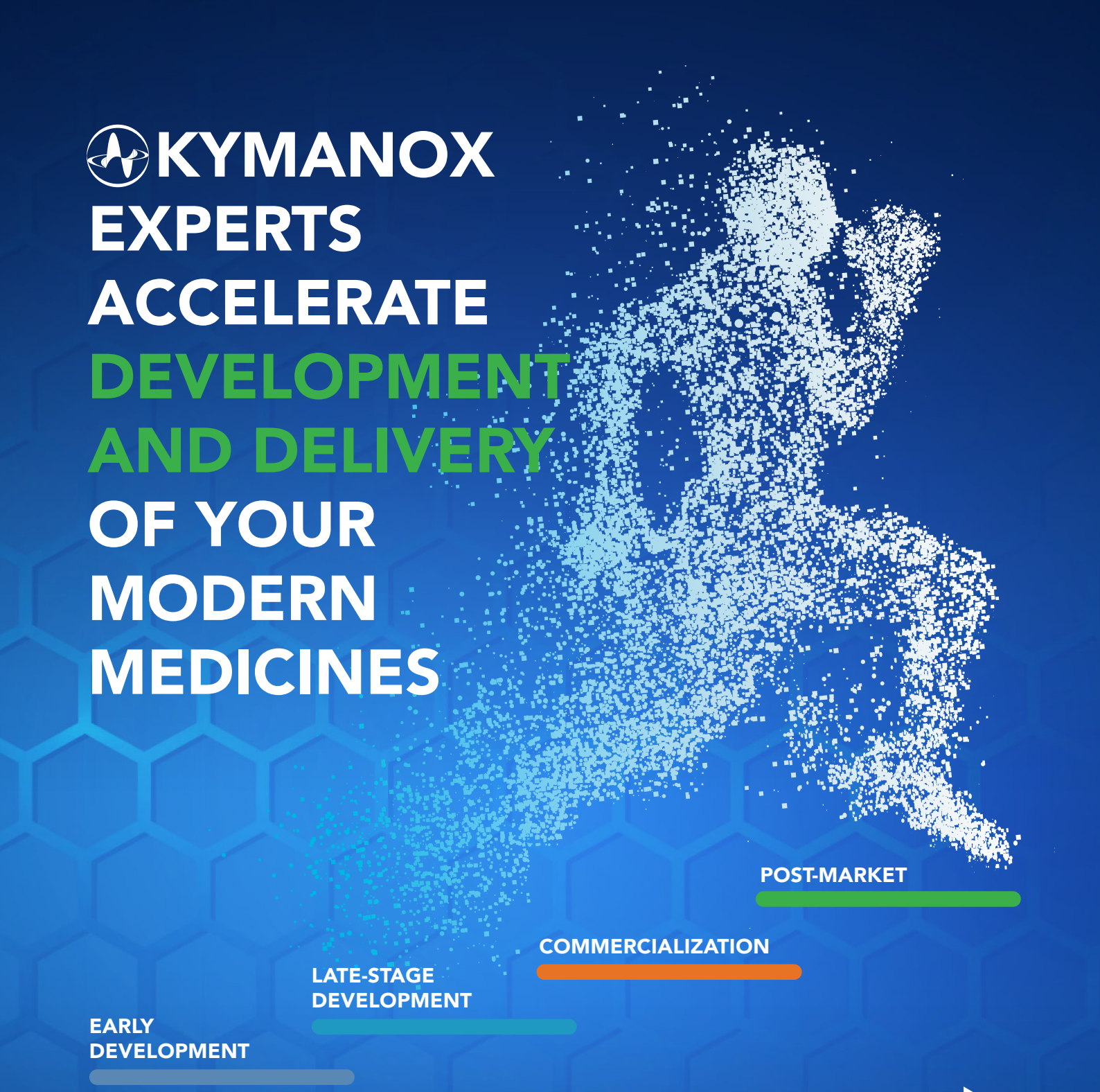

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