Interview
PDA Miniverse and Trends in Injectable Drug Delivery

In this exclusive interview, **Mathias Romacker** and **Evan Edwards** of **Kymanox** talk with ONdrugDelivery's Guy Furness about the inaugural **PDA Miniverse: Medical Devices, Combination Products and Connected Health** conference in Indianapolis (IN, US), discussing the inspiration for the event and what delegates can expect at this smaller, more intimate companion to PDA's annual Universe of Pre-Filled Syringes & Injection Devices. Following on from Miniverse, the conversation broadens into a wider consideration of the topics and trends currently being felt across the injectable drug delivery industry.

Q The Parenteral Drug Association (PDA) "Miniverse" conference will take place in late June in Indianapolis. Mathias, as the event's co-chair, can you tell us more how this event came about?

MR It's fair to say that PDA's Universe of Pre-Filled Syringes & Injection Devices conference is the event of the year in terms of content, networking opportunity and just getting the injectable drug delivery industry together. The way it's currently structured is that it alternates each year between the US and Europe. This year it's taking place in Vienna, Austria, which makes it an off year for PDA Universe in the US. So, within PDA, we've been having conversations over the years about whether it would be beneficial if we were to offer a slimmed down version in the US during off-years.

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We eventually pulled the trigger early this year, and I think that we have a really great programme. Hosting the event in Indianapolis (Figure 1) is also an exciting first for us – it's an innovation hotbed – and, as a bonus, delegates will be given a tour of Stevanato Group's local manufacturing plant.

Q Evan, before we move on to discuss your role at Miniverse, can you give us some insights into your fascinating career and the journey that led you to your current role as President of Kymanox?

EE It's something of a unique story. My identical twin brother, Eric, and I grew up with severe allergies and, as a result, we invented one of the primary competitors to EpiPen (Viatris), an adrenaline (epinephrine) autoinjector

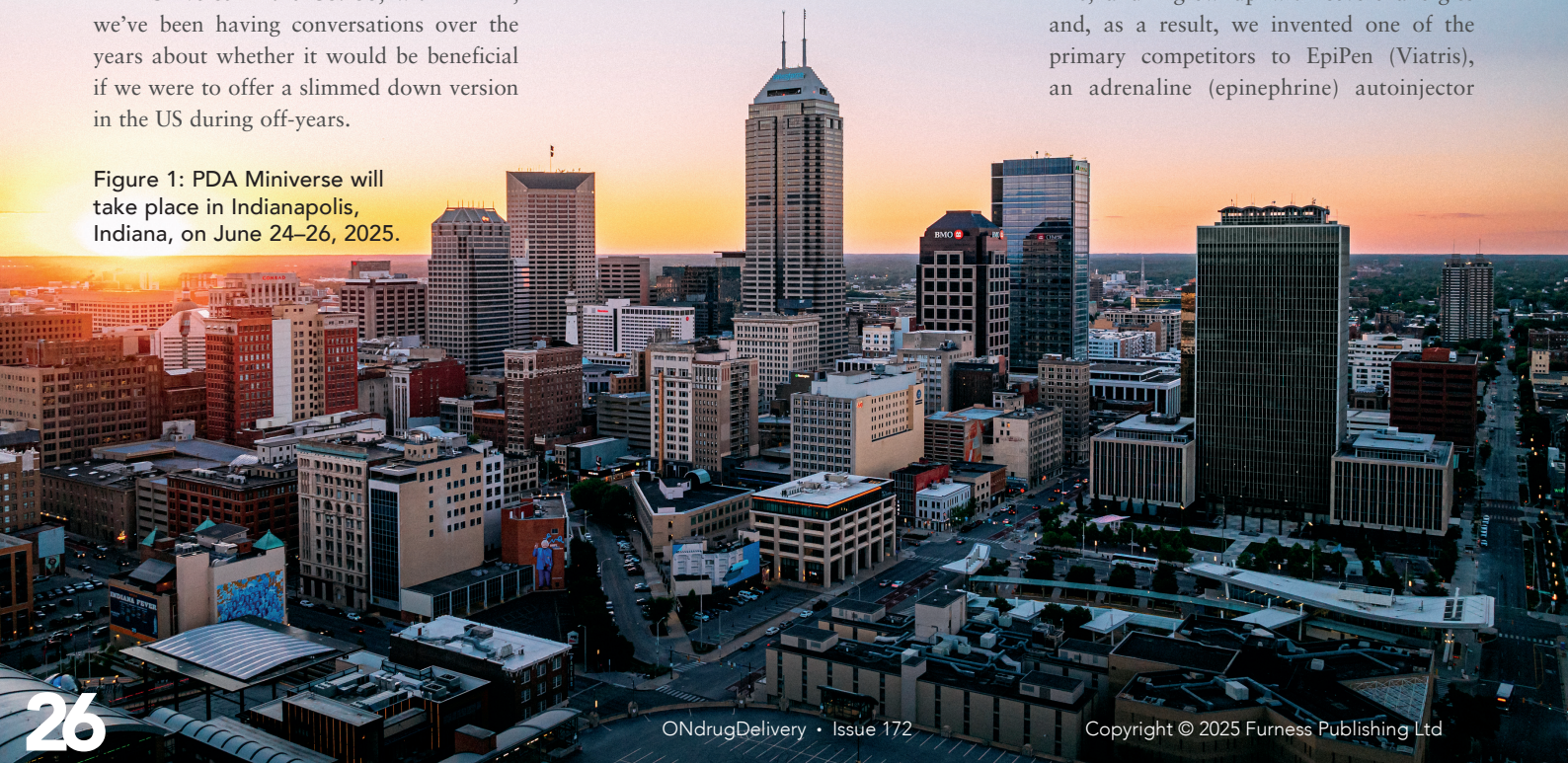

Figure 1: PDA Miniverse will take place in Indianapolis, Indiana, on June 24–26, 2025.

called AUVI-Q (Kaléo, Richmond, VA, US). So we spent 17 years working alongside some very talented leaders, developing Kaléo and inventing several drug delivery device platforms. Eventually, both my brother and I became fathers to children that were at risk of severe allergic reactions.

Our focus was on solving the challenges the industry faced back in the early 2000s – trying to identify unique ways of delivering injectables, for emergency use products in particular. Nowadays, you see all kinds of new drug delivery technologies, especially in the small-molecule space, even branching out into nasal administration. We're very proud of developing AUVI-Q, first for adults and then for paediatric applications. AUVI-Q 0.1 mg still remains the only autoinjector product on the market for infants.

The other thing that we then developed was the first out-of-hospital indication for naloxone. This was before the NARCAN nasal spray (Emergent Devices, Plymouth Meeting, PA, US) became readily available over the counter. At the time, naloxone was only administered by emergency medical technicians and healthcare providers. So we developed EVZIO (Kaléo), which was a naloxone autoinjector. That eventually transitioned off the market, but we used that technology to develop a 10 mg naloxone product for US soldiers in case of overdose of highly potent fentanyl or other opioids.

We spent a lot of time developing novel drug delivery platforms with Kaléo and, as a result, we worked with a lot of professional services firms. One of those companies was Kymanox, which is how I got to know Stephen Perry, the CEO and Founder. After I left Kaléo, I was blown away at the growth that Kymanox had achieved. I joined the company in 2020 as an adviser to help continue to build, scale and professionalise the organisation, starting with the human factors group, and the company has now grown to around 300 people.

Having spent most of my career in drug-device combination products, what really excited me about Kymanox was the opportunity to work with such a large number and variety of sponsors. Whether it's a small pharma, medtech or biotech company, all the way up to some of the largest pharma and biotech companies in the world, there's nothing quite like working alongside a wide variety of trusted partner companies; seeing what they're developing and helping them accelerate and advance those products through the regulatory authorities to get them into patients' lives is very rewarding.

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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 conference in 2013, 2017, 2019 and 2022, and received the PDA Edward Smith Packaging Science Award in 2018 for his contributions over the years.

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As an expert in the pharmaceutical and medical device industries, Evan Edwards serves as President of Kymanox. He was the Co-Founder of Kaléo and co-inventor of the AUVI-Q (adrenaline) autoinjector and Kaléo's drug delivery device technologies. He has extensive experience in drug-device combination products and is named on over 200 patents, issued and pending, both in the US and abroad. Mr Edwards is a subject matter expert in usability engineering, design controls, combination products, operations, industrialisation, quality systems, executive leadership, pre-approval inspection readiness, human factors, intellectual property strategy, and invention and design. He holds a BS in Mechanical Engineering and an MS in Systems Engineering with a focus on human factors engineering, both from the University of Virginia (Charlottesville, VA, US).

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Q Evan, you're one of the plenary speakers on day one of Miniverse, discussing the topic of risk mitigation and how to manage third-party resources. Can you talk about the relevance of this topic and give our readers a small preview?

EE When I was at Kaléo, we were a smaller company, so we had to rely on a lot of different third parties, including CDMOs and professional service firms like Kymanox. Now, at Kymanox, we're seeing increased use of third party and professional services for both the sponsor and the CDMO side within the industry. So I've seen the relationship from both sides; there are specific significant considerations when managing these resources.

We're also seeing CDMOs developing their own products internally, such as autoinjectors or other delivery platforms, which may not have been their core competency historically. As such, some of them are now trying to reach out to third parties to help them navigate how to identify and select the right partners, how to deal with the regulatory and quality management system considerations that they didn't have to before.

For me, it has a lot to do with risk. That can include quality control, regulatory concerns, supply chain issues, programme management and cybersecurity to name a few. All of these have significant impacts when you're trying to get products to market on time and on budget. Part of the topic I'll be exploring is how to mitigate these risks – what some of the key considerations are on both ends, especially for sponsors when they're looking to partner with a CDMO.

As an example, negotiating an appropriate master services agreement or quality agreement can take a significant amount of time. We've seen some of the sponsors we work with think that they're going to start this project in a month and, eight weeks later, they're still negotiating the terms of an agreement. So there are things that should be discussed to make sure that you're under-promising and over-delivering to your stakeholders, partners, leadership team and investors. I'm going to cover all of that, as well as some of the mitigation strategies on how to ensure that these companies are successful.

Q Mathias, you are a co-chair of PDA Miniverse this year. Can you talk about the programme and how Miniverse compares to the main PDA Universe conference?

MR As the name suggests, Miniverse will be slightly smaller than its Universe counterpart. It's still going to be a sizeable conference, but a bit more intimate than the main event, which I think is actually an upside for meeting people and networking. In my opinion, having a smaller crowd typically encourages people to speak with each other more freely.

In terms of programme, the theme for this year's Miniverse is "Integrated Innovation: Designing the Future of Injectable Drug Delivery", so you can see it still has a broad scope, with talks that will be relevant for most delegates in the typical Universe audience. In terms of topics, one key subject the talks will cover is the complexity of connected health, including cybersecurity. And, of course, they will cover how connected health is having an impact on clinical trials. Regulatory strategy is also always a very important topic to cover, especially with all the latest changes that have taken place this year in the US FDA, so we have a really good speaker lined up to cover it.

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Another topic that has been circulating for a while, which I think is really starting to take off, is large-volume systems, so I'm looking forward to the talks covering that subject. We also have some speakers that will talk about industry initiatives. To give some specific examples, we'll be hearing from the Subcutaneous Drug Development & Delivery Consortium (Beaverton, OR, US), with a presentation by one of their senior members from Halozyme.

Q Evan, there is a lot of uncertainty in the industry right now with changes occurring from the US administration, including layoffs at large companies and even the FDA. How are you all helping sponsors navigate these challenging times?

EE I think you hit the nail on the head that something we continue to hear about is uncertainty. What we've seen for the companies that we support is that it has increasingly been a challenge to raise money on the capital markets, especially for smaller companies. Most investors are trying to mitigate risk and, therefore, they want the companies they invest in to be further along the development journey, closer to the clinical or commercial stage than was the case even five years ago. Investors used to be willing to take on a bit more risk and invest in earlier-stage companies. So a key consequence is that we are seeing longer funding cycles for startups.

However, that comes with opportunity. You have to find trusted partners that can get you to that value inflection point as quickly as possible. It's been very beneficial for Kymanox to partner with these companies so that we can re-evaluate their programmes and find the least burdensome approach, putting them in a better position to raise capital.

For larger companies, the same thing is true, but in different way, with budgets tightening internally, layoffs occurring and the need for additional capacity support. Another factor is that larger companies are making more decisions to try to be careful and mitigate risk. For big pharma, a further consideration in their thinking is that there are several key drugs that are going off patent soon, so they need to be able to fill their pipelines.

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We've also seen that advanced therapies, such as cell and gene therapies, haven't picked up as quickly as industry analysts anticipated. We're still working alongside many sponsors in this space that have some incredible therapeutics and technology in the works, but overall progress has been slower than expected. CDMOs have been hit hard in this area in particular as well.

Of course, the FDA has also been strongly impacted by the new administration, and we've seen that start to cascade and begin affecting sponsors. An example of this would be longer response times when dealing with the agency. We are even seeing this affect manufacturing inspections on sites – the FDA does not have the capacity it used to because it has let go of several of the employees that were qualified to conduct those inspections. Naturally, this is having a negative effect on how quickly products are being approved.

I don't think that the true ramifications of everything going on have yet to be fully realised – there are still a lot of question marks. So, because of that uncertainty, people are being more cautious with the decisions that they make on commercial programmes. I do think that this means that there's an opportunity to have dialogue at events like PDA Miniverse where we can come together and share the challenges and discuss how we mitigate risk together as an industry.

I think we have to remain optimistic; this is an industry that has typically been able to navigate any headwinds that have arisen through external circumstances because, ultimately, patients need drugs. They need biologics. They need therapies. That ties into the other macro trend that we're seeing, which is that rare disease indications, oncology and glucagon-like peptide 1 (GLP-1) agonists are continuing to thrive. We have to focus on innovation and novel therapies that have significant promise.

Q You both keep your fingers on the pulse of the markets and trends within pharma, biotech and combination products. To round out our discussion, can you tell our readers what currently stands out most?

MR As a broad theme, I think many of the trends we were expecting to take off across the industry are moving slower than we thought they would. A major example of this is connected health, also large-volume systems. There's definitely something happening here, but I have the feeling that there's a discussion to be had first about how we navigate an environment that is still evolving before we see these ideas realise their full potential.

EE I'd agree with that, Mathias. Another thing we're seeing making steady progress is dual chamber syringes, including for lyophilised drugs and liquid-liquid technologies. Connectivity has always been a challenge – we've seen it have success in the clinical trial space, but I think from a payer and pharmacy benefit management perspective, it's been really hard to gauge the value of it – there hasn't been much enthusiasm to pay a premium for connected technology. That said, I do think that connectivity is coming and will gain support from a compliance standpoint in the future for certain therapies.

Of course, there are also GLP-1s. I think we're going to see them being applied to indication after indication after indication. They began as a therapy for diabetes, whereas, right now, obesity is the big thing, but that's just the surface. There are discussions happening across the industry about the enormous potential of these drugs, and I think we're going to see them at least investigated for a lot more therapeutic areas.

The other subject everyone is talking about is sustainability. When I went to Pharmapack Paris earlier this year, it was all about sustainability – a lot of European companies have put significant focus on it. Globally, the pharma industry is talking about carbon footprint, sustainability and manufacturing. There have been numerous talks and panels at conferences on developing sustainable drug delivery devices and how you minimise the overall environmental impact, from manufacturing glass all the way through to fill-finish and final packaging.

Packaging solutions is a big topic for sustainability, and it's not going away. However, the actual implementation of it and what it means is still a huge challenge. We're continuing to see sponsors struggle with how to extract value while committing to investments or certain targets, such as "We're going to reduce our carbon footprint by X% by 2030."

The actual implementation is still a real challenge because, at the end of the day, we're still working with standard container closure systems. We're still working with established manufacturing facilities and methods. Changing these represents significant infrastructure investment, and that's a time-consuming and expensive process. So what we're seeing is companies trying to go for the low-hanging fruit and minimise what emissions they can without too much investment. Personally, I think true change on the sustainability side is going to take a long time.

MR It seems clear to me that Europe is going to be leading the way over the US on sustainability. But, as Evan said, it's complicated and a lot of the low-hanging fruit has been already harvested.

Another trend I think we're definitely going to see more of is the transition of injectables from intravenous to subcutaneous formats. A big driver of this is moving healthcare from clinics to patients' homes, although that's not to say that if something moves from intravenous to subcutaneous it's always moving into self-injection. Subcutaneous injection is just more sustainable; it has so many advantages, and it's this part of the industry – combination products and drug delivery devices – that's done a lot of the work to make this transition possible. I think it's a

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really important shift in the way patients receive care, and I'm proud that PDA Miniverse can help facilitate part of that.

EE There's always an element where you need additional expertise as a part of lifecycle management. A lot of this is cost driven but, if patients have more options, it will drive down cost. The fact is that we have so many developers and CDMOs that fail to fully consider pricing and reimbursement. They think that if we just put a drug in a novel delivery device, someone would choose it over something else, but what we find time and again is that what drives behaviour, especially in the US, is the cost to the patient. So many companies are spending millions, sometimes billions, of dollars to come up with new drug-device combination products, but if they're not priced correctly, it doesn't matter that they have connectivity or a retractable needle. Sponsors are not getting rewarded for this differentiation, especially for small molecules that have several competitors on the market.

To summarise, the theme tying this whole discussion together is that patients deserve options, with treatment being able to take place in the clinic or at home being a major one. This is why we've seen companies, and regulators, put a bigger and bigger emphasis on human factors considerations. However, a lot of companies in the industry don't have that lifecycle management and strategic expertise in-house, so they have to rely on professional services firms like Kymanox to educate them and guide them. Overall, I'm really optimistic about where the industry is headed, and I'm looking forward to discussing these topics at PDA Miniverse next month.

PDA Miniverse: Medical Devices, Combination Products and Connected Health Conference will take place in Indianapolis, IN, US on June 24-26, 2025. For more information, visit the event website, here: www.pda.org/global-event-calendar/event-detail/pda-miniverse-medical-devices-combination-products-and-connected-health-conference-2025.

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