MATHIAS ROMACKER, PFIZER

As well as being a world-leading expert on parenteral delivery systems, Mathias Romacker is a very well-known, respected and much liked personality in the sector. Since the emergence of prefilled syringes onto the market in the 1990s and throughout the parenteral device sector's rapid evolution over the past two decades, he has been at the heart of this industry, working on both the device manufacturer side (including at Becton Dickinson and Gerresheimer) and then on the pharma/biotech side, most recently at Pfizer. Mathias has a true feel for the industry, the markets it serves, and where things are heading.

In this interview, Mathias shares his thoughts with ONdrugDelivery Magazine on the emergence of connectivity in drug delivery devices, from his current big pharma company perspective and also based on his previous industry experience. He explains why he thinks the buzz around connectivity in delivery systems is more than just hype and describes the trends in the pharma sector that mean it makes sense now to connect up devices. He also cautions, though, that connected technology must drive value in order to be successful, and points to some of the areas where he believes it could do so and how it might be done.

Q Connectivity has been called the next big thing in drug delivery. But you and I have both been around long enough to know that whenever we hear about "the next big thing in drug delivery", sometimes it's true, sometimes it is not. What's your feeling about connectivity in drug delivery? How important is it really? And why?

A It's a very good question to raise. Will something that is supposed to be the next big thing really be the next big thing? In this specific case, clearly we are looking at something that is part of the bigger ecosystem – the drug delivery sector is definitely not in a vacuum or a silo here. Think electronic medical records. And we hear more and more that payers need to see outcome-based therapies so they want to have ways to measure outcomes, measure success. So connectivity presents opportunities for diagnostics. And also, of course, connectivity presents the means to determine whether the drug is being taken at the right dose, as prescribed. From that perspective I think that connectivity – really being able to make the connection from a patient taking a drug to healthcare professionals, and beyond to pharma companies and to payers – it will happen. We don't know how fast but it will happen. First of all, the technology is now available and, secondly, the underlying need is also there.

Smart phones are obviously a crucial aspect – people having this technology at their fingertips, truly being connected. The internet of things has become reality and if you look across the board at who is using it, you have young ones but also older folks. People are growing up with it. Somebody who is in their fifties right now will be familiar with their smart phone. Fast forwards two decades and you'll have seniors – people in their seventies – who grew up with this technology and they aren't going to give up on it.

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Q There is this sense of two previously quite separate and distinct industries – digital tech and pharma – really coming together now. It seems like trends in both sectors are pointing to both being at just the right point to combine very effectively. What are the main trends and breakthroughs on either side – the tech side and pharma side – that are making now the right time to connect up our drug delivery systems. I guess I mean, why is this happening now? Why is this the right time – not earlier and not later?

A Explaining why this hasn't happened earlier is easier I guess. The technology was not there, or if it was then it was prohibitively expensive. Now of course the technology is there. I've always been a firm believer, though, that as well as just being available, the technology has to be driving value and it has to be affordable. I think we're seeing that now.

As to why it matters now, again it comes to the overall equation that in the pharma industry we have more and more biologics both being launched and in the pipelines of pretty much every large pharma company, and most smaller ones too. Many of these biologics are antibodies and so the injection frequency is changing. In the past most self-injection drugs – the growth hormones and the insulins – were mostly daily injection events. The more recent biologics coming through are injected less frequently – weekly, biweekly, monthly even.

So the question comes up, what actually happens between those injections? How can we monitor the patient and make sure of what is going on between these less frequent injections and between doctors' visits? How can you set up an individualised intervention system? Another industry that we have seen evolving is patient on-boarding. With so many self-injecting patients now, how do you do the on-boarding best?

Connectivity represents a tool that can help with both the on-boarding and with keeping the patient up to speed. If they are only injecting once a month, for example, the patient might forget how to do the

injection. There are opportunities now to have video on demand, training on demand. There are so many opportunities out there right now – where connectivity, in conjunction with devices and drug delivery systems, could be leveraged.

Q Is now the right time for us to connect in terms of drug delivery device industry trends too?

A As we discussed before, adding connectivity has to make economic sense. It seems to me that patient adherence is an important issue. Obviously it varies according to therapeutic area – it's higher in areas like oncology, for example, and lower in others, especially for asymptomatic indications. At conferences some speakers throw around numbers that are mind boggling! But adherence is definitely a big issue. We can improve adherence through better devices and better, more intuitive technology, for example, the needle should never be visible, pain should be minimised and safety optimised. The industry has made significant progress on this over the past decade or so.

Maybe the missing piece of the puzzle, something that you can't achieve otherwise, is that you want to interact with the patient and, in certain circumstances, monitor and log the use of drug delivery devices, such as inhalers and auto-injectors. But patients can't see their doctor every day and so this level of interaction can only be achieved through connectivity – there doesn't seem to me another logical technology out there. And as we mentioned earlier, the cost of this has come down substantially – think of low energy Bluetooth technology, think of energy harvesting.

Another very interesting question for me as an industry watcher is that historically the trend has been for simple, easy-to-use disposable devices, but is there an opportunity now for a reusable device with all the bells and whistles, patient comfort settings, you name it, and with connectivity, which users might prefer? A device like this could probably do a lot if it makes economic sense or if it can be reused, for example, for a chronic, long-term therapy.

Q There are potential advantages to be gained right across the board from connecting delivery systems – patients, payers, physicians/doctors, pharma companies, regulators, in clinical trials etc. Can you outline some of these advantages? Will connectivity become established in some areas, or for some purposes/functions, more quickly than others? Which groups of stakeholders do you see benefiting first? How will they benefit? Who has the most to gain overall?

A It's a very difficult question so I need to speculate here quite a bit. Clearly with the bond between patients and physicians/doctors this is an area that can definitely take off. Ideally healthcare professionals want to minimise the time they have to spend on training and adherence while still making sure that the patients get it right.

There is potential in the area of clinical trials but this is a little bit different. It's a much more controlled environment and the people in the trials are a little more co-operative than you'd maybe find in the overall population.

> "When you look at infrastructure from a pharma company perspective, how far do you want to go? Does a pharma company want to build up a whole infrastructure, or is this maybe an opportunity for some of the service providers in that space that they may be able to build the infrastructure or the ecosystem and within that space the pharma companies would operate and create value."

In terms of pharma and payers, this is an interesting one. Privacy issues may sometimes present a challenge that needs to be overcome. For example, I understand that with the device from Medicom (see this issue Page 52), Betaconnect, for Bayer's betaferon, patients actually have to opt in to share their device data with doctors/physicians.

It could be that for sharing data with pharma companies the information could be blinded and consolidated in order to anonymise it. So they could have information that tells them here are, say, 100 patients using the device, here are their adherence rates, these are the comfort settings they are using, and so on. For sharing data with payers, this is an interesting one that I've not read or heard so much about but obviously they have quite an interest in making sure patients actually take the drugs, and take themin the way they should, and also an interest in measuring outcomes.

Clearly medical records data is a very sensitive issue for patients so there needs to be some kind of confidence that it's managed in an appropriate way. What the appropriate way looks like still needs to be defined. It's in the interests of payers, doctors/physicians to have this information to enable them to make therapy decisions.

A recent partnership between West Pharmaceutical Services and HealthPrize is interesting (see this issue, Page 48). They are looking at reward systems whereby the patient is rewarded if they use a drug as it's prescribed and on a regular basis. I don't think the verdict on this is out yet. It's very interesting. For instance, in some markets payers could reward users with a co-pay they can manage. So it doesn't have to be that you have to give every patient something like a Starbucks voucher. It's evolving and of course the regulators have to weigh in with what they think is acceptable.

Whether or not the medicines regulators will be the ones making decisions on the issues of privacy and related matters, is an interesting question. I wouldn't say it would necessarily be regulated at that level. Although on the other hand they do listen to patient advocacy groups. Whoever makes those decisions in the end, one would hope it would be very inclusive.

Q What are the main drivers for this growth/emergence of connected drug delivery? And, crucially, what are the main barriers and challenges the industry faces?

A In this industry we like to talk about differentiation and in this instance – I may be totally wrong – I don't think connectivity is necessarily a great differentiation opportunity. A very good technology class comes along, connectivity tech, and it allows us truly to interact with patients, make sure they take their

medication, monitor and intervene if patients are not taking their drug. I think this is more an adherence play than anything. I think it's going to help multiple stakeholders across the board. Obviously the patient benefits from getting a prescribed drug and taking it the right way – best efficacy, best safety. The payer benefits because if the patients stay healthy because they are taking their medication well, this leads to fewer hospitalisations. And of course if patients are taking a medication that is therapeutically beneficial, and they are taking it for longer, then pharma benefits.

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In terms of barriers and challenges, I'm not really the expert as far as connected tech is concerned but the conversation about the security of electronic medical records has been going on for some time. I actually read recently that the application of Bitcoin encryption technology could be interesting in this area. My understanding is that for now there are a lot of different systems out there and they are not aligned. It may be a little bit like the VCR industry 30 years ago – with Betamax, VHS and so on. It's not exactly the same but clearly new ecosystems of technology are being established and are evolving and there may be an issue of compatibility.

When you look at it from a pharma company perspective, how far do you want to go? Does a pharma company want to build up a whole infrastructure, or is this maybe an opportunity for some of the service providers in that space? They may be able to build the infrastructure or the ecosystem and within that space the pharma companies would operate and create value.

Q How are large pharma companies such as Pfizer engaging with the developments around connected drug delivery systems, and the opportunities they present? Where do the most exciting opportunities lie for tech and other companies that could offer connectivity-related services, technologies and products as partners to large pharma companies like Pfizer?

A Not being Pfizer-specific, I can say that big pharma companies already have large IT departments, and they have already put quite a few apps out there. But it seems to me their usage is still not that high. People just don't use them much. I'm a strong believer that you need to make these things passive ideally, not active – like opening an app or with NFC holding a device next to a smartphone or the other way around. These are active processes whereas I think the opportunity is to create some kind of passive system, for example when it comes to injection logging.

Another aspect to consider is that device development in our world typically takes around three to five years and this timescale is largely under-appreciated. It looks simple but it takes a while to create and launch a new device! So obviously with the opportunity of connectivity coming we're going to have legacy devices, other devices that are already on the market, devices that are in development and devices whose development has not started yet. So, clearly it's a bit tiered. For delivery systems that are on the market or quite a long way into development you might want to consider add-ons to those devices. Whereas of course if you are starting from scratch or you leverage an existing device platform early, here is the opportunity to integrate connectivity fully at an early stage, and not to make it an afterthought.

> "Down the road the question might be, can you operate in the drug delivery device space without having a take on connectivity, without having a connected aspect to your offering?"

It's an interesting question, where the pharma industry stands on this. I don't have the answer. Is the industry now thinking when a new project starts, how do we actually integrate the connectivity? Or is it more a case of thinking well, we'll deal with connectivity when the time comes because we don't quite know exactly what it means and where the value is.

It's still very much a work in progress but it's an interesting space where we're hearing a lot of new names – companies like Qualcomm (see Page 27) have co-operations with pharma companies now, for example. We're also seeing a lot of the established drug delivery device players starting to adopt connected technologies seriously and to start going out and offering solutions to the industry.

Down the road the question might be, can you operate in the drug delivery device space without having a take on connectivity, without having a connected aspect to your offering? It's happening. There's a lot of excitement about the broad opportunity connectivity offers, to see how it is going to take off, who will be the main players and what will really drive it.

ABOUT...

Mathias Romacker is Senior Director, Device Strategy at Pfizer Headquarters in New York City. He joined Pfizer in March 2015. In this commercial role he focuses on the front end of device technology. He works with multiple functions and sites across the organization to develop a device strategy for Pfizer pipeline and inline products.

Previously Mathias worked over nine years in the device area for Amgen (Thousand Oaks, CA, US). Before joining Amgen he held multiple sales and marketing positions with Becton Dickinson and Gerresheimer in Germany, South Africa and New Jersey, US.

Mathias holds a Masters equivalent degree in Economics from the University of Freiburg, Germany.

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