BILL WELCH, PHILLIPS-MEDISIZE

Bill Welch has over 25 years of contract design, development and manufacturing experience, primarily serving customers in the drug delivery, health technology and diagnostics markets. In his current capacity as Chief Technical Officer at Phillips-Medisize, he leads a global, over-500 person development, engineering, tooling, program management and validation organisation with more than 75 concurrent schemes. He has been with Phillips-Medisize since 2002.

In this interview, Mr Welch gives ONdrugDelivery Magazine an exclusive preview of Phillips-Medisize's forthcoming workshop, "Realizing the Benefits of Connected Health in Respiratory Drug Delivery", at RDD Europe, which takes place on April 25-28, 2017, in Nice (Antibes), France. In the context of recents major acquisitions by and indeed of Phillips-Medisize, he explains the company's strategy around connectivity and electronics in respiratory delivery systems and highlights the importance of a coherent value proposition when developing connected or electronics-enabled products.

Q We've seen several strong trends in the industry over the past view years – the emergence of biologics sparking the increase in interest in appropriate delivery systems, especially parenteral devices; an upswing in the attention being given to drug delivery systems as patient-centricity, personalisation and self-administration become increasingly important in healthcare; and of course we've seen the arrival of digital tech and connectivity. Interestingly, across all of these, Phillips-Medisize has been right there on it, or ahead of the curve. Could you tell us how, and describe what the journey so far has been like from Phillips-Medisize's point of view?

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A This has been a long journey for Phillips-Medsize. We first identified the trend for what we call "smaller and smarter" back in 2009-10 and we've had an evolution of our thought each year since then as the market has changed and the patient needs have changed as well.

So, when we talk about "smaller and smarter", smaller relates to the patient expectation of devices engineered to be compact and portable in order to allow discreet usage and improve adherence. To take a look back 14-15 years at a well-known example, the Exubera dry powder insulin device was considered large and bulky and definitely not discreet. The system failed to gain acceptance among patients and physicians and was discontinued after a short period on the market. Meanwhile, if we take a look at some of the new inhalation devices that are reaching the market today, those that are electromechanical in nature, they are getting down to the size of a deck of playing cards and that is similar to the size of the mechanical-only devices. So there are things in clinical trials today that are in that form factor. Being small in size does not guarantee clinical, regulatory and market success for the entire system, which of course includes the drug. However, getting the device down to the size of a mobile phone, which does have consumer acceptance, may translate into patient acceptance on healthcare devices.

Addressing the "smarter" aspect, there are different dimensions of this to talk about, based on the device and the use needs. The first dimension of "smarter" is the creation of more intuitive devices – not necessarily electronic, but intuitive – that will help decrease patient error while increasing adherence, and also the desirability of the therapy in order to gain patient engagement. The second dimension is to improve the device's primary intended function: more effective, targeted delivery of the drug and greater efficiency of delivery, such that less drug product is required to obtain the desired benefit. So this area provides cost savings that will support improvements in other parts of the system, such as the inclusion of electronics and software.

This leads to the third and fourth dimensions of "smarter". The third is the integration of electronics to improve functionality via a electromechanical delivery system. The big benefit of electromechanical systems, even not connected, is to be able to use sensors and software to time the delivery of a dose, rather than depending on a purely mechanical device with which, study after study show, there are adherence problems even with patients who make a sincere effort to follow the prescribed regimen. So there are inhalers in clinical trials today that use electromechanical systems, and measure the patient's tidal breathing, to potentially gain increased delivery effectiveness while protecting against device misuse.

Then, the final dimension of "smarter" is wireless connectivity that allows the

device to communicate – smart phone apps, cloud databases etc – to share information with both patient and caregivers to improve adherence.

Often, when people think "smarter" they often jump straight to the concept of a connected device whereas, in reality, that's one of what we consider to be four dimensions of a smarter device. It's important to emphasise that simply adding connectivity to a device is not the solution. Success comes through making it about the entire system and considering outcomes, and not just putting Bluetooth or near field communications (NFC) in.

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What we know is that whether it's an electronics-enabled device or a connected device, there is cost being added *versus* a mechanical-only device, so the question becomes: what is your value proposition to improve the overall therapy, reduce healthcare costs to offset that investment needed in the electronics and software?

Q The company has gone through some major acquisitions over the past year. The two most prominent were first that Phillips-Medisize acquired Medicom Nordic, and then it was acquired itself by Molex. Tell us what these acquisitions mean for the business.

A We've actually had a third acquisition in the past year, which was the acquisition of Injectronics in the North East United States. All of these acquisitions really fit with our strategy around electronics-enabled and connected healthcare.

So starting with Injectronics, that acquisition was really aimed at getting us a location that was close to the biopharma hub of the North East US, and being able to localise our services there.

The acquisition of Medicom on June 1, 2016, was of course highly strategic for us. Two key aspects of this were particularly exciting. Firstly, the offering of a device strategy service to our customers, which relates directly to what we were talking about earlier as one of the big barriers: exactly how are you going to position your device, create the value proposition and reduce overall cost of care in order to fund an electromechanical, connected device? So the Medicom offering positions us very well on the front end, working with the drug owner / biopharma company on a device strategy that will help make a connected solution successful. The second thing, which was equally important, was that in Medicom we acquired a low-volume orphan drug delivery device capability in Denmark, so traditionally Phillips-Medisize has done things globally at volumes of hundreds of thousands at the low end up to tens of millions. Now with Medicom, we've got a great capability to do connected device manufacturing for devices that may require just tens of thousands of units per year. That smaller-volume capability is equally important in serving the broad spectrum of the market.

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Molex on the other hand, as a new owner, provides us with global capabilities in electronics manufacturing. Therefore, when we get into production and begin setting up a supply chain, we've got the ability to be vertically integrated in that supply chain. The reason that's important is many of our customers have viewed that ability not only just to engineer and supply-chain-manage as critical, but also to be able to do the manufacturing of the PCBAs [printed circuit board assemblies] and related components as critical too.

So with Medicom we cover the extreme front end of our device strategy, and with Molex we've got the supply chain elements covered. The great news here is that we've got several case studies where we have been able, with the combined Phillips-Medisize and Molex solution, to go back to our customers with new vertically integrated solutions that collapse the supply chain and in some cases reduce the cost of the device *versus* our prior solutions, which were very intensive on an outside supply chain.

Q We touched on the arrival of connected health earlier and this is without doubt one of the most fundamental shifts I've experienced since I began observing the drug delivery sector nearly two decades ago. We'll go on to talk in more detail about your forthcoming RDD Europe Workshop which focuses on Connected Health in Respiratory Drug Delivery but, leading into that, I wondered if you could talk generally about connectivity and the impact the arrival of this technology is having on the world, on healthcare, on pharma and in drug delivery systems?

A In terms of the general impact connected health technology is having on the world, this becomes yet another way of connecting people not only to their healthcare providers but also to others in the community who may be managing the same disease, and therefore being able to create networks where people are not finding themselves alone in the problems that they are facing. So that's some of the soft side benefits of connected devices.

Beyond that we have seen good applications of connectivity technology, obviously with their different challenges with sensors and communication, but we've seen applications in inhalation devices, injectors and indeed across the whole range of drug delivery devices.

The biggest common need, regardless of the type of delivery device, is to come up with a strategy that in the end results in the connected ecosystem. When we start to pursue that strategy, then gathering that data and managing that data becomes crucially important for the success of the therapy. And it is not one size fits all for different therapies, different delivery systems and different indications.

You can start with the basics of what dose was delivered and when. But when you start to conduct in depth strategy work to determine what you need for effective therapy, then you begin to bring in other data that are important to patient care. You can gather and consolidate it with the basic dose and time data and then you can start to do analyses and correlations that were impossible before. Now you gain the

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ability to use true information to develop personalised solutions for individual patients.

Q What are the major regulatory barriers that need to be overcome in order for connected drug delivery system development to progress?

A There are unique requirements in each region and even at the country level that need to be considered when building a connected health system.

As part of our device strategy and development process, we work with our clients to understand which markets will be targeted for the entire connected ecosystem, and ensure we have the right expertise on the joint team to address the requirements in parallel with the device development process. This includes technical requirements (infrastructure being scalable and durable, etc) and ongoing support for selected OS platforms (Android, iOS, Windows, etc).

Q Focusing now on your forthcoming Connected Health in Respiratory Drug Delivery workshop at RDD, as mentioned previously, Phillips-Medisize has been right on the money in identifying digital tech and connectivity as a major area of growth and has already built considerable expertise and know-how. What are the main points you are going to cover in the workshop? What value can those attending the workshop expect to derive?

A In our workshop we are going to be able to start by giving an extremely well informed view of the landscape, describing where things are in the development of connected inhalation devices. From there, we will have three different smaller breakout sessions, and we'll have each of the groups look at some of the challenges in implementation and some of those barriers. We'll be able to draw parallels and start to formulate solutions.

So we'll be able to say, here's the landscape that we have today, here are some of the challenges that we have for the implementation of connected health, how do we go about solving some of those strategies. We'll be able to hear points-of-view from the broad spectrum of attendees at the conference from industry and academia.

In terms of the value those attending the workshop can expect to gain, first, attendees will gain a very concise update as to the current state of the industry as it relates to connected healthcare as well as electronics-enabled healthcare. Secondly, they will be able to get into a very healthy small group discussion on specific issues and how to go about addressing them. So it won't simply be an hour-long presentation with a Q&A at the end. This will be an interactive discussion in small groups that is intended to engage people to think about the challenges and, from many different viewpoints, how you go about addressing them.

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RDD is a very interesting conference due to the global nature of the attendees. Going back to the earlier points we discussed about regulatory considerations, each geographic market has its own laws and regulations that have to be met in order to release a product where you're collecting personal data. So it will be interesting to see how these different regulatory environments translate into different approaches, from people who work in those different geographic regions, to overcoming some of the barriers.

Q The point about developing a coherent value proposition seems to be central and links the various other aspects. Perhaps you could expand on this a little more?

A To boil it down into a simple statement, it is about the industry going from selling a drug, to delivering improved outcomes. Once you start from there, then things begin to flow logically. Improved outcomes will be achieved how? By superior devices, improved patient engagement, and getting better therapeutic results. Once you reach that stage, now you are able to start monetising what is the value of that improvement with each new connected device, and that becomes your value proposition as to how you will pay for such a device.

Q To conclude, I wonder if you could tell us what the plans are for the short/medium term and also, more broadly and in light of the current trends in the industry, what the longer-term future holds for the company?

A We continue to be very focused on providing complete solutions to our biopharmaceutical, diagnostics and medical technology customers. With the acquisition by Molex, we add global scale in electronics to our existing capability set. Customer response has already been extremely positive, and we will continue to focus bringing connected health solutions to market for our customers.

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