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‘Context Is All’ – The User’s Role In Healthcare Innovation

Sustainability Is Becoming A Major Factor In Medtech Design

by Ashley Yeo

Healthcare product innovation and design evolves continually, and COVID-19 times were no exception. But patient-centred design has always been the platform on which medtech businesses build success, says Mike Phillips of outsourcing industrial design company Renfrew Group International.

For a large majority of medtechs intent on developing their international business, the first networking event written into the new year’s calendar is usually that of the Medica trade fair, the business building forum held over four days in mid-November.

The Düsseldorf, Germany event has for decades been without rival for medtech systems and disposables companies, as well as developers of diagnostics and lab equipment, digital and IT solutions and orthopedic aids. For medtech innovators and design outsourcing companies alike, Medica serves a number of purposes.

Top of the list is the chance of attracting new clients and partners, followed by unpacking the value of innovative technologies and profiling unique expertise. The networking opportunity among a vast and varied attendance – 81,000 visitors in 2022, say the Medica organizers – is a further major draw.

Contract designer and pilot manufacturing company Renfrew Group International is a stalwart at the annual event. The Leicester, UK company was back again at the 2022 event, making long lists of potential new clients to follow-up in post-meeting Zoom calls.

The in-person buzz was clearly back at Medica in 2022 after virtual and hybrid formats of 2020

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and 2021. The relief among delegates glad to be once again doing business in the field was visible – and audible.

In the middle of the maelstrom in hall 9 stood Mike Phillips, design development director at UK-based Renfrew Group International, fielding enquiries in the bustling environment. Phillips, an industrial designer with the dual remit of developing devices *and* business, has an impressive Medica attendance record in a 17-year career at the company.

Prior to joining Renfrew, Phillips held similar roles held at other design agencies, he told *In Vivo*. I barely hear him above the hubbub of half-shouted competing conversations mere feet away on and around Renfrew's exhibition stand.

Patient Centric Focus Paramount

Phillips explained that industrial design combines many disciplines – engineering, human factors, design for manufacture, manufacturing, prototyping. They must all be brought to bear in user-centered design.

"It's not about an engineering focus to make a device work better, but bringing all these factors together," Phillips said. "The role of industrial design is to put the user at the center," he added.

> *"Patient involvement has become a requirement – but it always was." – Mike Phillips*

"Patient involvement has become a requirement," he noted, adding quickly: "but it always was." The process of patient and public involvement (PPI) calls for members of the public to work alongside researchers to advise, add insight and possibly even do co-research on themes of how people can or should live with illness.

Publicly funded projects involving several partners to develop innovations must show evidence of patient involvement in applications. "For us, that's always been the case. It makes sense to have the user at the center of the process." Investors and funders of projects might see this as a new requirement, however.

The science can become all-absorbing and cut out the surrounding "noise," Phillips continued – but it is precisely that surrounding noise that makes the product, and shows how it fits in context and how it is used, he stressed. "Context is all. We

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MIKE PHILLIPS

must put technology in context." Renfrew's task is to keep a wider view in the early stages of the science and encourage scientists to "think ergonomically."

Sustainability Factor Related To The User

"Our role is to prioritize the key design drivers," Phillips said. "Sustainability is one of these, and has become a higher priority with each passing year."

Factoring in sustainability frequently calls for businesses to apply "trade off" decision-making in developing the business model.

"There is a development cost to sustainability, and to making a business more sustainable," Phillips observed. More time and effort must be deployed in the early stages to ensure that sustainability is considered. But at the end of the day, it could also be the case that the overall product cost is less, he speculated.

> *"Defining your target audience is the starting point for any design requirement specification."*

In researching new materials, a business may have to put more research into the planning stages to ensure it has factored in the sustainability argument. "A representative demographic has always been incorporated in properly run programs," Phillips added.

Every user must be considered, he said. For example, head mounted technology needs to take into account different skull shapes—of which there are largely three. "Ergonomics has long been about the centiles."

A properly inclusive design will work better for everybody, but there will be outliers who require a product extension or a different product. "Defining who your target audience is, the user and the user's needs are the starting points for any design requirement specification."

Phillips added: "When designing medical devices to ISO 13485, the user requirements are the beginning of the process, and everything flows from that, even if it involves a novel step in the

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technology."

The Demands On An Innovator

Innovators are both leading the argument and adapting to needs at the same time. Phillips describes Renfrew as a specialist in design, but also a "general practitioner" in the healthcare innovation space, as the company works across so many different types of technology – including outside healthcare too.

The size or type of technology does not matter to the company. For example, while Renfrew works on disposable surgical tools, it is also helping develop both the world's first bio-artificial liver with UCL, Royal Free; and the chemistry involved in the *artificial pancreas* (pictured above) being developed with De Montfort University in Leicester.

The latter projects are of a different order of innovation, and call for a depth of understanding and specialism that go beyond the science of more traditional hospital devices. But they all always factor in the constraints of ergonomics.

Phillips said Renfrew brings to bear a curiosity and broad interest in all kinds of scientific advancements. It can also "interrogate" the development, while always bringing thoughts back to the human requirement and how a product will be made.

Keeping ahead of rivals is a question of both talent and abilities, said Phillips. Competitors cannot offer the size of batch manufacturing – typically in runs of 50 to 100 – that Renfrew can for studies and to get engineering trials completed, he claimed.

Renfrew works with a UK medical robotics company manufacturing parts for its machines. In such projects, runs can extend into the low thousands. Not many factories in the UK have that capability, Phillips asserted. "For certain things, we don't have a lot of competition," he said. But it is still a complicated message to broadcast, as most of Renfrew's projects are confidential.

"We win contracts in robotics, say, but we can't talk about or show much, if any, of the work, which makes selling the process a challenge," Philips said.

Nevertheless, "working under the hood and looking down the microscope equally are our territory – and we stay ahead of the competition by being really pragmatic." For Phillips, being a pragmatic and useful technology consultancy calls for both for a questioning mind and understanding of science – as well as an ability to make tools and production parts.

The Rise Of Remote Technologies

Innovation in healthcare is often highly charged by the motivation of driven individuals. Phillips shares their enthusiasm. "There are so many brilliant people out there; you can't fail to be

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excited by or curious about what they're doing." It's tough and can be challenging – but never boring, he adds.

COVID did not alter the remit of the healthcare innovator, as Phillips sees it. "From my point of view, nothing has changed," he said. The essential role and demands have remained constant, while evolving over time.

The ability to have meetings via remote conferencing has been generally welcomed, but Renfrew had adopted this option for international clients before COVID struck. The difference for Renfrew now is that, post-pandemic, all third parties are seeing more clearly the merits of remote conferencing.

The bigger spin-off from COVID has been the laser focus on the patient/end user – which has always been a central driver for healthcare innovators but was augmented by the pandemic. COVID – coupled with economic considerations – helped to accelerate telehealth and telemedicine, which were already on the path to wider adoption pre-pandemic, Phillips observed.

Furthermore, the demographic change that has long been understood – that of the aging population and rising demand for chronic illness management at scale – has itself given impetus to care and monitoring at home. It has had the spin-off of keeping people out of the inpatient setting.

One of Renfrew's projects is an SpO2 monitor and smart wristwatch designed as the first to be a medical device to ISO 13485 to be worn by people at home living with COPD who adopt self-care options.

The home peritoneal dialysis product, Intellis, the development of which was sparked by a contact at a previous Medica, has gone from concept design through prototyping. It is now available. The technology, which remotely connects to the carer or nephrologist, is described by Renfrew as a user-friendly APD.

New R&D focuses at Renfrew include breath diagnosis technologies and remote heart monitoring products, both of which involve care away from the hospital. Both have benefited from patient involvement, as has the bio-artificial liver dialysis project.

The latter is at the Royal Free Hospital in London. Renfrew has partnered with UCL on the workstation technology to deliver user-centered design and prototyping. The complex system is about to go into first human trials. "At this stage of the project, we're seeking to expose the methods of operation and set out a clear logic for the user," Phillips said.

Patients waiting for donor organs have been part of the development process. "They have been

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involved at every stage to ensure that both they and their carers are not intimidated by the technology," he added.

The essential consideration with all technologies is that "you've got to be able to make it," Phillips said. "Whilst working with clinicians and scientists at the beginning of a project, you have to remind them who the user is and to factor in how it will be made." It is quite a simple message, but difficult to achieve, he observed.

Phillips summed it up: "If it was easy, we wouldn't be in business."

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