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By Ashley Yeo, 15 February 2017

FLEX HEALTH SOLUTIONS’ ROLE IN THE MEDTECH SPACE is helping other companies develop superior products for the broadest market appeal. Its ability to source ideas for medical design from other parts of its $24 billion business means it is already leveraging the Fourth Industrial Revolution, just at the point that the industry is undergoing dramatic change.

As the medical device industry matures and evolves, many manufacturers are seeing the merits of playing to their strengths – the clinical aspects – and are prepared to look for partners to whom they can outsource design and technology aspects.

Flex Health Solutions, formerly Flextronics International, offers itself in this space, being able to leverage technologies and ideas from diverse industries that are further along the evolution path, and help third parties plan for the future so their designs are not “old” at the point of launch.

It’s the shape of the medtech industry of the future, believes Flex’s president of Health Solutions, John Carlson, who says that the lean and efficient design-for-innovation processes deployed by his company and others have already been used effectively in many other markets.

How medtech deals with the new situation it is finding itself in is the talking point in the industry, bar none. Trump, TPP, Brexit, new EU regulations – these are all major issues that businesses need to navigate and accommodate in strategic ways. But in the evolving health care world of partnerships for patient outcomes, get the industry-customer needs relationship wrong and survival is at stake.

The industry is changing faster than ever, and manufacturers have to be leaner, sharper and not only more responsive, but also more predictive. And if medtech manufacturers are working flat out merely to play to their strengths in the clinical arena, how can they cover the technology aspects and new demands placed on them regularly?

John Carlson, the president of San Jose-based Flex Health Solutions, sees both the problem and the solution. “It’s impossible for companies to stay on the cutting edge of technology, given how fast things are changing,” he told In Vivo during the recent annual MedTech Forum, hosted by MedTech Europe (MTE) in Brussels, Belgium.
Carlson’s company, previously known as Flextronics International, is a $1.8 billion component of the $24.4 billion multi-industry Flex Ltd. group (sales to March 31, 2016) that partners with most of the world’s leading medtechs in design and development – often anonymously and never in a branded way. In medtech, its remit is devices, diagnostics and drug delivery, but Flex works globally in many other segments from aerospace to automotive to energy to co-develop innovative solutions to problems.

Flex Health Solutions is not naive to the requirements of the medical space, Carlson stresses, and has full quality systems (QS) in place, expertise in full design controls and the ability to embed augmented and virtual reality tools into its own processes. It also knows how to bring current and future regulatory requirements into the design and development of products, and works in almost any scenario where transformation is required. For instance, getting companies in the consumer space into the wellness space, and meeting International Organization for Standardization (ISO) standards or helping medical devices and pharma companies leverage consumer-facing technologies.

The spread of Flex’s industry coverage helps the group to see where medical technology is going to be, compared with where it used to be. For Carlson, this “light access” to a range of many other technologies means that Flex Health Solutions is already living the Fourth Industrial Revolution and meeting the interconnectedness challenges of tomorrow – incidentally, the theme of MTE’s December forum.

Interviewed by In Vivo at that event, Carlson explained that Flex Health Solutions can help accelerate its partners’ innovation pathways. He explained, “Today, we are not deep clinically – we are a very good technology company – and we look at different ways of solving problems within the health challenge.” He sees this as a huge competitive advantage and something that also helps the third parties understand their internal resource allocation.

Heath care is conservative, partly of necessity to avoid bad outcomes, and is perhaps 10 years behind other industries in this evolution. But because the economics will no longer support the old way of doing things, we are now on “the burning platform upon which change has to happen,” according to Carlson. Whether that’s alarmist or not, it’s likely to be accurate, and the availability of expertise at companies such as Flex Health Solutions is at least part of the answer.

But the group is now at the point where it wants its customers – potential and current – to know more about its identity and its value offering in the fast-changing medtech industry and health care sector. “Knowledge is in a different place to where it was two to three years ago, and technology moves at an ever more rapid pace,” said Carlson.

He goes deeper into these themes, and Flex’s ability to bring resources at scale, in the Q&A below.

In Vivo: Describe the role and relevance of Flex Health Solutions in helping meet the needs of medtech manufacturers.

John Carlson: It’s a question of where do you put your effort. If you’re in R&D, the best value you bring is in deeply understanding clinical problems. But at Flex Health Solutions, we understand technology across the board and can help our customers accelerate what they’re doing. We are seeing that the Internet of Things has now moved into health care. We work with most of the large pharma and device companies, on drug delivery, monitoring and patient compliance, as well as in design and manufacture of their current products. We are not a branded company and we don’t sell directly to hospitals or physicians. Regulatory and reimbursement services are not our claimed strengths, and they’re not currently part of our offering, but because we can see what’s happening, we are able to guide our customers through changing requirements.

IV: The company has changed its name and seems to be at a watershed. What are the new opportunities it is aiming for?

JC: We talk about it as our Sketch-to-Scale offering. We started out as a standard contract manufacturing company, but then customers began asking for efficient and effective design. And now we are at the stage where we start at the very beginning of the sketch; when customers come to us with the problem they want solved we can deploy over 600 medical device design engineers. The staff are located all over the world – including at our big sites in Dallas [TX], New Hampshire, Milan [Italy], Haifa [Israel] and Singapore.
Part of the reason for that geographic spread is to target and reach different technology pockets, but it’s also a result of our acquisitions over time: Flex has been buying design service companies to bolt onto the offering and to make us more competent. We now have the ability to move into industry spaces pretty aggressively. For instance, Flex acquired Farm Design, a full-service human factors and industrial design, FDA-compliant company that has been providing development and design services to medical device and diagnostic companies for more than 40 years.

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IV: Describe your health care sector coverage.

JC: We’re very broad, but selective, and there are certain areas we don’t participate in – for instance, today we’re not completing the final assembly of implantables [defibrillators, pacemakers, etc.,] but we do support their design and development by incorporating proven technologies in communication and hardware design/ manufacturing. The final assembly of these devices tends to be done in-house by the larger OEM [original equipment manufacturer] companies. But if you look at the large diagnostics systems, we make them complete with full assembly.

In outline, the devices we produce range from syringes and catheters to complex respirator monitoring equipment, leveraging expertise in medical design, validation, process engineering, manufacturing and precision plastics. In drug delivery, we work on pens, autoinjectors, pumps and inhalers. In the field of diagnostics, we don’t get involved in the reagent and the chemistry inside the machines, but we do the physical side, the electronics – building the design and optimization.

And we work with companies big and small to help them develop medical tools faster, and our portfolio contains life-changing medical solutions that range from insulin pumps to brain cancer treatments. A recent example is the technology from telemedicine start-up HealthTap that connects patients with doctors remotely and securely via phone, video or text. It gives 24/7 access to more than 100,000 licensed doctors in the US alone. Our work also extends beyond health care in its strictest sense to the world of automotive safety, where we contributed to the development of in-car systems that connect wirelessly to wearable glucose monitors.

IV: Are clients coming to you with different questions as the industry evolves – for instance how to maximize life cycle?

JC: For us, it falls under two major headings. The first is life cycle transformational opportunities, where we’ve seen tremendous consolidation in the medical space in the last few years. Here, we have the challenge of managing these growing portfolios. Some clients ask us to manage all their factories, products, all the life cycle supply, as they find it distracts from their ability to focus on innovation.

The second challenge is around innovation, where we are routinely asked, “How can you help me get to revenue faster, shorten my development cycle, get me cutting-edge technologies fast, or augment my capabilities?”

Basically, it means managing the complexity of the overall manufacturing portfolio and being partners on the innovation side to get revenues faster for the partner.

IV: What sort of projects does Flex get involved in, and how does it select and grade them?

JC: We don’t start out on innovation ventures without a partner in the first place. We don’t have commercial outlets and don’t take products to the market, but we do work very closely with our customers. And then some of our customers will turn down a product or a technology approach as just not being right for them, maybe because either the science or clinical side are not mature enough, in which case we can’t help them get them to market sooner.

Or we might decide that a project is not within our competencies. At any point in time we’ll be working on 40 to 50 development projects that can take from six months to two to three years, depending on the type of project and scope of engagement with the customer. Some-
times the customers want a narrow engagement and sometimes it’s a broader and longer commitment. And our business model allows us to meet the customer where their needs are going to be, from very early concept. Other times, it might be perfecting manufacturing.

**IV:** Flex is a group of many divisions, but how does it take ideas from other parts of the group and apply them to its own projects?

**JC:** What we’re seeing is a natural evolution in the medical space that’s happened in other industries already. There’s a rapid commoditization of technologies in the medical space and loss of pricing power in the marketplace. And pricing is being set by governments as opposed to by companies, as it was in the past. Just one example of the global industry transformation is IBM’s [International Business Machines (IBM) Corp.] strategy with personal computing, when it finally decided to sell to China’s Lenovo in 2005, which also agreed to acquire its Intel-based server business in 2014. This put IBM completely out of that space.

Health care has been insulated for quite a long time from that sort of development, because the regulatory burden of getting into this space – and its higher margins – have meant that there has been no need for companies to move things out of their own facilities. But we are now seeing substantial margin pressure hitting most of the large companies and they are having to rethink their fundamental business models. So they are looking at different means of innovation and different means of manufacturing and product support across the board. That creates different kinds of opportunities for a company like Flex.

**IV:** What kind of innovation are companies now looking to develop, in the current post-blockbuster era where commodities and breakthroughs live side by side?

**JC:** The larger medical companies are looking for partners like Flex that can do the ongoing incremental innovation for them to allow them to focus their resources on more of the transformational things. It’s not only development of the product but also the development of the clinical and economic data that substantiate the value proposition of a new technology. The cost of developing a new opportunity has gone up dramatically.

It’s a world where you have to make fewer big bets and must have a partner that can sustain the rest of your business. It becomes a very different choice to the one that manufacturers had in the past.

You have to be very selective unless you can prove that there has been a clinical outcome improvement, and improvement in patient satisfaction and a cost reduction. If you can’t prove that, then payers are not going to adopt the product. More and more, they want proof at launch as opposed to, “I’ll show you the data later.”

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**IV:** Your role at Flex includes a substantial element of forward thinking?

**JC:** We’re not looking at clinical trials, but as we look at the type of trials needed for the type of project we take up, in particular for start-ups, we ask the customers if they have the resources in that space to allow them to invest in the clinical and economic evidence generation. Because if they don’t, the chances of adoption of that product are going to be minimal at best.

The greatest value we capture is in the manufacturer side of things, when we focus on production and are able to work on the distribution side. Flex is a manufacturing company that is very lean, efficient and global, and the bulk of our revenues come through that manufacturing part. We’ve added the services and design and other parts to help our customers. We say, when we’re manufacturing they’re selling; when they’re selling they’re making revenue. That’s the symbiotic relationship.

As we look at deploying our design and development resources, we have to be judicious to ensure they actually lead to long-term manufacturing. If we are not sure that a product will succeed, we are not so interested in doing that design for them. It’s part of the evolving industry.
IV: *But you're in that part of the industry that can take the pressure off some companies?*

JC: We can help clients work in different ways, and even via novel financing for some of our customers: we'll help to finance their R&D, for instance, and help them re-address their P&L constraints. These are ways we are helping to shape the industry as it evolves.

One of the unique advantages we have is that we see across the industry. We're working with most of the large companies in the medtech space. We have a good view of their strategies, and we can pick up the trends as they happen. We have a very good vantage point on health care, and we have a good view into other industries. To me, health care is going through a normal evolution that other industries have gone through – they've been insulated for a long time, but the insulation is now being ripped off because the reality of the cost of health care coupled with budgets being squeezed is that no one can afford that any more.

IV: *Will Flex's involvement have a beneficial effect on time-to-market?*

JC: The pace of change in the other industries has been much more rapid. If you start a new medical product today, it’s unlikely to hit the market for up to 10 years. Health care is seeing a slower pace of change than elsewhere, but here, as has happened elsewhere, you can imagine a picture of commoditization, price pressures and regulation all affecting – and forcing change upon – the industry.

Will the changes result in the speeding up of development cycles? That all depends on the regulatory environment. However, we are seeing that more and more governments are matching approval processes with the economic considerations. While it may take less time today to develop a product, the proof needed for adoption may take longer.

For example, a company with a US PMA product starting in development can at best expect it to enter clinical trials in three years. After that, it probably takes one to one-and-a-half years to execute a clinical trial to get the evidence required for approval. Then it would need to be submitted to the agencies – say another year in review processing after that – to get approval. In general, that is when the economic studies are started. This adds another year or two. So in the end, it’s five, seven or maybe even 10 years before the product hits the market.

“Mid-sized companies will face a lot of the pressure as they won’t have the breadth to compete in a total offering space. Health care providers are moving away from acquiring products to trying to buy solution sets – a package – and are being reimbursed for the procedure, not for the individual line items anymore.” – John Carlson

And because of the regulatory process, that product is frozen from five years earlier – the product and its components are five years old the very day it launches. Those are the biggest barriers in health care. So the question is, how do you help companies start that project with a view to technologies that will be available four years from now, as opposed to those available two years before they started?

The evidence generation period and the risk aversion that companies and regulatory bodies face are there for a reason: no one – companies or government bodies – wants to be responsible for launching a product that has unknown risks. But risk aversion causes increased duration of clinical trials in order to give them the necessary robustness, which to me is the “long pole in the tent” of the development cycle.

That needs a look into the future, and we have that line of sight into the technologies that will be available. We are getting that from, say, the consumer space among other areas, and are able to know what electronics and communications technology will look like in three years’ time. We can future proof, because we see what’s happening in other industries, and then use that knowledge to leapfrog.

IV: *Will we continue to see the industry changing shape – bearing in mind the demands being made of health care systems globally?*
JC: We will probably continue to see an ever smaller number of very large medtech companies. There will be consolidation at the top end. It is what has happened in pharma, where there has been a trend toward consolidation of the industry. And there is also a trend to outsourcing of innovation. Most pharma no longer have their own drug development teams – they farm out that activity. So outsourcing will happen more and more, and larger companies will outsource cutting-edge innovation to the smaller start-ups. For example, Medtronic [Medtronic PLC] over the last few years has been very aggressive at acquiring these cutting-edge technologies, much like the pharma industry.

We think that a lot of the mid-sized companies will face a lot of the pressure as they won’t have the breadth to compete in a total offering space. Health care providers are moving away from acquiring products to trying to buy solution sets – a package – and are being reimbursed for the procedure, not for the individual line items anymore. If you’re a one-trick product provider, it then becomes very difficult for you to compete when you’ve got to provide solutions for outcomes.

You can see these types of companies being acquired as portfolios shift over time. But the innovation will come from smaller start-ups, the more aggressive, nimbler units that can get into that space more quickly. The larger companies will expand their partnerships to accelerate their internal innovation. Partnerships with Flex are ways the companies can expand their capabilities and accelerate their internal innovation.

IV: Are the high-profile political factors in the US having an impact on the medtech sector yet?

JC: Health care, as we look at it today, is unsustainable. Just look at growth of health care and the lack of efficiency – there have to be ways of becoming more efficient. As to how health care will pan out in the US, post Donald Trump, his Health and Human Services secretary Tom Price is known to be a proponent of the physician-patient relationship, which Obamacare fundamentally took apart.

Reimbursement will still evolve toward fee for outcomes as opposed to the current fee for service. In the past, it was a case of the more you prescribe, the more you’re paid. All the incentives were to deliver more health care, so providers got paid more under perverse incentives. But there will be some form of personal accountability coming into health care, and a system where individuals have to be more responsible for their own health. This, and more patient choice, will force a different kind of innovation.