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China Clinical Data Crackdown Sees Device-Makers Withdraw 101 Applications

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Just when the dust has settled on China's clinical-data crackdown on pharmaceuticals, a new campaign is being waged against the same types of violations for devices.

China FDA has plans to conduct no less than 50 "surprise" field inspections in 2016 following the release of a regulation on unannounced inspections for device-makers last year. The inspections are targeted on two categories of companies, according to officials at a recent medtech sector meeting.

The first category of manufacturers includes companies that have been identified by whistleblowers as having clinical data issues; the second category includes those that already have a history of clinical data problems from past inspections.

So far, CFDA has completed 36 unannounced inspections, and will publicize the results on the agency's website, according to Xintian Li, deputy director of medical device section at Jiangsu Provincial FDA.

According to Li, who spoke at the Device China conference held in Shanghai on Sept. 11, the regulatory agency will also be looking to crack down on irregularities in medical device distribution channels via inspections of distributors and wholesalers. This distribution channel crackdown will focus particularly on the following four points:

1. Proper legal documents of the seller;
2. Suitable capabilities;
3. Sales records traceability; and
4. Any illegal sale of second-hand devices.

In addition to the unannounced inspections, CFDA also plans to perform follow-on checks, routine inspections, and conduct cross-border inspects on global device firms importing devices into China.

One executive at a domestic manufacturer of respiratory machines likened the volume of inspections being conducted by CFDA to the volume of "raindrops."

DIRECT AND UNANNOUNCED

The unannounced inspections are conducted both discreetly and swiftly to increase the effectiveness of CFDA's regulatory enforcement, said Jiangsu FDA's Li.

"A new catchphrase is called 'Direct and No Announcements,' meaning inspectors go straight to a manufacturer and directly conduct the inspections, without previous announcements and notices," Li told the participants, according to local media outlet Biodiscovery.

In a bid to show its determination, CFDA put into place new inspector recruits at

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FROM THE EDITORS OF: **THE GRAY SHEET, CLINICA, START-UP** AND **MEDTECH INSIGHT NEWSLETTER**

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One of the leading experts in the field of interventional cardiology, Robert Byrne, discusses the questions that still need to be answered about bioresorbable stents and how this field can move forward.

August sees M&A activity trickle
http://bit.ly/2dheJTC
The dog-days of summer produced just a handful of mergers and acquisitions in the medtech sector, and no blockbuster deals. However, several companies made smaller deals for innovative products in a range of sectors including IVDs, cardiovascular devices and ophthalmology.

NEST news
http://bit.ly/2cZMw5K
http://bit.ly/2cVaZFH
A new set of recommendations have been issued to facilitate the launch of an FDA-championed National Evaluation System for health Technology. Read our coverage and listen to our podcast interview with Mark McClellan, who is coordinating the planning effort for the project.

Lab-developed tests on the Hill
http://bit.ly/2cDbxjW
Senate HELP Committee Chair Lamar Alexander suggested he would prefer to "start from scratch" in developing appropriate regulatory controls for laboratory-developed tests during a Sept. 20 hearing, despite a proposed regulatory framework for FDA for the tests that was more than 10 years in the making.

Device Week
http://bit.ly/2db8Ye3
Our weekly podcast, where *Medtech Insight* journalists discuss topics they are covering that impact the device and diagnostics sector.

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Medtech insight

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the beginning of the year. The agency does not let them know which factory to inspect until they get to the province where the plant is located, the official disclosed.

Out of the 36 factories that have already been inspected, 14 manufacturers were ordered to halt production, the licenses of four factories have been revoked, and 18 facilities were ordered to improve based on the findings. And almost all of the inspected firms were cited for various issues, he added.

DATA AUDITS LEAD TO REJECTIONS

Manufacturing issues aside, CFDA released on Sept. 7 the results of clinical data audits on four device-makers, and rejected their new device applications due to date-integrity issues.

The agency rejected the filings "due to data integrity issues, including that the clinical study sites can't provide original records, and samples provided by the sponsors can't be traced, and inconsistency between the study reports and field inspections," said CFDA on its website.

Meanwhile, the agency announced that 51 makers have voluntarily withdrawn 101 new device applications.

Although the majority are domestic manufacturers, the list also include multinational medtech firms such as **Boston Scientific Corp.**, which has withdrawn its applications for endoscope biopsy needle and accessories, **Olympus Corp.**, which withdrew hysteroscopy and accessories, and **Biomet Inc.**, which withdrew artificial hips.

"With the increasing number of mergers and acquisitions, and more capital flowing into this previously closed sector, there is a feeling that some companies are overly focusing on growth at the expense of regulations," says Xintian Li, Jiangsu Provincial FDA.

The agency has said that it intends to exempt certain low-risk medical devices from having to undergo local clinical trials.

But for now, CFDA said even more inspections could be on the way.

"We have also started increasing inspections on import devices from overseas," Jiangsu FDA's Li said. "With the increasing number of mergers and acquisitions, and more capital flowing into this previously closed sector, there is a feeling that some companies are overly focusing on growth at the expense of regulations."

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Asia Medtech Regulatory Update: Vietnam Decree, Malaysia Labels And More

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[**Editors' note:** *This is the first of what is planned to be a regularly occurring feature spotlighting important developments in Asia with the help of local regulatory experts.*]

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Vietnam's Decree on Management of Medical Devices (No. 36/2016/ND-CP) is coming soon – probably sooner than expected for the unprepared. The decree, issued on May 15, 2016, took effect on July 1, but a series of arrangements means that manufacturers won't be subject fully to the changes brought about by this first-time regulation of devices in Vietnam until 2017.

Jack Wong, secretary of the Asia Regulatory Professional Association (ARPA), which has more than 2,000 members, told *Medtech Insight* of his concerns about com-

Vietnam Transition Periods

- Classification: The company must obtain a declaration for device classification by an eligible organization in Vietnam before submitting for registration.
- Class A devices: Companies must complete Notification Dossier submissions between Jan. 1 and July 1, 2017.
- Class B, C & D devices: Companies must complete Registration Notification Dossier submissions between July 1 and Dec. 31, 2017.
- Current import licenses for class A devices will be invalid beginning June 30, 2017; and those for class B, C & D will be invalid from Dec. 31, 2017.

ISO13485:2016 in Australia and Japan

Another update from the region, according to consultant May Ng: Japan and Australia have announced that they will accept ISO 13485:2016 (QMS requirements), which was published earlier this year. Both countries have their own harmonized standards, but they will additionally recognize the 2016 version, and set a three-year transition period. This will doubtless be a theme discussed at the annual Asian Harmonization Working Party meeting on November 21-25 in the Philippines.

panies delaying their response to the new regulation. In an interview, he said companies of all sizes will face a heavy workload to come and should prepare now for the upcoming registration demands.

Currently only 50 products are controlled in Vietnam, according to May Ng, regulatory and quality consultant at ARQon, an Asia-focused consulting group. She noted that the new national regulatory system will employ the Association of Southeast Asian Nations (ASEAN) four-category risk-based system. The ASEAN system uses classifications A, B, C, D. Vietnam will implement this system and similar document requirements to ASEAN beginning July 1, 2017.

The Vietnam decree sets out two groups of medical devices, which are classified into the four risk classes based on the level of their potential risk related to technical design and manufacture. There will be Group 1 (class A medical devices of low risk); and Group 2 (Class B, C and D medical devices of low-medium, medium and high risk, respectively). Class D devices are those presently described as "controlled" in Vietnam.

DEVICE CLASSIFICATIONS

A major element of the decree is set out in its Article 5 – "Principles for Classification of Medical Devices." Manufacturers in Vietnam will be required to commission other organizations to classify their medical device before they can submit files to the Vietnam Ministry of Health (MoH). Wong observed that this differs from the process in nearby Malaysia, where under the conformity assessment process, manufacturers use third parties (so-called CABs) to evaluate the files, which they then submit to the Malaysian Medical Device Authority (MDA).

But in Vietnam, there are no third parties to perform evaluations. In Vietnam, the third-party organization will only complete the classification. "The workload for the Vietnam government, without much CAB involvement, is a concern," Wong says.

The Vietnamese classification of medical devices must be implemented by an eligible organization as regulated in Article 8, on the "Classification Principles of Risk Level." If a device is classified into more than one risk level, the highest level will apply. Devices designed to be used jointly with other medical devices must undergo their own risk classification. Further, classification will be based on the device's most important use.

However, under the decree's Article 10, "Adopting the Results of Medical Device Classification," a medical device will not need to be classified by an eligible organization in Vietnam if it has already been classified by a competent authority in a country that applies the same medical device classification categories as Vietnam based on international treaties or international agreements.

TRANSITIONAL PROVISIONS

Manufacturing facilities in Vietnam that were operating before the effective date of the decree (July 1, 2016) can continue their production activity, but they must complete a notification of manufacturing eligibility before July 1, 2017. As for Quality Management Systems (QMS), manufacturers must comply with ISO 9001 before Jan. 1, 2018, and ISO 13485 before Jan. 1, 2020.

Trading facilities that were operating before the effective date of the Vietnam decree can continue trading activity, but must complete a notification on trading eligibility before Jan. 1, 2017.

Similarly, organizations providing services for medical devices that were operating before the effective date of the decree can continue operations, subject to completing a notification of medical device engineering consultancy eligibility/testing, and being in possession of a practicing license by July 1, 2017.

Devices that were manufactured in Vietnam and imported into Vietnam before July 1, 2016, can continue to be circulated until the disposal date of the equipment.

Licenses for imported devices and IVDs are valid until their expiry date, or until June 30, 2017, for class A medical devices and Dec. 31, 2017, for class B, C and D devices. The circulation registration numbers of locally manufactured devices are valid until the expiry date on the circulation registration certificate.

Wong summed it up: "By next July, everything will be subject to the regulatory system, and by the end of next year we will

need to submit applications for high-risk products." He recommends that manufacturers prepare their documentation now and begin submitting. He observed that the Vietnam system is similar to Malaysia's, which recently put into place a new regulatory system, but started the registration processes and set deadlines several years ago. "It got companies there very busy. Now, it's Vietnam's turn," said Wong.

Certificates of free sale will still apply and will need to be submitted in Vietnam in addition to the Common Submission Dossier Template (CSDT), ARQon's Ng said. Unlike Malaysia, Vietnam does not have an online system. Ng expects Vietnam to set up several organizations that will be accredited to do the classification work on files that are to be submitted to the MoH in Vietnam.

Wong observed that these additional classifications are probably intended more for companies that do not know how to perform classifications themselves. He said, "Vietnam has probably foreseen that there will be an increase in classification queries to the authorities, since the applicants are mostly SMEs [small-to-medium enterprises] that may not know how to classify their devices. As such, an eligible organization is commissioned to help the industry on the classification of their medical devices. Ng concurred: "I believe experienced companies may not need to use it," she said, adding that the regulation mentions preexisting registrations in benchmark countries.

Wong observed that no other countries have this kind of system, which he considers unique. "While the additional workload is not welcomed, the additional service is a good thing," he said. The associated costs have not yet been established.

"It's good news that another market is being regulated, but we can expect that the authorities will have a lot of extra work related to the classification work," Wong stressed. Vietnam will certainly learn from the experiences of Singapore and Malaysia, but one year is not much time to play with. Indeed, Singapore and Malaysia needed extra time. "Maybe Vietnam might extend its deadlines, too, because one year is considered as a very short grace period."

Malaysia Home-Use Labeling Recap

- The use of Bahasa Malaysia shall be required for home-use medical devices.
- The authorities may require use of the local language on other types of medical device.
- Labeling is taken to mean all written, printed or graphic matter presented by a manufacturer that is meant to provide information concerning a medical device to users and others. It may be physically attached to or accompany the device, or may be available by electronic means.
- Manufacturers need to discuss with distributors the issue of whose name goes on the labeling.

MALAYSIA HOME-USE LABELING

Meanwhile, Malaysia has published new labeling requirements for home-use devices, and has allowed a two-year transition. May Ng said the labels, instructions for use and package inserts will have to employ the local Bahasa Malaysia language after Aug. 4, 2018. This is important to factor in early, given the need to use professional translators.

And it could cause big problems, as labeling takes some time to be prepared, necessitating discussions with the manufacturer. But there will be no postponing of the date, said Ng. Elsewhere, she said, Malaysia's transition to a new set of medtech regulations has been smooth to-date.

DEMANDS PILE UP FOR A SHORTAGE OF REG SPECIALISTS

The new regulatory demands are good news, in spite of the additional work ahead for all, according to Wong. With regards to the new Vietnam rules, he said, "It's a challenge. Will it be easier for larger companies? They certainly have more people to deal with the changes, but equally they have more products, and so a greater workload."

"Companies need to plan and do the necessary screening to see which are more profitable to keep on the market," Wong said. The new Vietnam regulations also apply to *in vitro* diagnostics.

The same is true for the Malaysian local-language labeling needs, the regulatory experts said. Companies will have to decide if they can secure the necessary order quantities and if the market is big enough to warrant the expense of relabeling.

There is also the additional problem of the supply of regulatory specialists. "If a market does not have a wealth of regulatory experts – only a small pool of talent – then we are facing a manpower crisis that even the governments are not fully aware of," Wong said. "The manpower and workload strains will present big challenges for medtech in the years ahead."

Wong observed that there is a short supply of regulatory affairs people in Asia generally. Europe and the US host courses that help regulatory affairs specialist develop and pursue careers in the field. In Asia, companies can always poach from others, but that does not solve the overall manpower crisis in the region, an issue that is exacerbated by a high rate of turnover, he said. "A lot of people come and go," Wong observed.

Ng stressed that the manufacturers' regulatory personnel in Vietnam and Malaysia need to be experienced enough to handle the changes in these two countries. "If they use their experience, we don't see a problem," she said.

On top of these existing challenges, there are medtech regulations yet to come out in some Asian markets, like India and Hong Kong, Wong said.

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Sanofi Joins Google's Verily In Diabetes Venture

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A joint venture established by **Sanofi** and **Google** parent **Alphabet** will combine medicines, devices and software into an extensive diabetes care product line, according to the head of the French drug maker's global diabetes franchise.

The US-based JV, named **Onduo**, was announced Sept 12 as an alliance focus on helping type 2 diabetes patients better plan their day-to-day medication management and habits. Based in Cambridge, Mass, Onduo plans to eventually focus on type 1 diabetes, as well as to people at risk of developing diabetes, helping them to better prevent the onset of the disease.

AIM IS JOINED-UP HEALTH

"Healthcare hasn't been very good at advancing connectivity so far. Diabetes is an excellent area to pursue and promote this, given the extent to which diabetics use the combination of drug and device, but for the most part there's very little connectivity there," Stefan Oelrich, who heads Sanofi's diabetes franchise, told *Medtech Insight*'s sister publication *Scrip*.

He said Google parent Alphabet and Sanofi plan to invest about $500m in a joint venture. The joint venture will be independent but can draw on its parents' resources. Sanofi hopes the partnership with Alphabet's **Verily Life Sciences** will also promote novel ways that diabetes can be monitored and treated, and in the process help the French drug maker better adapt to a changing and increasingly competitive market.

But Onduo will also have the freedom to work with other diabetes product makers.

"Onduo has the right to do work with other pharma companies, and when seen in the solutions perspective we – Sanofi – don't have all the drugs that a physician needs for any given solution, so it is perfectly legitimate that the joint venture as it seeks outcomes solutions will also turn to medicines other than Sanofi medicines. That also reflects the different emphasis of this approach. When focusing on a certain desired outcome, then that may require other drug classes that we do not offer," Oelrich said.

Oelrich, 48, told *Scrip* that the JV will bring technology and targeted diabetes therapies together with the focus on outcomes. In essence the aim is for innovative medicines to be "joined-up" with delivery and monitoring technologies.

"What we have today are the medicines in their various formats – orals or injectables or self-administered pens along with glucose measuring systems and digital platforms that let someone for example count your carbs at certain times of the days that let you titrate better, and so on and so forth; but all of these are pretty much used in isolation and one is separate from the other and so what Sanofi and Verily thought was that together we could start introducing a much higher level of connectivity between existing solutions and upgrade those in terms of technology – which can mean miniaturization as well as connectivity," Oelrich said. "So you can, conceivably, connect an insulin pen to a CGM or a pump to a CGM that's connected to the correct insulin, as well as other solutions. You can think of integration with numerous apps that will coordinate all of them. That's where this may be going."

> "Healthcare hasn't been very good at advancing connectivity so far. Diabetes is an excellent area to pursue and promote this."
> – Sanofi Diabetes Head Stefan Oelrich

The end result could eventually be moving from product-centric to outcomes-based offerings.

"It's turning the current model or approach upside down. That frees us up from thinking just in terms of product portfolio and rather to desired outcomes," he said. Sanofi is investing $248m in cash in Onduo while Verily is committing an "equivalent" amount, he added.

Asked when Onduo might have its first product ready, Oelrich replied "We're aiming for a product within the next two to three years. That's in sharp contrast to our pharmaceutical research and development timelines of between five to ten years so this promises to be faster."

Regulatory approval time frames should not be too much of a problem either, he said.

"If you really link a medicine to a technology then there is a strong chance that you'll get a needed drug-type approval by the FDA. There is the chance they may want clinical studies before approval, but there are also digital solutions that don't require approvals what so ever."

The first proto-type product from Onduo "might involve integrating a pump, a constant glucose measuring system and a drug in a near autonomous system that optimizes insulin delivery. But that's up to Onduo," he said.

OTHER THERAPY AREAS?

The joined-up approach could eventually be applied to other therapy areas.

"You could think of all kinds of therapy areas where this could also apply. The interesting part of diabetes is we have 400 million people out there that live day after day with the condition. But I can well imagine this thinking for other therapeutic areas as well," Oelrich said.

FOLLOWS GOOGLE / GSK PACT

In August, Google life sciences spinout Verily announced it was partnering up with **GlaxoSmithKline PLC** for a spinout venture focused on bioelectronic devices called Galvani Bioelectronics. Bioelectronic medicine is a new scientific discipline that seeks to treat a number of chronic diseases including diabetes, asthma, arthritis, and inflammatory bowel disease by using miniature devices implanted in the body that are able to modify the electrical signals of nerves in the body.

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J&J Buys Abbott's Ophthalmics Business For $4bn-Plus

Abbott Laboratories Inc. is unloading its ophthalmic business to **Johnson & Johnson** for $4.325bn.

The sale of Abbott Medical Optics unit comes as Abbott is overhauling its medtech portfolio. The firm has repeatedly told investors that it is focused on accelerating the growth of its cardiovascular device and clinical diagnostics businesses. Ophthalmics is not part of Abbott's growth strategy.

"We've been actively and strategically shaping our portfolio, which has recently focused on developing leadership positions in cardiovascular devices and expanding diagnostics," said Miles D. White, Abbott's chairman and CEO, in announcing the AMO sell-off.

Abbott Medical Optics sells intraocular lenses and other tools for cataract surgery, laser vision correction systems (LASIK) and consumer eye-care products such as contact-lens solution and eye drops. For J&J, the deal adds a surgical component to its vision-care business, which currently consists of contact lenses and solutions. That better aligns the business with some of J&J's other core device subsidiaries, such as **Ethicon Inc.** and **DePuy Synthes**, which focus on surgery.

Key AMO Products

- *Tecnis* toric intraocular lens
- *Catalys* cataract laser system
- *STAR S4 IR* excimer laser system for LASIK
- *WaveScan WaveFront* acquisition and diagnostic system for LASIK
- *Blink* eye drops
- *Complete* multi-purpose contact solution

Abbott acquired AMO, which was then called **Advanced Medical Optics**, in 2009 for $2.8bn. The firm was originally a spinoff from **Allergan**.

The deal, expected to close in the first quarter of next year, frees up some resources for Abbott as it works to complete two very large acquisitions. Abbott announced in April that it is acquiring **St. Jude Medical Inc.** for $25bn. And in January, it unveiled plans to buy diagnostics firm **Alere** for $5.8bn. Abbott has since tried to get out of that deal in the wake of federal investigations into possible corruption by Alere, but Alere has sued to keep the deal on track.

Abbott said it does not anticipate that the sale of AMO will impact overall targeted ongoing earnings per share in 2017.

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Robotic Arm Inventor Says 18 Months 'Too Long' To Approve Novel Device

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Deka R&D Corp. President Dean Kamen says 18 months is too long for "innovative technology" like the Deka *LUKE* prosthetic arm – an artificial limb with fingers sensitive enough to pick up and move an egg – to go through FDA's approval process for devices. The arm was commercially launched by **Mobius Bionics LLC** on July 8, but was initially OK'd as a class II device via the *de novo* pathway in May 2014.

He said the advanced capabilities and urgent need for the prosthetic arm by soldiers returning from the battlefield and for veterans from older wars who have had to rely on more primitive prosthetics means "it should not take so long to get approval."

"We need to have the agency [US FDA] have the same urgency as the American public deserves, and as industry asks," Kamen told *Medtech Insight* Sept. 14 after testifying at a House Energy & Commerce SubCommittee hearing on robotics. Kamen was there to promote the FIRST program, which he founded to encourage grade school and high-school children to learn science and math, and compete in robot competitions.

WATCH

Go to http://bit.ly/2cZQdsh to view a video demonstrating use of the LUKE arm to pick up and place eggs into a carton.

Asked about his experiences at FDA, Kamen commented, "What I said to them was, we had a predicate device that was a two-pound hook, [so unwieldy] that it could break your face … and what we *now* have is a much more delicate and sensitive, slow-moving device that by any standard is less dangerous than that, and that you should just give it a 510(k) clearance right now."

"But," he added, "it took 18 months, and $5m of the taxpayer's money to answer all the questions they had at the agency. It's not because anybody there is bad, it's because they have a mandate, and they believe their goal is to prove beyond a shadow of a doubt that no bad consequences can come from use of this product."

Kamen said that while he thinks FDA serves an important role in being certain that devices are safe and effective, he disagrees with the premise that any device could be totally problem-free.

"I say if your standard is, 'Prove to me nothing can go wrong,' then the way they can solve that problem is to approve *nothing*, and then nothing will go wrong."

"Industry has enough reasons to not want to make a bad product – you won't sell any, you could get sued. There [are] plenty of reasons why companies need to make their products better, and there's plenty of reasons to have regulators make sure everything they are telling the public is true," Kamen continued.

"I just think that when they go to work every day [at FDA], they should have the same urgency as the Department of Defense does when there is a war."

"I just think that when they go to work every day [at FDA], they should have the same urgency as the Department of Defense does when there is a war," Deka's Kamen says.

PRAISE FOR PATIENT-PREFERENCE FOCUS

The proflic inventor, who has also made key developments for drug infusion, peritoneal dialysis and diagnostic equipment, and invented the *iBOT* stair-climbing wheelchair among other systems, praised FDA Device Center Director Jeff Shuren for his leadership of the medical technology review program at the agency, and for pushing to incorporate patient preference into FDA risk-benefit decisions about devices.

"I think Jeff Shuren is the light here, he's the hope here. But I think Jeff Shuren is running an organization who, when you talk to them at their reviewer level say, 'It is my job to look for every possible thing that can go wrong [with a device] and to not allow anything that I can find a flaw in to move forward.'"

Kamen said that instead, agency reviewers and officials should take the time to make sure all the risks of a new product are properly explained to the public, to make sure everything with it works as well as possible, and "then leave people and their doctors the ability to make a choice."

The inventor also said he liked "the spirit" of the 21st Century Cures Act, approved by the House in July 2015, and a parallel package under debate this fall in the Senate. What the bill means to him "is simply that a government has to start acting appropriately at a pace that will allow the [medical] miracles that are happening at an accelerated pace."

LUKE PROSTHETIC ARM

The robotic arm, developed by Deka as part of the Defense Advanced Research Projects Agency (DARPA) Revolutionizing Prosthetics program, was the result of years of research and testing by nearly 100 amputees for more than 10,000 hours of use, according to the firm.

It has a powered shoulder that can reach over the head or behind the back, a powered elbow with the strength to lift a bag of

groceries from floor to tabletop, and multi-movement wrists with enough dexterity to hold a glass of water without spilling.

Users have a variety of ways to control the arm, including electromyographic electrodes, and foot-mounted inertial measurement sensors.

"Up to this point, design in prosthetic arms has been limited to incremental changes. We developed the LUKE arm to change the game for amputees by creating an innovative, integrated system," Kamen stated.

The inventor also spoke at the Sept. 14 hearing about the future of robotics, telling House Commerce, Manufacturing, and Trade Subcommittee Chair Michael Burgess, R-Texas, that in the future, he expects robots to be less anthropomorphic, unlike Rosie the Maid and other robots portrayed in the classic TV cartoon "The Jetsons," or envisioned in earlier works of science fiction.

"I think that robots will be used to augment what humans can already do, and that there will be robots who are much smaller than us … but robots will not look like us.

"And they will change so dramatically the process of taking care of people that we will not recognize it, and certainly a hospital [of the future] will not look like what it looks like today," Kamen predicted.

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Device Firms Invited To Join MDSAP Ahead Of 2017 Full Launch

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As regulatory authorities participating in the Medical Device Single Audit Program prepare for the full implementation of the initiative in January 2017, the MDSAP Regulatory Authority Council has issued a formal invitation asking medtech manufacturers to participate in the program.

MDSAP, which is currently in a pilot phase, was created by the International Medical Device Regulators Forum. It allows device manufacturers to undergo a single audit to satisfy the quality requirements of five participating nations (the US, Australia, Brazil, Canada, and Japan), instead of having to undergo individual inspections from different regulators.

The invitation from the MDSAP council states that device manufacturers can appoint an MDSAP-authorized auditing organization to conduct a single audit. At present, six organizations are available to conduct MDSAP audits.

The audit process, the invitation explains, is designed to thoroughly cover the requirements for a quality management system for medical devices derived from: ISO 13485:2003 - Medical devices - Quality management systems - Requirements for regulatory purposes (and ISO 13485:2016); the Brazilian good manufacturing practices (ANVISA ROC 16/2013); the US Quality System Regulation (21 CFR Part 820), and certain other requirements of the regulatory authorities that are fully participating in MDSAP, including related to registration, licensing, advisory notices or recalls, adverse event reporting, and more.

The EU and the World Health Organization are not participating in the MDSAP project but are observers at the MDSAP Council and in the subject matter experts' group. As observers, the EU and WHO authorities cannot use MDSAP audit reports to replace or supplement their own regulatory inspections.

REVISION OF ISO 13485

The council said it would analyze the impact on MDSAP of the impending update to the ISO 13485 standard – ISO 13485:2003 is to be replaced by ISO 13485:2016 in March 2019. The audit model, in particular, is to be revised as necessary, the council said.

In a recent update, Australia's Therapeutic Goods Administration advised device manufacturers participating in the MDSAP pilot to contact an authorized MDSAP auditing organization to discuss the implications of the ISO 13485 update. TGA explained that MDSAP auditors are required to conduct all audits for the MDSAP in accordance with ISO 13485:2016 by the end of the ISO transition period. Individual auditing organizations are establishing their own transition timelines to ensure that all clients have transitioned by Jan. 1, 2019, the Australian agency said.

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New UDI 'Learning Community' Aims To Help Firms Implement Unique Identifiers

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A so-called "Learning UDI Community" has been launched so early adopters of US FDA's Unique Device Identification program can share best practices and work to make UDI implementation smoother for others in industry.

The Learning UDI Community – or LUC – will be a broad-based coalition made up of health-care leaders from the manufacturing and supplier sectors, industry associations, and standards organizations, among others. The group is convened and hosted by the Association for Healthcare Resource & Materials Management.

AHRMM, an arm of the American Hospital Association, is a membership group for supply-chain professionals; however, anyone is welcome to join the new UDI learning community.

"The FDA has identified the need to actively engage with a coordinated, action-oriented, and early adopter Unique Device Identifier community," AHRMM says in a Sept. 16 statement announcing the learning community.

Despite answering that call, "the LUC is not an advisory committee to the FDA; rather, it is a community whose goal is to develop a common understanding and approach to UDI adoption for supply chain and clinical care," AHRMM's statement reads. "The intention of the findings and recommendations of the work groups and their products is to benefit the health-care field by collaboratively developing progressive practices and other resources to support UDI adoption."

> "There will be much more to report on [LUC] within the next three-to-six months as we have more work groups coming online, and hope to have deliverables from the work groups to share across the health-care field," AHRMM's Michael Schiller says.

The LUC will focus on identifying issues that impact UDI adoption in the manufacturing and health-care settings, and will establish cross-functional work groups made up of subject matter experts and industry stakeholders.

The work groups will publish progressive practices, proposed solutions, and any resources developed that focus on particular UDI topics and enabling technologies that can accelerate UDI adoption. Such progressive practices, as well as any tools, will be shared through a proposed publicly accessible LUC repository.

"Capturing, storing, maintaining and providing public access to this shared knowledge base will increase the likelihood of success in accelerating UDI adoption practices while shortening the UDI adoption learning curve," AHRMM says.

"Accelerating UDI adoption across the health-care field is essential to meeting the call for cost, quality, and outcomes; the "Triple Aim"; and evidence-based care," the group adds. "The Learning UDI Community is looking to its participants to influence and assist in achieving these objectives."

Stakeholders interested in joining LUC work groups should email ahrmm@aha.org.

In an Aug. 22 email to *Medtech Insight*, AHRMM Senior Director Michael Schiller wrote: "There will be much more to report on [LUC] within the next three-to-six months as we have more work groups coming online, and hope to have deliverables from the work groups to share across the health-care field."

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Engaging Patients and Navigating Laws: What To Consider When Developing Health Apps

VICTORIA HORDERN & AMY MERRICK

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Digital technology and health apps are increasingly being used to offer patients more effective health care, at a cheaper price, and a chance to participate more in managing their conditions. In order for these technologies to be successful, the technologies need to engage their users effectively, encouraging patients to trust and use them regularly.

Encouraging patient use and trust depends on a number of factors, ranging from the look and feel of an app to the developer's compliance with the regulations governing clinical trials, medical device development and data protection and data security. Patients need to be confident that an app's processing of some of their most sensitive information will help with their treatment and will be kept secure.

The digital health sector faces significant challenges. The various rules that policy-makers and regulators rightly expect industry to follow to ensure that patient safety remains paramount are complex and not always clear, and significant resources are often needed to develop a compliant app. Industry also faces practical challenges in providing technology that can be easily understood by all age groups.

To help app developers understand the regulatory framework and processes involved in producing health-care apps, initiatives are under way to explore developing new industry standards, policy guidelines, and self- or co-regulation. For example, the European Commission and other stakeholders are working to develop draft guidelines on assessing the reliability of mobile-health apps.

This article explores some of the key challenges in developing effective and trusted digital health apps in the EU and discusses initiatives that are under way that might make things easier for industry.

WHY PATIENT ENGAGEMENT IS KEY

Patients can now access more medical information than ever before. Technological advancements, and the ease with which the internet is accessible, means that patients are increasingly researching their ailments online before visiting their GP. One in 20 Google searches now is related to health care.

Patient engagement should be a central consideration when developing a digital health app. No matter how effective an app may be at recording outcomes or reminding patients to take their medicines, if patients don't find the app user-friendly, they are unlikely to use it. It is critical for digital health apps developers to engage with participants at the development stage, to ensure that their apps are accessible and easy to use.

Developers should also focus on providing solutions for genuine problems, not for those that don't exist. For example, an app that increased the text size of websites to allow patients with impaired vision to view the text was rejected by patients on the basis that the old fashioned magnifying glass was more user-friendly. This should serve as a key lesson for developers, and will help to prevent them from wasting resources and negatively impacting patient participation.

Motivating patients to engage with new technologies is also vital. Apps need to ensure that patients can take responsibility for managing their illness and its treatment. Patients that seek to cheat the technologies, for example by putting their Fitbit in a tumble drier to obtain higher "footstep" readings, will mislead their health-care professional and such action may result in patients not receiving the

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correct treatment. For the software provider, it can lead to false-positive results and distort the value of their product.

Digital innovation should be built around patient-centric, data driven decisions.

THE NEED FOR HCP ENGAGEMENT

Certain digital health devices are deliberately designed to be used by health-care professionals (HCPs). Often these are designed to help HCPs save time, resources and/or costs in their everyday roles. But for these devices to be successful, they need to engage with HCPs in a way that is clearly understandable so that the HCPs can see the benefits of using the device.

Consequently, developers should think about how they can demonstrate simply the benefits to an HCP, how a digital health tool can integrate with existing resources used by HCPs, and how the tool will use any HCP personal information (if such data is collected). An HCP who sees the benefit of a digital health tool and understands its implications will be a better ambassador of the value of the digital tool for the patient.

USING DIGITAL HEALTH IN CLINICAL TRIALS

Digital health apps can also be used in a clinical trial setting. Again, patient engagement is a key consideration in making the health care app a helpful addition to the clinical trial process.

Digital health apps can be used to assist with:

- Recruiting patients (including when genomic profiling is used);
- Patient participation during the trial (e.g., by using reminders to improve patient compliance); and
- Improving patient engagement (e.g., developing digital health opportunities to meet patients' specific needs – for instance by taking particular steps to improve an individual patient's quality of life).

Engaging patients at an early stage in the app development process could allow a number of patient-focused improvements to be built into the app, which might result in more efficient and effectively run clinical trials. For example, app developers could use pilot clinical trials to obtain patient feedback on the usefulness and usability of their health-care apps, before the clinical trial commences in full.

By involving patients at the outset in the design of the clinical trial, the trial is likely to be more efficient and patient-focused. Ultimately, a more user-friendly end product is likely to be produced.

THE DIFFICULTY IN NAVIGATING MEDICAL DEVICE LEGISLATION

An issue for both app developers and policy-makers at present is that it is relatively easy for developers to place non-compliant health-care apps on the market in the EU. It can be difficult to distinguish between apps that fall under the scope of the EU medical device directives and products that are considered general health or wellbeing apps, which are not subject to these laws.

A health-care app that monitors vital physiological functions, for example, should be effectively tested before it is made publicly available. The consequences of failing to do so are serious. It's easy to see the dangers of a heart-rate monitoring app for the treatment for heart disease that produces incorrect results, for example.

Under current UK legislation, health-care apps (i.e., those with a medical purpose) are generally classified as medical devices. This means the app will need to go through a conformity assessment (potentially involving clinical studies) and be validly CE-marked before it is placed on the market in the EU.

It is an offence to place a medical device on the market that has not been validly CE marked. Therefore, app developers need to be aware of medical device legislation and need to establish from an early stage whether their app will fall within its scope and requires CE marking.

The commission recently updated its "Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices" to clarify the definition of software and help manufacturers decide whether or not their mobile app should be classified as a medical device.

However, the revised guidelines arguably do not include sufficient guidance on, or examples of, which mobile apps would or would not fall within the scope of medical devices legislation. Therefore, further clarification from the authorities would be helpful.

Meanwhile, one strategy that many technology companies developing digital health products have adopted to help navigate the medical device directives and deal with the significant resource often needed to produce a compliant app is to partner with a life sciences company. The experience that life sciences companies offer, as well as their large R&D budgets, offer benefits to both parties.

BEST PRACTICES IN THE PIPELINE

In another effort to help app developers understand the regulatory framework and the processes in producing health-care apps, the commission is pursuing dialogue with stakeholders on different policy options – ranging from industry standards and policy guidelines, to self- or co-regulation and legislation.

For instance, the commission and representatives from patient groups and HCP and industry bodies are working to develop draft guidelines on how to assess the reliability of mobile-health apps. According to the commission, the aim of these guidelines is to agree a common set of criteria and assessment methodologies that public authorities, health-care providers, professional and patient associations, developers and assessment bodies could use when assessing health apps. The draft guidelines are expected to be published by the end of 2016.

A number of voluntary codes already exist in the life-sciences industries, establishing best practices across key areas. The development of a set of standards for health-care app development would ensure that apps are designed to high levels, and would assist developers in complying with complex regulation.

DATA PROTECTION AND CYBERSECURITY

Digital health tools that collect personal information need to comply with data protection and privacy laws. Additionally, there is an increasing expectation

that such tools will be designed to deal with threats to security and will comply with cybersecurity standards set out in law. Health information can be among the most sensitive information about an individual. Understandably, there can be greater risks to data associated with mobile technologies. Regrettably, these two factors combined – sensitive data which is held on mobile devices – can amount to a greater risk of data loss, tampering, interception and theft. Medical records and health data are frequently seen as more valuable to criminals than credit card data.

To help keep pace with data protection and cybersecurity requirements, a draft code of conduct on privacy for mobile-health applications was developed in June 2016. The code, which was produced by the commission and an industry-led working group, is designed to reflect certain central EU data protection principles and includes a governance framework to enforce the rules against those members of the code who fail to comply. The code is currently being considered by the EU data protection authorities working group – the Article 29 Working Party – and, if approved, will mark a positive step in helping those developing m-health apps to understand their obligations to comply with EU privacy rules.

Likewise, in August this year, the Future of Privacy Forum produced Best Practices for Consumer Wearables & Wellness Apps & Devices, which aims to set out high-level principles influenced by both US and EU law.

WHY PATIENT TRUST IS IMPORTANT

Compliance with data protection and privacy rules is closely connected with the trust patients have that their data will be properly looked after. Patient engagement will almost inevitably fail if patients receive no reassurances about how their personal information will be protected and if they have evidence that the organization is failing to look after their data. Therefore, the need for organizations to be transparent and to give patients choice on how their personal information is used becomes even more important.

Additionally, organizations should ensure that patients are given a right to complain and to access their data. The requirement to respect individuals' rights to their personal data will become increasingly important in the future given how central individuals' rights are in the new EU general data protection regulation, which will apply across the EU from May 2018. Building trust between organizations and patients will be crucial to the success of a digital health tool. Patients will also need to be confident that there is proper accountability for those who fail to meet the required standards.

APP ACCREDITATION

In such a fast moving industry, it is tempting for app developers to try to outperform their rivals by producing large numbers of different health-care apps that essentially serve the same purpose, with only minor differences between them. Over time, the plethora of apps risks overwhelming patients and might reduce, rather than improve, patient engagement with these technologies.

As a result, regulators could choose to introduce a system of app accreditation, whereby particular technologies are endorsed over other alternatives. The UK's National Information Board, for example, is currently reviewing how the National Health Service Health Apps Library can be used to recommend patient-focused health apps.

While app accreditation may benefit patients by ensuring they use only the best apps, such a system would take time to build and would be expensive for regulators to maintain. The industry may decide that a system of "peer-review" is in practice more efficient.

CONCLUSION

The law, in general, struggles to keep up with the pace of technology and this is certainly the case with the fast-moving m-health industry. There is a need for greater guidance in this area for manufacturers.

The self-regulatory guidance that has been and is being developed should assist developers to bring apps to market and an effective accreditation scheme would help to drive recognition of those apps that are best positioned to engage with patients.

In the meanwhile, digital health app developers should bear in mind the importance of engaging with users effectively in order to boost the likelihood of an app's success.

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Bulked-Up Glooko To Launch 'Unified' Diabetes Offering Next Year

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A new diabetes management product that combines the mobile-based remote monitoring platform of **Glooko** and the data management know-how of **Diasend** is expected to be released next year.

The "unified" product will be the first to emerge following the merger of Mountain View, Calif.-based Glooko and Gothenburg, Sweden-based Diasend, announced Sept. 13.

To accelerate this product development, as well as other integration and sales efforts, the combined entity – which will operate under the name Glooko – has received $8m in new funding. This round of financing was led by **Canaan Partners**, with the participation of **Social Capital, Samsung Ventures**, **Medtronic PLC** and other individual investors, Michelle de Haaff, VP of marketing and customer success at Glooko, told *Medtech Insight*.

Medtronic, which has been an investor in the pre-merged Glooko since last year when it took part in a $16.5m series B round, is one of the company's many medical device partners, and de Haaf said the medtech heavyweight is "positive" about the news of the Diasend merger.

Both Glooko and Diasend partner with makers of insulin pumps, blood glucose meters, continuous glucose monitoring systems and activity trackers to extract and analyze data from these devices to allow better management of diabetic patients. Glooko "brings a mobile-first mindset with modern and engaging visualizations," capabilities that enable important patient and provider decision support with its new *Glooko Advise* platform and US market expertise, explained de Haaff. Diasend, on the other hand, "brings deep expertise in device integration … clinic penetration, broad language support and global sales and marketing expertise," she continued.

As a combined entity, the new Glooko now serves 4,000 diabetes clinics in 23 countries across 15 languages, impacting tens-of-millions of people with diabetes. The joint platform will download data from more than 160 different diabetes management devices, in total covering more than 95% of diabetes devices used worldwide. The joint offering will provide support to diabetics during and in-between doctor visits, as well as in-office diabetes data uploads and analytics, Glooko stated in its merger announcement. The products will also provide smartphone enabled self-management and a population health platform that supports diabetes coaches globally.

There is a "decent amount" of overlap between the industry partnerships that the two firms have inked, de Haaff acknowledged. Manufacturers that have existing relationships with both Glooko and Diasend include **Abbott Laboratories Inc., Insulet Corp.**, J&J's **LifeScan Inc.**, **Roche**, **Ascencia** and **Nipro Corp.**, among others. There are also several relationships that are unique to either Glooko (Medtronic, for example) or Diasend (e.g., **Tandem Diabetes Care Inc.**). In addition to medtech manufacturers, Glooko and Diasend also have partnerships with pharma companies and "end customers" like payers, employers and health systems.

Source Glooko

The newly merged Glooko

Source Glooko

Glooko's mobile-enabled solution for better diabetes management

When asked if any challenges might arise as a result of this substantial overlap in industry partners, de Haaff responded: "Just prior to and just after the announcement we connected with our counterparts at each of the med device companies we work at to ensure they understood our commitment to working with them. Without fail, all expressed great support for Glooko and Diasend and our strategy to combine our efforts and deliver a broader, scalable solution to help people with diabetes and their care teams access, analyze and improve health-care decisions using data.

"We intend for not only the existing partnerships to continue as they are, but to expand and grow as we integrate and build on our combined solutions. In many of our conversations with med device partners, we immediately moved from 'the news' to 'the future,' focusing on how we can deliver a combination of ease of use and insights to our shared users."

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James Mazzo: Growing A Goliath With A Small Company Mentality

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Start-ups often look to market leaders for strategic guidance, but there are lessons that industry Goliaths can learn from their smaller, more nimble counterparts, believes medtech industry veteran James Mazzo.

Big multinationals may have the advantage of bulk, but unless this growth is properly controlled and leveraged, the organization – specifically the sales and marketing function – can get unwieldy and lose its focus, explained Mazzo, whose 35-plus years' experience in the ophthalmology industry includes two decades at Allergan's eye-care business before leading the unit's spinout in 2002 and becoming CEO of Advanced Medical Optics. Abbott acquired AMO in 2009 and Mazzo went on to head start-ups like corneal-inlay developer AcuFocus.

Small companies like AcuFocus, where he was CEO until this August when he took on his current role as Carl Zeiss Meditec's global president of ophthalmology, have a "laser focus" when it comes driving their message to the customer. And it is this "small company mentality of focusing, educating and sticking to a consistent message" that Mazzo is intent on bringing to Zeiss's ophthalmology business and implementing it across the German company's global structure, he told *Medtech Insight*.

While Zeiss boasts the broadest product offering in the ophthalmic industry, the company has not leveraged its capabilities as well as it should, he believes. This, though, is not a problem unique to Zeiss, said Mazzo. "I was chairman of [US medtech industry association] AdvaMed and I've seen that this is actually a problem of all major global companies. The bigger you are, the more difficult this gets."

Zeiss' portfolio of products covers diagnosis and treatment of eye diseases, serving opticians, optometrists, ophthalmologists, and ophthalmic surgeons, across the globe. So getting a strong consistent message across the organization and across the customer base will not be an easy task, Mazzo acknowledged.

However, as a man who confesses he likes things to move fast, Mazzo has already set the wheels in motion. Just a month after Mazzo moved into his role at Zeiss, the company has tapped a senior executive from one of the ophthalmic market leaders, Bausch & Lomb, to lead global sales for ophthalmic devices. Andrew Ihan Chang was general manager and senior VP for B&L Surgical, where he led the sales, marketing, operations and business development for the US.

Chang's appointment is part of Mazzo's broader strategy to realign Zeiss's internal structure, sharpen the company's focus and make it conducive for collaboration across the different product line.

In the Q&A below, Mazzo discusses this strategy in more detail and the objectives he has set for the business.

Source: Carl Zeiss Meditec

Jim Mazzo, global president of ophthalmology, Carl Zeiss Meditec

> "I want to take that small company mentality of focusing, educating and sticking to a consistent message, and using Zeiss's global structure to implement that."

Medtech Insight: As you say, Jim, you've been in this business for a very long time. How different or similar is Carl Zeiss' ophthalmology business compared to, say, Advanced Medical Optics?

James Mazzo: It's a great question because obviously I helped start AMO from its spinout from Allergan, so it's a really good comparison. The similarities are that they have the same type of customer base. Not to the same degree though – AMO really wasn't in retina nor glaucoma, but they both have ophthalmologists and refractive surgeons as their customers. There' also the similar geographic spread – AMO was a global company, Zeiss is a global company.

But I think that's probably where the similarities stop because one of the reasons that I decided to join [Zeiss] and one of the greatest opportunities as well as the biggest trait is the [company's] diversity of its product line. Zeiss takes

care of the patient from diagnostic properties to treatment properties; no other entity, no other competitor does that.

So if you're a patient who walks into the physician's office, the physician needs to first diagnose what your issue is and we lead in diagnostic equipment across retina, glaucoma, cataract, etc. Then once we understand what your issue is, the physician treats you and of course, that's where Zeiss comes in with intraocular lenses and other type of therapies. So [the breadth of its offering is] where Zeiss has the greatest power. It's not without its issues, of course, in terms of where we meet gaps, but it is the most diverse product line from the doctor to his or her patient. And it's not only versus AMO, but versus Alcon, versus Bausch & Lomb, versus every other ophthalmic company.

During your time at AMO, you saw Zeiss as a competitor. But did you view them as a peer or a company to aspire to?

Mazzo: I admired Zeiss for a couple of reasons; No. 1 is its history. I think in our industry we have a lot of young companies. Sometimes that young-ness is great but you don't have that history of technology that helps you know how to continue to innovate. Zeiss has been around for about 180, 170 years so that's very powerful; it speaks to the company's commitment to this space.

No. 2, I admired and have a lot of respect for the global reach of this company, they really are in most of the major countries with presence and AMO and other companies don't have some of that same geographic presence.

What I believe Zeiss can do better is leverage [its competitive advantage]. No company is perfect so we all have our strengths and areas of improvement, and one of the areas that we need to improve on is to leverage this. When you have a diverse product line sometimes what occurs is that each individual takes care of that product line but the customer could care less how you organise. The customer wants you to meet his or her requirements no matter what technology you have. So we became a bit siloed in that and as a competitor I noticed that it wasn't being leveraged. You're going to see that change dramatically over the next months. There is going to be a strong leverage that we're going to take it from the customer inside to Zeiss. So I don't care where you are, if you're a diagnostic specialist you're going to make sure that your refractive colleague is as powerful as you are in that office because we need to leverage the great technologies across, so that's probably one area when I was on the other side of the fence that I'd never felt was leveraged. And now that it is I'm glad I'm on this side of the fence because that is going to be very powerful.

So I was always admiring [Zeiss's] history, I was always admiring the strong fundamental business, I was admiring the geographical presence but I never was overly concerned [as a one-time competitor of Zeiss] on the leverage capabilities, but now we're going to unlock that and take advantage of that.

Could you elaborate more on your strategy for improving Zeiss's leverage capabilities?

Mazzo: Let me break it down into various components. First off, before you can even leverage externally you need to be leveraged internally, because if we're not structured accordingly, you're never going to implement it successfully.

One of the things we're doing now is that we are improving the accountability of the organization by articulating the following. I just hired our head of sales – Andy Chang is coming from Bausch & Lomb and he will have global responsibility for the sales structure. So all the sales structure across all product lines will report under Andy for the ophthalmology / optometry business. That's very important; you've got that collaborative effort.

When you go down the direct level though you will still have [sales] specialists, because when you have this many product lines you can't just have someone opening up his bag and saying, "Which product would you like?" You'd never sell that way. But it starts to tone at the top and then you move down collectively. And when you move down collectively, you're ensuring that the representatives are trained and have a good understanding of the other product lines. So when Dr. Mazzo says to the retina specialist, "Oh, I understand you have a glaucoma product line," instead of the retina specialist looking at Dr. Mazzo with question marks, he'll say, "Of course we do," and then refer him to his colleague who handles glaucoma, or vice versa. They'll know who their colleagues are in the [different] field, that's very important.

Another thing is you need to align service-wise. Think of yourself as a consumer – when you walk into a retail outlet, you want to make sure it doesn't matter what department you're in, that you have the same service across all products

so that one department is not better in service than the others. We're aligning and coordinating our service component at Zeiss, so that when someone comes to fix your machines or upgrade or whatever the requirement is needed, it's across the collective product lines and you're not being handled by different service people.

Then I think that other very important component is how we speak to our physicians. We have some inconsistencies across the globe in the messaging of our product line, we're going to make sure that is consistent. I'm going to be hiring a chief medical officer, who will ensure we're aligned across our collective messaging, so that when we're talking to an ophthalmologist, an optometrist or an optician, the message is consistent across the globe.

So to answer your overarching question, we need to get internally aligned then when we do that, which we're getting close to, we will roll this out so that when we're talking to an optometrist who is co-managing a retina or glaucoma patient with an ophthalmologist in the US, they will have the same training, they will have the same understanding of our product line, so thus we have continuity across our businesses by continuity across our customer lines.

We'll never take away the speciality of the sales rep or the speciality of the physician but when a patient is co-managed, which happens across the globe, we're going to ensure that we have alignment from a service component, from an education component and from a scientific messaging component.

What sort of timelines are you thinking for rolling out this plan?

Mazzo: It's not that we're going to have to completely turn the ship around; the ship is already moving in the right direction. We just need to get everybody on the ship understanding their roles and responsibilities, and to do that you get the people toned at the top. I now have Andy [Chang] running sales, I'm going to get a CMO, we've got the three heads of our business sectors in line already, so it's not really having to make a total restructuring, it's really a philosophical discussion and clear measurable goals. If you know what at the end of the day your responsibility is then you're going to act against that.

Zeiss works on an October to October timeframe, so we're going to start this Oct. 1 with these new goals that are aligned all the way from the bottom to the top and top to the bottom – from sales rep to management.

Earlier on when talking about Zeiss' extremely broad portfolio being a strength, you said there were some gaps that you've identified. What would those gaps be?

Mazzo: Again, there's not one company out there that has everything, so I would say we're going to spend more time in the following areas: glaucoma, dry eye, retina and presbyopia. Now I don't want to sit there and say that cataracts are not important, they're very important. Cataracts are still the leading cause of blindness outside of the US, the No. 1 surgical procedure done in the US, so we're not going to neglect it, we're really strong there. But if you look at those four categories, they are the four leading categories because they're chronic, and no one has nailed it yet.

So let's speak about dry eye. I'm talking devices here – we're a device company, not a drug company, at least in the foreseeable future. We have some product lines but really not anything that I would say is at the leading edge to help diagnose dry eye from a diagnostic standpoint than to a point of some more treatment, so that's one.

With presbyopia, we're just getting in. We already have a refractive IOL offering with our trifocal, which is a great product, and we obviously have the SMILE, which is our [small incision lenticule extraction] corneal refractive procedure to rid you of glasses, but there are also other refractive procedures.

Glaucoma, we have a great diagnostic but as you know there're devices out there that can actually help in the treatment of glaucoma. And then, as I just said, retina, really one of our most severe diseases today: age-related macular degeneration, orphan diseases like MacTel (macular telangiectasia). We can diagnose but we can do a better job of helping any potential treatments as well from a device standpoint.

So those will be the four areas where you're going to see a greater concentration of, both internally and externally. We're not going to have the "not invented here" syndrome. There are a lot of bright people that don't work for Zeiss who are entrepreneurs and have great technologies, so if we can't do it internally, we have the resources – which are another benefit of Zeiss – to acquire it externally.

You stressed that Zeiss is very much a device company, but first-line treatments for conditions like dry eye and retinal diseases are still very much pharmaceuticals. In order to achieve your objective of making Zeiss a one-stop shop for eye care, do you think that Zeiss would diversify into pharmaceuticals?

Mazzo: First off – I'll never say never – but I think what you do before you really start to expand into one area is making sure you know that one area real well. And I'll challenge the thought process a bit; let me talk about retinal disease. The only way to treat this terrible disease is by getting to the site, and the site is in the back of the eye. Injections use a device but we all know that injections are costly, they're not patient-compliant, and we also know that after a period of time the patients are coming back. So can we get a device that is implantable and then release a drug? Why not? So that to me is a [device-based therapy], and devices will actually play a greater role in retina than pharmaceutical preparations.

If you think about glaucoma, it's really no longer drugs to a grand degree. You still use prostaglandins and things of that nature, but what's the greatest thing in glaucoma today? Glaucoma implants. And if you think about dry eye, you got a diagnosis and a lot of devices are actually working on the meibomian glands. When the meibomian glands become clogged that could actually induce dry eye, so now you have a device that potentially will open up that gland and allow the natural function of your eye apparatus to work on a consistent basis.

Devices can actually be synergistic, if we can say such a word, or can actually substitute where drugs aren't effective because they can't get to the site or they can't maintain it. I believe we have more than enough products to go after in devices [for these four disease categories] before I have to think of pharma.

Let's say it's a year from now. How would you like to see Carl Zeiss Meditec's ophthalmology business?

Mazzo: I would say there are a couple of basic principles, and again it would all come from our doctors. I think the doctors would say the following, that a) we did not change the culture of Zeiss. I love the culture of Carl Zeiss, which is dedicated to treating severe diseases with a strong heritage and a commitment to technology. One thing I don't want to do is change things that are strengths. That would be No. 1. So I don't want anybody to come back to me and say, "Hey, you did things really well but you screwed up the culture." I don't ever want to interrupt this strong culture that I really respect.

No. 2, that the pace of our actions is faster and the doctor can feel it. That when he or she makes a call or needs a service that it is done within the appropriate amount of time, we're a little slow, so I would have feedback, and we're going to measure this, that our pace of service, our pace of receptivity, our pace of acknowledgement of technologies is quicker.

And then No. 3 – and I think this is the most critical component – we are seeing in our productivity for generating new technologies, improvements in our existing technology about every 18 to 24 months, through software upgrades or better designs. And then about every 36 months we come out with a new design across all of our product lines. We have some strengths in some [product lines]; we don't have that consistently across. And then I will add one more thing: I think in a year you're going to see us in a couple of those four categories that I just talked about, probably through acquisitions.

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New Vibration Tech Holds Promise For Early Diabetic Neuropathy Detection

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A new generation of vibration technology has shown promise in a Swedish study as a tool for detecting early diabetic neuropathy in the foot. Diabetic foot ulcers are one of the main complications resulting from diabetic neuropathy, and a new device to diagnose the latter in the early stages could play a significant role in preventing hard-to-treat foot ulcers and reducing health-care costs.

The device, developed by Malmö-based **VibroSense Dynamics**, uses a multi-frequency vibrometry method pioneered in the early 1990s by Göran Lundborg, a professor of hand surgery. The instrument works by stimulating the skin to measure tactile sensitivity at different mechanical frequencies.

The VibroSense Meter for hand neuropathy

VibroSense is developing a foot device based on the multi-frequency vibrometry technology used in the VibroSense Meter

Source: VibroSense Dynamics

VibroSense assessed the device in a study designed to evaluate the effectiveness of multi-frequency vibrometry in measuring sensory perception in the sole of the foot of diabetic and healthy subjects, and to evaluate the link between diabetic foot ulcers and vibration perception thresholds .Vibration perception thresholds were investigated at six different frequencies (4, 8, 16, 32, 64 and 125 Hz at two sites – first metatarsal (MTH1) and fifth metatarsal heads (MTH5) – in 364 type 1 diabetics with and without foot ulcers and 137 healthy people.

The study, presented on Sept. 13 at the European Association for the Study of Diabetes (EASD) in Munich, Germany, indicated that vibration perception thresholds measured at MH5 were significantly higher in type 1 diabetics compared with healthy people at all frequencies. Vibration perception thresholds measured at MTH1 were also significantly different, but only at 32, 64 and 125 Hz. The correlation between different frequencies was strongest between 4 and 8 Hz, measured at MTH5, indicating low frequencies were associated with an increased risk of diabetic foot ulcer.

VibroSense CEO Ulf Rogers told *MedTech Insight* that current vibrometry-based tools on the market for detecting diabetic foot neuropathy are single-frequency devices and can only detect neuropathy once the patient is already experiencing loss of sensation. Manufacturers of single-frequency devices include Swedish company Somedic, Bio-Thesiometer in the US, and Horwell.

Rogers explained how VibroSense's multi-frequency technology is the first of its kind: "Low frequency vibration has not been tested in diabetic foot patients before. The multi-frequency technology is so sensitive due to the fact the method stimulates different types of mechanoreceptors in the skin that are sensitive to certain frequencies. What has been presented at the EASD is that the research has found a correlation between low frequency vibrations and foot ulcers."

VibroSense, which is publicly listed on the Swedish stock exchange, AktieTorget, already has a CE-marked device based on its underlying multi-frequency vibrometry technology. The *VibroSense Meter,* from which the new diabetic foot neuropathy device is being adapted, is designed and approved for early detection and diagnosis of impaired vibration sensibility in the hand. VibroSense currently sells this device to major occupational and environmental medicine clinics in Sweden and Norway. It is also sold in Belgium and used to detect neuropathy in industries where vibration injury is common, such as mining and construction.

> The multi-frequency technology is so sensitive due to the fact the method stimulates different types of mechanoreceptors in the skin that are sensitive to certain frequencies.
> – Ulf Rogers, VibroSense Dynamics CEO

VibroSense Meter consists of a measuring instrument and PC software that interprets measurements via internal algorithms and reference data. The software records measured values and reports results as vibration thresholds which are compared with age-matched reference data collected from a healthy controlled population.

Sales of VibroSense Meter for fiscal 2016, which ended June 30, came to SEK341,459 ($39,854) and the company estimates that fiscal 2017's revenues would be around SEK500,000.

In 2014, the company had set its sights on expanding beyond the vibration injury market and into diabetes care, which led to its public offering in 2015.

"Since we've had the multi-frequency technology for hands, we have discovered that this is a small market but we see the potential for a much larger market for diabetes," Rogers told *Medtech Insight*.

He added that the foot neuropathy device it is developing is expected to launch by the end of 2017 for commercialization across Europe. This foot device, currently at the prototype stage, would feature much stronger vibrations and increased sensitivity than the hand neuropathy device.

The ergonomics of the new device will be adapted for use on the foot and the range of frequencies will be extended. Three research projects supporting the development of the device are due to begin soon, financed by a SEK3.7m grant from the Swedish government funding agency Vinnova.

VibroSense has also received €50,000 ($55,000) from the European Commission Framework Horizon 2020 to assist its business plan. The Phase 1 grant was delivered following the Commission's evaluation that a new device will fill an identified niche on the market and contribute to better clinical outcomes for diabetes patients.

Around 10% of people with diabetes will develop a foot ulcer at some point in their lives and late diagnosis can incur substantial health-care costs. According to the National Diabetes Foot Care Audit (NDFA), the NHS in England spent an estimated £650m ($850m) on diabetic foot ulceration and amputation in 2010-11 alone.

VibroSense's technology is currently protected by patents approved in Sweden, China, Japan and – most recently – India.

India is a potentially valuable market for VibroSense Dynamics where, according to the World Diabetes Foundation, an estimated 8.5% of the population suffer from diabetes.

The company is also exploring the potential use of its multi-frequency vibrometry technology for other indications, such as in cancer patients.

Rogers said: "Multi-frequency vibrometry could be used for treatment of cancer patients as chemotherapy has the side effect that it can cause neurological injuries. We are researching to establish more context of how the technology could be used in this area."

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Medtronic Alumni Take Up SetPoint Regulatory Leadership Roles

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SetPoint Medical Corp. has expanded its senior management team, promoting Lusin Markaryan to the role of vice president, regulatory affairs, and appointing Raju Joshi as vice president, clinical affairs.

Markaryan was previously SetPoint's senior director, regulatory affairs. Prior to that, she served as director, regulatory affairs for **Medtronic PLC** 's non-intensive diabetes therapies business. Joshi joins SetPoint from biopharmaceutical company **Amgen Inc.**, where she was medical sciences director and director of clinical development. Like Markaryan, Joshi has also worked at Medtronic, in the role of senior manager of clinical research, regulatory and reimbursement.

The appointments come as privately-held SetPoint gears up for clinical trials of its implantable neuromodulation device, designed to treat inflammatory diseases by stimulating the vagus nerve and activating the body's natural inflammatory reflex to produce a systemic anti-inflammatory effect. The Valencia, California company recently published results from their first-in-human study of its therapy for rheumatoid arthritis. It is also running an open-label clinical study for Crohn's Disease. SetPoint is a portfolio company of Action Potential Venture Capital (APVC), a $50m fund set up in 2013 by **GlaxoSmithKline PLC** dedicated to investing in neuromodulation technologies.

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NuVasive Names New President, Taps Former Prez As Vice Chair

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Spine surgery solutions firm **NuVasive Inc.** has promoted Jason M. Hannon to president and chief operating officer from his former position as executive VP, International. Hannon has served with NuVasive for more than 11 years, and took on the executive VP post in July 2015.

In his newly expanded role as president and COO, Hannon will be responsible for directing NuVasive's global products and services, including product management and development, as well as operational duties, including manufacturing, customer fulfillment and quality engineering. He will also continue to oversee international operations, alongside NuVasive's international leadership team.

Hannon succeeds Patrick S. Miles, who has been appointed vice chairman of NuVasive, and will continue to sit on the company's board of directors. As vice chair, Miles will focus on enhancing the company's strategic plans for the future of spine surgery and he will support technology device. He will also support NuVasive's next-generation spine solution R&D efforts.

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Photo credit: Nuvasive Inc.

Jason M. Hannon, president and COO, NuVasive

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