Personalized Care Drives Innovation in Medical Product Design and Manufacturing

By Mark Shortt, Design2Part Magazine

But the more things change, the more they *stay the same, as medical device OEMs hold fast to requirements for quality, reliability, and shorter lead times.*

Digicom Electronics' component placement process is geared toward flexibility, fast changeover, quick setup, and excellent accuracy and repeatability. Photo courtesy of Digicom Electronics.

It's hard to talk about medical devices without getting into what makes them tick. As with so many other products that are entering the commercial marketplace today, it all starts with electronics, which play a key role in control management, monitoring of medical device function, and — most recently — connectivity.

"What's really neat about electronics today is that so much of it is computer controlled," said David Estes, senior systems engineer at Digicom Electronics, an electronics manufacturing services provider based in Oakland, California. "And, of course, with computer control, you have the concept of software. The really nifty part about software is that it allows the instant customization of devices to incorporate very finely honed ideas and concepts and their operation. It also allows for the incorporation of refinements through software updates, just as your phone is updated. So I think that's one of the nicest aspects of electronics today."

Welcome to the new age of smart, connected products, where the smooth interaction of electronics, software, and hardware is fast becoming a central design requirement that knows no boundaries. Wireless technologies that fueled the rise of consumer electronics have quickly spread to the medical device industry, where they're reshaping product designs and spurring new business models. Lux Research, a market research firm focused on emerging technologies, sees big things ahead for mobile health (mHealth) devices, projecting eight-fold growth in the market from $5.1 billion in 2013 to $41.8 billion in 2023. Rising adoption of clinical vital signs monitoring devices and in vitro diagnostic (IVD) devices are expected to drive growth in the mHealth market, according to Lux, which anticipates vital signs monitoring devices to grow from a $372 million market in 2013 to $16 billion in 2023.

“Consumer devices have seen a lot of hype, but clinical devices will surpass their consumer counterparts in revenues by 2020, helped by value-added software services and generally larger revenue streams,” said Lux Research Associate Nick Kurkjy, lead author of the report, “mHealth Showdown: Consumer and Clinical Devices’ Battle for Market Dominance,” released last July. “Clinical markets will be able to pay much more for comparable services, especially if a device is able to reduce patient recovery times or readmission rates, which can lead to outsized cost savings for the health care provider,” he added in a release from Lux.

Point-of-care diagnostics is spawning its fair share of startups seeking to build a business around, for example, innovative sensing technologies that “bring the device to the patient” wherever he or she may be. But even if they’ve been fortunate enough to receive funding to get started, many of the founders of these companies really don’t have a good understanding of what their product ultimately needs to do in the marketplace, said John Zeis, president of the Plastics and Single Use Disposables Business at Foundry Medical Innovations (FMI), a Carlsbad, Calif.-based medical and diagnostics device development firm that provides engineering services and serves as an incubator for cutting edge medical technology.

“One of the things that we try to really get our customers to do a good job of, on the front end, is defining what the user’s needs are and really understanding what need we’re servicing,” said Zeis in an interview. “We try to guide them towards ‘What are your user needs and what does this product really need to do?’ as opposed to, ‘Hey, let’s just make this nice gadget that looks cool and can diagnose something on a bread board.”

After helping a customer define the user’s needs, FMI will follow the project all the way through to manufacturing. “We can make the molds, and then, once we verify that the parts function properly, we’ll find the critical tolerances and dimensions, and critical features and critical functions, and then help spec out potential manufacturers,” Zeis said. “And then we’ll work with those manufacturers to give the product a transition.”

Paul DiPerna, president of the Systems Engineering and Incubation businesses at FMI, said that a number of manufacturing improvements, including the growing reliance on rapid prototyping and 3D printing technologies, has contributed to “a strong expectation of getting things done faster than ever before.” Because of this, he said, medical device OEMs are looking for companies that have experience in completing projects similar to what they’re trying to accomplish.

“I think the expectation of the length of the project has gotten very aggressive,” he said. “A lot of people will come to us because of our prior expertise, and their expectation is to hit the ground running. If you’re working on something in the diabetes space, you want to be sure that the company has done other things in that space. I think that’s a trend, whereas, before, it was more about your specific technical expertise. For now, it’s more about where you’ve been.”

Pia Kumar, director of corporate development for Mayfield Plastics, a custom thermoforming company based in Sutton, Massachusetts, can vouch for medical device OEMs' reliance on suppliers that have experience in medical manufacturing. Mayfield, which recently completed a highly cosmetic, complex, multi-piece housing assembly for a major medical OEM customer, has more than 40 years of experience in the industry. The company has won awards from the Society of Plastics Engineers (SPE) Thermoforming Division in multiple categories, including Best Pressure Formed Parts.

"When a new customer comes to us, they want to know that they are working with a company with experience, a company that understands the highly cosmetic and functionally exacting requirements of this market," said Kumar. "Along with Mayfield's track record of successfully working with major medical device OEMs, our in-house engineering, design services and tooling are important differentiators for customers." For more on Mayfield Plastics, see *A Medical Device Manufacturer's Dream*.

DiPerna also said that he's seeing a trend toward more entrepreneurial startups, even among people who are unemployed. "Nowadays, people say, 'I could get a job, I could do some consulting, or I could start a company. Whereas, 10 years ago, it was pretty unusual for people to talk that way; now, it's almost everybody. Now that things are improving, there's a lot more activity in the air."

Wireless Medical Devices Enabling Personalized Healthcare

Point-of-care products are part of a rapidly evolving movement in healthcare today toward more personalized care — an aim enabled and supported by the pervasive adoption of wireless-based mobile health (mHealth) devices for remote monitoring and assessment.

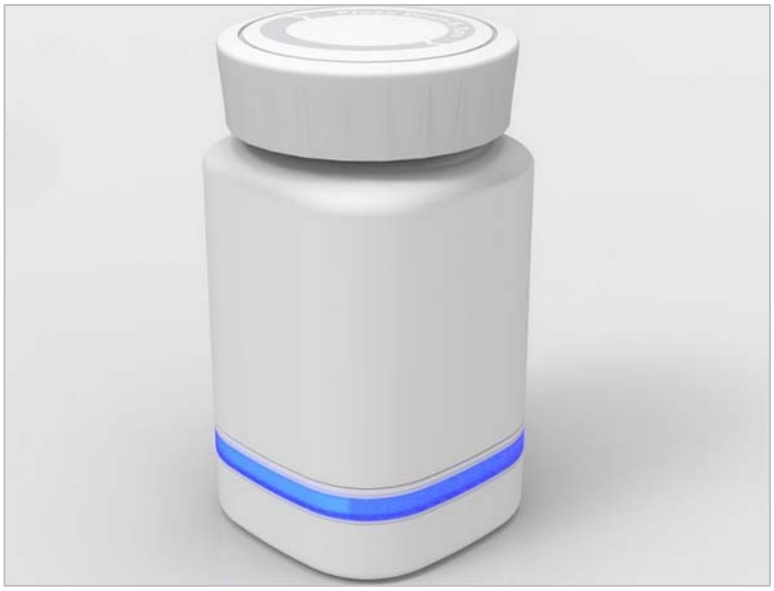
"There are a lot of personalized care products out there that attempt to get information onto your Android or iPhone about everything imaginable — your weight, your heart rate, what you did, where you were," said DiPerna. "There's a lot of this information getting to the patient, and there's a whole medication adherence field that's beginning to evolve. It's in its infancy, as far as getting people to actually take care of themselves, as well as take their existing therapies. The whole economics of that is starting to be really understood, and a lot of the changes in the Affordable Care [Act] are motivating people to begin to work in that area. So that's an area that I see taking off in the next few years."

The Center for Disease Control (CDC) estimates that medication non-adherence — the problem of patients' not taking their prescriptions — is responsible for adding some $300 billion per year in costs to the United States healthcare system, according to Michael Morena, chief operating officer of AdhereTech, a small startup company in

New York City. Morena and AdhereTech CEO Josh Stein started the company two years ago with the aim of bringing to market a smart, wireless pill bottle that electronically reminds patients to take their medications and provides alerts to caregivers if doses are missed.

AdhereTech has developed a first generation Smart Pill Bottle that's currently in trials, and is now working with Intelligent Product Solutions (IPS), a New York-based product design company, to develop the next generation of the product. The second generation of the product, due out in mid-2015, is expected to be smaller, less expensive, and easier to mass manufacture, and to provide additional user enhancements, such as longer battery life, a larger cap, and capacity to hold a higher volume of medication.

Morena says that medication non-adherence also represents "about $100 billion a year" in lost revenues for U.S. pharmaceutical companies, while contributing to approximately 100,000 deaths a year.



AdhereTech is working with Intelligent Product Solutions, a New York-based product design company, to develop the next generation of its wireless Smart Pill Bottle, which electronically reminds patients to take their medications and provides alerts to caregivers if doses are missed. Photo courtesy of AdhereTech/IPS.

"It's considered a very large problem in health care, and the way we're approaching it is we're developing a cellular, connected smart pill bottle that is distributed to patients for free at the pharmacy, so that we can track their behavior in real time and generate interventions based on their behavior or lack of behavior," Morena said in an interview. "So when people don't take their medication, we can detect that in real time and generate a reminder. We can also solicit feedback when people aren't taking their meds, and find out why. There may be reasons other than forgetfulness. For example, if someone's dealing with side effects or financial stress as a result of their medication, we can detect when they're not taking it and then provide them that information by connecting them to the right person at the right time."

Dana DeMeo, who has been working directly with AdhereTech as chief technical officer at Intelligent Product Solutions, calls the AdhereTech Smart Pill Bottle a unique and novel solution. "It's an intelligent pill bottle that has electronics inside, and it's completely standalone," DeMeo said. "It has a cellphone radio inside that's already pre-configured when you receive it. As a patient, there's really no setup that you have

to do. You receive a bottle like you normally would, the prescription's inside, and the only real difference to you is that it will occasionally beep and light up to remind you when to take it. And that's really it."

The pill bottle, which requires no syncing or programming, is designed for simplicity because its users — the least adherent patients — are the least likely to buy a product, set it up, and help themselves, Morena said. Rather than trying to sell the product to them, AdhereTech would rather give them the pill bottle.

"You don't have to learn how to use it; you don't have to worry about how it works, and the reason we make it that way is we want people to benefit from it right off the bat," Morena said. "We don't want any friction. It comes with the medication in it; the idea being that when it comes to the patient, they use it no differently than a regular, standard pill bottle. They open and close it like a standard pill bottle; they take pills out of it like a standard pill bottle, and they don't have to charge it. It can work for up to 90 days on a full charge, where it will actually come to the patient fully charged. The idea is that you get all the benefits without having to do any additional work, and we see that as our unique approach to solving the problem of medication non-adherence."

Mitch Maiman, president of Intelligent Product Solutions, says that wireless medical devices are an emerging product category that IPS is well prepared to handle. "One of the areas where we provide a lot of core competence is in smart and wirelessly connected devices," said Maiman. "Because of our experience, a lot of us having been ex-Symbol, ex-Motorola people, we have a lot of expertise in wireless communications in all forms — everything from low level things like ZigBee and Bluetooth, and near field, up to Wi-Fi and GPS and wide area radio communications. There's a lot more things going on, and you're seeing them all over the place in terms of connected devices. This is an area where we have a lot of competence."

Another consumer electronics trend that's rolling into the medical space is the increasing preference for wearable devices with monitoring capabilities. Maiman also touts IPS's capabilities in this area. "When you talk about wearable, body mounted and body worn technology, especially when you get into mission critical things, like in the medical space, this is where we have a lot of domain expertise," Maiman said. "There are a lot of nuances to designing a wearable device that's reliable, that somebody can wear all day long and all night long, that they can wear in all kinds of conditions — like when it's 100 degrees outside and 90 percent relative humidity. We've got a lot of experience in what it takes to make devices that are reliable over a long period of time, and in wearable devices that work in those kinds of environments.

"We've worked in medication dispensing systems before and we've done work in computer navigation methods for quadriplegics, who are unable to manipulate a cursor control, but yet they need to interact with a computer," he continued. "We're doing work right now on mobile and fixed mounted defibrillators. So it's a pretty broad range of products, but the common thread is that there's a lot of electronics, and they're all smart."

What to Look for in an Electronics Manufacturing Services Provider

Quality, a universal concern across complex product manufacturing market segments, is at the top of every medical device manufacturer's list of priorities when selecting an electronics manufacturing services (EMS) provider. But it's also important to consider the location of the manufacturer, the degree and type of service and support that they provide, and whether or not the person you interact with is a high-level engineer, according to a white paper recently released by Oakland, California-based Digicom Electronics. The white paper, *What Medical Device Companies Need to Consider in Selecting an EMS Company*, was co-authored by Digicom executives Mo Ohady, general manager, and David Estes, engineering specialist.

"Although most EMS companies perform the same basic services, every EMS is different," explained Ohady in a release from Digicom Electronics. "You can tell when you walk into a place, examine the equipment and processes, and speak to the people. It's important to use due diligence in choosing an EMS company, but the rewards can be great. A properly functioning EMS brings decades of experience and knowledge to embrace and enhance the product you want to build in a time-efficient and cost-effective manner."

A big part of choosing a supplier involves deciding if you want your product to be manufactured close to where your company is located, or close to where the product will be distributed or sold, say Ohady and Estes. Factors to consider when weighing the location of a supplier include the complexity of the device, the need for intellectual property protection, shipping costs and time, and the degree of supplier involvement that you'll expect throughout the manufacturing process.

Manufacturing at a great distance from home — say, the other side of the world — can become a problem when a production issue arises, Estes said in a phone interview. "If you need to travel there to resolve the problem because the expertise to do that just doesn't exist at that location, then you're looking at maybe a $20,000 trip to travel overseas, and the delays that that introduces. And so being local allows a very quick response to resolve an issue and get on with production."

Digicom, because of its location in the San Francisco Bay area, offers a special advantage to local OEMs. "We are certified to California standards, and so when you're building medical devices in California, we are approved of," Ohady said. "We are registered with the FDA; that addresses the U.S. built devices and those that are distributed throughout the United States. And the ISO 13485 [certification] tops it by addressing most of the rest of the world's regulatory issues and compliance."

Ohady got to know his colleague, David Estes, when Estes was once a potential customer of Digicom. At the time, Estes was doing considerable research as part of the process of selecting a manufacturer for a product that he was helping to develop. "He has a very rich level of experience," Ohady said.

“I can say, from a device manufacturer point of view, that selecting a manufacturer when one has little manufacturing experience is really daunting,” said Estes. “It’s very much like going out to buy a car when you really haven’t driven a car; you don’t have that experience. And so it’s critical that you select a manufacturer that’s willing to accommodate your lack of knowledge and expertise. It almost is like an educational process that occurs between the manufacturer and the company.

“If the manufacturer is very large and is used to working with very large companies that have a lot of experience, they may feel it’s a burden to take on this chore of educating and working with a customer that’s new to manufacturing,” he continued. “The advantage for the manufacturer, though, is that it’s a potential win-win because as one learns new products and overcomes new problems, this becomes part of the repertoire of the manufacturer. And so the manufacturer can actually gain expertise in new technology by working with new companies.”

Digicom marketing representative Andrea Roberts said it’s important to work with an experienced engineer who can look at your boards, box builds, or devices and tell you if your design is going to work — that is, whether it can be manufactured. During the prototype phase, experienced engineers can provide ideas about better ways to manufacture the product, she said. Later, when you want to build the product in volume, they can tell you if the prototype can be transferred to volume manufacturing.

“There’s a whole lot that goes into it — the sourcing and the whole picture of Design for Manufacturability,” she said. “And that’s why you really need an engineer to work with you, to see if that design can actually become a reality.”

Quality is much more of a concern with medical devices because poor quality can directly affect safety and lead to fatal consequences. It’s important to know what types of inspection and tests are performed by an EMS provider, whether they have tracking mechanisms in place, and how clean their printed circuit boards are, said Ohady. That’s because quality is directly related to the cleanliness of the boards, an issue that Digicom addresses in its white paper, *Cleanliness of PCB Assemblies Leads to Medical Device Reliability*.

In the paper, Ohady and Estes discuss the important role that cleanliness of electronic components and circuit boards play in preventing component failure, as well as the benefits of the company’s Diamond Track Cleaning Process. The process, part of the company’s Diamond Track Manufacturing program, employs a proprietary combination of chemicals, temperature, wash cycles, and timing to render circuit boards extremely clean and includes stringent test and evaluation procedures.

“Independent tests showed that boards that went through this [Diamond Track] cleaning process tested 75 percent cleaner than the 10-2 micrograms/in2 specified by IPC as its highest level of clean,” they wrote. “In addition, a lab analysis for ion contamination found zero levels of sodium chloride ion contamination on the assembled boards.” (The IPC is a global trade association that serves the printed board and electronics assembly industries.)

The level of cleaning attainable by the Diamond Track process is said to eliminate failures caused by board contamination and make products less susceptible to corrosion-induced failures, reducing the need for maintenance or repair. Medical device manufacturers that use the process can realize significant cost savings as a result, according to Ohady and Estes.

“When we’re looking at the devices now being made for the medical device industry, including all the wireless and implantable devices, it is time to take a new look at cleanliness standards and the processes used in manufacturing to ensure that these products do not fail,” they wrote.

3D Printed Patient-Specific Implants

Wireless medical devices aren’t the only technology that’s facilitating the trend toward personalized healthcare. Another key enabler — one that’s providing some of the most impressive examples of customization — is 3D printing, now being used to produce patient-specific implants for reconstructive surgeries of the skull, face, jaw, spine, hip, knee, foot, and ankle.

WEB Medical recently announced that surgeons have implanted over 3,000 of the company’s 3D printed orthopedic truss implants. Photo courtesy of 4WEB Medical.

But although 3D printing is the most visible step in a process that reduces lead times, it’s actually part of a larger digital thread that begins with a medical imaging study—usually a CT scan or MRI — of the patient’s anatomy. The digital thread includes, among others, a medical image processing step that builds up a 3D model of the anatomy from the 2.5D representations of the imaging study. It’s that 3D model of the patient’s unique anatomy that becomes the basis for 3D printing of a personalized implant.

One of the more interesting companies in the space is 4WEB Medical, an implant device company headquartered in Frisco, Texas, that is reported to be the first company to receive FDA clearance for an additive-manufactured spine implant. Founded by company president Jessee Hunt, 4WEB Medical has combined the novel 4WEB geometry — a building block for creating high-strength, lightweight web structures — with leading edge 3D printing to develop a proprietary implant platform.

Surgeons have implanted more than 3,000 of the company's 3D printed, orthopedic truss implants, which are designed with a distinctive open architecture that reportedly allows for up to 75 percent of the implant to be filled with graft material to maximize the incorporation of bone. The 3D printed implants also have a unique, roughened surface texture that is said to promote bone adherence and, by increasing coefficient of friction, reduce the possibility that the implant will move from its original position.

Other companies that have achieved prominence in patient-specific 3D printing include ConforMIS, developers of a proprietary iFit Image-to-Implant® Process, 3D Systems – Medical Modeling, known for its role in integrating 3D printing into a comprehensive digital thread for personalized medical implants and surgery, and Oxford Performance Materials, a specialist in the high performance polymer, PEKK, that has received FDA clearance for the manufacture of patient-specific cranial and facial implants (see One of These is Not Like the Other).

Another company, veteran-owned Osiris Biomed 3D, is preparing to offer 3D printed, patient-specific implants that it believes can further reduce lead times to surgery. The company's proprietary software is expected to facilitate real-time production of customized implants from patients' medical scans. If approved by the FDA, the technology reportedly will enable surgeons to design and print custom implants for immediate use in surgery.

Osiris Biomed 3D has applied for a patent for "single anesthetic reconstructive surgery," which, the company says, will allow a patient to be scanned and a custom device or implant printed, sterilized, and surgically implanted "on the operating table," all in one surgical procedure. The company is preparing a highly mobile 3D printing CONEX (contingency employment exercise) for the military that can establish operating suites in a theater of operations, reducing time to surgery for wounded soldiers.

In a phone interview, Chief Operating Officer Christopher Gerstle said that the company will be initially using an FDM (Fused Deposition Modeling) process to ensure that, when starting to build an implant, the build chamber is sterile and contains no material from a previous build. "You're extruding at very high temperatures, which are sterile, and what I refer to as the 'nest within the box' is much more controllable at this point. So it (FDM) is a good first step for us."

Quick Response Manufacturing Cuts Lead Times for Medical Device OEMs

Gordon Knott had just gotten back from the MD&M show in Minneapolis last fall when we asked him what types of things the medical device manufacturers that he spoke with at the show wanted to know about Alexandria Industries' capabilities for meeting their needs and solving their engineering problems.

“The manufacturers we met with asked about our lead times,” said Knott, the medical market leader for Alexandria Industries, a vertically integrated supplier of engineered, customized aluminum extrusions, as well as precision machining, plastics molding, finishing, welding, and assembly services. “Because we use Quick Response Manufacturing (QRM), we are able to offer some of the shortest lead times in the industry, enabling us to compete well with other suppliers.”

Quick Response Manufacturing, used to cut lead times in all phases of manufacturing and office operations, allows Alexandria to focus on the continuous improvements of eliminating non-value-added waste, improving quality, and reducing cost. Since implementing QRM, the company has reduced quote times from 12 days to three-to-five days, and extrusion product lead times from 30 days to as little as five days, Knott said. Significantly, QRM has given Alexandria the opportunity to gain a substantial foothold in markets, including medical, that value short lead times.

Medical is one of Alexandria’s prime markets, accounting for “about 13 to 15 percent” of its total sales, said Patty Hoffman, the company’s marketing and communications specialist, in an interview with D2P. “It’s not our biggest market, but it’s definitely one of our larger ones, so it’s a significant industry for us.” That’s not surprising, given the company’s location in Minnesota, one of the nation’s top states for medical device innovation, and its proximity to a thriving medtech hub — Minneapolis/St. Paul — a little more than 130 miles to the southeast on Interstate 94.

Alexandria manufactures a wide variety of components for the medical industry, including components for durable and electro-medical equipment. This includes structural components for mobile or stationary diagnostic equipment, monitors, heat sinks, IV poles, medical carts, structural equipment, X-ray systems, and CT systems, among others. Knott said that all of Alexandria’s manufacturing capabilities are well-suited to address the product development needs of its medical industry customers, but customers typically choose the company’s aluminum extrusion, precision machining, and welding services.

Having partnered with a number of local medical device makers, Alexandria Industries has developed a good understanding of some of the biggest concerns that medical device manufacturers have — and the constraints that they’re up against — when attempting to bring a medical product to market. Other than the high cost of bringing a product to market, medical device OEMs struggle with managing their supply base and making sure that their products are safe to use, Knott said.

“Medical OEMs often need to manage hundreds of suppliers, which is costly and time-consuming,” he explained. “Add to this the increasing trend in mega-mergers and acquisitions, and an OEM’s supply base can double or triple. The more suppliers, the more time, money, and significant effort it takes to evaluate, qualify, and keep a supplier list held to a manageable level.

“Product safety is also a top concern for medical device OEMs,” he continued. “Many medical products have movable parts that interface directly with patients, and anything

that could potentially cause harm — pinch, stab, or tip over on a patient — needs to be addressed. Medical device manufacturers need to make sure their suppliers know which parts and component dimensions are essential to patient safety and function. They will require that suppliers identify dimensions that are essential to safety."

Alexandria's ability to operate as a one-stop component shop — a vertically integrated supplier that offers OEMs a single source to design, produce, assemble, and deliver a range of components — has direct and positive implications for both cost and lead time, two of the foremost concerns that medical device companies have when bringing a product to market. Medical device OEMs who outsource component manufacturing from multiple — often, hundreds — of suppliers face stiff challenges in managing these complex relationships and purchasing processes, which can take a heavy financial and logistical toll on their resources. This ultimately slows product time to market and drives up the cost for the company.

"Instead of interacting with several different suppliers, OEMs should find a supplier who can help simplify their supply chain needs by offering a range of complementary manufacturing services so they can do more of the work for them," Knott said. "OEMs should seek a supplier who also offers value-added services, such as design engineering assistance and advanced geometric dimensional accuracy, to help reduce their time to market even more."

Executing on its vision of being a single source, vertically-integrated supplier of "high quality, short lead-time engineered products," Alexandria Industries acquired the plastic injection equipment assets of a North Dakota-based manufacturer of injection molded components in 2012. These assets, as well as TIG and MIG welding services, were rolled into Alexandria's Wheaton, Minn., facility.

Knott also stressed the importance of evaluating suppliers based on total-cost-of-purchasing criteria instead of the cost of the parts. That's why it's important to seek suppliers that combine their manufacturing expertise with value-added services like ease of purchasing, engineering assistance, finishing, and assembly, he said.