Intricon
MICROMEDICAL TECHNOLOGY

OEMs Are Demanding Designs that Challenge Suppliers

Innovative technologies enable outsourcing providers to offer design solutions to OEMs with complex requirements.

Mark Crawford, Contributing Editor — May 2, 2002, Medical Product Outsourcing

Intricon is a joint development manufacturer (JDM) that integrates micromedical components and assemblies to advance technology across a range of device platforms for global customers. Image courtesy of Intricon Corporation.

Product design is on the rise in the medical device industry as the COVID-19 pandemic wanes, the result of higher demand for medical devices for the growing number of elective procedures being performed and other medical care. Complexity of design ranges from simple modifications to legacy products to new, first-in-industry devices. This is especially true for minimally invasive (MI) interventional approaches, which increasingly combine technologies such as robotics, artificial intelligence, and advanced imaging and navigational systems.

"Product design is becoming more focused on procedural solutions, rather than discrete devices," said David Schechter, president of Meddux Development Corporation, a medical device design, development, and manufacturing partner for complex single-use devices. "This requires a committed emphasis on human factors/usability engineering and incorporating a systems approach to product development."

This is especially true for smarter, miniaturized products for MI procedures, earlier diagnosis and treatment of disease states, and body-worn devices that monitor patient recovery and well-being at home. "The cost pressures on healthcare overall are driving two key trends—the need for home care and the need for clinic-based procedures, rather than hospital-based procedures," said David Liebl, vice president of R&D for Intricon Corporation, a Minneapolis, Minn.-based joint development manufacturer for medical devices. "These trends will lead to less-invasive approaches for diagnostic and therapeutic procedures and non-invasive technologies to help visualize and/or transmit key health data for analysis."

Supply chain woes continue to frustrate medical device manufacturers (MDM), with long lead times, obsolescence of parts, and unreliable forecasting causing the worst delays the industry has seen in decades. Perhaps the hardest-hit part of the design process is prototyping. The quick release of new products depends on rapid prototyping with the right materials. It is imperative to iterate quickly in order to receive critical feedback from stakeholders early and often during the design cycle—especially if alternative methods and materials need to be found to stay on schedule because of supply chain shortages.

"Lead times for raw materials required to prototype new product concepts have definitely increased—often two- or three-fold—from pre-pandemic levels," said Liebl. "Thus, companies that can find a way to prototype faster in the current environment will rise to the top. One example is 3D printing technologies, which can at least partially fill the void of long lead-time materials."

The resurgence in product demand after two years of slowdown, coupled with supply chain issues, regulatory challenges, and remote communications, as well as virtual processes that further complicate product development, have led some MDMs to deepen their collaborations with contract manufacturers (CMs) to stabilize/streamline design and development as they move forward.

"It's an interesting time," said Jim Reed, general manager for Minnetronix Medical, a Minnesota-based company that designs, develops, and manufactures medical devices for its partners in the industry. "The flow of startups is strong and nearly all of them are virtual, which creates opportunities for companies like Minnetronix Medical to provide capabilities and end-to-end solutions that can minimize capital burn for startups. At the same time, larger, top-tier companies are trying to focus on what they do best by outsourcing some non-core activities."

Latest Trends

Product design is trending toward smaller and smarter devices that combine multiple technologies—for example, increased wireless data-gathering capabilities in non-invasive and minimally invasive devices. "These technologies enable the use of artificial intelligence, which is an important trend as Medicare and health insurance practices evolve toward reimbursement strategies based on documented patient outcomes and take into account the patient experience," said Liebl.

"We're also seeing more customers understanding the value of accessible and insightful data," Reed added.

Outsourcing is in high demand, especially as devices become smaller and more complex, particularly with data-related functions, which are more complicated to design. In response, more MDMs seek experienced CMs that can help with designing individual products and also manage multiple projects to keep the "pipeline" flowing.

"For many companies, the number of products in development exceeds their bandwidth," said Justin Bushko, principal for Concise Engineering, a Clearwater, Fla.-based design firm that helps medical device companies design, iterate, or accelerate new products. "The business potential of many products requires outsourcing to capture the revenue sooner, avoid delays, and realize market growth."

Additive manufacturing (AM) technologies, materials, tolerances, and surface finishes improve every year—especially for short-run production of polymer components. AM is rapidly becoming a favored approach for building prototypes and testing fixtures and initial product concepts because it is faster than other methods, such as injection molding.

Data capture and analytics is another rapidly growing field.

Nearly every project MDMs bring to their CMs has a data component that is transferred via wireless communications and logged into the cloud. It is rare to have a product discussion where the connectedness of the device is not discussed, noted Bushko. "In some cases," he said, "the product itself cannot be successful without the data and the ecosystem developed in parallel around the product. The primary user needs of the device and its communications and data requirements should be discussed as early as possible. The addition of these features later in a project will cause significant delays. Failure to review the data transfer rates increases the risk of choosing an inappropriate means of data transfer, leading to longer than expected data transfer rates."

What OEMs Want

It's simple—speed, speed, and more speed. Of course, they also want top quality systems, technologies, and lower costs, but every MDM wants to be the first to market with innovative technologies.

"Speed to submission is the one constant," said Reed. "With uncertain regulatory and market uptake timelines, OEMs want to be as fast as possible with the parts of the process they can control."

MDMs must balance the entire production process, and its cost, with speed to market. Will extra testing/analysis (time) be worth the delay in production? By taking extra steps, what risks can be eliminated up front, and at what cost, to ensure a smoother, problem-free production process and streamlined regulatory approval?

For example, human factors and usability engineering testing is increasingly used in the early design process. It removes any surprises that might appear later in design or production that would delay production or require redesign—an extra step, yet it might save money and time in the long run.

"We need to think procedurally to understand how a device solution is going to fit within the proposed clinical workflow," said Schechter. "This typically involves detailed task mapping and story boarding to understand user interactions with the device, systems we need to be compatible with, and clinical variability patient to patient that is likely to be encountered—all of which reduce the risk of delays or even failure in product development or end use."

Outsourcing to trusted and experienced CMs is another way to speed up product design and development. CMs often have deeper experience than MDMs do because of the wider range of products CM make—not only medical devices, but products in other industries, such as electronics and aerospace.

"OEMs often seek third-party assistance for product design as their own quality management systems [QMS] often extend the time to develop and design products internally," said Liebl. "These OEMs seek a more streamlined, compliant QMS that will allow them to move quickly and stay competitive in their target markets."

Any aspect of medical device development can be outsourced, including design, sourcing, regulatory, and documentation. "This takes pressure off an OEM's already overloaded engineering teams, because they know the design will go through a rigorous process for risk mitigation, design for manufacturing, and other considerations for the entire product lifecycle," said Jim Medsker, president of Keystone Solutions Group, a Kalamazoo, Mich.-based FDA-registered product development and medical device contract manufacturing company.

"MDMs are looking to partner with companies that can provide complete solutions," agreed Chris Tellers, director of the Delano, Minn.-based Rapid Development Center for Trelleborg Healthcare & Medical, a partner to pharmaceutical and medical device companies at all stages of product development from concept to serial production. "Creating a 3D model is only a small part of the development process. The designer needs to think of how the part will be manufactured, inspected, assembled, and packaged. Often making simple changes to a product design will save significant time and effort on the manufacturing floor and reduce the risk of poor quality."

Yet another reason to partner with CMs is they know how to better navigate the disrupted supply chain—chances are, they have invested in innovative technologies to manage their supplies and workflows, developed a network of alternate suppliers, or stockpiled key materials, thereby making it easier to keep design and production as predictable as possible for their MDMs. This is vital to expeditious design, manufacturing, forecasting, and regulatory submittal.

For example, in the global electronics supply chain, current lead times and shortages make it entirely possible that, within a few months of a product being designed with available components, some of the key components will suddenly be unobtainable.

"As a result, supply chain and design must be integrated like never before," said Reed. "If a company needs a certain launch quantity of product, it makes sense to purchase components as soon as they are

selected for the design, otherwise they take on huge risks, such as launch delays and redesign work."

New Tools and Technologies

Wearable devices, with flexible fabrics and even flexible/3D-printed electronics, sensors, and electrodes are a hot design segment, with countless applications, especially for health monitoring. Miniaturization in particular requires higher-density, more flexible electronics, such as thin-film substrates for electronic assemblies. Combining sensor technologies with flexible circuits "has opened the door to many new applications," said Medsker. "Wearable devices can now monitor a myriad of physiological parameters, which are often used within the same device to administer various therapeutics."

"We have done considerable design work with traditional polyimide flex circuits, but have also designed circuits on elastic substrates such as urethane," said Schechter. "An area of special interest for us is the use of photochemical machining and sputtering to build thin-film structures for integrated circuits and sensors."

The use of conductive fabrics is also on the rise as advances in the manufacturing of these materials has allowed for a wider range of parameters such as usable temperatures, electrical resistance, and shielding capabilities. Many wearables are shifting toward using flexible adhesive materials that better adapt to various body types and locations. "The use of various adhesives and hydrogels allows for firm adhesion, easy removal, and a softer feel, in order to avoid the removal of hair or damaging skin when removed," said Bushko. "These aspects must be considered when determining a wearable patch design."

Researchers at Penn State University are developing medical sensors that can monitor vital health signals to track treatment compliance or diagnose health conditions. In particular, the team has designed a stretchable health monitor using foam-based, conductive graphene materials that are lightweight and can be formed into various shapes with a laser. The monitor is also self-powered, harvesting energy from the wearer's body movements that is then stored as electrical energy in micro-supercapacitors.[1]

Electronics can also be used to protect the health of patients and physicians in hospitals or clinics. Healthcare professionals involved in catheterization labs have long realized the inherent risk of continued exposure to fluoroscopy radiation. The ionizing radiation from fluoroscopy requires significant shielding and body protection garments for clinicians to avoid its adverse, long-term health effects. Even with these protections, however, an elevated health risk exists for those working in the presence of fluoroscopy radiation. "Electromagnetic field [EM] generators and EM sensor technologies are emerging as alternatives to fluoroscopy for many procedures," said Liebl. "EM sensors do not utilize ionizing radiation. Better yet, they are more accurate in locating the device, plus they enable the ability to integrate with a 3D image of the patient's anatomy, giving the clinician more information for treatment approaches while minimizing radiation exposure."

Software, Iteration, and Design

Software is advancing very quickly on all medical device fronts. The main tool for product designers continues to be computer-aided design (CAD) software. Finite element analysis (FEA) is another key tool in product design that is essential for reducing iteration cycles in the early development phase. FEA has improved immensely over the last 10 to 15 years. "Today, most mainstream CAD packages have FEA options built in," said Medsker. "The add-ins are also much easier to use than their predecessors. Product designers can easily call up an FEA analysis on their parts and assemblies and get results quickly."

FEA is an evolving practice that is increasingly utilized in product development. When done correctly, a proper FEA analysis will save project time and costs. "Empirical testing can become very costly when working through different iterations of the design," said Daniel Riveros, principal mechanical engineer for Concise Engineering. "FEA allows the design to get closer to a final design without having to get to functional prototypes. Depending on the product, a single prototype might be all that is allowed in the budget so, at the end of the day, running FEA analysis should save time and money in the product development design."

Using the latest FEA techniques and software will accelerate time to market, improve quality of design, and reduce overall costs of new and existing product designs. When FEA methods are combined with expert engineering and a portfolio of tried and tested materials, the optimal material or product design for an application can be quickly determined, leading to increased performance and reduced downtime.

"By simulating the performance and behavior of a component within a virtual environment, rapid modifications and design iterations can be tested for viability," said Tellers. "Testing out minor changes in a virtual environment quickly identifies failing concepts without having to make physical samples, reducing costs and lead times for a product launch."

FEA is being used more frequently as product designs become smaller and more complicated, especially for the evaluation complex assemblies. Fortunately, "the added cost of FEA is typically not too high unless it is a central part of the designer's focus in a very high-performance application," said Liebl. "FEA provides an important high-level data point as a ballpark indicator, but in most cases, the only way to know if a design approach is stable and repeatable is through actual builds. There are also many human factors in the assembly process that don't lend themselves to FEA."

Today, with FEA availability within CAD, and its ease of use, it is a relatively simple task to obtain FEA results, even without specialized training. However, this does present risks. If the software is used without a fundamental understanding of key aspects of FEA such as proper constraints, meshing parameters, linear/non-linear considerations, and others, inaccurate results could be

obtained. "Therefore it is imperative that, even with today's accessible, user-friendly FEA tools, that those charged with running the analysis have an in-depth knowledge of the fundamentals behind FEA," said Medsker.

Innovation and Product Design

Any medical devices that enter the market must be proven to be both safe and effective for patients. New products should be more effective than current standards. It is, however, not easy to innovate in product design—there must be balance between cost, time, and risk.

"Innovation in product design can happen by applying technology to simulation and modeling, processes, project management, verification, validation testing, manufacturing methods and technologies, service, and lifecycle management," said Reed. "All of these areas can be enhanced through innovation."

However, Bushko pointed out, true innovation is rarely possible in this current environment.

"All products are expected to materialize in the shortest time possible, even beating prior successful projects, to capitalize on a specific new feature or enter a market at a desired time," he said. "These restrictions allow for innovation, but true innovation requires time to fail and then improve. However, with restrictive budgets and schedules, most projects need to restrict iteration, forcing many to take the safe approach to ensure success, thus hampering true innovation."

Additionally, there have been many regulatory changes in the last five years. As regulatory requirements evolve and become more stringent, "these requirements can limit innovation because they can escalate the costs and time required to design, validate, and gain approval for new innovations," said Liebl. "This is especially true in higher-risk devices, where the time from concept to approval can take up to five years, driven in large part by regulatory requirements that require extensive data to prove safety and efficacy."

As MDMs emerge from the pandemic, it has never been more important to have deep (and trusting) partnerships with CMs and other suppliers to share advice and expertise. MDMs sometimes hold back because they think CMs might not have the experience, tools, quality systems, or resources in-house to execute their product designs. However, the reverse is often true—CMs often have the dedicated capabilities and experienced teams needed to solve even the most complex design challenges. For example, Trelleborg Healthcare & Medical's Rapid Development Center offers core competencies critical to medical device and pharmaceutical component development, including design consultation, toolmaking, high-precision machining, silicone and thermoplastic molding, assembly, and other secondary operations.

Quick time to market depends on MDMs having meaningful conversations early in the design process with their component manufacturers. MDMs that do not engage their part suppliers about design for manufacturing can encounter serious issues with expensive tooling and increased part costs. "Early discussions with component manufacturers can avoid issues with part geometry or air traps, short shots, or tear outs, for example, preventing quality issues that can cause delays in delivery and added costs," said Tellers.

Sometimes, MDMs and their internal development teams see product design through the lens of their own systems and teams. As a result, their internal processes may be too complex and/or resource-heavy to be agile enough to meet demanding, highly accelerated development timelines.

"Joint development manufacturers have systems that are nimble and 'external eyes' with deep category expertise to foresee both opportunities and challenges—now and down the road—during the manufacturing stage," said Liebl. "As more OEMs experience this, they embrace the practice of third-party development for its efficiency and are able to leverage the resources and the expertise of the joint development manufacturer, that then becomes a valued extension of their team."

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Reference
1. bit.ly/mpo220591