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FEATURE

Due Process: Orthopedic Design and Development

Amidst the complexity of today's designs, simple methods mean shorter timelines and superior products

In today's world of orthopedics, the magnitude and complexity of orthopedic devices are matched only by the processes used to design and develop them. When you distill the process, however, handling shorter lead times, using the most current solid modeling software and addressing safety concerns are the key factors to being successful in bringing new devices to market.



Team members assemble for a "protostorming" session to develop orthopedic designs. Photo courtesy of dj Orthopedics.

Once ready for market, however, designers may find that for their devices to be truly profitable, they cannot rely exclusively on innovative designs or gimmicks. Rather, they must address actual patient needs and solve critical, real-life problems.

Leading the Pack

As in many medical industries, the need to get products to market in an attempt to rival competition constantly decreases lead times, and orthopedic designers address this situation with a variety of methods and a team effort.

"It's always a challenge to continually decrease our time to market," said Jack Czajkowski, vice president of advanced operations for Stryker Orthopaedics in Mahwah, NJ. "You're always working with the product development and marketing people to try to shorten that time to market."

Czajkowski believes that one way to streamline operations during this phase is to develop three or four concepts concurrently, because the development process will achieve results even if one of the designs fails for any given reason.

Additionally, experts say shorter lead times can be achieved by applying adept knowledge of patent issues during the design and development process.

"Patents take time to clear, and if a design infringes on another manufacturer's patent, the process can be forced back to square one," said John Pepper, president of Creative Orthopaedics in Cheshire, CT. "With patent issues resolved upfront, there's less chance of that happening."

The concept of due diligence also plays an important role in getting products designed quicker. If orthopedic companies are able to talk to surgeons and pinpoint the problems that need

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to be solved prior to development, then chances are good that they will reach their goal once the process has started—rather than starting from square one again.

Rich Gildersleeve, vice president of research and development for dj Orthopedics in Vista, CA, said that by eliminating non-value add activities and vertically integrating by bringing tooling and prototyping in-house, time to market can be reduced drastically.

"Our average cycle time was more than 12 months for a product," he noted. "Last year, however, our average time to release a new product was only 5.4 months. We've made dramatic improvement."

All these methods for moving the process along cannot be applied in random fashion during the development phase, however. Instead, they need to be applied in stages.

Setting the Stage

Before entering any phase of development, the primary concern for any orthopedic manufacturer is to determine whether a concept fulfills a particular patient or surgeon need.

"Nearly every successful project I have seen has grown from a problem or proven need," said Larry James, president of New Concepts in Seattle, WA. "So many people simply try to dream up a cool idea because it's a cool idea, and that's a bad idea. It's a very mundane rule of thumb, but you'd be surprised how many people just don't get it."

James also added that if a company performs its due diligence and addresses real-world problems, the chance of a product achieving success is much greater.

Whatever the goal might be for a particular device, many companies break down their design and development process into stages or phases. Not all are identical, but basic methods universally apply to each phase.

For some, the first stage is where customer needs and requirements are defined, as well as what the company is trying to accomplish in the marketplace. The company must determine whether the concept would be a competing device, an incremental improvement on an existing product or a revolutionary product.

"That's always one of the biggest challenges in product development—getting the inputs well defined and documented so that we really know what the target is," said Steve Maguire, general manager of Unique Design & Development in Shelton, CT.

The second stage is primarily concerned with concepting and, depending on whether the device is implantable or external, it is when materials are considered. In this phase, brainstorming sessions are undertaken and consideration is given to marketing, quality assurance, manufacturing and research and development concerns.

"We get as many people involved from the different organ-

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Finite Element Analysis is used by engineers to analyze mechanical stresses of implants and instruments prior to prototyping. Photo courtesy of Unique Design & Development.

izations as early as it makes sense, as early as it is practical," said Czajkowski. "[Therefore,] certainly marketing, quality, R&D and manufacturing are involved very, very early on."

Stage three is where the feasibility of a device is considered. (Feasibility asks the question of whether a device can actually work.) Solid CAD models are turned into basic, working prototypes so that form and function can be examined, and testing can be done to mitigate any risks.

"If it's an implantable device for which safety and efficacy are significant issues, then you would prototype with actual materials and representative processes to ensure that the design is being tested in realistic ways. In these cases, materials and processes become important aspects of design feasibility," said Maguire.

The fourth stage can consist of product design—this is the time to focus on the item's look and feel. Manufacturing has its biggest role in this stage, as the focus turns to how the device is going to be made. Human factors such as ergonomics are also taken into consideration. Finally, after this stage is complete, mass production is discussed.

Different strategies work for different companies. According to Gildersleeve, dj Orthopedics employs a process of five "gates," similar to stages, where the same problems and goals are addressed.

Software Into Hardware

Aside from business strategies and development phases, cutting-edge software used in the design phase plays a major role in effectively meeting tight timelines. The primary tools used in orthopedic design and development are SolidWorks and ProEngineer, two CAD-based, solid-modeling programs that enable designers to see their concepts as three-dimensional representations. These applications benefit users by enabling rapid prototyping of extremely complex designs in less time—often within a few hours or overnight, rather than days or weeks.

In addition, solid model data can be imported into rapid prototyping machinery systems utilizing processes such as stereolithography, or even into CNC machining, to create working prototypes for demonstration, testing and approvals.

"Historically, you would probably go to a machine or model shop with drawings to get your prototypes made," Czajkowski explained. "And that would obviously take quite a bit longer than just using a CAD model and having a rapid prototyping system simply bring the model out."

Even if a company still uses model makers for building prototypes, software can help overcome certain limitations of the human mind, such as complex ergonomics and multi-directional axis of movement. (For more on "human factors" in the design process, see the sidebar on page 40.)

"A model maker can really only think in two planes at once. That's just human nature," said James.

Designers see solid modeling software gaining enhancements that will provide virtual simulation for form, fit and function and simultaneously produce documentation for FDA compliance, according to Larry Crainich, founder of Charlestown, NH-based Design Standards.

In addition to solid modeling software, another popular program is Finite Element Analysis, an application that allows a user to input load variables into a CAD model to examine stresses and determines whether a design will fail under those loads.

For all the benefits today's software offers, experts caution that the

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very innovative features these applications offer can also sometimes lead designers to lose touch with reality.

"You can zoom in on the head of the pin and make it look really nice, but manufacturing might not be able to reproduce what you've designed on screen," said Pepper. "You need a little reality check from time to time, and it emphasizes the need for manufacturing to be involved during the design process."

One of the challenges associated with the latest software applications is incorporating the human anatomy into what is essentially a sterile, microchip world. CAD programs can't identify that people come in all shapes and sizes, and thus it is difficult for the program to translate cold and rigid algorithms into variable, ergonomic designs.

"We can laser scan skeletal pieces and produce a 'cloud of points,' but the downside is that this imported body of data, what we call a 'dumb blob,' cannot be manipulated, or at least not very easily," said James.

"If you take into account the simple needs of form and function, patient need and safety, the design process stays focused and a quality product reaches the consumer."

Crainich additionally explained that human anatomy is not always identical. "People have abnormalities in their anatomy—age, mass, birth defects, disease and injury also alter the body's configuration," he said.

The need for software upgrades can pose challenges as well. Many orthopedic companies upgrade their applications yearly, only to encounter incompatibilities with other vendors and customers who are late in upgrading their own systems.

However, as CAD-based software has matured in the past 10 years, most companies see these interfaces as crucial to the efficient translation of concepts into tangible and successful orthopedic designs. One thing that software cannot do, however, is infuse the human element of safety into the design.

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The Human Factor

An often-overlooked element in orthopedic design and development is the "human factor." Many companies employ a team strategy in which employees are divided into different teams to compete with each other to brainstorm new device concepts. This method is a double-edge sword and, according to some orthopedic companies, has either been highly successful or an absolute failure. One of the downsides of the team approach is the inherent human frailty of ego.

"Egos have to be checked at the door in order to realize synergy, because that's ultimately what you're trying to do," said Larry James, president of Seattle, WA-based New Concepts. "You're trying to combine everyone's ideas and thinking to find solutions that are better than any one individual's. That's the definition of a synergistic relationship."

Others have found that the team approach works very well. Rich Gildersleeve, vice president of research and development for dj Orthopedics in Vista, CA, has developed a team approach called "Protostorming," a process that helps his employees navigate through difficult design challenges while keeping them motivated and "juiced" throughout the entire design and development process.

Using this method, more concepts can be evaluated in shorter periods of time using smaller, multiple teams, each with their own particular skillset. Additionally, teams choose their own ideas to develop which fosters a feeling of pride and satisfaction, added Gildersleeve.

"People enjoy working on things if they were part of the original genesis of the idea," he explained. "It's just human nature to get a little more excited by an idea that you've helped create."

Other methods require a consulting company performing field observation to determine what products are currently being used and then to obtain feedback as to what works and what doesn't. The data are collated and presented in poster form for design meetings.

Steve Wilcox, principal of Design Science Consulting in Philadelphia, PA, a design consultancy that employs this type of approach, said that condensing the information into poster form for use in development meetings makes for much better informed decision making.

"All the key design decisions are made in meetings, and nobody really reads reports anymore," said Wilcox. "If we didn't take the information and put it in a form that could be absorbed in five seconds, chances are it's not going to be used in making decisions."

Regardless of which method a company uses to generate ideas, the one constant throughout the entire process is people skills. The key to successful design and development, experts say, is to solicit input from everybody involved—if the team players don't work together, a design-in-a-vacuum approach could be a recipe for disaster.

Wilcox offered some sage advice: "It's always a challenge to develop mutual respect and communication. But that's really the essence of good product development." ❖

Liability Factors

Patient safety is obviously of utmost importance when designing an orthopedic device, and one of the largest factors taken into consideration during the design and development process is liability.

Some companies, though—especially startups, experts say—simply develop a product and build a company based on their exit strategy, hoping to one day be bought by a larger company. In doing so, many take shortcuts to achieve their goals.

"We've actually chosen to discontinue doing business with people in the past because it was clear to us that they were not concerned with the safety and efficacy of their product. Instead, getting it to market was their only concern," said Crainich.

Symptomatic of this strategy, some companies go abroad where regulations are less stringent for clinical trials to gain FDA approval noted Crainich. Approval is a key milestone to progressing a company with investments or position for sale.

Aside from a business or design standpoint, material selection for an orthopedic device is usually based on safety standards. For example, an implanted device must not be magnetic because this could compromise a patient's safety if he or she needed to undergo a magnetic resonance imaging (MRI) procedure.

Some designers believe that if the quality of design and production are held to high standards, then liability is mitigated.

"It should almost be a non-issue," said James. "If you do your homework, it naturally falls in place that liability issues will be greatly reduced."

Crainich also offered a practical perspective: "If you wouldn't use it for yourself or your children, don't put it out there."

Throughout the complex design and development process for bringing a new orthopedic device to market, the multitude of factors that must be considered at every stage can raise the question of how designs even come to fruition. However, if you take into account the simple needs of form and function, patient need and safety, the process stays focused and a quality product reaches the consumer. ❖