VIEW FROM THE TOP

Embracing the Unknown Is Key to Innovation at Edwards Lifesciences

Let’s start with a look at Edwards Lifesciences, which develops devices, primarily valves, for people with heart disease. Could you give us more detail on the kinds of devices we are talking about?

Edwards has more than 50 years of experience of continuous refinement in heart valve technologies to treat aortic and mitral valve disease, as well as successful collaboration with clinicians to develop leading medical technologies. Our trusted expertise in valve innovation has helped more than 1 million patients in critical need. We established our leadership in heart valve therapy first with the development of the Starr-Edwards mechanical valve and later with the world’s most widely implanted tissue valves, the PERIMOUNT family of valves. Decades of refinement through experience, scientifically rigorous studies, and further collaboration with clinicians led to the innovation of the Edwards SAPIEN platform of transcatheter aortic heart valves. These valves can be implanted without open heart surgery and while the heart continues to beat.

In our Critical Care division, Edwards has been advancing the care of the acutely ill for more than 40 years. Starting with the development of Swan-Ganz advanced hemodynamic monitoring devices for measuring cardiovascular performance in high-risk surgical and critically ill patients, Edwards continues to evolve to less invasive and noninvasive devices to provide valuable hemodynamic insight for an expanded patient population. Edwards has continued to advance hemodynamic monitoring platforms to enable proactive clinical decisions for surgical, anesthesia, and critical care clinicians. We provide evidence-based programs (e.g., the Enhanced Surgical Recovery Program) that support the implementation and compliance to protocol-driven care pathways in the operating room and intensive care unit.

What do you consider the most noteworthy innovation in heart devices during the past 50 years?

Fifty years ago, cardiac surgery was in its infancy and the field of interventional cardiology as we know it today didn’t exist. The cardiovascular clinical community widely regards transcatheter aortic valve replacement (TAVR), which allows the placement of the valve through the groin without cardiopulmonary bypass or opening the chest, as a breakthrough in care for patients with the disease of the aortic heart valve called aortic stenosis. TAVR is changing the way these patients are treated, both by allowing previously inoperable patients to be treated with the therapy and for shortening the recovery time. In fact, one leader in the cardiac surgery field called it the biggest development since heart transplants.

Thomas B. Morrissey, MD, is vice president of quality assurance for advanced technology and product safety at Edwards Lifesciences LLC in Irvine, CA.
Edwards SAPIEN valve platform continues to raise the bar as the most widely studied transcatheter heart valve worldwide, as well as one of the most widely used transcatheter heart valves in the world. As part of our studies, we know that when transcatheter aortic valve replacement is less invasive, the patients have excellent outcomes and a short length of stay, and patients report improved quality of life.

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You’re a medical doctor. How and why did you join Edwards?

When you are in medical school and deciding on what field of medicine to choose as a career, you’re typically young and single and, as a result, a bit self-centered when it comes to the future. I happened to choose a field, thoracic surgery, that required 8 years of training after medical school in addition to a pretty busy schedule after you’re done. By the time I finished training and relatively early in my career, I was married and a baby was on the way. When I learned that my son had significant congenital heart disease, it was life changing, and I realized I needed more balance in my life. As one of nine children, I understand the importance of family and decided I needed to be a dad more than I needed to be a surgeon. The reactions from friends and colleagues were interesting, and most were supportive. An anesthesiologist I worked with asked, “What are you going to tell your parents?” This was pretty amusing, since I was 40 at the time! I think I can speak for the thousands of physicians working for life sciences companies when I say, while we cannot have the direct impact that physicians at the bedside have, we work on programs, technologies, and therapies that have the potential to help patients all around the world. It is a truly meaningful and rewarding opportunity.

Your title is vice president of quality assurance. What does that mean in terms of your responsibilities at Edwards?

I have dual responsibilities at Edwards. In one role, I report to John McGrath, the corporate vice president of quality, and am responsible for patient safety across the entire company. We have a team of nurses and clinicians that monitors and investigates issues affecting patients, whether they are related to a postmarket event or assessing risk in the development of products. I am the owner of a process that identifies and evaluates these issues. I also am the head of quality for a group within Edwards under Stan Rowe that develops products in the early feasibility phase—these are very exciting next-generation devices.

How has the notion of quality assurance evolved, especially in terms of how Edwards develops and designs its products?

We continuously ask ourselves what a product, activity, or decision will mean to the patient who will receive or be treated with it. This helps us to make the best possible decision each time, and quality assurance decisions and processes are at the heart of this. Of course, we utilize all the modern and proven quality assurance processes, have achieved the appropriate regulatory certifications, and are subject to a host of U.S. and international regulations. We are proud of our performance in this area and continue to use the “patient first” lens as our most important guidance in decision making.

Edwards is an innovative company, and being able to contemplate and embrace the unknown is essential to innovation. We are continuously faced with surprises, both good and bad, as we explore novel technology and the next generations of our existing platforms. Risk-based decision making, where the patent is first, has been a critical success factor for us. It has helped us determine when we should proceed and when we need more development and data before proceeding. We use every surprise or opportunity as a learning experience.
I would think your work involves a fair amount of interaction with the Food and Drug Administration (FDA). What’s that relationship like? What kind of information are you providing to the FDA, and what kind of guidance is the agency providing you?

The FDA has a tough job. It gets criticized if it moves too fast and criticized if it moves too slow. My primary involvement with the FDA is during the postmarket period. The FDA realizes that issues will surface at every company and is interested in how companies respond.

I speak at a lot of industry/FDA risk management conferences. One of the most enlightening talks I attended was by a high-level administrator from a large U.S. healthcare provider. He spoke about the chaos that occurs at his hospitals during recalls. Part of this chaos, he said, resulted from the lack of infrastructure for addressing these issues, while the sheer number (>100/month) and many different departments and patients affected by recalls also contributed to the chaos.

The FDA’s mission is to protect the public health. It deserves a lot of credit in proposing the recent postmarket risk initiatives, factoring benefit/risk into some of these decisions. I think that FDA realized that it may not make sense to remove thousands of products from the field for an issue that does not affect safety. If a shortage results from a product recall, public health can be affected adversely.

How does risk management factor into the development and design of devices at Edwards?

Risk management is a decision-making process related to the safety of a medical technology, beginning during design and development and continuing through the entire life cycle of the product. At Edwards, two scenarios commonly occur. In the first, we may be improving the design of commercially available products to further reduce risk in the next-generation versions. In the case of SAPIEN, our first-generation TAVR (transcatheter aortic valve replacement) valve, we recognized that if we could reduce the diameter of the device, it would not only allow more patients to be treated but also reduce the incidence of vascular complications. Treating patients gives you important information on how you can improve your products. When making decisions on how to control risk in our next-generation products, we have the benefit of having that predicate product and all the data about how the product performs, how physicians are using it, and in which types of patients you need to reduce risk further.

In the second scenario, you are developing a novel therapy in an effort to solve an unmet clinical need. Although we don’t have the benefit of a direct predicate product, we have accumulated a tremendous amount of clinical and anatomic information that we can leverage regarding a group of fairly sick patients. In addition, these projects typically involve an implant and delivery system. Although the implants are different, we utilize all of the information in delivery systems, as well as data from suppliers, physician training, and our manufacturing processes. For these new products, though we learn a lot through our preclinical work, getting the products to patients in need is incredibly valuable. For these novel products, patient screening and physician training are becoming increasingly important as risk management tools. You want to get the products to the sickest patients who have limited options, but choosing patients who are healthy enough to undergo a procedure is challenging as well.

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You are actively involved in an AAMI working group that is looking at risk from the postmarket perspective. What is the working group trying to accomplish, and why is this initiative important?

The AAMI group, in conjunction with the FDA Center for Devices and Radiological Health (CDRH), put together a group of industry and FDA team members to specifically look at postmarket risk management. ANSI/AAMI/ISO 14971 is the principal guidance document regarding risk management for medical devices. It focuses...
primarily on risk during the product development stages and does not offer much guidance on the postmarket time period. The goal was to come up with a shared view of evaluating risk between industry and the FDA. One important result of these types of initiatives is recognition from the FDA that the process needs improvement. The employees from the FDA are conscientious, talented people who want the best for patients. On behalf of the working group, I’d like to thank Jeff Shuren, CDRH director, and his team for their vision on this topic, and Mary Logan, CEO of AAMI, for spearheading the effort.

How would you describe the approval process with the FDA? What’s working well? What needs improvement?

The FDA’s recent initiative on Early Feasibility Studies (EFS) is an example of what is working. Not that long ago, a great deal of frustration surrounded the ability of medical technology companies to get products to the market and the regulatory impact on innovation. Although the United States is the world’s leader in medical technology innovation, the initial clinical testing of novel, next-generation devices moved to other continents due to uncertainty in the U.S. regulatory environment. This ultimately resulted in a delay in access of these devices for physicians and patients. Edwards has had a positive experience with EFS, gaining approval for several studies and providing an opportunity for collaboration with the FDA. It has resulted in a lot of interaction in a more affirmative context among the parties involved. We talk as engineers and scientists rather than in a more inhibitive environment as regulators and sponsors. As far as premarket approval submissions to the CDRH Office of Device Evaluation (ODE), my regulatory colleagues are pleased with the increased level of collaboration and responsiveness, particularly with lead reviewers at ODE during the last few years. There still is an opportunity for consistency across ODE.

It has been widely publicized that although transcatheter heart valve therapies were invented in the United States, we were the 42nd country to make the technology available to patients. To its credit, the FDA introduced multiple initiatives, in part to address this discrepancy. Edwards’ CEO Mike Mussallem testified before the U.S. House Committee on Energy and Commerce, Subcommittee on Health Hearing on “21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communication” on July 22, 2014, addressing this balance and offering possible solutions. I encourage your readers to read this testimony.

I understand that your work at Edwards has a very personal connection in that your 16-year-old son has one of the company’s valves. Can you tell us what that experience was like, to have to consider the value and safety of a medical device from the perspective of a family member?

When considering options prior to surgery, patients are sometimes told to ask their surgeons, “Would you recommend this surgery if I was a member of your family?” The intent is to erase any doubt that the procedure under discussion is the best course. Analogous to that, our valve is sustaining his life, and there is no other valve in the world that I have more trust and confidence in. I think about that every day.

Did going through that experience with your son change how you do your job? If so, how?

It has impacted every part of my life. I think I can speak for most parents out there when I say that there is no greater stress in life than having a child with a significant illness. There is a common feeling of helplessness among families with this experience—that we don’t have any control over things. Having a purpose in life and being able to work for a company like Edwards, whose mission is to help patients, helps.

I’ve also been fortunate to join the board of the local chapter of the Children’s Heart Foundation (CHF), a nonprofit made up primarily of children’s families and their friends, whose goal is to raise awareness and
money to fund congenital heart disease research. We also hope to raise awareness of the profound need for such research.

Nearly twice as many children die from congenital heart defects each year in the United States as from all forms of childhood cancer combined, yet pediatric cancer research receives nearly five times the funding. As a result, young lives are lost or significantly compromised. It is our profound hope that we can help make a difference for the children and their families affected by congenital heart disease. The Edwards Lifesciences Foundation has donated to CHF for the past several years, which is incredibly meaningful to me.

Before he got his Edwards valve, my son would call me at work from the bus stop, short of breath, having difficulty walking the three blocks home. I cannot tell you how heart breaking that was. Whenever I feel bad for myself, I remember that he has never complained once about his condition. When we go to the children’s hospital for checkups, we look around the waiting room at all the families, and he tells me how lucky he is. It is the combination of working at a company like Edwards and being involved with CHF that has helped me keep my sanity through some pretty rough times.

I also understand that your son participated in Patient Day at Edwards. What is Patient Day and why is it important to the company?

He did, and it was a special day for us to spend together, both as part of the community of heart valve patients and their families and for me as an Edwards employee. During the last several years, Edwards has hosted heart valve patients at its headquarters in Irvine, CA, to learn more about heart valve disease, see and learn how heart valves are made, and have an opportunity to connect with each other and organizations that support patients with heart disease. At Patient Day, approximately 50 patients and their family members or caregivers have the chance to spend the day connecting with others and exploring opportunities to become engaged with other cause-oriented organizations that relate closely to our corporate mission, such as the American Heart Association, Mended Hearts, and WomenHeart. Oftentimes, patients get to meet the employees who actually made their valve. It is rewarding and very emotional for the patients, as they have an opportunity to meet others who have had similar journeys and learn more about how their heart valves were developed and made. It also is a rewarding day for our employees, as they have the chance to meet patients who have benefited from our heart valve technologies.

What are you most proud of about your work at Edwards?

With the help of my boss, John McGrath, I have been a part of incorporating the clinical aspect into decision making at Edwards. We have an incredible roster of experienced surgeons, cardiologists, and intensivists who provide amazing guidance into our product development. In addition, we have many brilliant people working on issues that have brought and will continue to bring tremendous benefit to patients and their families. It
is amazing to see engineers with no previous medical background tackle complex anatomical and physiologic challenges. Many of them surpass my knowledge of these things! The background that internal clinicians at Edwards possess, and can’t be duplicated, is that we have been at the bedside with patients and their families, making decisions on a daily basis that impact their lives. Edwards was founded as a result of a collaboration between an engineer and a physician, which gave us the Starr-Edwards valve. We knew from the start that it takes a team.

What’s the most exciting development in healthcare technology that you see on the horizon?

A few things come to mind. In pharma, advances in immunotherapy and other targeted therapy for advanced cancers like melanoma, which used to be a death sentence not long ago, is incredibly exciting. As for medical technology, the momentum generated in treating aortic valve disease by transcatheter technologies seems to be carrying over into finding similar therapies for heart failure, mitral, and tricuspid disease. There are a lot of smart people working on these solutions and making amazing progress in very little time. When you attend any cardiac-related scientific meeting today, the number of devices being studied in these areas seems to grow exponentially every year.

I am a big believer in technology, and healthcare in general has lagged behind other fields in utilizing technology to create efficiencies and bring down costs. I am optimistic about this changing. I also hope that there is an increased focus on developing solutions for congenital heart disease, as most devices used today on kids are designed for adults. Edwards is working on products that have great potential to impact these vulnerable patients, and I hope other companies are doing so as well.