Perspectives on Looking Back and What's Ahead (Part I)

Elfie Schwarzinger

This year has presented a variety of important headlines affecting everyone throughout the medical device industry, whether centered around emerging technologies, challenges in finance, or legal affairs. Further, it is exciting to wonder what the coming new year will bring. In this month's Perspectives feature, participants from a variety of sectors in the industry share their thoughts on what was most significant in 2008 and what's ahead for 2009.

What was the most significant headline in the medical device manufacturing industry in 2008 and what is likely to make a huge impact in 2009?

President, MEGA Electronics Inc.

Nothing will impact the medical device manufacturing industry in 2009 more than the subprime mortgage meltdown and resulting credit crunch. The ability to finance the long term design, testing, trials, and FDA approval of medical equipment will be severely hampered by the tightening of credit. In 20 years of supplying the industry with the hospital grade power cords to power their equipment, I have seen the bulk of growth in the medical devices coming from the small innovators that have managed to survive start up and either license their new technology or sell it to larger established device corporations. With increases in the cost of financing, there will be a serious challenge to raise the capital needed to fund the start-up segment of the industry and a need to shorten the cycle to profitability. In addition, the credit crunch will limit the pool of money available for acquisition of these start-ups. The impact will be felt further through the chain as a higher and higher percentage of manufacturers have been using contract manufacturing, which relies heavily on financing to purchase components and complete their builds.

Completing the design and getting a revolutionary product to the market that can change the face of healthcare may not be enough. The challenge at this point will be to recoup the costs and make new devices affordable to doctors and hospitals,

which rely heavily on credit to make their purchases possible. Nothing will impact the industry in 2009 more than having a sufficient pool of credit throughout the global economy.

Robert Hoctor
Vice President of Medical Devices, Johnson Electric

In 2008, there were a number of technological advances that enabled medical devices to become smaller, more precise, less invasive, and more portable. The trend of clinical treatment and select monitoring applications moving from the hospital to the clinic setting and now even into homes has driven the need for this innovation among device manufacturers. One reason for this is that now more seniors are opting for home care rather than hospitalization. Some surgical procedures that were classified as major operations and required months for recovery have now been replaced by less invasive precision methods from which recovery is possible in just days.

The medical device market is changing the way medicine is practiced, and this revolution will continue through 2009. In the coming year, I expect to see further developments in cardiovascular surgery and neurosurgery as applications continue to be enhanced with image-guided devices. Medical device companies are also developing more robotic clinical assist devices to combine functions and supplement the lack of nurses and doctors available to support medical requirements of the aging population.

I believe that 2009 will also yield greater convergence between pharmaceutical and medical device companies, as well as further integration of nanotechnology, electronic, mechanical, and chemical functions with other developments, such as neural stimulators, blood chemistry sensors, and devices.

The new year will also produce new developments in the growing trend of applying motion in medical devices. More efficient motors utilizing advanced magnets coupled with advanced gear technology will continue to help miniaturize devices, and the ability to use non-magnetic piezo-ceramic material to produce motion for medical devices operating inside an MRI environment will also bring new innovations. Although automated systems cannot totally replace traditional manual functions, the growth of motion systems in medical devices will certainly continue.

Stacy Taylor
Partner, DLA Piper LLP

In 2008, the United States Supreme Court ruled in Riegel v. Medtronic that certain tort claims against medical device manufacturers are pre-empted under the federal Medical Device Amendments Act of 1976 (21 U.S.C. §360(k)a). The Riegel decision has been inaccurately reported as shielding medical device manufacturers from product liability claims.

In reality, Riegel's immunity is limited to Class III medical devices (those which support or sustain life or whose use poses significant health risks) that have undergone the full rigors of pre-market approval (PMA) before the FDA. PMA is only obtained for a small percentage of medical devices versus the relatively streamlined 510k procedure. As such, the impact of the Riegel decision on U.S. product liability litigation involving medical devices is relatively limited.

In 2009, the sinkhole widening under the global credit market offers few positives, but medical device investment may be one of them. Device investment growth significantly outpaced other healthcare sectors in the U.S. from 2006 to 2007. To the extent capital provider interest was driven by increasing access of small device companies to public markets, that trend may slow in the short term as those markets struggle to recover. Yet compared to biotech and pharma, devices can be commercialized relatively quickly. Therefore, companies who can leverage strong IP rights in potentially large markets should continue to attract investor support.

The weakening economy will also impact emerging device markets. The Chinese device industry has been enjoying one of the highest investment rates in the country. But a majority of its device partners are in regions whose economies have been hit hard—the U.S. and Europe. Additionally, the country is soon expected to adopt more rigorous certification procedures. Increased domestic production costs combined with slowing activity from the West could put the brakes on the industry's growth in China.

Chris Turner
Director of Technology, Nexergy Inc.

Headlines such as "Start-up Looks to Improve Battery Life" or "Company Introduces New Battery Technology" and variations thereof were repeated often in 2008. While such stories appear rather generic on the surface, they will have a profound effect on the medical industry.

Some time ago, portable medical devices began the transition from the older battery chemistries, such as lead acid, nickel cadmium, and nickel metal hydride, to newer lithium ion based batteries. Concerns over reliability and safety, as well as the effect of medical specific practices, such as sterilization, had initially delayed many companies from making this switch. Those concerns have been allayed. As a result, many companies have started to design lithium ion into new devices.

However, one ongoing challenge remains. Conventional lithium ion was developed and tailored to meet the requirements of the consumer electronics industry, which places the highest priority on runtime and increasing energy density and often trades off on other design parameters. This has left the medical industry to implement a technology with a rather narrow scope in terms of performance.

Despite that, the headlines mentioned above give an indication of the renaissance in battery technology development—one that is ongoing and that will significantly diversify the options available to the medical industry. While still primarily driven by other industries, such as the power tools or electric vehicles, there are now variations in battery technology that have addressed some of the shortcomings of conventional lithium ion. These include significant improvements in discharge rate capability, longer cycle and calendar life, safety, and energy density.

Outside of lithium ion, there has been significant development particularly in zinc-based rechargeable batteries, such as silver zinc, nickel zinc, and rechargeable zinc air, which offer improvements in energy density, power, and, very importantly, safety because of their non-flammable water-based electrolytes.

All of this development will lead to an interesting 2009, as medical device companies try to characterize and understand the impact of battery advancements and to capture competitive advantages as early adopters of these new technologies.

Jeff Randall

PEVice President of Engineering, MRPC

The most significant industry influencer in 2008 was the economy. Rising oil prices, contraction in the automotive industry, and the tightening of credit resulted in the closing of several businesses and reallocation of resources for others. As automotive, traditional industrial, or other non-medical companies scrambled to find viable markets, many decided to "jump in" and market themselves as medical device or component suppliers. While some may bring value to this market, many underestimate the demands of the medical device industry.

The lack of experience may add undue risk with very little potential reward for medical device companies. Reliability, quality, efficiency, continuous improvement, speed-to-market, and the ability to optimize product design through the development phase of the program are the characteristics of a valued supplier. Companies that can demonstrate an open, collaborative, creative approach to providing high-performance, cost-effective components will be more likely to grow even in this unfavorable economy.

As for what's ahead, multi-material components will gain attention. In order to thrive in 2009, device manufacturers must introduce innovative, yet cost competitive new products to the market. Designers can often improve product performance by combining two or more materials into one component.

Combining two or more materials into one manufacturing process improves product quality and reliability (bond) while reducing waste. Fewer assembly operations translate into less handling of sub-components, fewer opportunities for contamination, and ultimately, reduced cost. The introduction of new products to the market will inspire new design approaches and reinforce the importance of working with a development partner, rather than just a vendor.