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

Yeoh Keat Chuan

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?

Executive Director, Biomedical Sciences, Singapore Economic Development Board

FDA's recent announcement to establish overseas satellite offices in Asia to monitor imported devices, drugs, and food into the U.S. may not be surprising to the medical device industry given increasing concerns about the quality of healthcare products made in Asia. However, its impact is significant, as this sends a strong message about the need for products manufactured overseas to meet rigorous quality standards.

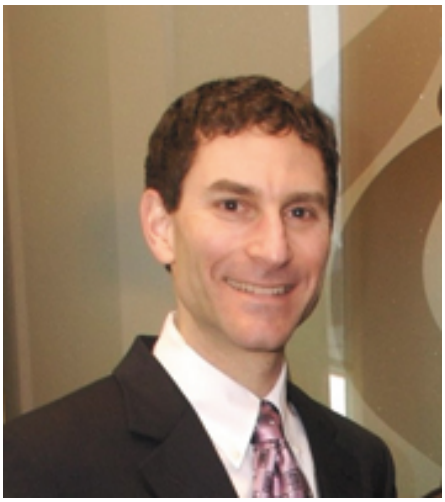
For companies who seek to ensure high quality operations when outsourcing manufacturing activities in Asia, Singapore presents an attractive location. It has established a strong track record as a reliable and trustworthy site for high quality manufacturing in Asia. Today, 17 of the world's leading medical technology companies have set up manufacturing facilities in Singapore to manufacture products for regional and global markets. They include Affymetrix, Becton Dickinson, Ciba Vision, Edwards Lifesciences, Siemens Medical, and West Pharmaceuticals.

Moving forward, the transformation of Asian regional players into global leaders is set to impact the industry in 2009 and beyond. For example, Mindray Medical's

acquisition of DataScope's patient monitoring business in March 2008 has positioned the company as the world's number three in global patient monitoring device after General Electric and Siemens. Indeed, Mindray's acquisition is strategic, as it offers a potential win-win situation in terms of costs and revenue by combining low-cost manufacturing in China with established distribution channels in the U.S. and Europe. We can expect to see more of such acquisitions taking place in 2009, as more Asian medical device manufacturing companies aspire to become global players and take advantage of the debt crisis in the U.S.

In response to the increased competition, it is imperative that companies constantly innovate. One way to do so is by cost-down engineering, where skilled manpower and advanced automation are combined to re-engineer processes. Another way would be tap on the burgeoning Asian market by developing Asian-specific solutions. Singapore hopes to play a part in the industry's changing landscape by offering Asia's best intellectual property (IP) protection, access to global talent, deep R&D capabilities, and a wide network of financing options to help companies innovate, design, and engineer medical technology solutions for Asia and the world.

David Rubin
Director, Vertical Market Strategy, Medical Devices, PTC



In 2008, device manufacturers throughout the world took a big step towards consolidating their IT footprints by enacting initiatives to unite heretofore disparate systems. For example, quality management systems that manage complaints, non-conformances, and CAPAs are being integrated with PLM systems that manage the product development process, including change and document control. Device manufacturers are now able to drive their manufacturing process planning (Design Transfer) and technical publications processes from the same product information contained within their PLM system. Additionally, device manufacturers are beginning to centralize and mainstream their clinical study data instead of keeping it in an isolated system.

Companies stand to enjoy significant paybacks from a reduced IT footprint, but perhaps the most attractive aspect is the improved product quality and subsequent reduced risk, and that will result from a single integrated system responsible for product development, quality systems, and clinical trial management.

Kevin Quinley, CPCU

Vice President, Advisory Board at Council on Litigation Management

Consumer, trial bar, and legislative outrage over the Supreme Court's decision in Riegel v. Medtronic has fuelled a campaign to "neuter" preemption for medical device companies. 2009 may bring fresh opportunities for anti-preemption proponents. Three 2009 developments may give Federal preemption an abbreviated shelf-life.

First, outraged lawmakers are pushing laws to overturn Riegel. In late June, Reps. Frank Pallone and Henry Waxman introduced The Medical Device Safety Act of 2008 - HR 6381. In late July, Senators Leahy and Kennedy introduced similar legislation. Given the results of November's elections, many predict that Democrats will push legislation to "neuter" preemption and re-open consumer access to courts for damages against device companies.

Second, Sen. Barack Obama's victory may give anti-preemption proposals some legs. Further, an Obama administration may produce an FDA with a much more circumscribed view of Federal preemption.

Finally, the Supreme Court heard arguments on November 3rd in Wyeth v. Levine, a case that could limit liability claims against drug makers. The key legal question is whether the FDA-approved label pre-empts state product safety laws, as Wyeth and other drug companies argue. They say state juries looking at one patient's experience don't have the expertise to decide if a drug has proper warnings. The Court's opinion may not arrive until June. Even if the Court supports Wyeth, pundits speculate that a Democrat in the White House and a Democratic Congress could erase any preemption protection companies have won in the last eight years.

Gabe Gurman
VP of R&D, Sparta Systems

Over the course of 2008, we saw the medtech industry continue on with further innovations, greater consolidation, and slimmer margins. In the upcoming year, medical device manufacturers will continue to strive to minimize the complexity of regulated business processes while reducing the costs associated with production, design, and customer service.

We also expect to see greater FDA scrutiny to guarantee consumer safety. Tough economic times, coupled with a greater scrutiny on quality will push medical device manufacturers to further innovate and streamline critical business processes in 2009. With greater FDA oversight, including the forthcoming electronic medical device reporting (eMDR) mandate, and a sharper focus on economic issues resulting in tighter margins, enterprise-wide quality management and compliance will have significant importance on the medtech industry in 2009.

Combining tighter systems integration, consolidated practices, streamlined business processes, and far-reaching global initiatives, Sparta Systems predicts that medical device companies will need a centralized and holistic view of their compliance and quality activities across the global organization. Without this centralized, enterprise-wide view of activities, organizations will be unable to streamline processes, drive organizational efficiencies and ensure competitive success with greater regulatory pressures in a tougher economic climate.

Robert R. Andrews
Medical Division Manager, Foster-Miller

One of the most significant events in 2008 that had and will continue to have sweeping effects on the medical industry was the reintroduction of legislation by federal and state officials for regulations limiting the amount of compensation physicians can receive from commercial medical corporations. In addition to federal and state regulations, in 2008, the American Medical Association (AMA) updated its guidelines setting strict gift limits for physicians. Prior to the introduction of these regulations, physicians were paid for their input on new products and ideas, which helped device manufacturers create solutions to meet industry needs. These new compensation guidelines will impede doctor-company collaboration because without appropriate monetary compensation, there will be less incentive for practitioners to engage in non-obligatory—but very necessary—consultation. As a result, it will be more difficult to bring truly revolutionary medical products to market.

In 2009, the economy will be the major issue across all industries and the medical device industry will be no exception. The result is that medical innovation is likely to suffer due to the risk-averse climate, which will deter investment in long-term programs. Publicly traded American medical companies that answer to investors and anxious boards will be less likely to take chances, such as funding the development of potentially innovative products, and will instead focus on maintaining a steady profit margin. These firms will focus on creating lower-risk products with a high probability of market success rather than taking risks to bringing innovative ideas to market.

While the effects of the downturn could be felt across the entire medical industry, start-up companies will take the hardest hit. The scarcity of available capital will intensify competition for funding. In addition, venture capitalists and large corporations seeking new investment projects will favor low-risk options. As inherently risky, start-up companies will have a difficult time finding funding. To secure investment, start-ups will either have to table more radical ideas for safer projects or take steps to minimize potential risks.

Contracting out R&D efforts is a common risk-mitigation strategy, and it is likely that outsourcing will increase in 2009. Partnering with a reputable engineering firm can assure potential investors of the stability of a product design and development project and eliminate the financial burden of a full-time staff.

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