# Perspectives on 2010 Year in Review

**What was the most significant headline in the medical device manufacturing industry in 2010?**

**Jay Tourigny**
**VP of Operations, MicroCare Medical**

At MicroCare Medical, we have seen recent trends in the medical device industry that point to increased device manufacturer expectations on supplier and sub-tier supplier quality. This has always been a carefully controlled process, but recent trends we've seen indicate heightened scrutiny on supplier controls to ensure end-user (patient) safety, including verification that appropriate measures are taken in the manufacture of all components, materials, and processes used in the manufacture of finished medical devices. This is also seen through a strong movement to eliminate quality related issues and product variables coming into assembly plants—addressed most visibly through heightened vigilance on supplier manufacturing issues including the elimination of foreign matter, improved documentation, improved labeling, handling, waste reduction, and robust process controls. While device manufacturers use traditional controls, such as receiving inspection to verify and track quality, there are increased expectations placed on controls within the supplier’s operations to address issues before they arrive at assembly plants. MicroCare Medical has seen this trend manifest through significant increases in engineering requests for assistance in improving existing cleaning and lubrication processes.

This trend creates significant opportunities for suppliers who are consistently evaluating opportunities and putting proper resources and attention in place to drive improvement. Vendors who have the expertise and quality systems that meet those expectations will see significant growth opportunities.

**Ojas Sampat**
**Practice Head—Medical Devices, Equipment and Supplies, Infosys**

There were several topics that made news in the medical device manufacturing industry in 2010. Topics ranged from device miniaturization to device recalls to emerging markets to home/self care medicine to outsourcing of manufacturing, engineering, and quality compliance activities to reduce cost and improve efficiency.

From our vantage point, the area where we have seen significant momentum in 2010 has been in the area of home/self care and preventative medicine where medical device manufacturers are working to make devices smarter and easier to use for the demographic segments that they cater to. As an example, manufacturers are creating next generation devices on consumer oriented platforms, such as Android, that make devices smaller, faster, smarter, and cheaper. These devices are allowing patients to be more mobile and allowing them to be in control of their medical data through seamless integration with Public Health Record platforms such as Google Health and Microsoft Health Vault.

We believe that these advances in technology and integration with the right web based platforms have started ushering in a new paradigm in healthcare where the patient is in significantly more control over the care they receive and how their medical data is managed.

Looking ahead, we believe that emerging markets will play a significant role in the future of medical device manufacturers, both in the short term (in 2011) and also in the mid-to-long term. With the economies of countries such as India and China growing at nearly double digit rates, an ever expanding middle class in these economies and the high prevalence of chronic diseases (e.g., cardiovascular disease in India) make these countries as large market bases for medical device manufacturers.

Medical device manufacturers have traditionally viewed emerging markets as “sourcing centers” for low cost manufacturing. However, over the last few years, companies have been looking at these geographies as their “innovation hubs” for high-end design and engineering for their next generation devices. The next phase for these companies will be to address these markets as “demand generators” for their products.

Successful front runners have taken a long and sometimes arduous journey to be successful in these unstructured economies. There are significant challenges and “institutional voids” that need to addressed and medical device companies will have to internalize proven emerging market strategies, such as seeding a local leadership structure, relinquishing control, and most importantly, creating “localized” versions of their products that cater to the unique (but high quality) demands of these countries.

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**Mark Schwartz, CEO**
**Product Development Technologies, Inc. (PDT)**

One of the hottest topics has to be healthcare reform and how it will affect the entire healthcare system - from providers and insurers to patients and device manufacturers. No matter what the personal opinions on the issue, one positive influence is the innovation in TeleHealth. The need to effectively manage care for a growing aging population and people’s desire to keep healthcare costs down is coming together with advancements in smart phones, connectivity and apps. It’s converging into the perfect storm for TeleHealth innovation.

The TeleHealth movement is shifting some of the responsibility for managing our own health much the way gas stations forced us to shift the management of our cars years ago.  We used to pull into a gas station and have someone pump our gas and check our oil.  Not anymore. The responsibility is now put on the driver or monitored by the car, as in the case of oil sensors. TeleHealth devices and systems will better enable people to monitor their own health and wellness and alert us when we really do need to seek professional medical help.

Going forward in 2011 and beyond, it will be important for government spending to not only address our physical infrastructure , but also the information super highway that will become ever more important in supporting healthcare databases and tools that will enable devices to monitor, predict and heal.

**Gabriel O. Adusei, MSc, PhD**
**Consultant, Founder—International Association of Medical Technology Consultants**

One of most significant headlines is the FDA's proposed 510(k) changes which has got the industry twittering more and it is likely to make a huge impact in the coming year. On a yearly basis, the FDA sees thousands of submissions through the 510(k) process alone in addition to devices submitted through other routes, such as the Premarket Approvals (PMA) and Investigational Device Exemptions (IDE) routes.

Among the 70 or so proposed changes outlined by the FDA, one of the most significant is the creation of a "class IIb" device category to increase the predictability of 510(k) data requirements and this would help harmonize the classification of devices with that of Europe; that would be of higher risk, enough to require more detailed clinical or manufacturing information, but with not so high risk that they warrant a full-blown and costly premarket application.

FDA's Center for Devices and Radiological Health reckons it would help its review staff to obtain, in a more efficient and predictable manner, the type and level of evidence they need to make reliable, well-supported decisions."  FDA report also recommends manufacturers include all the background scientific information on a product regarding its safety and effectiveness.

These proposed changes in the FDA 510k programme is somewhat seen as similar to objectives of the Amending MDD 2007/47/EEC which has also raised the bar in relation to the safe and effective devices on the markets.

**Alex Brisbourne**
**President and COO, KORE Telematics**

The most significant news in 2010 was the government's intent to increase the budget for telehealth in the coming year. This year, the government, enterprises and healthcare workers are beginning to recognize the potential for mobility and telehealth to improve patient outcomes and control costs.  This paradigm shift in beliefs about telehealth results in regulators, managed care organizations and the likeinstituting policies that support telemonitoring capabilities to simplify the overburdened healthcare system, increase patient responsibility and provide real-time monitoring for rural patients that live far from healthcare facilities.

Telehealth applications are being driven by the availability of low-cost devices incorporating discrete sensors and the reality of inexpensive, ubiquitous and reliable 3G cellular network access.  These two factors will continue to make a significant impact on the industry as a whole in 2011. In the long term, the Obama administration has committed $10 billion per year for the next five years to transition to a standards-based electronic information system, including a specific line item for telemedicine infrastructure expansion. The rapidly-expanding area of telehealth is influenced by all of these factors and new markets and technology developments will truly improve the healthcare industry and change the face of patient care.

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