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White Paper:

Five Trends Transforming the Medical Device Industry in 2014

Introduction

Because the term "medical device" covers a vast range of equipment, from simple tongue depressors to the most sophisticated life-supporting products, the medical device industry is constantly evolving. Trends such as an aging world population, emerging markets, increased regulation, healthcare provider consolidation, and consumerization are radically transforming the industry as we know it. Device companies poised to take advantage of these trends are destined to become market leaders. Companies that are hindered in any way, perhaps by antiquated operational processes or technology, will find it difficult to adapt to the transformative nature of today's global medical device market. This white paper will highlight some of the current trends shaping this extraordinarily diverse industry and discuss the various technologies available to help medical device manufactures successfully navigate these trends.

Trend #1: Aging Global Population

People are living longer. Moreover, senior citizens are remaining healthy well into their golden years, thanks in part to the innovations being made in the medical device industry. According to the U.S. Department of Health and Human Services, the "60 years or over" population segment in developed countries is expected to increase from 23 percent to 32 percent by 2050. In fact, the senior segment has already surpassed its youngest cohort, "15 years and younger."[1]

As the aging developed world population continues to grow, so does the demand for medical devices, particularly diagnostic equipment and other devices that focus on disease prevention. While this is certainly good news for the medical device industry, there are some caveats. Because a large part of medical device spending will come from government-subsidized healthcare, profit margins will be lower. To succeed in this higher-volume, lower-margin environment, device companies must streamline their internal processes, including their quality management processes, to continue to reduce costs and increase efficiency.

Trend #2: Growth of Emerging Markets

To counteract lower profit margins at home, U.S. medical device manufacturers are expected to continue to pursue a greater share of their sales revenue from emerging markets. China, India, and Brazil are providing the medical device industry with substantial revenue opportunities. In less than 40 years, the combined economies of these three countries could eclipse the G6 countries (the U.S., Canada, the United Kingdom, Germany, France, and Japan), which means these markets could drive the medical device industry for the next 50 years.[2] Since China is considered to be the most promising emerging economy, its medical device market is examined in greater detail below.

China's Fast-Growing Medical Device Sector

China's plan to extend healthcare to every Chinese citizen by 2020 is expected to create huge opportunities for foreign medical device companies; spending is projected to grow from $357 billion in 2011 to $1 trillion in 2020.[3]

While competition is beginning to trickle in from local medical device manufactures, at present, consumer confidence in China lies with Western brands, for which they are willing to pay top dollar. Consider this: the developed industrialized markets of the United States, European Union, and Japan comprise nearly 75% of all medical devices sales revenue.[4] Although this is music to Western device manufacturers' ears, long-term success is by no means guaranteed. Late entrants, in particular, are expected to struggle.

To successfully tap into the burgeoning medical device market in China, as well as in other developing countries, Western device manufacturers must be willing to rethink their current business models and distribution strategies, which may contradict local business and distribution procedures and be barriers to entry. The biggest stumbling block for many device companies will be their lack of local regulatory knowledge. Learning how to navigate the varying rules and regulations in these emerging countries is a challenging process, but one that is critical to establishing local operations and attracting government tenders.

Changes to China's Medical Device Law Call for Increased Penalties

The FDA's counterpart in China is the China Food and Drug Administration (CFDA), formerly known as the State Food and Drug Administration (SFDA). Headquartered in Shanghai, the CFDA regulates all medical devices and drugs in China; all imported devices must be registered with this agency. While many industry observers have characterized the agency as being unnecessarily complicated and intentionally ambiguous, the modernization of its decade-old medical device law suggests that Chinese regulators are making strides to facilitate the approval process, while simultaneously cracking down on overpricing and corporate malpractice.

The new regulations, which will come into effect in June 2014, categorize medical devices into three segments, depending upon risk, with higher risk products being subjected to greater scrutiny. Additional measures for monitoring the quality of medical device production, as well as best practices for risk and quality event monitoring, are also addressed.[5]

The new rules increase the range of possible punishments, and the level of fines for the most serious violations, according to a Q&A published by the State Council, the chief administrative authority of the People's Republic of China. For example, the fine for illegally manufacturing or selling medical device equipment has been raised to 20 times the value of the goods. This is a substantial increase from the five times the value cap established in 2000.

Despite the recently improved regulatory framework, many device manufactures continue worry that the approval process will still take too long. Others charge that more emphasis must be placed on the need for companies to establish and implement quality systems. Even Lin Xianyong, former director of the SFDA's medical device safety supervision department, acknowledged China's "lack of a strong sense of quality management" during his candid discussion of the systems flaws at the 2012 MEDTECH China exhibition and conference.[6]

Whether the new laws will remedy this flaw remains to be seen; however, one thing is clear: the need for technologies that will help device companies implement and maintain good quality management processes will continue to grow. In order to maintain a competitive edge, Western brands must take care to avoid product recalls and regulatory sanctions, which will negatively impact brand equity and consumer confidence. By automating quality processes, such as document control and supplier management, manufacturers will be able to better maintain product safety and accelerate compliance.

Trend #3: Increased Regulation

Regulatory oversight of the medical device industry is at an all-time high—and not just in China. Consumers, as well as industry stakeholders, are demanding better, safer products, and regulators are being compelled to act on their demands. In a recent study conducted by the global medical device consulting firm Emergo Group, respondents, composed primarily of QA/RA professionals and senior managers, cited the "changing regulatory environment" as their greatest challenge in 2014. When asked if they felt the process of obtaining regulatory approval in emerging markets has become easier or more difficult than it was in 2013, respondents in all regions indicated that registration has become more difficult. Results showed China to be the most challenging region, with 41% of the firms indicating that device registration has become more difficult now than it was last year. Thirty-five percent of respondents rated the U.S. market more difficult. Note: These findings are based on 2,527 responses.[7]

There are many regulations impacting the medical device market, but the following are the biggest:

- **Affordable Care Act**
  The Patient Protection and Affordable Care Act (ACA) of 2010, which included a $20 billion dollar tax on the medical device industry, signaled a shift in the U.S. government's focus from the "more is better" philosophy of healthcare toward one that emphasizes a higher quality of care.

  Designed by Congress to help pay for part of its expansion of healthcare to uninsured Americans, the ACA imposes a 2.3 % excise tax on the sale of any taxable medical device by the manufacturer or importer of the device. The new tax

does not apply to sales of eyeglasses, contact lenses, hearing aids, or other devices typically purchased by the general public at retail for individual use.

Opponents of the tax, which became effective on January 1, 2013, argue that it will be devastating to job creation, patient care, and innovation, and make it harder for startups and smaller device firms to secure venture capital (VC) or reach profitability. According to the *MoneyTree Report* by PricewaterhouseCoopers and the National Venture Capital Association, VC funding of medical device startups fell to $2.1 billion in 2013—down 17% from the previous year.[8] Furthermore, a study conducted for the Washington, D.C.-based trade association AdvaMed claims the tax could ultimately cost more than 45,000 jobs.[9]

Proponents of the tax argue that lobbyists continue to distort the tax's impact. They claim that the expansion of health coverage will increase the demand for medical devices and could offset the effect of the tax. What's more, they argue that health reform will promote innovation, not postpone it, by promoting more cost effective ways of delivering care.

Further complicating matters, many device manufacturers are unsure which products are subject to the tax. Two products, in particular, that are prompting a lot of confusion and debate this year are mobile health apps and software. "There are battles being fought right now over mobile health apps and software products," said Clinton Mikel, a partner at The Health Law Partners in Southfield, Michigan "If you have a medical app cleared through the FDA's process as a medical device, are you now subject to the medical excise tax?"[10] The government has not stepped in yet to answer those questions clearly.

The medical device excise tax has been controversial since day one, and it is expected to incite disagreement throughout 2014 as the device industry continues its fight to repeal it.

- **FDA's 510(k) Controversy**
  The FDA's 510(k) submissions process, the most widely used approval path for medical devices, has also come under scrutiny. The 510(k) program rests on the idea that if a low- to moderate-risk medical device has already received FDA clearance, then similar devices that are "substantially equivalent" to the already approved device (called a "predicate") would require little if any clinical testing and scrutiny. Consumer advocacy groups argue that the policy, which was created more than 35 years ago in an era of much simpler devices, is outdated and has failed to keep dangerous and ineffective devices off the market, citing the safety concerns associated with vaginal mesh implants as a prime example.

  In the case of vaginal mesh implants, the FDA continued approving the devices under 510(k) even after the original version of the implant, on which the approval was based, was recalled due to safety complaints. 510(k) opponents argue that the chain of approvals for vaginal mesh devices unveiled a key weakness in the 510(k) approval process: 510(k) approval permits device manufacturers to clear a product by citing its similarity to a predicate. If the first iteration of the device is recalled, the FDA and manufacturers do not necessarily look at later generations of the device to see if the same safety issues that lead to the recall exist in the later versions.

  In response to consumer concerns, in 2010 the FDA proposed more than 60 changes to the 510(k) policy that will require device manufacturers to provide more evidence of product safety. Manufacturers argue that such an extensive list of changes will further complicate a path to market that is already fraught with obstacles, pitfalls, and delays. They also argue that it's unnecessary, citing a study of recall data conducted by Ralph F. Hall, JD, a professor at the University of Minnesota Law School. Hall's study revealed the majority of Class I safety recalls (55%) are due to post-market issues, such as manufacturing failures, and that 99.78% of 510(k) submissions do not result in recall due to premarket issues. A separate study, conducted by Battelle Memorial Institute and commissioned by AdvaMed, demonstrated that of the nearly 47,000 medical devices cleared by the FDA through the 510(k) process since 1998, only 0.16% were involved in a serious recall event. [11]

Achieving and maintaining regulatory approval looms as an especially imposing task for U.S. manufacturers of cardiac devices. From 2006 to 2011, European regulators approved mid-to-high-risk medical devices, including heart devices, an average of four years ahead of the more conservative U.S. FDA, according to a 2013 report by Boston Consulting Group. Moreover, the study showed that the Europe's expedited approval process did not lead to a discernable increase in recalls or safety problems.[12]

One example cited was the replacement for diseased heart valves made by U.S. device maker Edwards Lifesciences. The Sapien transcatheter aortic heart valve is particularly suited for elderly and frail patients because it can be put in place via a catheter threaded through an artery rather than replacing a valve by cracking open the chest for heart surgery. This less invasive insertion dramatically reduces post-op recovery; patients are typically released from the hospital in one or two days rather than one or two weeks, plus they often avoid extensive rehab therapy. Unfortunately Edwards' Sapien valve did not receive FDA approval until 2011, four years after Europe and elsewhere. Moreover, European cardiologists have been using a next-generation version of the device (the smaller Sapien XT), which doctors find easier to maneuver into place and may cause less trauma to the artery, since 2010—a full year before U.S. cardiologists and patients even had access to the original valve. If the manufacturer had not had effective quality processes in place, the approval in the EU and U.S. could have been delayed even further, thus more lives would have been lost.

The delays are also costing devices makers hundreds of millions of dollars in potential sales. For example, if Edwards had been able to sell the original Sapien device at the same time it debuted in Europe, the company would have earned an additional $800 million. Approval lags have forced many device start-ups to close their doors, leaving employees without jobs, and physicians and researchers charge that the delays are hindering innovation, and worse, are denying patients life-critical products.

The medical device industry is expected to struggle with striking a balance between regulation and innovation in 2014 and beyond.

- **UDI Legislation**
  Recent UDI (unique device identification) legislation further illustrates the FDA's focus on product safety. UDI compliance will require medical device manufacturers to establish an identification system for each device; the system is intended to reduce counterfeiting and increase supply chain security and efficiency. The FDA intends to phase in the UDI system over the next seven years, although the regulation will be enforced for Class III devices as early as September 2014. That's a relatively short amount of time to gather the data required for each device and properly submit it into the FDA's new Global Unique Device Identifier Database (GUDID).

  No doubt, implementing UDI will be a major undertaking for medical device manufacturers. With deadlines for many devices less than one year away, a manual approach to UDI compliance seems almost impossible. However, developing and implementing a homegrown automated UDI solution seems equally challenging, not to mention risky. Perhaps this is why many manufacturers are integrating off-the-shelf UDI compliance solutions into their enterprise quality management system (EQMS) to help them manage the complexities of UDI compliance.

Regardless of the regulation in question, one thing is clear: a key strategy to successfully navigating the regulatory landscape boils down to being prepared, organized, and thorough. A good quality management solution, one that enables robust recording keeping, traceability, change control, and document control, will help manufacturers streamline operations, nimbly navigate unexpected regulatory speed bumps, and ultimately expedite time to market.

Trend: #4 Healthcare Consolidation/Mergers & Acquisitions

The staggering number of hospital mergers and acquisitions that has occurred over the last few years transformed the way physicians and hospitals deliver patient care. Independent hospitals are being acquired by large healthcare systems in

record numbers, and the shift toward larger healthcare delivery systems is expected to continue to evolve, particularly if economies of scale can be gained.

Companies use mergers and acquisitions as a strategy, along with product line expansion, to better serve customers with a more complete offering. They may also use acquisitions to get into faster-growing or higher-margin businesses. However, mergers also increase complexity, and thus the likelihood of problems and risk.

With volume growth and competition as the top threats, companies can no longer continue to operate in an environment of disconnected departmental silos, wherein each department acts independently with their own processes and systems for collecting and accessing critical data. Innovation and acquisitions will continue to increase the variability of operations and the amount of information to analyze and manage. To survive this transition, medical device manufacturers will need to invest in commercial software tools that can help lower business risk in core quality process areas, such as document control, design control, root cause analysis, and supplier quality. Investing in robust reporting tools will also allow them to better illustrate the clinical value of their devices by tying their products to measurable health outcomes.

Trend: #5: Consumerization

Although still a relatively new topic, the consumerization of medical devices, also referred to as the medicalization of consumer devices, has gained significant momentum over the past couple of years. It will continue to be a hot topic throughout 2014. The main drivers behind the concept—the emergence of new technologies (e.g., smartphones and social media), increased focus on costs, and elevated customer expectations—are prompting the device manufacturers to increase their commitment to and investment in developing patient-empowering technologies that leverage very specific information.

One example of such a tool is the AliveCor ECG Heart Monitor. When used with AliveCor's free app, AliveECG, it offers individuals with suspected or diagnosed heart conditions the ability to immediately record and store single-channel ECGs. The monitor fits most mobile devices and is easy to use. The patient simply rests the monitor on his/her fingers or chest to record an ECG, which can be printed or emailed directly to caregivers and other health care professionals. Providers can review and track their patients' ECG data on AliveCor's Provider Dashboard, a free web-based application.

While AliveCor's ECG Heart Monitor may be one of first examples of the marriage of consumer product and medical device, experts predict more technologies are to come, particularly in the diabetes space. Since Medicare expects over 70% of patients to have four chronic comorbidities by 2020, the market for consumerized medical devices looks promising in 2014—and beyond.[13]

How MasterControl Can Help the Medical Device Industry

Hundreds of device companies throughout the world use MasterControl's quality and compliance software to comply with FDA 21 CFR parts 820 and 11, the Medical Devices Directive (MDD) 2007/47/EC, ISO 13485 and 14971, and other requirements and standards used in the medical device industry.

An end-to-end solution, MasterControl provides an effective framework for a company's QMS by automating and connecting all system processes (everything from design control to audit), and providing a web-based, centralized repository for all documentation and records. The solution suite can help device manufactures improve operational efficiency, agility, and achieve continuous compliance.

In addition to automation, MasterControl offers medical device companies two key advantages:

- **Mobile Access:** MasterControl allows users to access important compliance-centric documents and information and perform tasks using a tablet or a smartphone. Mobile access offers greater flexibility for users and helps boost overall efficiency and productivity.

- **Cloud-Based Services:** For companies that want to avoid the cost-prohibitive upfront investment typically associated with purchasing an on-premise QMS system, MasterControl offers private cloud-based services. MasterControl's cloud-based QMS offers the same robust system in a secure environment without the need for large IT staff. Companies can deploy faster, a benefit that can improve compliance and deliver a much faster and higher ROI.

MasterControl offers the following modules:

MasterControl Documents: For many manufactures of medical device and diagnostic equipment, the MasterControl Documents module typically serves as the foundation for building a robust enterprise QMS. It allows users to track, search, retrieve, route, review, and approve documents electronically, increasing efficiency while simultaneously reducing the possibility of human error and lost documentation. Because the module has been designed to consolidate document control with other quality system management processes, such as design control, audit management, CAPA, risk management, supplier management, and bill of materials (BOM) management, it provides the enhanced visibility medical device managers need to react and adapt to the latest business and industry trends.

MasterControl Training: Medical device manufacturers use the MasterControl Training module to automate the distribution and monitoring of training tasks. Because enhanced regulatory oversight is expected to continue to increase throughout the medical device industry in the coming years (the UDI regulation being just one example), implementing a robust training module is critical to ensuring that all employees are properly trained on the latest standards and regulations and internal company procedures.

MasterControl CAPA: Medical device manufacturers need to maintain control of their CAPA processes to avoid regulatory penalties. MasterControl CAPA is a closed-loop, easy to use solution that streamlines the management of quality events from root-cause investigation through implementation of preventive action.

MasterControl Audit: Medical device manufacturers use audits to prove their processes and procedures are in compliance with SOPs and regulatory standards, mitigate risks, manage supplier quality, and increase organizational transparency. The MasterControl Audit module is robust enough to handle all of these tasks. It offers robust reporting tools and the capability to connect the audit management process with other critical quality processes.

MasterControl Risk: In the medical device industry, risk management has become an integral part of the design, development, and production processes. Risk management is applicable to all types of medical device equipment, and evidence of its application is required by most regulatory bodies. The MasterControl Risk module provides a single platform for all risk-centric activities and documentation to help drive an organization's compliance goals.

MasterControl Supplier: This "one-stop shopping" solution integrates supplier management with the quality management system and provides a single repository for all supplier quality data and documentation. It allows users to create scorecards for the effective evaluation of suppliers. It also provides robust tools for tracking and trending supplier quality events such as deviations and SCARs.

MasterControl BOM: The bill of materials (BOM) has always been critical to a medical device company's overall success, but never more so than now. As outsourcing and expansion into emerging markets continue to increase the number of suppliers involved in the manufacturing of a particular device, the margin for error also increases. MasterControl BOMs "where-used" feature displays exactly where a part is used across multiple BOMs, permitting users to determine the impact of a single part change and updating subsequent changes where needed.

Conclusion

The medical device industry, which is known for producing life-saving innovations that benefit millions of people worldwide, is facing unprecedented challenges in 2014, but many opportunities as well. To succeed, U.S. device manufacturers must understand and learn to navigate the industry's most pressing trends: an aging global population; the growth of emerging markets, including Brazil, India, and China; increased regulation; healthcare consolidation; and the consumerization of medical devices.

Device companies of all sizes must continue to explore ways to leverage foreign markets to offset domestic regulatory challenges, such as the ACA, and also develop more efficient and effective routes to launch new products and expedite early cash flow. These new products must not only provide successful outcomes, but also be customer-driven, with the ability to change patient behavior through support services and analytics. An automated QMS can help manufactures ensure that they are operating efficiently and compliantly, and give manufacturers the tools they need gain a competitive advantage in 2014.

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MasterControl produces software solutions that enable regulated companies to get their products to market faster, while reducing overall costs and increasing internal efficiency. MasterControl securely manages a company's critical information throughout the entire product lifecycle. Our software is known for being easy to implement, easy to validate, and easy to use. MasterControl solutions include quality management, document management, product lifecycle management, audit management, training management, document control, bill of materials, supplier management, submissions management, and more. Supported by a comprehensive array of services based on industry best practices, MasterControl provides our customers with a complete information management solution across the enterprise. For more information about MasterControl, visit www.mastercontrol.com or call 1.800.825.9117 (U.S.); +44 (0) 1256 325 949 (Europe); or +81 (03) 5422 6665 (Japan).

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