

Medical Devices—Supporting a Patient-Driven Market

CIMdata Commentary

Key takeaways:

- *New life sciences technology, treatment strategies, and therapies are able to address and manage more health care issues than ever*
- *Consumer education has raised awareness of what is possible and they want it customized to suit their needs*
- *Medical device manufacturers around the world are challenged by balancing the increased pressure of the changing regulatory environment and with the needs of consumers and healthcare providers*
- *Dassault Systèmes' solutions can help medical device companies innovate, develop and deliver superior experiences to patients and healthcare providers*

The Pressure On Medical Device Manufacturers is Continually Increasing

Medical device companies are under a lot of pressure from all of their stakeholders including patients, health care providers, shareholders and regulatory agencies around the world. In order to succeed medical device companies must develop products that have a significant impact upon improving patient outcomes, overall product quality and improved patient safety. In addition, manufacturers must be able to contribute towards improving clinical staff efficiency, reducing hospital length of stay, and reducing hospital readmissions. Finally, as shown in Figure 1, they need to provide products that address issues and unmet needs that are cost effective, reliable and safe and deliver clinical and economic value.

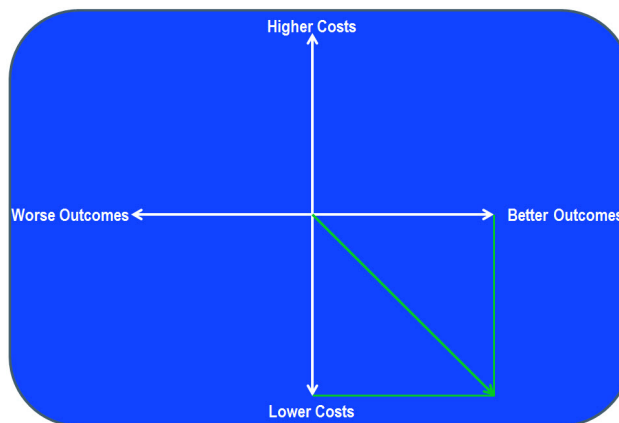


Figure 1—The Goal is to Deliver Better Clinical and Economic Value

Medical device manufacturers around the world are challenged by balancing the increased pressure of the changing regulatory environment with the needs of consumers and healthcare providers. Consumers want to improve their quality of life by leveraging capabilities that can help prevent the onset of disease or illness or that provide effective therapy for their medical issues at the lowest possible cost. Medical device companies must continuously improve internal business processes so they can simultaneously address these pressures and remain profitable.

Once a product is approved to provide an acceptable therapy in a specific market, consumers will get access, and the device manufacturer will see demand for the approved products.

However, the key to sustainable profitability in today's climate is to ensure that the product information is available to subsidiary organizations in other markets and relevant to local regulatory bodies. In this regard, companies that can streamline the regulatory preparation and submission process will create and maintain a market leadership position.

At the business level, shareholders want to see the value of their assets increase. Fortunately, the medical device global market is large, varied and projected to grow about 6% a year for the next five years¹, so opportunity exists. Managing cost to maintain and improve profitability is key to long-term business health, but it is only part of the overall value equation. The other key part of the equation is growth; sales growth is key to increasing shareholder value. A stock value is based, in part, on expectations of future sales. The potential future sales are based on the size of the addressable market, and the company resources and capabilities to exploit that market opportunity. So, in addition to controlling costs and margin, medical device manufacturers need to have a strong innovation product portfolio pipeline and the ability to convert ideas into marketable products that are cost effective and safe. As long as this conversion happens, the value of the company should increase. While conceptually simple, execution is hard. Companies need to invest in the right solutions that support cost reduction, improve efficiency, innovation and time to market. At CIMdata, we see software solutions that simulate and predict product and process performance and manage regulatory related information as key execution tools. In addition, companies that have effective simulation and information management technology will bring their products to market more efficiently, more cost effectively, and more timely and will deliver on the promise to shareholders more effectively.

Leaders in the Medical Device space cannot only focus on cost reductions or product extensions. The most lucrative parts of the Medical Device industry are also the highest risk, and require innovative solutions. Segments like cardiovascular products or complex implants require complex simulations in order to reduce the probability of post clinical trial product redesign, so that when clinical trials are complete the risks to patients are minimized, and the results are effectively used to support device registration and approval. Simulation technologies can shorten the approval timeline in getting products to market sooner and help ensure product safety.

The Healthcare Market has Changed Dramatically

Over the past two decades, the healthcare market has changed dramatically. While costs have increased considerably, the capabilities of healthcare providers and the issues they can address have also gone up dramatically. Diseases and injuries that were debilitating and even fatal are now manageable and even curable.

Consumer demand is driven by their awareness of what is possible. Information sources that help increase awareness include websites and social media services, regular media including print, radio and television, and family and peer connections. As consumers absorb all this information they develop an understanding of what can be done to address their issues, and they communicate with their health care providers to make more informed requests and decisions which ultimately improve their healthcare experience.

Medical Device technology has also improved in recent years. Product planning has become more data driven. The computerization of medical records allows device manufactures to identify opportunities for new products. Product performance data enables continuous

¹ <http://www.prnewswire.com/news-releases/global-medical-device-industry-2012-2017-trend-profit-and-forecast-analysis-162557666.html>

improvement opportunities to be identified and improvements assessed. Finally, one of the most recent trends is cost-effective mass customization. Advances in diagnostic, communication, and manufacturing technology have enabled the production of medical devices custom engineered for an individual patient.

In addition, the most advanced medical device developments come from companies that focus on leveraging R&D to develop effective patient experiences that improve outcomes. These companies understand that features, products and services are rapidly becoming commodities and that a holistic view supporting “experiences” is an important aspect to improving patient outcomes. For example the GE Healthcare Adventure Series™ diagnostic imaging systems were designed to be more child friendly. By reducing the noise from within the imaging machine, children are less anxious and remain calmer, which allows better images to be taken and reduces repeated imaging procedures, radiation exposure and costs. The improved images allow radiologists to make better diagnoses, which lead to better outcomes. Another technological innovation that improves patient experience is using animations of procedure simulations to aid in explaining procedures to reduce anxiety in patients.

What is Dassault Systèmes’ 3DEXPERIENCE?

The 3DEXPERIENCE platform is Dassault Systèmes’ vision of how the next generation of PLM must evolve to support industry trends and requirements. At the highest level it consists of three key concepts: social, industry, and experience.

According to Dassault Systèmes, social is a part of the 3DEXPERIENCE platform because many companies across all industries are recognizing the demographics and computer usage patterns of both consumers and product development organizations. People use Facebook, Twitter, and other social applications in their daily life and companies want to leverage this energy to benefit their businesses. These technologies are increasingly being used to communicate with and educate people who influence decisions, and product development companies also see these tools as a means to gather valuable information to support product and process development.

Industry is core to the 3DEXPERIENCE platform: Dassault Systèmes made a big commitment to reorganize sales, marketing and R&D to ensure that the product experience is driven by industry needs. Typically solution providers focus sales and marketing by industry, but product strategy is still driven by R&D. Dassault Systèmes went much further and industry solutions are built on top of an existing solution portfolio, encapsulating data, processes and other knowledge into an offering targeted to that industry. The industry solution organization has complete responsibility for driving the solution to fit the segment’s needs. The concern with this type of strategy is the potential fragmentation of the underlying solutions, which can add overhead.

The notions of user and customer experience are common in business strategy, and Dassault Systèmes’ goal is to provide solutions so that their customers, who develop products, can provide those user and customer experiences to their customers as early as possible in the product development process. It is a tenet of product development that most of the cost is committed very early in the development lifecycle. If customers can experience the product early in the lifecycle, companies developing those products can build the right products at minimal cost while ensuring the promised customer experience. Dassault Systèmes believes that bringing consumers more into the product development loop is a major difference between them and the other major PLM players in the marketplace.

Life Sciences 3DEXPERIENCE

The focus of 3DEXPERIENCE in the life sciences industry is to provide a 360-degree, view of all the information that defines the patient's experience with the product. According to Dassault Systèmes, the "Licensed to Cure for Medical Device" industry solution experience provides an end-to-end solution for medical device companies that enables innovation while ensuring compliance, design efficiency, patient safety and reduced time to market. The solution is designed to provide all elements of a medical device company's quality system regulatory compliance and ISO-regulated design controls, using a single, global, online system. This includes managing all quality issues such as product complaints, non-conformance reporting (NCRs), audits and CAPAs. The intent of this industry solution experience is to help medical device companies avoid compliance risk, improve productivity and drive innovation in product development that delivers delightful product experiences to patients.

Dassault Systèmes recently announced that Smith & Nephew, a long-term Medical Device customer, has purchased the "Licensed to Cure for Medical Device" industry solution experience². CIMdata looks forward to seeing this solution function at Smith & Nephew as well as other customer sites, which will help us gauge just how much impact it can have on medical device companies.

Conclusion

The global healthcare system is evolving from a healthcare provider driven system that focused on features and functions to one driven by developing products that deliver clinical and economical value to patients and health care providers that demand more personalized experiences. Ensuring that patients receive the right outcome and improvement in their quality of life is the goal for all healthcare companies and providers. Improving the experience for the patient is a significant component in the achievement of that goal, and is the focus of best in class medical device manufacturers.

"Licensed to Cure for Medical Device" from Dassault Systèmes provides an extensive lifecycle solution for medical device companies to develop, produce and support products that provide great experiences for both healthcare providers and patients.

About CIMdata

CIMdata, an independent worldwide firm, provides strategic management consulting to maximize an enterprise's ability to design and deliver innovative products and services through the application of Product Lifecycle Management (PLM). CIMdata provides world-class knowledge, expertise, and best-practice methods on PLM. CIMdata also offers research, subscription services, publications, and education through international conferences. To learn more about CIMdata's services, visit our website at <http://www.CIMdata.com> or contact CIMdata at: 3909 Research Park Drive, Ann Arbor, MI 48108, USA. Tel: +1 734.668.9922. Fax: +1 734.668.1957; or at Oogststraat 20, 6004 CV Weert, The Netherlands. Tel: +31 (0) 495.533.666.

² <http://www.3ds.com/fileadmin/COMPANY/Investors/Earnings/13Q2/13Q2-Earnings-Newswire-conf-call-EN.pdf>