The Challenges of Medical Device Manufacturers, and How Outsourcing Partners Can Help

Naveen Kodandaram

Outsourcing began as a way of addressing some of the peripheral jobs in development, sustenance, and maintenance of product lines, areas where companies felt that both risk and cost were low. For medical device manufacturers, it is now more important than ever to consider the options in outsourcing partners. This article examines the extent to which medical device manufacturers ought to take advantage of the opportunities provided by outsourcing, and the most beneficial ways of doing so.

During the early days of outsourcing, the risk was in delay of product releases, while the extended, outsourced team learned some of the work on the job. The core part of the product development consisting of the company's intellectual property (IP) remained at the main R&D center in-house. As the outsourced teams continued working on the peripheral part, they inevitably started gaining knowledge of the core part of the product. However, this transformation didn't happen overnight, but took a few years and in some domains, more than a decade. The engagement process involved the outsourcing team gaining the trust of the customer engineering organization, and making recommendations and contributions on feature additions to the core of the product through feature implementations. This demonstrated the capability of the outsourced engineering team to take a larger role in the product development life cycle, bringing in knowledge of the requirements of local and global markets. Today, in some domains and product developments, the complete product validation part of the life cycle is being outsourced.

Penetration of New Markets

As medical device manufacturers introduce products into new markets, it's critical that they receive the marketing support of local doctors and scientists, particularly in the case of personal health care devices. For example, in the area of medical diagnostics such as blood glucose measurement, technology has moved from specialist hospital labs to the hands of the patient. Over time, devices like the blood glucose meter, heart rate monitors, pedometers, etc., have become commodity products in developed countries.

Often, however, medical device manufacturers who are not from the same

geography don’t have access to local doctors, scientists, and patient communities. However, outsourcing partners have easy access to these communities and are able to bring them together to influence new buyers, thereby benefiting the manufacturer. Access to these new communities creates a larger pool of influencers and support for the product, providing more marketing mileage.

Region and Race Specific Disease Isolations

In India and other South Asian countries, disease physiologies related to the heart and diabetes are different from those in the US or Europe. Understanding these intricacies requires knowledge related to local culture, food habits, genetic makeup, etc, which can present a challenge to foreign medical device manufacturers. Collaboration with local researchers and the scientific community can produce demographics and profiling related to local communities. This data can help improve the design of equipment and its diagnostics capability in areas including ultrasound, ECG, blood glucose monitors, etc. Outsourcing companies can also help the partner company participate in conducting clinical trials with new technology. If the trial is race or region specific, they can participate together in global staging of trials and market launches (also validating the technology).

Software as a Differentiator in Medical Devices

Software is becoming one of the key differentiators for medical device manufacturers as software is more adaptable and easily customizable. The ease and speed at which software applications can be changed for different use cases, prototyped, and readied is far superior when compared to hardware.

The area of portable ultrasound is one in which software is a key differentiator. Traditionally, ultrasound algorithms, which are used to convert sound waves to visual representation, are implemented in complex hardware for real-time behavior, and are expensive. Ultrasound equipment usually is equipped for aiding in diagnosis of multiple body organs. In a portable ultrasound, where power usage is one key differentiator, with the use of very low power and high speed Digital Signal Processors (DSP’s), the same functionality that was achieved using expensive hardware can now be achieved using software implementation. If the traditional hardware based approach was taken, then products would have to be completely developed and validated before a release could be made. Through the software-based approach, development teams can make feature-by-feature releases through software upgrades, while the rest of the base platform remains unchanged. A flip side to this is the need to go through multiple regulatory approvals, but it allows for faster time to market.

Another example in which software is the key differentiator is the standardization on interoperability of personal health care devices like the Blood Glucose (bG) meter or Blood Pressure (BP) meter driven by the Continua Health Alliance using the IEEE 11073 standard. Adoption of this standard, typically implemented through a software layer over a USB or Bluetooth transport, enables the devices to exchange personal health data and information across medical devices, disease management service providers, and healthcare service providers over wireless or a wired medium. The typical wireless technology adopted by the medical device manufacturers is Bluetooth. This trend is enabling applications that interact with the medical devices to be available on cell phones and smart phones for ease of communication and transfer of data to a hospital server. Once the data is available on a hosted server, it is easily accessible by a healthcare service provider.

In both the above examples of Ultrasound algorithms and the IEEE 11073 standard, medical device and equipment manufacturers can look at tapping the capability of Signal Processing or Protocol Stack implementation through their outsourcing partners. Companies like MindTree are continuously investing and innovating in these areas through IP creation in both Ultrasound and Bluetooth.

New Technology and Trends in Medical Technologies

Continuously, new standards, regulations, and technologies come into the market, making it very difficult for a product company to bet on all of them, as they evolve and mature. However, today there are outsourcing companies investing in developing IP in the areas of short-range communication such as Bluetooth, IEEE 11073, imaging algorithms, 802.11n, etc. Using these new technologies, medical device manufacturing companies are able to reduce time to market and R&D costs. With outsourcing partners providing these evolving technologies, medical device product companies and OEMs are also left to focus on their core technology and areas of strength.

Telemedicine is another area where the medical device manufacturers can expand the scope of usage of their devices from a patient’s home to make medical data available to a doctor or a nurse providing primary health care. Traditionally, a patient would do tests for chronic diseases like diabetes or cardiac care through blood glucose or blood pressure measurement. This data would be shared with a doctor or a nurse over a phone, or in a few advanced cases, a device that would collect the data and transmit to a server over a traditional telephone line. With the availability of Internet and broadband technology in almost all the developed and rapidly developing countries, technology today is available where a patient or a primary health center located in remote or rural regions can have a video conference with the doctors and specialists in the larger hospitals. Advanced

diagnosis can be done for cardio care (through exchange of ECG), orthopedics (through exchange of digital X-ray) etc, connecting the medical devices to the Telemedicine unit along with the user application software.

Regulatory Challenges

Medical devices have very long life cycles; regulations related to the environment and hazardous substances are applicable to medical device product manufacturers. These regulations differ slightly with geographies and sometime have a few nuances. Some of the regulations to be considered are RoHS, (Restriction of Hazardous Substances Directive), REACH (Registration, Evaluation, Authorization and Restriction of Chemicals), Persistent Organic Pollutants (POPS), etc. Medical product companies have to be on top of these regulations and understand the regular changes in the regulations as non-compliance can have larger business impact. To be compliant with these regulations requires understanding their scope, and managing them takes a significant amount of time and resources. Medical product and manufacturing companies need to understand the composition of materials and substances sourced, or screen their supply chain and maintain their compliance records. This activity is not a core area of expertise for medical device manufacturers. Outsourcing the screening of supply chains and record maintenance to organizations that deal with this on a regular basis, across different geographies is a more cost-effective approach.

Regulatory compliance requires medical device manufacturing companies to redesign some of the products in their existing product lines. These again are excellent cases for outsourcing, including re-designing to meet the original product specification and regulatory compliance requirements. At the same time, the final product certification is still owned by the medical device product manufacturer.

Cheaper After Sales Support and Technical Support

Another challenge for medical device manufacturers is access to low cost, on-call 24/7 Technical Support. Outsourcing partner companies working on the engineering side are able use their engineering knowledge to build a Technical Support team, which can address the global market.

Naveen Kodandaram *is Technical Director and Head of the Medical Electronics Industry Group at* MindTree Ltd. *[1] And can be reached at naveen_k@mindtree.com* [2]

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[2] mailto:naveen_k@mindtree.com