

Medical Device Challenges

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A number of innovative new medical products have been recently developed that have a dramatic impact on our quality of life. One example is a nebulizer that utilizes vibrating mesh technology. A nebulizer is a medical product that has been used as a way of transforming respiratory medication from liquid form into vapor form so that it can be breathed in through the lungs. The Vibrating Mesh Technology creates a nebulizer that is highly portable and can actually fit inside the patient's pocket. Those that are suffering from health conditions like asthma and COPD find great comfort in such a device to help them relieve their symptoms and live a more normal life. Another example of advances in medical products involves hip replacement technology. My neighbor Doug recently had hip replacement surgery as an out-patient! He was doing great in a matter of weeks. An even more recent innovative medical product was developed by a company called Accuray. Accuray has a device that can annihilate cancerous cells without surgery. It is particularly helpful in cases of brain, prostate and lung cancer. Another company, Ablation Frontiers (recently acquired by Medtronic), is marketing a device in Europe (attempting to get FDA approval in USA) for people with a heart condition called atrial fibrillation. Those fortunate to benefit from these procedures can now go back to living more normal lives.

Developing these innovative medical devices also includes risks. When there are problems in the field, it can lead to catastrophic problems. One recent example involves infusion pumps used in the medical device industry. These devices can deliver up to three different medications to a patient intravenously. Unfortunately, a number of companies have experienced problems with these devices in the last decade. One of the most infamous cases involves an infusion pump marketed by Baxter. In 2010, the FDA asked Baxter to pull all of their units of a particular model from the market place. The FDA required Baxter to destroy many thousands of units due to the risk of having them in the field. According to a FDA News Release on May 3, 2010, over 500 deaths have been attributed to malfunctions in this device. Several problems were identified. One involved an interaction between the batteries and the controlling software. It seems that if the batteries died the software allowed for a "free flow" of medications to the patient. In August of 2010 Johnson and Johnson issued a global recall of two hip aid systems after more people than expected suffered pain which required additional surgery. According to Johnson and Johnson, 1 in 8 patients who received the ASR total hip replacement needed a second surgery to fix issues.

How can a medical device company enhance their probability of success in the market place and minimize these risks? What can management do to assure products being produced are timely, low-cost, reliable, FDA compliant, customer delighting, and hit their market window? In order to assure business success, medical device companies have some special challenges. Key ones are as follows:

1. Organizational segmentation
2. Massive sourcing from low cost suppliers
3. Organizational dysfunction
4. Understanding of true customer needs
5. Plan for success

Organizational segmentation

In highly segmented organizations communication is good up and down an organizational silo but poor across organizations. Unfortunately, this type of structure is rampant in many medical device companies. The Marketing group communicates poorly with the Product Design group. Product Design communicates poorly with Advanced Manufacturing Engineering. Advanced Manufacturing Engineering

in turn communicates poorly with Manufacturing. The Quality group tends to live outside this circle, functioning in a classical “quality cops” role.

The FDA contributes to this organizational malaise by generating separate documents for design control, process validation, test methods, and software validation. Their attempts at communicating that an overall “systems approach” is necessary is not being received by all in the medical community.

Many organizations have had excellent success by using truly cross-functional teams. One approach is to have teams that actually wear different hats as the primary product activity shifts from pre-design to detailed design to prototype to volume manufacturing. Additionally, having the cross-functional teams use tools such as quantitative market research, KJ diagrams, simplified QFD, and Designed Experiments can greatly enhance the combined organizational intelligence about the product and process required to create the product.

Utilizing a truly cross-functional team that can communicate and work together toward a common goal is especially important for Process Validation efforts. Recently I was working with a medium sized medical device company on some experimental design and process validation activities. The validation team consisted mainly of manufacturing operations and mechanical engineering personnel. The function of quality was to generate procedures, then audit and critique protocols and completed qualifications. Audit is certainly an important role within a medical device company but wouldn't the team be in a better position to conduct validation activities in an effective and efficient manner if the quality engineers were party to PV activity from its initiation? Quality engineering concerns could then be raised and resolved early in the development of the validation protocols, not after they had been prepared. Quality engineering needs to partner in the process...not just “quality cops”.

Massive sourcing from low cost suppliers

Sourcing in China is an ever increasingly popular strategy for medical device, however, business ethics can be very different in Asian companies as opposed to North American or European companies. It is almost a certainty that you can be assured of the lowest *initial* price with this strategy. But organizationally are you aware of the overall business risk you are assuming with this strategy? Two huge risks are sourcing ethics and exposure of your intellectual property (IP).

Let's first discuss sourcing ethics issues. An intriguing book I read a couple of weeks ago is titled “Poorly Made in China”. I recommend it to anybody who is making sourcing decisions in China (or purchasing anything from the big retail stores in the US). The author recounts experiences as a liaison for US and European companies sourcing products in China. The author was educated in US but has lived in China for a number of years and is fluent in the language and culture of the east and west. Most of the companies represented by the author are in the cosmetics business. The author's examples follow a consistent framework. Initially the customer is overwhelmed by the amazingly low price agreed to by the Chinese manufacturer. All goes well with the first shipment. Products meet agreed to specifications...but then problems begin to emerge. The Chinese supplier has taken the original business “at cost”. Of course, they need to make a profit and have a couple of common strategies they employ in this regard. One is to “cost-reduce” your products...without making you aware of this activity. In one classical example from the cosmetics industry, the Chinese company was producing liquid soap in plastic bottles. The suppliers decided to make the container walls thinner (even though the thermoplastic molds were owned by the US customer). The US customer only became aware of this after a shipment arrived in the US and the bottles actually fell over because they had insufficient wall thickness to support the load of the liquid. In another example from the cosmetics industry, the Chinese supplier decided (without consulting the customer) they could swap out an ingredient component to reduce cost. The component in question

affected the scent of the liquid detergent (it was formulated to have the scent of almond). With the swapped component the scent was no longer that of almonds...more like apricots. Of course, having a scent of apricot vs. almonds is perhaps not the end of the world and not likely to create any great obvious afflictions to consumers but the principle is compelling. Several examples in the book point out this disturbing fact. Some suppliers like to play this game of "catch me if you can". Unfortunately, this game can have serious consequences in the right situation.

One tragic recent example involves the blood thinning drug Heparin. Baxter is a provider of this formulation. According to the TV program "60 Minutes", Baxter sourced a key active component through a third party who in turn sourced the component in China. The Chinese supplier provided a component that was structurally close to the active component of Heparin but did not have the redeeming properties of the real component. During quality testing, neither the third party nor Baxter was able to pick up on this difference. This scenario has led to a number of deaths and litigation involving Baxter, the FDA, and individuals. The final impact has yet to be determined, but the final financial impact alone will likely be in the billions of dollars. Of course, the legal teams are not going after the Chinese supplier or even the third-party...just Baxter.

My belief is that Baxter was able to get a dramatic initial cost reduction through the third party supplier of the Chinese sources material but would like to be able to make that business decision over.

Another scary example involves infusion pumps. Infusion pumps are used to deliver multiple drugs to patients typically in a hospital situation. In December of 2010 the FDA asked Baxter to recall and destroy all shipped units of the Collegiate Infusion Pump. Many thousands of these units had been shipped in the last 6 years. A number of problems had been found by customers and the FDA during the life of this product. After much effort on the part of the manufacturer the FDA literally asked Baxter to give up on this device and recall all devices. Unfortunately, a number of deaths have also been attributed to this device. Many problems were uncovered with the device (as well as infusion pumps designed and manufactured by other companies). One involved a divergent interaction of the batteries/software. In some units, it seems if the batteries failed the software would allow for the free flow of drug to the patient. The litigation and human tragedy of this scenario is continuing to unfold. Where were the batteries produced? How about the software?

It happened again this week! I was having dinner on the east coast with a former client who now works at a director level for a leading medical device company. I told him about the book "Poorly Made in China" as well as what I had heard from other folks who have major sourcing initiatives in China. When I mentioned the Chinese "cat and mouse" game regarding ingredient/process changes without customer approval his eyes widened and he said "we found a couple of supplier who did the same thing to us....material switches without our approval. He went on to say that when this happened they immediately disqualified the supplier as a source. But what if you do not make this determination until it is too late for your customer?

What about your intellectual property? It is common knowledge that many Chinese companies have little regard for US copyright laws (some suggest this is beginning to change slowly). While in Shanghai in 2006 at a break in our seminar one of my US sponsors was having a discussion with his team regarding my products (books, analysis software, training aids). Consensus amount the group was that all would be easy to reproduce cheaply in China. Visits to the "Shanghai Market" in this same era could yield incredible prices for knock-off watches, purses, jewelry, and software. Software was priced based upon number of CD's required to copy. If it all fit on one CD, \$10.00 was the prices. Two CD's meant you needed to pay \$20.00.

The bottom-line is that medical device companies need to carefully consider the business risk associated with sourcing decisions. Again, the promise of an almost unbelievably low cost is very alluring to US and

European organizations....but what is the risk? What about your Intellectual Property? What would happen to your product if the process was to change without your authorization? Would you be able to catch the change? What would the impact be on the user? Can you afford to take this risk?

Organizational dysfunction:

My daughter Cass is a grade school teacher. A year ago over coffee she was telling me about some conflicts her teaching team was working through. One of the other teachers and Cass seemed to be having trouble communicating with each other. About this same time the school district decided to give each teacher a profile-exam to determine their primary approach to problem solving. It seems Cass was a classical “green”. Green’s tend to start with getting a handle on the big picture first then working down to the details. The other teacher with whom she was occasionally having communication problems was “gold”...the opposite of a “green”. “Gold’s” tend to start with the details first then gradually work their way up to understand the whole picture. The risk with being a “green” is never being able to get down to the details. The risk with being “gold” is getting so immersed in the details that you never get the big picture.

Most effective teams should have both personality types in order to solve various challenges. Importantly, team members need to appreciate the special talents (and limitations) of the other problem solving types and ensure there is a working balance on the cross-functional team.

We frequently see seriously conflicted teams within medical device organizations. Both green and gold types are needed. If the greens tend to dominate the team, there is a tendency to completing only cursory level validations....they may gloss over important details. If the gold’s dominate the team, they can get wrapped up in minute details while making only incremental progress.

Allow each member to become aware of their primary approach to learning and problem solving. Make sure all have an appreciation for other team member’s strengths and weaknesses. Preplanning tools can be of great assistance to both problem solving types on the validation team. Design Failure Mode Effect and Criticality Analysis (DFMECA) and Process Failure Mode Effect and Criticality analysis (PFMECA) can guide the team regarding focusing on the key risks both at the design and process level. These tools help them go after the big risk items first! Detailed process maps supplemented by Design of Experiments (DOE) characterization studies can delineate the key input factors for the key output characteristics. Control plans can provide useful insight into key parameter management. This information can be of great assistance in focusing the validation team on the essential parameters so they can get on with their important work.

Understanding the true customer need

In the 70’s, I worked as a quality manager in a small company that produced packaging component for big medical device companies. One of our product lines were polymer closures for the tops of blood collection tubes (pix). We made millions of these components each week. Red closures were a big volume item but a problem area for us. We seemed to consistently have problems getting the proper shade of red. We had a three shift operation with a heavy focus on inspection (in-process and final). We had big differences of opinion on what constituted the proper shade of red in the final product. In a typical week we scrapped about 30% of the product. I was assigned the task of resolving this problem and improving overall consistency. It was a big effort and involved numerous heated meetings with quality inspection and manufacturing. After about 4 months, we got to the point where the team was at least more consistent in agreeing upon what constituted an acceptable range of color variation in red. Keys in the activity were to define limit samples, take pictures, and communicate, communicate, communicate.

A few weeks after we had completed the above, we were proud to present our efforts to our key customer representative who was in town for an annual supplier review. After our presentation, we were taken aback by the representative's comments. He basically indicated that they did not care about the red shade variation. He informed us that if the red looked like a black or a green it was a problem but shade variations were of no concern. I learned an important lesson from this activity. Make sure you really understand the customer and their needs. Assuming you have the answer is risky. Had I employed some of the simple, but powerful, market research tools I could have saved the company a great deal of time and money.

Plan for success

In the summer of 2001 my 27 year old son, Randy, was at my place on a Sunday evening. We were watching an edition of Sunday night football and having some refreshments. Randy brought up the fact that there was a marathon in Colorado Springs planned for two weeks from that weekend. During the summer, we had both completed a couple of 5k's but never anything longer. We naively decided that doing a marathon should be no big problem for us. After all, upon reviewing the course map, we noticed that it was all nearly down-hill.

So we enthusiastically signed up and arrived in Palmer Lake, Colorado at the appointed date and time. Needless to say, we had no concept of what we were in for. The first couple of miles were just fine but about the 12 mile marker, bad things began to happen. At mile 16, I totally cramped up in my right hamstring muscle and started to walk. I was unable to run anymore and I finished the course by walking the last 10 miles. My finish time was an embarrassingly slow 5:37. After the race I decide to sit for about 15 minutes before embarking on the journey to my vehicle. This turned out to be problematic as I was barely about to stand up and walk by now. With much effort, I eventually was able to get into my vehicle and drive the 30 minutes home. By this time, I was even in worse shape and literally had to crawl out of the truck, across the yard and up to my house. After about 3 weeks my legs had finally recovered....but with much agony along the way.

Some medical device companies approach process validation with a similar amount of pre-planning as above. Suddenly they are about to manufacture a device when someone realizes they need to consider FDA requirements for process validation. Confusion in this context is rampant. Should we validate, verify, or qualify the process? Can we just 100% test? What about suppliers? Can we afford to do all of this? What about a hazard analysis? Where do we start?

Much like being successful in a marathon, effective, low-cost, risk reducing process validation requires great cross-functional team work, appropriate tool applications to support product and process design, profound technical knowledge, and a passion for low-cost, risk mitigating excellence.

Process validation planning needs to begin long before the product design is completed. Process flow charts, detailed process maps, DFMEA, PFMEA, hazard analysis, control planning, requirements maps, VSM, VMP's, DOE characterization studies all need to be completed before Process Validation is initiated. In this way an organization can provide low-risk, low-cost, compliant products that delight the customer.

Summary

How can medical device organizations begin to address these challenges? The answer is all about an organizational passion for excellence, marketing/sales/engineering excellence, outstanding processes,

truly cross-functional teams, valid life-cycle risk assessment, and powerful tools to support these processes. Marketing and sales in conjunction with engineering representatives must be able to conduct quantitative market research and transform these requirements into the key overall drivers for the design team. Engineering needs profound knowledge of applicable technologies, manufacturing processes, and optimization tools to ensure design concepts are low-cost, reliable, and easy to manufacture. Advanced Manufacturing Engineering needs profound knowledge of state-of-the-art manufacturing processes, VSM, and optimization tools. Executive Management needs a methodology to tie together the wealth of information in a simple but effective manner. We like to refer to this methodology as “Management by Analytics”. (Please look for follow-up articles regarding Management by Analytics).