Changing Times, Convergence Opportunities

Carl Marin

The healthcare and life science industries are going through a change in methodology of treatment and cost containment pressures under a focused government controlled or nationally administered health insurance program. These new pressure points are making the pharmaceutical and medical device industry re-evaluate target therapy, point of administration, method of administration, portability of the product, country of origin, associated costs, and convenience for use. All thoughts are on how to address a global growing demand for better healthcare, and have a proven effect on the quality of life, while maintaining a cost/benefit profile.

The healthcare professional is under tremendous pressure to see more patients at a lesser cost per patient visit with quality service to ALL. This objective to see more patients opens the door for new methodology to administer and prescribe therapies on a routine basis with confidence for all involved.

The ideal situation would be for the patient to self administer medications, whether solid dose or liquid form, but this is not always a simple solution based on age, technical skills, complexity involved with the device, and target site for administration. Therefore, the approach that works for one group of individuals may not work for another.

Under the current economic situation, one must consider all the facets of the product/medication's intended use and keep in mind the cost/benefit. As an OEMer to the life sciences and healthcare industries, my company, Advanced Scientifics, Inc. [1] needs to consider all aspects of the medication and medical device.

1. Point of sale or target market?
2. Where is the medication currently being administered?
3. Who is administering the medication?
4. What sophistication level of reconstitution or administration is required for safe, effective use?
5. Which regulatory body governs the device or final form of presentation?
   a. PMA
   b. NDA
   c. 510K
6. What is the life cycle of the product?
   a. New medication or therapy
   b. Another method of packaging the product or medication
   c. Extending the patentability of the medication's target use
   d. New use of an established medication/therapy
   e. Moving onto OTC style of marketing
7. What is the risk or exposure of my company with this combination product?

8. Is the convergence cost beneficial to the overall marketability of the combined medication and medical device?

There are many more considerations that go into the discussions with clients, but the mentioned are core questions that must be considered before either company moves forward with a combination project. Using the previous mentioned conceptual ideology, let’s explore a couple of products that will help one visualize the thought process from both companies’ perspectives.

As the manufacturer of the device, my company wants to make sure the ideas and/or medications are ethically proven and acceptable in current or combination form. I cannot subject our current reputation as a reliable contract manufacturer or dilute resources to an unproven product or unnecessary product concept. Nor can I commit company resources on any “Red Herring” without an economic model of realistic return on investment.

The Idea

The product is a pre-packaged, sterilely filled, vaginally administered medication for female fibroid tissue control which is a self-administered, prescribed drug. The market is currently being serviced by several different marketers using a kit form with the patient needing to fill an applicator with medication that is packaged in another dispensing container.

First, the question arises of the need for another competitor in the marketplace, or if the current market is being serviced adequately. As the client or marketer of the new concept discusses their reasoning and idea, the product takes shape and evolves as a producible product which allows my company experts to inject enhancement ideas to the device.

Second, the company requires an economic model or justification for moving forward:

- Over 13,000,000 females, age 13 (puberty) or older, suffer in some degree of fibroid tissue growth in the vaginal or female reproduction system in the United States alone.
- Using marketing theory that 10% of the target group would use, or are using some type of control medication for this situation, means that the idea has potential for 1.3 million patients or females. If the medication is to be given daily for a period of six months or 180 days, that translates into 234 million units of the medication and administrative device. And, according to the marketer, the patient is never cured but controlled with systemic continued maintenance schedule of the drug.
- Estimated target pricing to the end user was given at $6.50 per administration, or a $1.52 billion market potential in the US.

Third, the marketer must prove that they have something new and novel to add to the current situation, so that Advanced Scientifics feels comfortable in expending resources on this concept. According to marketing information, the competition supplies the medication or kit as a two step filling procedure that requires the patient to fill an applicator with medication from another supplied container which isn't exact science. Therefore, the patient administers an inaccurate amount which may or may not be the prescribed dose intended.

Our client, the marketer, established that they wanted to use the applicator as the package and administration device for an accurate fill from the supplier, elevating any further need to measure or calculate dosage amounts. Then, to make the product more systematic, they would package 30 prefilled applicators per tray for an average month's supply of prescribed medication dosage.

Fourth, the product must be regulated under the FDA guidelines. The marketing group had already identified the product and proved dosage with the FDA, therefore, all that was needed were stability studies with the medication and intended material of the applicator. Before the stability study could start, we needed to understand the individual methodology for self administration of the medication for proper design input.

The dosage was set at a prescribed amount in micro-milliliters, and an average orifice diameter and insertion depth were determined so a concept container could be designed. We recommended an "off the shelf" standard grade polyethylene base material and over molding technology, to give the device a soft comfortable feel during the insertion phase of administration.

Next, the concept was prototyped using an SLA sample profile, which gave the marketer a better understanding of the concept and gave them a hard pattern to visually understand the design concept. This was probably the most important step that Advanced Scientifics took during the design analysis. The marketing people could visually see the parts and do mock procedure runs before the next costly step of the project, cutting hard steel. But, our job wasn't over yet, we wanted to discuss the filling procedure with the contract filler before going any further with the design. Of course, the marketing personnel didn't truly understand the necessity for involving the filling company prior to molding components, but we spent the time understanding the equipment and handling procedure before finalizing the harden steel tool design. (Please be aware, ASI was given a prototype tool from the previous vendor). This single step helped improve the design and was instrumental in reducing the overall estimated cost of the final finished product for market.

Regulatory Issues

Since the product had been supplied in a different concept by another contract vendor, ASI needed to establish various parameters on material and medication contact so the marketing company did not need to re-invest in additional stability and material studies. The company still had to do necessary tests and checks, but it was not the long, drawn-out studies required with a totally new concept or design, incorporating new materials of construction. However, ASI was changing the

method of construction using a co-molding or over-molding process, which reduced the number of molded components, while giving the same contact area of medication to container (applicator). Both companies maintained the idea of moving forward with the new design while continuing to use the same approved materials of construction.

Both companies collaborated to introduce a new design with enhancement features while using materials of construction that were previous approved and documented in the original PMA.

The Risk Factor

What is, or would be the risk to our company if there were a product failure? This is an important question and concern of any contract manufacturer when patient health is involved. After presenting the opportunity to the entire management team at Advanced Scientifics, every discipline within the company was encouraged to submit their ideas and voice their concerns prior to assuming any involvement with the product or concept. Engineering, QA & QC, marketing/sales, project management, plant management, and the President of the company were asked for input to the project and available resources that would be spent on evaluating this product concept.

It was determined that the only true exposure was involved with the supply of quality injection molded assembled components. The materials of construction were already established and approved by the client and FDA. We controlled the new design and built the tooling for the product. Our molding department would be making and inspecting the components prior to assembly in our plant, therefore, we were building quality in not inspecting it in. So, the true risk of product failure would be caught at filler’s operation, reducing our exposure even further to failure at the user level.

So, it was perceived that our only risk was realizing a return on our investment of resources with the marketing company’s successful launch of the product idea. With the understanding of the market potential and size, we felt that the product concept was worth the effort to move forward with the marketing company.

The Reality of the Project

The project met our project criteria from just about every standpoint in our company strategy and focus.

1. The marketing company was established with a focused target audience and understood the problems of the user and benefits of the medication.
2. The features of the combination product address the immediate needs of the end user
   a. Improvement of the medication delivery, in turn reducing the possibilities of error
   b. Ease of use
   c. Comfort of delivery

d. Disposability
3. Potential for large volume sales on a continuing basis
4. Limited regulatory involvement
5. Utilized ASI's area of expertise in molding and assembly
6. Materials were currently used with our molding department
7. New design offered synergies with the contract filling company
8. Final design helped reduce or maintain the cost profile for product success

Understanding the customer and their customer's objectives truly helped expedite this product profile through the system. Many times, companies request and expose contract vendors to projects in which neither company understands all the hurdles and avenues for product failure in the development cycle. Just asking the mentioned few questions can identify whether either or both companies are aligned for success together.

Carl Marin *is the CEO and founder of Advanced Scientifics, Inc.*

Source URL (retrieved on *08/22/2014 - 5:55am*):
http://www.mdtmag.com/articles/2010/06/changing-times-convergence-opportunities

Links:
[1] http://www.advancedscientifics.com/