

# When the outsourcers outsource

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Over the years, the cost of developing a new drug continues to climb. Estimates today place the average cost to develop a new drug over \$ 800 million and 10-15 years. More important only three out of ten drugs launched actually generate enough revenues to match or exceed the development costs.

In 2001, a Merrill Lynch study of the fine chemical industry predicted that the fine chemical market was worth around \$ 12 billion per year. Based on 20-30% estimate of life science manufacturing being outsourced, they would estimate that the overall fine chemical market would grow to over \$ 23 billion.

Based on predicts by several sources, they feel that the fine chemical and specialty chemical markets should continue to grow. In 2001 article in Chemical Specialties, Mr. Fahmy of Kline and Company predicted that US pharmaceutical companies would continue to sell off production and more aggressively outsource.

While European pharmaceutical companies retain a large part of their production, US companies are driven more to outsourcing. With an increased demand for research dollars, pharmaceutical companies are looking to cut costs. One way of doing this is to do more outsourcing of manufacturing.

It would seem that the stage is set for more aggressive programs of outsourcing of pharmaceutical manufacturing. Assuming that the pharmaceutical companies seek to reduce costs and minimize risk, one may ask the question why would the contract manufactures follow the same model. The reality of the situation is that contract manufactures play as much in the outsourcing as does their customers. The real question is simply, what

happens when the outsourcers outsource.

Over the years, the policy and procedures of most pharmaceutical companies regarding outsourcing have been documented. Most major companies have participated one of numerous presentations looking at outsourcing. In general, the fine chemical industry has discussed how it tries to deal with the pharmaceutical companies but little is published on how it deals with each other and what it is looking for.

In its Fifth Annual Outsourcing Index, the Outsourcing Institute surveyed over 500 companies and reported the following. In the same study, they looked at the reasons that companies chose a vendor (Table I) - In both cases, the sums do not add to a hundred since the participants were allowed to select more than one.

While this study covered a wide range of industry, it would seem that no matter what industry you chose, the outsourcing phenomenon has very similar drivers. It seems interesting that while the number one reason for outsourcing was to improve customer focus, still the number one reason for selecting a vendor was price.

In the case of the contract manufacturer looking for an outsourcing partner, they are looking for the:

- Why
- What
- How
- Where
- When

## WHY

While there are many reasons for a CMO to outsource, I think that there are four primary reasons why some one looks outside of its internal production.

## Capacity

A primary concern would be overall capacity. There are two concerns to consider here. On a temporary basis, the CMO may not have the capacity to reach either the target volumes or timing. Based on the risk, acquiring new capacity may not be an option. Based on this, the CMO will need to either reject the project or look to a third party to increase its own capacity.

Directly related to capacity, the CMO may use external capacity to increase its own portfolio. They could contract out some of the steps and use that capacity to do other projects. Often, CMO's will outsource early steps once a product has been launched and the volumes appear to be stable. This allows them to bring on new projects without increasing their capacity and minimizing or delaying any investments.

Another major reason for outsourcing chemical steps has to do with technology or the lack there is. In this case, the CMO may have capacity but the wrong kind. The Outsourcing study showed that utilizing world-class technology was important.

There are two issues that effect technology. To begin with, often companies do not want to practice certain types of chemical reactions. In particular, many companies will stay away for exothermic reactions. In addition, the requirements based on market size or types of reactors may not fit with the current situation at the CMO. In either case, both cases, the CMO can overcome the problems with an investment. However, the company may not have the assets available at this point in time. This point will be covered more shortly.

A second critical area could be the lack of ownership of proprietary technology. Consider the number of companies that own homogeneous chiral catalyst. Dr. Jacobson of Harvard has discussed the "privileged few". The lack of ownership could prohibit the CMO of using the best technology to perform the specific chemical step. In today's competitive market this could be the difference.

## Risk

Every organization views risk differently. Larger companies tend to go in the direction of risk avoidance. Smaller companies often tend to be more opportunistic. The problem here may not actually be related to risk avoidance but to the systems put in place in larger companies for asset allocations. Larger companies more often have more people competing internally for capital.

Therefore, the lower risk projects often get approval faster since it is easier to justify.

One way around this problem could be by sharing the risk. In fact when the major pharmaceutical company outsourcers, in affect, they are sharing the risk with several companies. The CMO's are not different. By using some one else's capacity, they can delay or eliminate the need for investment. One could equate less investment to lower risk.

There are other considerations that the CMO's has to consider when it takes on a new project. For example, the CMO does not have the detailed information regarding the product and its clinical profile. Some CMO's could consider new class of compounds for a given clinical application has having more risk. They may question the overall market size and ability to penetrate the market by its client.

## Capital

We see how capital is directly connected to capacity. Many companies review their capital requirements on an annual basis. If you come in at the wrong time, you may have a long delay. Also, based on the risk, the return for the investment may change radically making the capital unavailable relative to the project.

Simply put, the CMO may not have the capital, may need to delay spending the money or may want to avoid it completely. Based on this finding an outsourcing partner may be the only way the project can go forward. Relying on investments that have already been made can positively affect the economics and timing of the project.

Even if you have the money, you may seek a third party partner. Most companies will require some type of contract before any investment is made. Furthermore, it could easily take over one year to design build and validate the investment. This could delay your project by an unacceptable amount of time.

Unfortunately, most companies have designed strategic customers and this could limit the CMO from bringing in a new customer. Bruce McCracken of the Outsourcing Center described how the smaller companies often get lost in our quest to work with the big guys. In our case, smaller and emerging pharmaceutical companies may not be subjected to the same evaluation standards. Some CMO's would consider them to be higher risk and want to minimize their investments (both time and money) for these potential clients.

## Flexibility

A major concern for the smaller CMO's is flexibility. They will consider outsourcing even to some one they consider a competitor if it allows them to increase their ability to be flexible. For a small well organized CMO, flexibility in manufacturing can minimize down time and increase capacity without investments.

There are many other reasons for a CMO to find a partner. Some of these reasons mimic the justifications that the pharmaceutical companies use. In the end, the key elements are

- The Customer
  - The CMO's organization and management style
  - The CMO's pipeline
- Once the decision has been made to go outside, one must look at evaluating potential partners. A few things should be considered before looking for a partner:
- Outsourcing relationships work only if both parties understand what the other wants and needs.
  - Outsourcing works only if both sides understand the inner workings of the CMO.
  - Outsourcing works only if there is clear well defined lines of communications.
  - Outsourcing works only if both parties understand that they are in this together.

Table I

### Ten top reasons for outsourcing (1)

1	Improve customer focus	55%
2	Reduce and control operating cost	54%
3	Free sources for other purposes	38%
4	Gain access to world class capabilities	36%
5	Resources not available internally	25%
6	Accelerate reengineering benefits	20%
7	Reduce time to market	18%
8	Share risks	12%
9	Take advantage of offshore capabilities	12%
10	Function is difficult to manage or out of control	10%

### Five top criteria for choosing a vendor (1)

1	Price	65%
2	Commitment to Quality	51%
3	Flexible Contracts	39%
4	References/Reputation	34%
5	Scope	28%

## WHERE

Now we understand that outsourcing is the way to go. The next step is to decide where we are going to go. There are several issues that need to be addressed.

An obvious choice is one that has experience in the technology that we want to perform. A second issue would be our experience with the company. We work better with people and places we know and understand. We do not have the time or the desire to re-invent our relationships.

Depending on the organization and its people, the physical location

could be important. People not companies outsource projects. The ability to visit the manufacturing site and communicate with the technical people is important. Language barriers, time differences and long flights can make outsourced projects more difficult.

Often when we look to outsource a project we underestimate the human aspect of the work. I like to speak directly with the process chemist and find out what really interests him. I want to know if the company has the human resources and interest to do my project. Does the R&D staff understand the problem and have both an interest and a desire to solve my problems? Have they done similar things and are they ready to listen and learn if necessary? I want to know if I am working with a company that is open to new ideas and new ways of doing chemistry.

There are also some issues that are standard. In particular, I want to know information regarding not only the FDA but want to understand their environmental position as well. Keep in mind, if the CMO pick the wrong partner it is their fault. The pharma company will remember that you did a bad job not your partner. Always remember "Choose wisely."

## WHAT

Once you know why you are going to go outside, you need to decide what is going outside. I like to think of it in very simple terms. For me, it must meet one of the three criteria

- If I cannot do it
- If I do not want to do it
- If I do not like to do it.

This seems overly simplified but it covers almost everything. Hazardous chemistries by the organizations definition will most likely go outside. Remember, you decide that the chemistry is hazardous or dangerous for you to perform; your customer may easily be well suited to do this type of reactions. After all this is way the two companies are talking.

After reviewing the chemical step, you may decide that the chemistry is questionable and you do not have the time to develop it. You may also decide that it is too early in the synthesis for you to be interested in doing it or developing it. Your best bet would be to find a partner quickly.

## WHEN

There are only two considerations when you think of the "When". Do I go early or late. Often, this decision is based on capacity issues and R&D resources. If either is limiting, you will think quickly to go outside. I remind everyone that when we discuss capacity, it really needs to deal with not only what I have but also what is available.

I think that it is better to start talking early on. It gives both sides the opportunity to learn and properly evaluate the opportunity. This allows to better plan for the long-term approach. I believe in portfolio management and for this it means managing the portfolio not just in the short term but in the future as well.

If you delay this, you may be more into crisis management and you may choose a less desirable partner. It is important to remember that your partner has his own portfolio and he needs to manage it as well.

If you wait until after the launch of the product, you are most likely looking for the best price. The products that you are outsourcing need to be early on in the synthesis to avoid any regulatory issues.

## HOW

Now that you have already decided to outsource, you know what will go out and you have some idea of where it is going to go. Now you have to find a partner. Obviously, if you have had experience in the past, you will try and do it again. On the last project, did your supplier meet their targets, where the innovative and did the tow of you have a good relationship. In my opinion, you will do everything to work with people that you like and are comfortable. It is like that old sweater, no matter how much time goes by, it feels right.

Often, your customer may select the outsource partner. If you are not comfortable with this, it is important to have a frank conversation to air your concerns. Customers often forget that they chose the partner if something goes wrong.

One important point is the definition of success. Things do not always go right. In chemistry during scale up, things do and will go wrong. How your supplier handles these things are important.

### Criteria for choosing a partner

- Knew Key people
- Developed a long-term relationship
- Visited the plant
- Customer chose
- Considered to an expert in their field
- Sounded like a good idea
- Innovative problem solving
- Reactor mixes

After you have come to the realization that you need to outsource, chosen the partner, selected the site and began to move forward, it is a good idea to stop periodically and ask what was I thinking in the beginning. Projects tend to develop their own life. As things begin to change, your original criteria may no longer fit. It is important to remember that once you begin an outsourcing project, it does not end until after the deliveries begin.

One question that often comes up in these discussions is the process in finding these partners. There are several ways of doing this. We meet many people at symposiums and trade shows. Some of our partners are former classmates or employees. Some are old friends that we meet along the way. Often, these people are competitors. The real key is that we have a short collection of people that we can go to quickly and with trust.

The Outsourcing Institute listed seven steps to a successful outsourcing process (1):

1. Identify your needs
  - a. Put together a scope of the work
  - b. What do you want
  - c. When do you want it completed
  - d. Prepare a detailed document
2. Develop an RFP (Request for Proposal)
  - a. Explain in great detail
  - b. Criteria
  - c. Pricing structure
  - d. Terms and conditions
3. Evaluate the Process
  - a. Technical evaluation
  - b. Completeness of the submissions
  - c. Overall financial stability
4. Selection Process
  - a. Consider a few of the proposals
  - b. Determine key criteria (cost versus technology)
5. Contract Execution
  - a. Sign the deal
6. Administrative Functions
  - a. Reports
  - b. Follow ups
7. Close-Out
  - a. Final report
  - b. Metrics
  - c. Final evaluation

Finally, I put great importance on people. I want to work with people I like and trust. I want to visit places that I am comfortable with. Simply put, let me have a good meal and a good wine.

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