Improving The Cost Efficiency In Pharmaceutical Outsourcing

Corresponding Author:
Mr. Hui Xiang,
Arizona School of Health Sciences, A T Still University, 5850 E. Still Circle, Mesa, AZ, 85206 - United States of America

Submitting Author:
Mr. Hui Xiang,
Arizona School of Health Sciences, A T Still University, 5850 E. Still Circle, Mesa, AZ, 85206 - United States of America

Article ID: WMC00975
Article Type: My opinion
Submitted on: 12-Oct-2010, 05:36:39 AM GMT   Published on: 12-Oct-2010, 03:13:53 PM GMT
Article URL: http://www.webmedcentral.com/article_view/975
Subject Categories: BIOTECHNOLOGY
Keywords: Cost efficiency, Outsourcing, Cost/benefit analysis

How to cite the article: Xiang H , Zhu Y . Improving The Cost Efficiency In Pharmaceutical Outsourcing . WebmedCentral BIOTECHNOLOGY 2010;1(10):WMC00975
Improving The Cost Efficiency In Pharmaceutical Outsourcing

Author(s): Xiang H, Zhu Y

My opinion

There is a growing demand to contain the sky-rocketing drug costs. The driving forces for such demand come from public awareness of high drug price, rising R & D expenses, tighter FDA regulations, higher NDA/BLA requirements, and competition of generic drugs [1]. Drug companies are looking into ways to cut costs in order to stay competitive. Outsourcing is one of such measures to reduce cost and risk in drug development and production. While enjoying the gains brought by outsourcing, many drug companies do not have a systematic cost evaluation program. Often they are unaware of the significant internal costs associated with outsourcing when making decisions [2].

Implementing the Scoring System in Cost/Benefit Analysis

In brief, cost efficiency is defined to achieve the business goal with minimal cost, or make maximum on the money invested. Cost/benefit analysis, one of the widely used tools, gives a glimpse of what kind of benefit will be generated based on what cost. In order to evaluate cost efficiency in pharmaceutical outsourcing, the scoring system could be adopted to measure both the deliveries[3], as well as the costs [2]. The deliveries are scored in the following five categories: regulatory compliance, supply assurance, quality, service, as well as innovation [3], as summarized in Illustration 1.

The costs are scored in the following 3 categories: manufacturing costs, CMO profit margin, and sponsor's internal costs [2], as shown in Illustration 2. The manufacturing costs and sponsor's internal costs are further traced to material costs, labor costs, and overhead costs. Activity-based cost system should be used to evaluate these costs. Many sponsors are not even aware of such internal costs, thinking that once they contract it out they do not need to do anything about it [2]. Examples of sponsor’s internal costs include project management, relationship building, process transfer, document translation, training/support, as well as studies required by regulatory affairs.

Based on Illustrations 1 and 2, the cost efficiency can be estimated by the following calculation:

Deliveries = Compliance + Assurance of Supply + Quality + Service + Innovation (1)

Costs = Manufacturing Costs + CMO Profit Margin + Associated Internal Costs (2)

Cost Efficiency Index = Deliveries / Costs (3)

This scoring system is not the only way to estimate cost efficiency. Other factors could be added in if they need to be considered. Also, the scoring weight could be changed to better reflect the criticality of each factor, as long as it is consistent in the same comparison.

Strategies to Improve Cost Efficiency

Based on the above equation, sponsors need to improve deliveries meanwhile reduce the costs in outsourcing. However, the above equation just helps us to compare the cost efficiency from period to period or from options to options. It does not tell what should be done to improve the efficiency in outsourcing. Due to the complex features in pharmaceutical manufacturing, simply say increase the deliveries while reducing the costs is not enough. In order to improve cost efficiency, the following strategies are recommended:

1) Commit to quality and regulatory compliance: Improvement in cost efficiency should be built on the pre-condition that quality and compliance are not compromised. With rising bar of drug regulations, cost increase to meet regulatory requirements should be viewed as an absolute requirement. Pharmaceutical business is not purely commercial because any violation of regulation or quality standards will result in tremendous financial loss, even judicial prosecutions [1].

2) Perform thorough quotation analysis: At bidding stage, sponsor should list the criteria and perform thorough quotation analysis, requiring contractors to quote costs of materials, labor, overheads, as well as profit [1]. Details, such as pay by hour, by milestones, or by service, need to be discussed. “Beware of low upfront costs that hide high fees of all varieties” [4].

3) Balance the capacity and demand: It is important to estimate the contractor’s capacity when making outsourcing decisions. Either over-estimation or under-estimation will have significant financial impacts. As Ransohoff estimated, operation at 50% or 150% capacity could increase costs up to tens of millions of dollars each month for a typical monoclonal antibody product2. “An optimal capacity mix for API [active...
pharmaceutical ingredient] manufacturing is 70%. The remainder of the time will be needed for clean-up, changeovers, validation and training” [3].

4) Gain access to new technologies: Pharmaceutical industry is heavily technology driven. New technologies can significantly improve return on investment. Contract companies offer a variety of their in-house technologies, as well as experiences in cGMP manufacturing, process development, scale-up, and validation. Dr. Andrew Racher at Lonza Biologics said, “As a contract manufacturer, we have developed more than 300 robust manufacturing processes,..., we leverage our previous experience, which allows us to develop these robust processes more quickly than companies that have less historical data to draw from” [5].

5) Manage projects efficiently: Because contract manufacturing needs to use facilities, technologies, and experiences that are often unavailable in-house, efficient project management is very essentiall [1]. However, this does not mean to micro-manage every activity. “For the project to be successful, the sponsor must manage it carefully and competently. It’s a fine line to walk between neglecting the project and micromanaging it, but walk it you must” [4]. It is good that sponsor and contractor form a joint project management team, which makes decisions on scope of work, specifications, milestones, responsibility, etc. This requires effective communication and clear responsibility.

6) Develop long-term partner relationship: A recent survey showed that majority outsourcing goes to preferred contract companies on the basis of good service [6]. The overhead costs to start with the new CMO was enormous: searching, negotiation, relationship building, process transfer, document translation, process modification, training, stability studies, fill and finish modification, comparability study, rewriting the CMC report, and revalidation. In addition to delays in launching the drug, the risk of failure was increased dramatically. Many companies face difficult choices when the contract companies are not performing well or do not fit their need in issues such as capacity, supply, or compliance. At late development or commercial manufacturing stage, it is hard to switch to another contractor [7].

7) Incorporate risk assessment in decision making: Several tools, such as discounted cash flow analysis and Monte Carlo simulation, could be used to estimate the risk in decision making [2]. It is recommended to defer large capital commitment to a later clinical stage when risk is significantly reduced.

8) Review performance periodically: This would help both sponsors and CMOs to identify issues needing improvement in the future. Both sides should agree on performance metrics, and measure the progress against such metrics1. At the same time, sponsors should measure the cost efficiency, and compare it with previous records to see if it is improving. If not, find out the reasons.

9) Go international. While currently the majority of drugs are still produced in North America, EU, and Japan, the trend is that pharmaceutical industry is catching up with other industries in moving to developing countries with low labor costs and market potential [1, 8]. Such move is greatly facilitated by global harmonization on drug regulation, as well as electronic communication in data transfer and regulatory filing. It is recommended that pharmaceutical companies actively look for such opportunities for future outsourcing partners.

Conclusion

The trend to curb drug prices requires drug companies to improve cost efficiency in outsourcing. Cost/benefit analysis should be implemented and measures need to be developed to improve deliveries and contain costs. It is better to plan early and develop effective and long-term strategies to maximize the gain from outsourcing.

Acknowledgement(s)

Hui Xiang*
Arizona School of Health Sciences
A.T. Still University
Mesa, AZ 85206
*Corresponding author. E-mail: hxiang@atsu.edu

Yi Zhu
Chengdu No. 1 People’s Hospital
Chengdu, China 610031

Reference(s)

### Illustrations

#### Illustration 1

**Breakdown of outsourcing deliveries**

<table>
<thead>
<tr>
<th>DELIVERIES</th>
<th>SCORING SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Regulatory Compliance</td>
<td>Current major compliance issues</td>
</tr>
<tr>
<td>Supply Assurance</td>
<td>Current severe supply issues</td>
</tr>
<tr>
<td>Quality</td>
<td>Unmanageable quality issues</td>
</tr>
<tr>
<td>Service</td>
<td>Not responsive</td>
</tr>
<tr>
<td>Innovation</td>
<td>No innovation program</td>
</tr>
</tbody>
</table>

Note: This illustration is prepared based on [3] with modifications.
Illustration 2

Breakdown of outsourcing costs

<table>
<thead>
<tr>
<th>COSTS</th>
<th>SCORING SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing Costs</td>
<td>1</td>
</tr>
<tr>
<td>CMO Profit Margin</td>
<td>Significantly lower than benchmark</td>
</tr>
<tr>
<td>Sponsor's Internal Costs</td>
<td>Comparable to benchmark</td>
</tr>
</tbody>
</table>

Note: This illustration is prepared based on [2] with modifications.
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