Virtual Firms & Outsourcing

Why the Project Management model may represent the best option

By Christopher Kulp and Linda Tedeschi Miller
Richman Chemical, Inc.

TECHNOLOGY-BASED COMPANIES, such as those in the life science arena, face increased competition in today's global economy, and the demand for more efficient "concept-to-market" strategies for product introduction has become critical. Consequently, for more and more companies, this reality entails finding alternatives to traditional in-house manufacturing options. In fact, many such companies have evolved into so-called "virtual firms," in which intellectual property takes precedence over physical production assets. Scientists within these virtual firms develop novel concepts on small-scale platforms (or sometimes simply on paper alone!). Outsourcing allows them to take their concepts to market without large investments in human and physical capital, allowing for more efficient product development and rapid scale-up to commercial product. Pilot scale-up work and eventual end product manufacturing is achieved via outsourcing relationships, and some virtual firms attempt to use the particular skill sets of individual suppliers strategically.

Typically, however, virtual firms approach the outsourcing aspect of their project requirements via a piecemeal, "one vendor at a time" tactic. The result is frequently a tedious, time-consuming, and sometimes disappointing experience with third party contract suppliers. For the virtual company, outsourcing success may be most easily achieved via the use of an external project management firm capable of placing, coordinating, and facilitating all aspects of the outsourcing process. These specialized service providers leverage the expertise and capacity of capacity-laden custom processing facilities and transform client innovation into tangible products—often more quickly and at lower overall costs.

Outsourcing as an Essential Business Function

Larger pharmaceutical companies often maintain dedicated departments for contract management and outsourcing. Historically, these project management roles may have been a responsibility of the procurement department, but no strict protocol currently exists. In smaller companies, the responsibility often falls to executives and/or department heads.

There is good reason to have dedicated people responsible for outsourcing activity. An individual who is experienced working with the regulations governing drug development, as well as both fundamental and "cutting edge" technologies prevalent in the industry, can help to ensure a successful outcome to the project. Furthermore, cumulative experience involving the potential obstacles inherent to all outsourcing projects can help avoid additional ones down the road.

Outsourcing Models

From a virtual firm's perspective, numerous outsourcing mod-

Christopher Kulp is manager, new business development of Richman Chemical, Inc.
Linda Tedeschi Miller is marketing associate at Richman Chemical, Inc.

els can be utilized depending on specific need, company philosophy, and/or time and financial constraints.

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Vendor Competitor Model

In this model, multiple vendors with similar capabilities compete for business. Vendor selection is generally based on time and cost, although cost is frequently the overriding factor. Customers frequently use the potential of multiple vendors to drive costs down.

Typically this may only offer a short-term advantage to the prospective customer. Many potentially good vendors may drop out because they perceive a poor chance of gaining the business. Even the successful vendor may not support the project adequately because, in the end, it may not be receiving an adequate return on its efforts.

Pre-Qualified Vendor Selection Model

Many firms maintain extensive data on past and present suppliers, with details of capabilities and performance levels. Companies may use an outsourcing department to assure an appropriate match for a particular project can be made with regard to a potential supplier's capabilities, past performance, and business model. If not on record, this information can also be generated on a case-by-case basis for evaluation purposes. Many pharmaceutical companies pre-qualify potential suppliers and set up preferred provider relationships, pre-defining outsourcing strategies for particular areas within the company. Even more important is the ability to have a trusting relationship with the vendor, with open, frequent communication. The ability to properly cost out a project and mesh two corporate cultures must also be considered.

This model typically works well, but it is costly in terms of manpower and economic expenditures. From a practical standpoint, the theoretical payoff is simply not compatible with existing financial and timing constraints.

Partnership Model

A company may choose to partner with one specific vendor for certain aspects of product manufacture. Usually, this is a contractual relationship, and the risk is shared so that outcome is equally important to both parties. The vendor who partakes in this type of business relationship has a keen interest in seeing the project through to a successful conclusion, and payment is at least partially contingent on a successful outcome.

While this strategy can be tremendously successful, it is severely limiting in terms of scope, capabilities and, frequently, capacity. Ideal partners for one stage of the product development process may not be optimal for later stages of the outsourcing process. Furthermore, external factors affecting one of the partners in a negative manner can often result in a trickle-down effect on the partnership as a whole.

Principal Vendor Model

The Intellectual Property (IP) owner uses one outsourcing vendor with full knowledge that the vendor will be further outsourcing parts of the project to other vendors. The principal vendor is still the supplier of the outsourced product and is responsible for due diligence and meeting associated government regulations.

This is a somewhat complex arrangement, and it effectively places all outsourcing requirements (contracted and sub-contracted) into the hands of personnel who may be inexperienced with project management arrangements involving third parties. Significant attention is allotted to the principal contract work; sub-contracted efforts may suffer, however, due to a lack of experience and/or an absence of long-term client-vendor relationships.

Project Manager Model

In this model, a firm (virtual or otherwise) possessing valuable intellectual property will hire a company to provide project management services for the project being outsourced. Ideally, the Project Manager (PM) does not conduct physical manufacturing in company-owned facilities; instead, it provides access to a large network of potential suppliers with which the PM maintains established relationships. Enlisting the services of a PM effectively amplifies the efforts of a life sciences company engaging in outsourcing. This is achieved through the use of the PM's extensive knowledge of the industry and his or her corresponding relationships with many potential service providers. In most instances, a firm needing outsourcing is assigned one project manager to handle its specific requirement(s), and the project management firm itself functions as the client's de facto outsourcing department—but without the internal cost!

A competent PM should provide extensive technical and manufacturing experience, leading to compressed timelines, lower costs and increased technical capabilities. In the case of virtual firms, this allows for improved focus on new technology development and sales/marketing efforts. Furthermore, PMs can facilitate the provision of auxiliary services related to the typical outsourcing effort, including: product development, full raw material sourcing, logistics coordination services, and regulatory filing advice, to name just a few.

Within the parameters of the Project Management model, the outsourcing client certainly is significantly dependent upon the expertise of the PM to provide compatible service offerings. However, the model itself is based upon a cooperative, risk-sharing foundation between the client and the firm offering project management services—especially since it is not uncommon to invoice for services rendered only after the project has been successfully completed.

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Advantages of the PM Model

Life sciences companies face growing regulatory pressures and consumer demands for cost reductions. IP owners must concentrate not only on meeting and maintaining strict FDA compliance, but also on minimizing expenditures throughout the product lifecycle of a particular drug candidate. In an effort to achieve this, virtual drug companies (or virtual departments within companies) have become more prevalent as outsourcing is utilized to streamline the entire development process.

There can be significant advantages to outsourcing if the project is managed properly from inception to product delivery. Searching for an optimal contract manufacturer can be like looking for a needle in a haystack, an inefficient use of limited resources. With the Project Management outsourcing model, the expertise of the PM firm is leveraged with respect to knowledge of a contract facility's technical competencies, scope of capabilities, and overall business culture. Thus, it is critically important for a firm in need of outsourcing services to retain an independent service company that focuses its resources on optimizing the outsourcing arrangement for its clients. As a consequence, this customer-centered strategy allows the PM to determine contract sites most compatible with the outsourcing constraints presented, such as (but not limited to) niche technology, business culture, equipment capability and timing/availability.

Choosing the correct PM often gives the outsourcing firm additional credibility in the eyes of potential CMOs that seek to "pre-screen" projects more efficiently. This is certainly the case if the particular contract facility has developed previously successful business relationships with the selected project management firm.

The overriding advantage to outsourcing, however, transcends effective project management; at the end of the day, it's all about getting things done more quickly, efficiently and successfully. This, of course, often speaks volumes with respect to the corporate strategy of the outsourcing firm.

Additional Advantages for Virtual Firms Using the PM Model

For the virtual firm, which often needs to commercialize (or license) its technology quickly and successfully in order to survive, the Project Management model can be particularly advantageous. For instance, should a virtual firm have multiple commercial candidates in the development pipeline, this approach allows the company to manage multiple projects through one basic channel. This can be especially beneficial if human resources are a limiting factor. Second, the relationships developed with both the project management firm, and corresponding contract sites, typically are long-lasting ones (especially if commercial success is achieved).

Both of these advantages support what should be the overriding objective of any virtual firm: to commercialize technology in the shortest amount of time. Lost time during the development and commercialization process represents potential revenue that can never be recouped, especially if time constraints on IP protection exist. Utilizing the Project Management outsourcing model can effectively hedge this risk.

Responsibilities of Project Management Firms

When a virtual life sciences client enlists the services of an outsourcing project management firm, the client is looking for clarity, in terms of both timing and cost factors for the project at hand. Thus, with respect to the outsourcing firm, it is crucial to manage expectations, provide regular and periodic communications, and update relatively often. The most pragmatic approach is to flesh out as many of the details and upfront costs to be associated with the project prior to beginning the project. This will save everyone from significant anxiety, as clear expectations on both sides serve to promote the cooperative nature of the "project management firm/outsourcing client" relationship.

Furthermore, service should always be customized for the client with whom the PM is working. While technical project details are often the predominant considerations when evaluating a project opportunity, it is also crucial to be cognizant of extraneous factors that could influence the business relationship, including: outsourcing firm business or industry, culture (regional or international customers), geography and environment considerations. Being able to incorporate value-added services that take all of these factors into consideration results in a truly competitive advantage for the virtual (client) firm.

Virtual firm proliferation and the corresponding need for outsourcing provides a significant opportunity to accelerate product development, maintain operating budgets, and use internal resources effectively—for the life sciences industry as a whole. A wider acceptance of the benefits of such a relationship can only be gained by fostering a greater understanding of the outsourcing process. Ways to improve this understanding include an emphasis on journal articles, workshops and marketing presentations geared toward presenting alternatives to traditional in-house product development and commercial manufacturing. ■