Smart Outsourcing: Strategic Alignment, Risk Management, and New Relationships

Outsourcing decisions should be made to foster potential long-term strategic partnerships.

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Outsourcing in the pharmaceutical industry, until recently, has been largely confined to commercial manufacturing, packaging, and support for clinical trials. The industry is rapidly changing; companies are facing rising costs, a fast evolving global market, and weak pipelines. Many companies are outsourcing activities that have historically been kept in house, freeing themselves to concentrate on their core competencies and become more agile in responding to changing conditions. These new outsourcing models include discovery and R&D, regulatory, chemistry and manufacturing controls (CMC) support, and back office sales and marketing activities—virtually no activity is out of bounds. Instead of building or acquiring specialized technologies and facilities, many companies are seeking access to them elsewhere.

Smart outsourcing provides the following operational and business benefits:

Reduced operating costs and greater return on investment (ROI)

Shorter time to market through faster accesses to increased capacity, new technologies, specialized facilities, intellectual property (IP), and expertise

More efficient use of critical internal resources (e.g., human and facilities)

Avoidance of large expenditures to bring new or expanded capabilities in house as well as the cost of staffing those capabilities

Increased velocity and flexibility in responding to rapidly changing global markets.

To reap the full rewards of outsourcing over the long term and significantly enhance shareholder value, however, companies need to take a comprehensive approach. Companies that adopt a smart outsourcing strategy include:

Pursuing outsourcing in the context of an end-to-end, global supply chain strategy that is directly aligned with the company's strategic business goals

Managing outsourcing as part of a continuing, mutually beneficial, long-term strategic partnership

Assessing and effectively managing the increased risk that comes with more extensive and diverse outsourcing.

Companies can use outside expertise to help carry out such an approach. This article outlines the benefits of using a third party in strategic outsourcing.

Leveraging external expertise

Effective use of outside experts who have the requisite industry-specific technical, quality and compliance, operational, and business experience can provide an invaluable, independent source of perspective, methodologies, and tools to help ensure the best decisions are made each step of the way. Experts can help to tightly align outsourcing strategies with a company's strategic business and supply chain plans, re-affirm core competencies, and make informed recommendations regarding which current outsourcing needs represent the highest ROIs and competitive advantages going forward.

The right consulting partner can give advice on how best to support these strategies with ongoing operational excellence and risk-management programs, as well as develop and maintain highly effective and mutually beneficial strategic relationships with prospective outsource providers. But whether a company engages external advisors or not, the company will need to be able to skillfully blend strategy, risk management, and a new mindset and approach to outsourcing partnerships to remain competitive in today's, and tomorrow's, rapidly changing and increasingly challenging global markets.

A new kind of partnership

The effective selection, qualification, and management of outsource partners begins with the way one thinks about those partners, no matter what the nature of the partnership (e.g., innovator–CMO or innovator-to-innovator). Short-term thinking about outsourcing as a stopgap measure or commodity solution to operational needs based largely on cost or capacity must be replaced by thoughtful and robust evaluations of both the current and future benefits of developing long-range strategic partnerships that deliver flexibility and value to both parties involved.

Consider not only what outsource partners can provide in the near term, but also what they may be able to do as the relationship grows. Long-term strategic partnerships can have substantial benefits to each of the outsource partners in revenue, capacity planning, and potential access to new technologies and markets.

For example, consider that two large pharmaceutical companies enter into mutually beneficial, long-term (>10 years) strategic relationships. These are innovator-to-innovator partnerships that are based on a progressive schedule of mutual exploration and cooperation. Among their short- and long-term goals are the use of each other's available capacity and specialized facilities, technical and scientific information-sharing, and potentially, the codevelopment of future products and technologies.

Maintaining such long-term, strategic partnerships requires a significant shift in thinking and organizational culture on both sides—from a purely transactional relationship to one of shared planning, shared risk, and collaboration.

This shift requires developing and nurturing a highly cooperative working relationship that incorporates trust, a shared vision, open communication, and a dedication to quality, timeliness, compliance, and continuous improvement.

Risk-based due diligence

Selecting a strategic outsourcing partner goes far beyond a checklist of their capacity, capabilities, and cost. A company should thoroughly assess all of the risks associated with that partnership, develop the appropriate remediation plans and contingencies with the potential partner, and agree to jointly manage those risks to successful outcomes. Conducting a thorough and intelligent risk-based due diligence, performed as a shared exercise with the outsource partner, can identify key areas of uncertainty that need to be addressed. Due diligence can also help align each party's expectations with regard to their relative roles and responsibilities, accountability, and what success looks like for each of the parties involved.

A number of alternative risk- assessment and risk-management methodologies and toolboxes exist. One should be selected that effectively identifies, prioritizes, and helps manage the risks that exist but that also provides an objective and quantifiable output that clearly supports the business case for that outsourcing decision.

Due Diligence Checklist

Key areas to be considered in these risk-based assessments are outlined in the sidebar (see "Due Diligence Checklist").

At the conclusion of the assessment, both the company and potential outsource partner should have a comprehensive profile of the major risks of the overall outsourcing strategy, including those related to time, cost, and deliverables as well as the degree of regulatory, operational, and cultural risk.

The prospective partners can then collaboratively determine the relative priorities of those risks to each party, how those risks will be mitigated, and the contingency plans that will need to be put in place. The time and cost of mitigating each risk and the ROI for doing this must also be carefully considered so that an informed business decision can be made about entering into the relationship.

This risk-based assessment should not be a single undertaking. Conditions change and risks change with them. The evaluation should, therefore, be conducted periodically as a formal part of the business relationship process in order to continue to manage change and uncertainty, assure alignment of the partners with the goals and deliverables of the agreement, and to validate that the work or services being conducted continues to support the strategic supply chain and business strategy.

Establishing and maintaining successful relationships

The success of strategic outsourcing relationships, both in the short and long term, depends upon effective planning and project management, appropriate metrics, successful knowledge transfer, ongoing open communication, and periodic reassessment to help assure the long-term viability and health of these critical business partnerships.

Effective planning begins with the development and execution of the appropriate business and quality agreements that clearly define and specify the relative roles, relationships, specifications, and deliverables that are expected. These include the proper controls and contingencies that may be needed to address any unexpected situations that may arise. Metrics must be established to serve as an early warning system for potential issues and to measure the relative success of the outcomes that are expected. It is also highly recommended that companies establish dedicated resources to manage these relationships as they move to a broader and more strategic sourcing strategy. These dedicated resources should also monitor progress against plans, quality of the deliverables, costs, and other parameters that have been set forth in the business, technical, and quality agreements.

The relationship begins in earnest with complete and reliable IP and knowledge transfer between the sponsor and the contract partner, including effective technical transfer if the outsourcing involves a process to be run or product to be made. Companies that intend to engage in outsourcing need to assure they have an effective information and technology transfer process in place that is formal, efficient, scientifically and technically sound, compliant, cost-effective, and reliable. This is a core competency that consistently produces maximum strategic impact. Too often, however, such transfers are treated as one-off events that are the responsibility of a single function, department, or site, rather than part of a comprehensive transfer framework supported by well-trained and experienced resources on both sides of the agreement. That framework should include the following:

- An overall transfer program management process, including a governance structure, the establishment of executive sponsorship, and the clear delineation of roles and responsibilities, including those of support functions and transfers. In this way, the company can manage its outsourcing transfers as a portfolio and apply risk management techniques to the portfolio as a whole.
- Project-level management for each individual transfer, including a set of requirements, activities, decision points, milestones and best practices that help ensure predictable, on-time transfer that is able to be validated.
- Transfer strategy, including the means to fill any gaps in the organization or the receiving organization, an overall description of the transfer, and measures of success.

Process understanding and control

When a process or product is being transferred, the organization must have the proper level of process understanding and control over that product or process so that it can provide clear, complete, and technically sound specifications to ensure successful transfer.

Elements for achieving process understanding include employing QbD principles and techniques; identifying the appropriate critical-to-quality attributes and associated critical process parameters to limit variability and maximize control; identifying drivers of variation and of interactions in critical processes; and understanding the right process-control strategies.

When older or insufficiently developed processes with a high or uncertain level of variability must be transferred, improved control can usually be obtained retrospectively from conducting a highly structured, statistical analysis of the historic data associated with those processes. Such process capability and control evaluations, if implemented properly, can help achieve an improved level of understanding and control over these older and more variable processes in a relatively short period of time, often in just weeks. The risk of prolonged and costly transfer attempts, or even failure, is thereby, significantly reduced. Achieving process robustness is a critical success factor for right-first-time transfers to outsource partners, as well as successful validation and reliable operation of those transfers.

Sustaining the relationship

Once the operational relationship is under way, the open and honest two-way communications, continued risk assessment, and cooperative problem solving upon which the partnership was first based must continue. This can't be emphasized strongly enough. Too often when outsource providers encounter technical problems or have quality or compliance issues, they tend to conceal those problems from the client while they attempt to resolve the issues on their own. Sooner or later, news of the problem comes to the attention of the client as a sudden and unexpected surprise, with potential negative impact on both the client and outsource partner. What otherwise may have been a minor problem potentially escalates into a major issue, which could have been more effectively managed if the outsource partner had communicated with the client and enlisted their help in a more timely and effective manner. Conversely, clients must keep the outsource provider fully informed of plans that will increase or reduce the volume and level of services that will be required so they can plan their resources and capacity accordingly.

Finally, continue to assess the strategic outsourcing strategy at regular intervals to assure continued alignment with the strategic business goals of the company, the strategic supply chain strategy, as well as with changing patient needs and market conditions. Conduct a regular re-assessment of the performance history and potential risk at each of the partners along with a re-assessment of the entire outsourcing portfolio. This will help assure the continued success of those partnerships, the identification and remediation of any new risks that may arise, and also help to identify additional opportunities for strategic outsourcing as your company continues to evolve and grow.

Questions to be asked during re-assessments include:

- What are the highest-priority and highest-ROI opportunities for additional outsourcing that will support manufacture of our current products, introduction of future products, and overall strategic business plan?
- Are there some outsourced projects that should be brought back in house?
- Has there been a shift in any of our core competencies, technologies, or internal capacity to support our current and upcoming products?
- Has there been a shift in our company's strategic business or supply chain plans as a result of changing competition, patient, or market conditions?
- What are the relative priorities, timing, costs, risks, competitive advantages, and ROI of making a change in our current outsourcing strategy? What if the change isn't made?

The bottom line is that today's outsourcing decisions should be thought of as potential long-term strategic partnerships in support of an overall strategic supply chain strategy, and aligned closely with the business goals of the company. Decisions should be based on a solid business case, technical, and quality foundation that is further supported by a robust risk-based assessment and management methodology. Only then can the most important requirement of all on both sides of the relationship be fulfilled, thereby protecting and enhancing shareholder value.