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Driving the *Next Wave* of Biopharmaceutical Competitiveness

by Michael H. Thomas, Julian Millstein, and Ram Iyer

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In a competitive environment, biotech companies need the agility that enterprisewide outsourcing can provide. But making the strategy successful requires executive skill.

The complex array of drag forces affecting the biopharmaceutical industry requires companies to make radical adjustments to maintain and improve their competitive fitness—even to ensure their business survival. Companies need to become first-movers that are more adept and agile at reaping returns while managing risk. They will have to adopt wider outsourcing scope to encompass enterprisewide business process outsourcing.

Biopharmaceutical companies already have significant experience with outsourcing for clinical, R&D, and manufacturing processes, but they have little experience in enterprisewide outsourcing. Their outsourcing focus has been largely tactical—focused on a limited set of discrete processes. Moreover, supplier management experience in the industry is generally limited to a small and select group of preferred providers, rather than a larger, global network. Frequently, management is guided by a mentality of purchasing commodities from suppliers, rather than building and nurturing partnerships.

CxOs DRIVE SUCCESS

The success of outsourcing is pivotal to the fortunes of biopharma companies. Wider outsourcing, with attendant greater risk, produces greater returns. But despite outsourcing's huge potential, more than half of all

outsourcing projects fail to meet significant expectations. Nearly 25% of them fail in the first year, producing painful negative effects such as higher project costs, longer times to market, blockage in product pipelines, and loss of business continuity.

Key people in underperforming projects are often caught up in everyday tasks and do not see the classic danger signs of impending failure. Sometimes they know that there is a problem but lack the skills, knowledge, time, resources, or authority to take necessary remedial actions. Most important, they don't want to be seen seeking expert help.

The prescription for success may lie with the CxOs (anyone in an executive role—CEO, COO, CFO, CIO, VP sourcing, and so on) because achieving business goals is their paramount concern. Therefore, CxOs can and should drive outsourcing that successfully meets business goals. Executives have a more expansive view of the business, greater authority, and access to more resources. And they have a personal stake in the business outcome of outsourcing projects.

CxOs need to know the signs to watch for to exploit an opportunity or accomplish a turnaround. However, given their expansive role and the nuances of outsourcing, even experienced CxOs sometimes fail to recognize the signs or lack the expertise to turn projects around.

This article examines the essential role of outsourcing to the future of the

biopharmaceutical industry and explains how to obtain its full benefits. It also examines the warning signs of outsourcing failures and specific steps CxOs can take to turn around troubled or failed outsourcing initiatives.

ESSENTIAL STRATEGY

Effective outsourcing is becoming the weapon of choice to counter the increasing pace of global competition, shrinking profit margins, growing regulatory and compliance burdens, and rising drug discovery costs in the global biopharmaceutical industry. Outsourcing delivers cost savings, efficiencies, and market agility; faster product development; lower capital investment; and even company transformation.

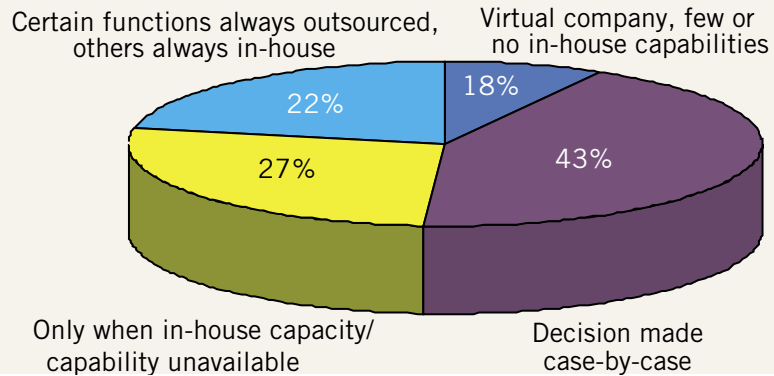
A report published in December 2004 by the Pharma Futures Working Group (www.pharmafutures.org) declares that sweeping, fundamental change in the biopharmaceutical industry is inevitable. Pharma Futures—a collaborative project of leading biopharmaceutical company executives, major institutional investors, analysts, and industry experts—assessed both opportunities and threats facing the industry through 2015. The authors of the study noted, “The industry faces a period of transition that requires a step change to more adaptive, flexible, and open-minded leadership. . . . There is an erosion of investor confidence in the sector’s ability to deliver sustainable long-term shareholder value.”

The most compelling finding in their analysis was that biopharmaceutical companies must now *accept* and actively *manage* the risks and benefits of becoming first movers in adopting new ways of doing business. That adjustment will require companies to repudiate the late adaptor’s mindset, which is cautious, risk-averse, and seeks to mimic more innovative competitors.

TRANSITION TO STRATEGIC OUTSOURCING

Biopharmaceutical companies urgently need to work with external partners to compress the drug development timeline, decrease costs, comply with a growing body of rules and regulations,

WHAT IS YOUR POLICY ON OUTSOURCING?



Source: 2004 Outsourcing Survey, *Growing Demand for Services and Performance. Outsourcing Resources for the Pharmaceutical Industry 2004*, supplement to *Pharm Tech*, 28 2004: 14–28.

BETTER BUSINESS CONTROL WITH OUTSOURCING

CONTROL POINTS	< LOSE	GAIN >	
Implementation of Ideas	-14	+33	↑ STRATEGIC ↓ INPUT-RELATED
Variability of Costs	-19	+38	
Reductions in Spending	-16	+39	
Ability to Plan	-12	+47	
Reliability	-19	+49	
Revenue	-10	+32	
Business Outcomes	-7	+37	
Employees	-27	+23	↓ INPUT-RELATED
Headcount	-26	+27	
Salaries	-25	+22	
Hire/Fire Decisions	-25	+20	
Promotions	-28	+12	

PERCENTAGE OF RESPONDENTS

Source: Accenture. *Gaining Control Through Business Process Outsourcing* November 2003.

and achieve faster innovation and market agility. *Enterprisewide outsourcing* that transcends limited clinical and manufacturing processes is the tool that can deliver solutions to these challenges.

Mark E. Kolb, chair and CEO of Taratec Development Corporation (www.taratec.com), a regulatory compliance consultancy, agrees that the industry needs to move from tactical to strategic outsourcing. “We are currently engaged with a few senior pharmaceutical executives who truly understand the importance of this strategic approach,” he says. “They are among the ‘early adopter’ companies that address compliance challenges by implementing solutions on an enterprisewide, strategic basis. Working with an outsourcing partner, they

develop solutions that cross business units, leverage lessons learned, and ultimately drive quality across the drug development lifecycle.”

The findings of the 2004 annual *PharmSource Bio/Pharmaceutical Technology Outsourcing Survey* (<http://asp.pharmsource.com>) suggests that by early 2005, almost 42% of all drug development outlays will, in some way, be pledged to outsourcing, compared with only four percent in the mid-1990s. Although the scale of outsourcing is growing in this industry, increases in the *scope* of outsourced functions have been minimal. The dominant share of outsourcing has been limited to clinical and manufacturing processes and does not encompass broader *business* functions such as finance and accounting,

PROBLEM: STRUCTURAL ISSUES

CxO'S SOLUTION:

IMPLEMENT THE RIGHT
FRAMEWORK WITH EXPERT GUIDANCE.

EARLY WARNING SIGNS



- Only one person knows vital details of all project components.
- No change-management plan is in place; or the existing plan isn't working.
- Incentives for internal/external project staff aren't aligned with business objectives.
- Senior management lacks interest and commitment.

EXAMPLES



- Vendor takes over already unstable or flawed process.
- Outsourcing project is an island, not integrated into business objectives or functions of business unit or company.
- Governance structure has gaps and/or is managed by inexperienced and unqualified staff.

PROBLEM: CONTRACTUAL ISSUES

CxO'S SOLUTION:

ENSURE THAT CONTRACT MEETS YOUR
BUSINESS NEEDS, NOT JUST THE PROJECT NEEDS.

EARLY WARNING SIGNS



- Vendors are not closely monitored.
- Contract business objectives are limited to single project.
- Confrontational relationship shows a pattern of escalating disputes.
- Contract is treated as a legal document (not a business document) and handed off to lawyers

EXAMPLES



- Either party thinks it got a good deal.
- Scope definition is too wide or too narrow.
- Inflexible contract doesn't allow for changing business needs.
- Exclusive dependence on SLAs (which don't exclusively assure quality).
- There are inadequate benchmarking or benchmarking errors.

human resources, transaction processing, customer service, and so on. Fully 43% of respondents reported that outsourcing decisions are made case by case, lacking any kind of strategic drivers. (See "What Is Your Policy on Outsourcing?")

In a 2003 survey by Accenture (www.accenture.com), 53% of respondents reported that outsourcing permits them to "implement strategies and manage change at a faster and more controlled rate." Although more than half of the executives surveyed recognized this strategic benefit, their companies outsource a very small set of business processes—a paradox that indicates a late adopter's mindset. (See "Better Business Control Through Outsourcing.")

Jim Miller, president of PharmSource Information Services and publisher of the *Bio/Pharmaceutical Outsourcing Report*,

noted in the August 2002 issue of *BioPharm Outsourcing Outlook*, "In business today, one fact has become clear: The ability to forge, manage, and sustain strategic outsourcing relationships is increasingly critical to competitive success. Such relationships, however, are often handled ad hoc, using trial-and-error methods. Pharmaceutical companies can, and must, take a more planned approach."

Of equal importance is the corollary to his conclusion—that outsourcing, in practice, must be *successful* if it is to yield the critical benefits. However, assuring peak performance—and avoiding poor performance or outright failure—requires a high quotient of outsourcing competency not commonly found in most biopharmaceutical companies, even among CxOs. The use of skilled advisors offsets this deficiency and dramatically increases outsourcing success. Specialists in

the disciplines of outsourcing know where problems usually appear and how to solve them, so they can help companies reap the full benefits of outsourcing.

A 2004 joint survey of outsourcing by the International Association of Contract & Commercial Managers (IACCM, www.iaccm.com) and Argea found two simple things. First, companies of different sizes and from different industries repeatedly made the very same mistakes. They are not learning from each other's outsourcing errors. Also, companies with greater experience in outsourcing were much less likely to have problems than those that were new to outsourcing.

Those two findings identify a key problem with outsourcing today: Companies are learning by doing, often through costly trial and error. They are not learning from others or seeking skilled help to avoid common and repeated mistakes.

High Failure Risks: A Gartner Group (www4.gartner.com) study released in 2003 predicted that half of the year's outsourcing projects would fail to deliver on bottom-line promises. In 2004, Meta Group (www.metagroup.com/us/home.do) reported research that showed "80% of organizations have suffered from problems ranging from time and cost overruns to nonadherence to specifications and requirements when outsourcing."

Although many companies are naturally averse to publicizing disappointments or setbacks, the corroborative evidence is clear on this point: Many companies have experienced—and will experience—substantial difficulties in successful transition, implementation, and management in outsourcing.

FIVE CLASSIC FAILINGS

Outsourcing deals fail for many reasons, but the root causes can be organized into five categories: problems with structure, contract, vendor, relationships, and execution. However, two reasons for failure are fundamental across all categories.

First, company management may not recognize that outsourcing is a new way of doing business. Complex

outsourcing relationships require alliance management skills in addition to subject matter knowledge. Grooming or hiring an experienced relationship management team is the most essential element of successful outsourcing.

The second common underlying source of failure is mismatched expectations between company and vendor. Brian Maloney, former COO of Perot Systems and a veteran of many outsourcing projects says, "Assessing an underperforming or failing project must be a straightforward examination of reality without emotions—from the company's perspective and the vendor's perspective—in order to decide on whether to repair or replace."

Structural flaws stem from both unrealistic expectations and a process and structure that has—or hasn't—been put in place. (See "Problem: Structural Issues.") For example, management may harbor unrealistic expectations about how soon cost savings will be realized.


Classic warning signs appear when the best talent is not deployed on outsourcing projects or an executive's performance is not linked to that of an outsourcing project. In another common scenario, one individual holds the project together. Have you ever heard something like this? "If John leaves, this project will fall apart." That indicates a dangerous lack of structure and process.

Outsourcing has been done in various industries with varying levels of success. Many people involved in those efforts have migrated to other sectors and companies. People with experience in small outsourcing projects—or with a small role in a large outsourcing effort—are often made into outsourcing "gurus." Although some of them succeed, many fail. Their failure gives outsourcing a bad name and makes management hesitant to embark on new outsourcing projects.


The contract embodies all that has been discussed until the deal is signed. (See "Problem: Contractual Issues.") Many clients file it away permanently, and vendors who have been squeezed on business terms live by it to exact every change order they can get. The

PROBLEM: VENDOR ISSUES

CxO'S SOLUTION: OBJECTIVELY DIAGNOSE ALL ISSUES AND REACH A NEGOTIATED SOLUTION.

EARLY WARNING SIGNS 


- Uncommunicative or unresponsive vendor
- High vendor staff/management turnover—the A-team is gone
- Frequent vendor change orders

EXAMPLES 


- Vendor staff lack strong project management skills or experience.
- Transition to vendor was rushed, with no transition plan or ownership.
- Vendor is running up losses on the contract.

PROBLEM: RELATIONSHIP ISSUES

CxO'S SOLUTION: IMPROVE COMMUNICATIONS AND REDEFINE ROLES AND RESPONSIBILITIES.

EARLY WARNING SIGNS 

- Responsibility for relationship success is not shared (unequal burdens).
- Cultural/business culture issues are affecting communications, quality, and/or timetables.
- Vendor has a harvesting mentality.
- The contract, not business need, is the guiding force in the relationship.

EXAMPLES 

- No vendor/client equivalency (vendor is too large/small for client)
- Adversarial service relationship (vendor expected to agree to any and all demands)
- Provision of service treated as a commodity by vendor

contract needs to be a "live document" that is flexible.

If your project manager has not read the contract in detail (or does not know where it is), and your vendor's project manager pulls out the contract every time you ask him to do something, it's time to examine the contract.

Vendor Conflicts: In the early stages of outsourcing, many vendors were "trained" by companies who wanted to leverage lower costs. Those vendors tend to do the "fresher switch," replacing experienced personnel with "freshers" to save costs or to work them into new clients or projects.

If a vendor is more concerned about what the contract says it needs to do—rather than what you need—you have vendor issues. If new faces are showing up on your project (onsite or offsite) or the vendor is deploying "tiger teams" to get a project back on track, you have serious vendor issues.

Relationship Management: Outsourcing is a new way of doing business, which requires reliance on an external vendor and potentially threatening the job security of your

in-house employees. (See "Problem: Relationship Issues.") A good change management plan needs to be in place to communicate with employees and get buy-in from key people. When the talk about an outsourcing initiative at the water-cooler is predominantly negative, your star employees are quitting the company, or your project team is doing its own thing (failing to leverage vendor capabilities), it is time to examine people issues.

Implementation failures may arise from failures of the client or vendor—or both. (See "Problem: Execution Issues.") Vendors and clients can create implementation failures when they lack the right resources or delivery capacity to execute a project. Outsourcing readiness assessments—to ensure that the right framework is in place—can ensure outsourcing success.

Poor transitioning and vendor monitoring can lead to missed early warning signs of impending trouble. In the IACCM survey, supplier monitoring was identified as the most important issue for ensuring implementation success. Most important,

PROBLEM: EXECUTION ISSUES

CxO's SOLUTION:

LEVERAGE EXPERIENCED OUTSOURCING PRACTITIONERS TO QUICKLY ACHIEVE TURNAROUND.

EARLY WARNING SIGNS



- Poor transition planning
- Missed SLAs and/or reduction in service levels
- Budget overruns in project
- Vendor/client audits fail to identify and fix problems.

EXAMPLES



- Failure by either party to follow change control process
- No client exit strategy or contingency plan
- Vendor and/or client lacks required skills, resources, or capacity to fulfill responsibilities or expectations.
- Client audits service provider infrequently, or rarely meets with vendor managers.

packages are CXO Systems (www.cxosystems.com) and Digital Fuel (www.digitalfuel.com).

TURNING AROUND

At the outset, companies must adopt and promote a strategic view. Remember that the primary goal is to fix a problem—not create new ones. Objectives must be clear, and everyone must fully agree and align with remedial actions. Measure and reward what is important from a business-success point of view. If you have done a proper root-cause analysis, the gaps in delivery, monitoring, measurement, communication, and expectations will stand out in stark relief.

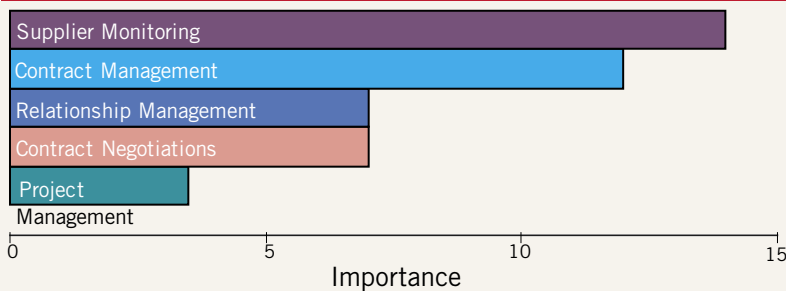
Factors critical to final success include:

- Unqualified executive commitment and support
- Leadership and flexibility from key project staff
- Transparent and effective channels for knowledge transfer
- Use of only proven project management tools and best practices
- Constant and clear communication among all stakeholders in the outsourcing chain to prevent conflicting expectations
- Vendor–client equivalency
- Shared responsibility between vendor and client for outsourcing success.

Executive Commitment: In companies that have underperforming projects, the most common characteristic is denial. In some cases, project owners do not recognize that problems exist, even though the data say otherwise—and the word is out on the street. In other cases, project owners are unwilling to bring in experienced practitioners because it is a tacit admission of their own inability to fix the situation. In a few cases, management has felt that the added expense of bringing in experienced practitioners would blow their business case—even though inaction was eroding it already.

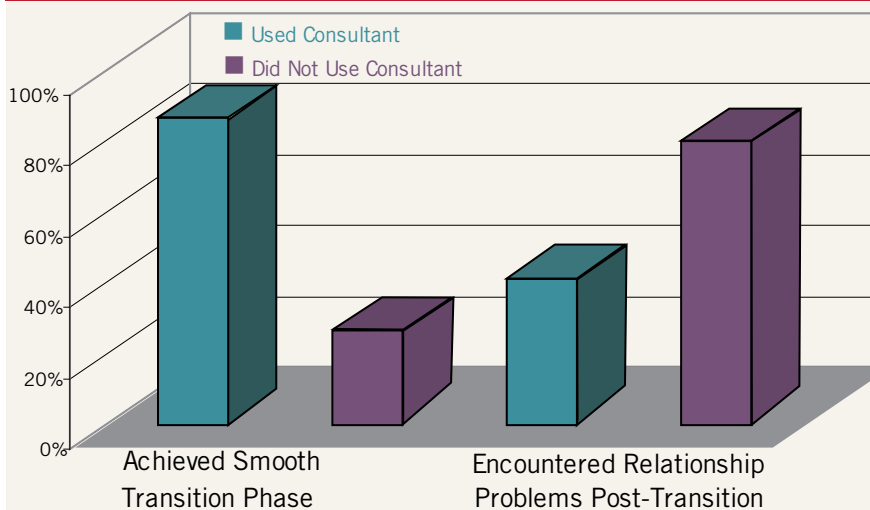
Leverage Experience: Companies are making the same mistakes because they fail to leverage external knowledge and outsourcing experience adequately. Using experienced

PERCEIVED IMPORTANCE OF OUTSOURCING EXPERTISE



Source: IACCM/Argea Outsourcing Survey 2004

EFFECTS OF SKILLED ADVISORS ON OUTSOURCING SUCCESS



Source: Outsourcing Center, *Outsourcing Journal*, November 2003

many companies know what to do but do not have the personnel to do it. (See “Perceived Importance of Outsourcing Expertise.”)

If the personnel involved cannot explain why a project is behind schedule, over budget, or not delivering the


expected results, it could be due to a lack of monitoring data: a critical early warning of impending problems. Many governance structures and software packages could be implemented to provide such early warning. Two places to start looking for such

practitioners—for assessment, improvement, a turnaround plan, or short-term operational advice—will produce quick results. (See “Effects of Skilled Advisors on Outsourcing Success.”)

GETTING IT RIGHT

Outsourcing, done right, offers a powerful model to build a global network of vendors and partners—for greater agility, flexibility, and access to specialized skills. Abandoning troubled projects may cause companies to completely forsake the advantages that successful outsourcing can deliver.

It takes experienced outsourcing practitioners to help diagnose the root causes of troubled projects and execute a plan to “turn the dirt into gold.” Such expert assistance can make the difference between abject failure and substantial, sustainable business advantage.

In the biopharmaceutical industry, success will be driven by becoming an early adopter. CxOs are in the best position to be change drivers and ensure their companies’ viability in a period of unprecedented change and challenge. 

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