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Best Practices in Managing Contract Manufacturing Partnerships

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Pharmaceutical manufacturers are outsourcing more critical functions to contract manufacturing organizations. How are they monitoring quality and performance, and what are the best practices for communication and knowledge transfer?

This reference examines current and best practices, offering insights from regulators, consultants and our magazine. We hope that you find it useful.

CMO MANAGEMENT:

Do We Have a Failure to Communicate

Are you managing your CMOs or are they managing you?

By Agnes Shanley, Editor in Chief

As competitive pressures increase, nothing can stop the pharmaceutical outsourcing juggernaut. What started off as a "back office" practice for business, IT, HR and real estate management has become well established in manufacturing, and the use of outsourcing continues to grow in other strategic functions, including R&D and clinical.

Developing an accurate assessment of the pharmaceutical outsourcing market's size is nearly impossible, says Nigel Walker, managing director of That's Nice, LLC (New York, N.Y.) whose Nice Insight market research program studies the evolving contract pharmaceutical services market closely.

First, a wide range of companies offer services from tiny, privately held and extremely niched players to generic drug manufacturers and even big pharma companies.

The market research company Frost & Sullivan estimates that the pharmaceutical contract services market is roughly $10.7 billion in the United States alone, and growing by roughly 10% per year[1].

While pharmaceutical manufacturing and development outsourcing has increased, so have pharmaceuti-

cal recalls and other regulatory issues including 483s and consent decrees (Figure 1, next page).

Observers say this parallel growth is no coincidence. Over the past five years, McKinsey & Co. consultants have found there has been a 16%/yr increase in pharmaceutical recalls that can be directly traced to quality failures on the part of suppliers or contract partners.

Paradoxically, operating pharmaceutical companies say that quality is the top reason they select a contract partner. CMO's ability to comply with regulatory requirements is another one of their CMO top selection criteria.[2, 3]

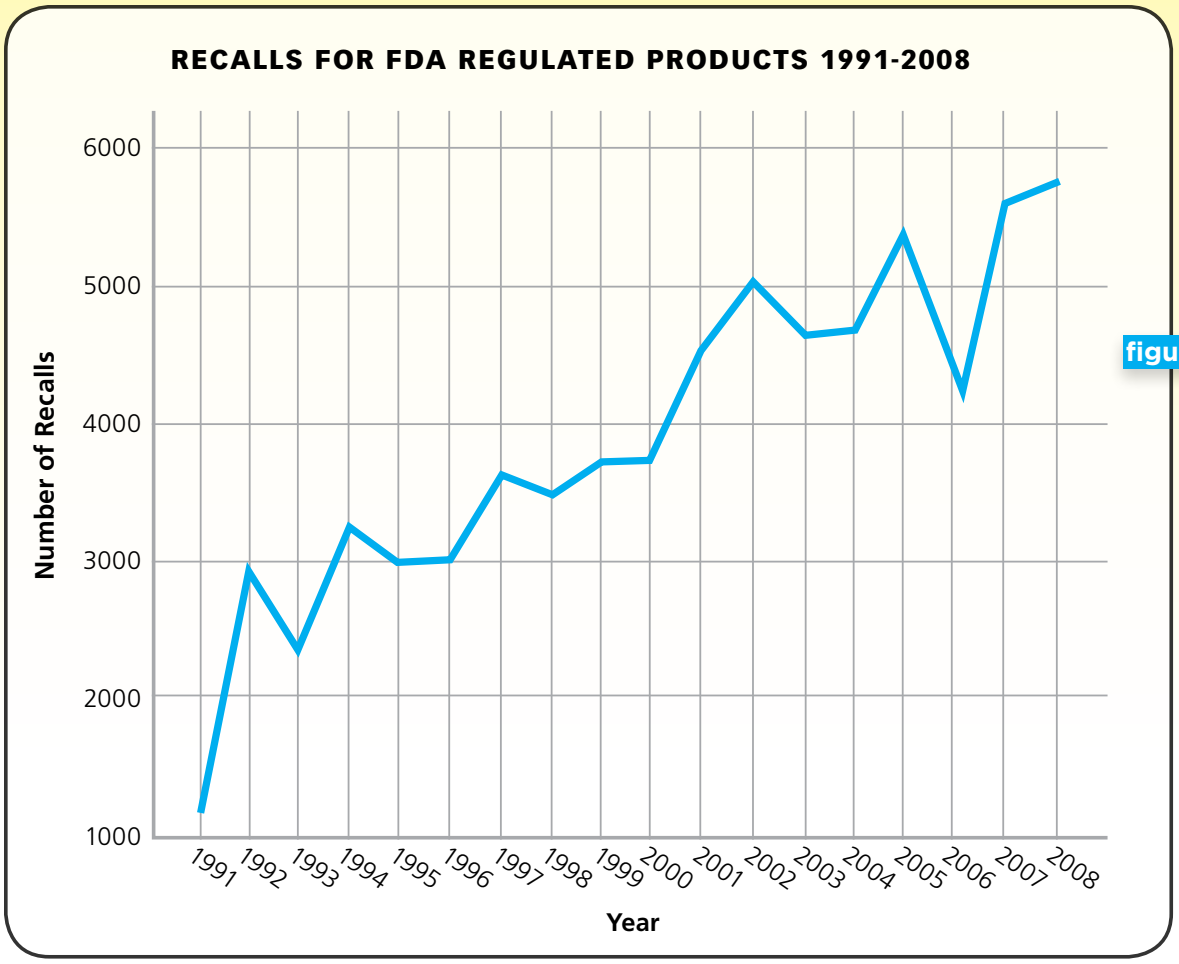


figure 1

Michael Long, from FDA data

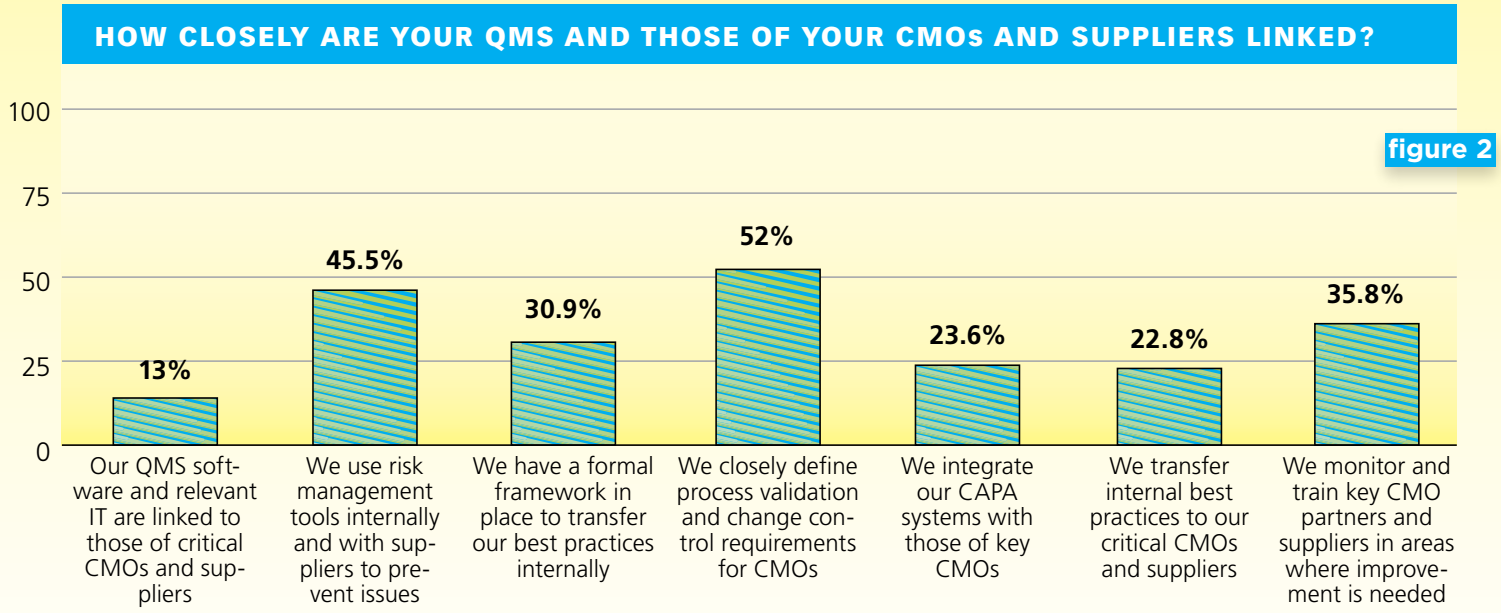
Regulators continue to emphasize the need for better risk management. "There has been an evidentiary shift that places the burden on the industry to prove appropriate levels of risk management," says Michael Long, director of consulting services for ValSource, Inc.

In the future, he says, pharma supply chains may more closely resemble those of the automotive industry, with Tier 1 and 2 suppliers. However, in the short term, Long says, expect more questions from regulators surrounding risk management, product and process knowledge, he says[4]. Not only regulators, but observers and experts within the industry are calling for much stronger outsourcing governance[5]. The subject is complex, touching on risk management, staffing, training, tech transfer and communications. Are drug manufacturers ready for the challenge?

In this article, two industry experts comment on the issues playing out right now, and suggest best practices. The article also examines results of a recent reader survey, which sheds some light on how drug manufacturers are responding to the challenges of contract supplier oversight.

RISK MANAGEMENT 101

Clearly, many are at an early stage in developing risk management strate-



gies. "Even though ICH Q9 was published six years ago, drug manufacturers are just starting to find their footing in the areas of risk management, quality by design and quality systems," said Long. Their progress, he says, depends on how advanced they are in applying risk management tools and concepts.

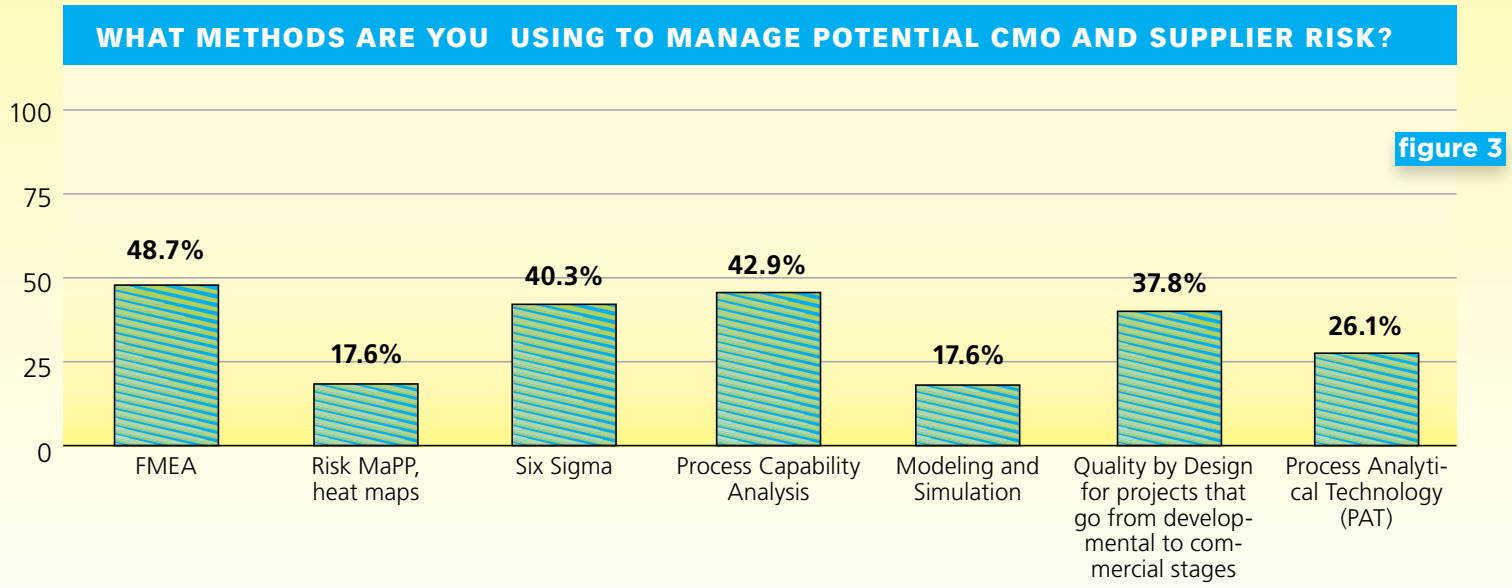
"If you do not have an adequate quality system in place, with adequate controls, all the product and process development, and the process understanding in the world, may go to waste," he told attendees at PDA's annual meeting earlier this year in Phoenix.

In addition, he says, some professionals have fundamentally misunderstood the concept of a 'risk-based approach," Long says. "It is not a gift card for reducing testing and other precautions," he said. "Instead, it requires a balance between identifiying and mitigating threats, while taking advantage of opportunities. It should never become a hammer in search of a nail, and all systems must be evaluated if it is to be robust."

Managing contract manufacturers requires asking two key questions, according to Hedley Rees, consultant and founder of the U.K.-based consultancy, Biotech PharmaFlow, who established and chairs the Drug Industry Modernization group on LinkedIn and whose extensive book on optimizing pharmaceutical supply chain management was published two years ago[6]:

1) Do I understand the extent of my obligations to manage my CMOs?
2) Have I the right processes in place to deliver on those obligations?

All manufacture and testing carried out at third parties must be treated as if they were carried out by the drug manufacturer itself, Rees says, and the working supply chain must comply to regulations at every stage. This means:



- Investigating out-of-specification results and appropriate (root cause) corrective and preventive actions

- Examining complaints handling processes

- Reviewing technical documentation and ensuring that it is approved by suitably knowledgeable and qualified personnel

- Ensuring that supply and quality agreements are worded to provide maximum alignment between standard operating procedures (SOPs) across organizational boundaries.

"Contracts must closely spell out such widely ranging activities as corrective and preventive action (CAPA), technology transfer, operation of interfacing quality systems, specific mitigations emerging for risk assessments as well as newer approaches, such as the adoption of a pharmaceutical Quality by Design (QbD)approach," Rees says.

"If your contract did not spell out alignment, it may not happen."

The best approach, he says, is to view outsourcing as a specific case of procurement, and to remember that it is a strategic, organizational function. Rees urges the following:

1) Identify and involve all stakeholders in the outsourcing process from the start, and do not leave key issues to either the procurement department or the CMC group.

2) Beware of checklist Quality Agreements based on legal boilerplate. The commercial and technical terms for the agreements (Supply and Quality) must form part of the tender and the pre-contractual negotiations. Terms should be based on the practical ways you will work together to meet your mutual obligations.

3) Remember that power shifts after contracts are signed, especially if you are entering a single-provider

arrangement. If anything important is left out of the contract, such as the requirement that certain information be provided by the contract company on a regular basis, that requirement must be explicity written into the contract.

HOW ARE WE DOING?

Is the typical pharmaceutical manufacturer developing the right approach to CMO management? *Pharmaceutical Manufacturing* surveyed readers to get a snapshot of contract partner management practices. Over 173 industry professionals responded to the survey, results of which are highlighted below. (For more information, check www.pharmamanufacturing.com.)

When asked how closely they synchronized their internal quality systems with those of CMOs and suppliers (Figure 2), 64% of respondents said they defined process validation and change control requirements closely for their CMOs; 46% said they used risk management tools internally and with suppliers.

In addition, 36% said they monitored and trained CMO partners in areas where improvement was needed, and 31% described having a knowledge transfer process available to transfer internal best practices to their contract partners. Twenty-four percent said they had integrated CAPA systems with those of their suppliers.

Fewer respondents are using technology to facilitate connection to CMOs; 13% said they had connected QMS and other IT platforms to those of conract partners and suppliers.

DO YOU HAVE A FORMAL PROCESS IN PLACE FOR CONTINUOUSLY MONITORING THE SOURCE AND QUALITY OF RAW MATERIALS BOUGHT BY CMOs AND SUPPLIERS, THAT ARE CRITICAL TO YOUR PRODUCT'S QUALITY?

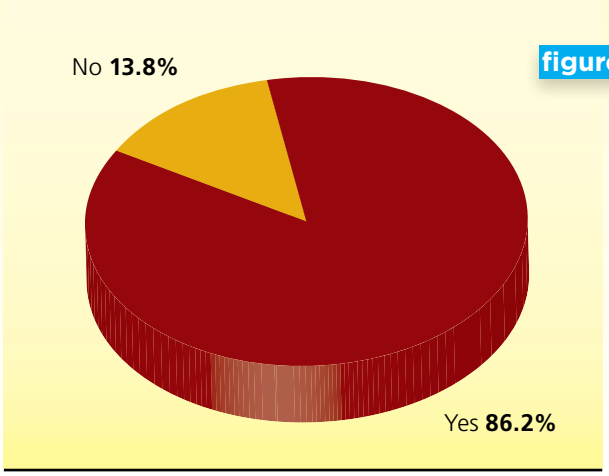
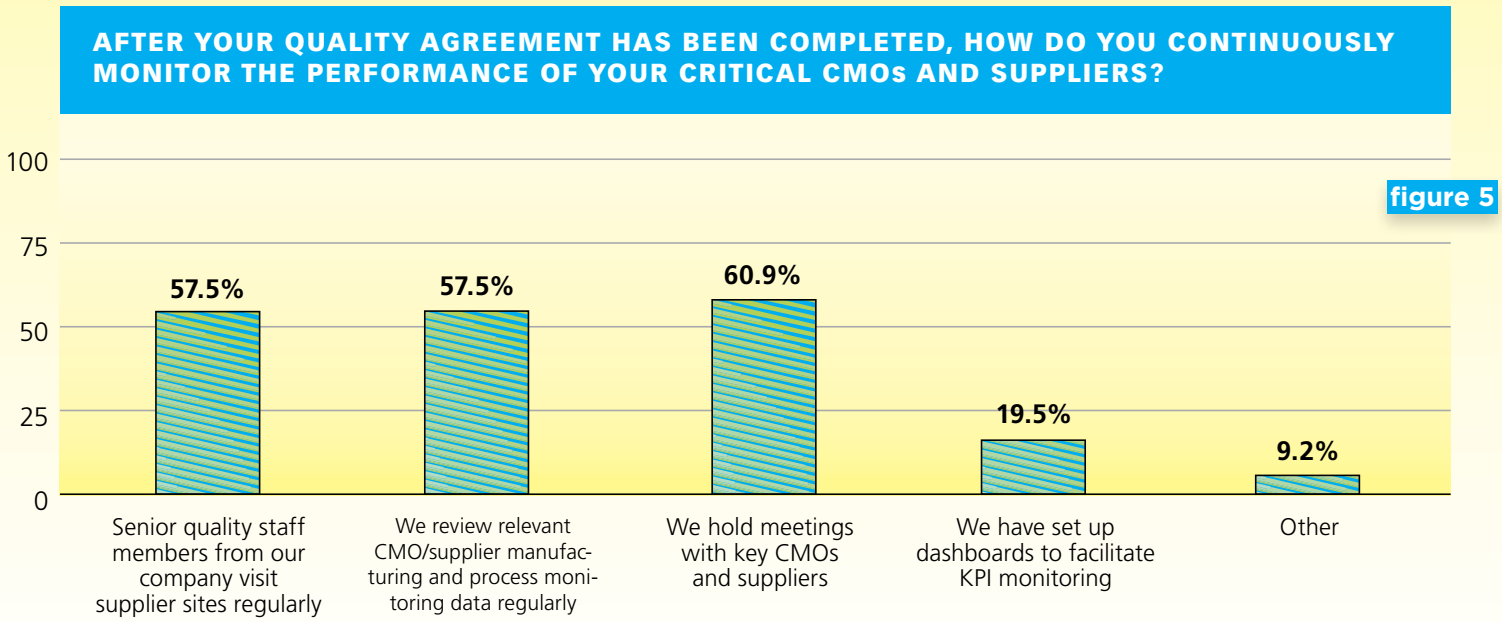


figure 4

As far as specific risk management tool kits and methods are concerned (Figure 3), 49% of respondents said they were using failure modes and effect analysis (FMEA), 43% are using process capability analysis, 40% are using Six Sigma, 38% say they use QbD, and 36% report using process analytical technology (PAT).

Eighty-six percent of respondents said they have a formal process in place to monitor the source and quality of raw materials critical to product quality bought by suppliers (Figure 4). The remainder did not.

On the positive side, most respondents to the survey said they have a system in place for monitoring the quality performance of critical CMOs and suppliers. Sixty-one percent said they hold regular meetings with contract partners, 58% send senior quality staffers to visit supplier sites, 58% say they re-



view relevant manufacturing and process monitoring data regularly; and 20% have set up dashboards to monitor KPIs for contract partners.

When asked to define their biggest challenges in managing CMOs, most respondents (30%) cited knowledge transfer; 24%, process validation; and an equal number, change control. In addition, 23% said that risk management was their top challenge; 21% reported monitoring; 15%, CAPA coordination; and 14% tech transfer. "Someone always seems to be asleep at the switch," wrote one. Another described high attrition rates at smaller CMOs, with poor knowledge transfer the result.

"If you don't have a quality and technical rep on site for each batch produced at a CMO, there are items that don't get documented at the same time, so resulting deviations aren't always documented efficiently."

Among other issues respondents cited:

- A lot of manufacturing and quality data for CMOs can only be seen during on-site visits
- CMOs need to prevent process drift and poor decisions by management
- Insufficient knowledge of CMC issues
- Wrote one respondent, "It can be difficult to ask informational questions from most of our suppliers. They are reluctant to provide helpful information for fear of incriminating their own products."

Other respondents noted that, given limited internal resources, it was becoming more difficult to maintain close and meaningful contact with suppliers. Said another, "review of documentation alone does not provide a full picture of actual performance."

HOW FREQUENTLY DO YOU FORMALLY CONNECT WITH YOUR KEY CMOs AND SUPPLIERS TO VERIFY THEIR PERFORMANCE AND QUALITY MANAGEMENT?

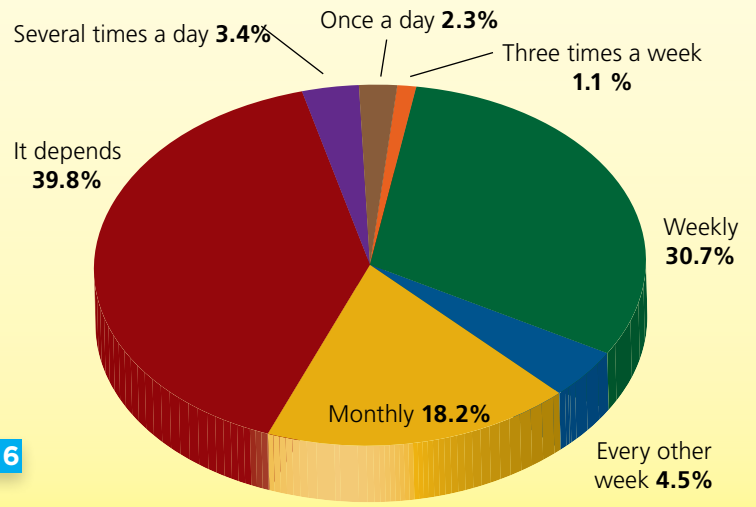


figure 6

COMMUNICATION AND KNOWLEDGE TRANSFER

Communication, or the lack of it, has clearly become a factor in the overall CMO management picture. In the survey, 5% of respondents describe communicating with key contract partners at least once a day; 31%, weekly; 18% monthly; but 40% answered with a vague "it depends."

Relatively infrequent communication would appear to conflict with the stated goal of better managing knowledge and tech transfer, said Long.

Pharmaceutical operating companies often fail to communicate adequately to their CMOs, as contract manufacturing companies reported in BioPlan's ninth annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production[7]. Eighty-six percent of the CMO professionals who responded complained that biopharm clients didn't build in enough time for projects, or communicate effectively, while 83% said they didn't plan their tech transfer process or recognize variability in process development.

Another complaint? 67% said that clients just "handed off a project" without planning for ongoing interactions. Some CMO respondents said their clients did not adequately use QA and QC expertise and expected CMOs to make regulatory decisions for them.

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SUPPLY CHAIN MANAGEMENT IN THE DRUG INDUSTRY: **Delivering Patient Value for Pharmaceuticals and Biologics**

by Hedley Rees

Excerpted from Chapter 9 (pp 201-206), with the permission of J Wiley & Sons

There are two main rationales for outsourcing:

1. The company does not have the resources to maintain an in-house capability to perform the necessary activities.

2. The company believes that the core competencies required could be carried out more effectively by an experienced third party. This is typically called a make vs. buy decision.

The first rationale is obviously not always a choice. Many SMEs (biotech/virtual companies in pharma) cannot afford to set up their own facilities, other than to provide office space and pay wages to core staff. Outsourcing is a way of life in these cases, and effective procurement practices are critical to success.

As learned earlier, the growth of SMEs in pharma development was facilitated by the availability of third-party service providers, which in turn drove demand for the services. This has been an ongoing spiral ever since. Below is an extract from my Biotech PharmaFlow website, which explains further.

For many biotech and emerging pharma companies intent on getting into the clinic, or indeed carrying on to commercial supply, outsourcing is the only feasible option given the need to conserve cash. Often and perversely, skills and experience of the laws of commercial exchange are not regarded as high priority, even though vast sums of money may be spent with third parties. Not only that, but the third parties need to be managed in a relationship where the balance of power shifts dramatically

pre and post contract. Ignore that at your peril!

It is now becoming increasingly recognized that procurement of outsourced services is a vital cross-functional process (not a function called "procurement") with a lifecycle that covers definition of need, supplier selection, terms of agreement and payment completion. Involvement of the appropriate people at each stage is of fundamental importance. This process is not rocket science, can be applied using structured tools and techniques, and can be adopted across the organization for maximum impact on "value for money."

If a company outsources major operational activities such as clinical trials, manufacture, logistics services, etc., these will likely have a significant effect on financial statements. The company's procurement processes are a large contributor to internal controls. The following questions are relevant to ask:

- How are outsourced services and materials being controlled through the lifecycle?
- What controls are there on consumption and movement of inventory?
- What controls are in place at the contractor's subcontractors?
- Do contracts reflect the need for higher levels of audit access?
- Do you have a register of all third parties subject to corporate governance?
- Are legal, finance, purchasing, internal audit and end-users all on the same page?
- Is information being supplied by third parties accurately and appropriately?

You may well have this all under control, but it may be worth checking again.

It should be clear that I am sounding a warning bell to those who are not professionally prepared for outsourcing. It should also set the scene for later examination of some of the challenges of outsourcing once the second case has been identified. In the second case above, the make vs. buy decision, the buying company has a choice.

Is it more beneficial to carry out the activities internally or to pass them on to more qualified companies that can spread their costs over a number of clients? This is a very important choice and, as always, should be considered in the light of sustainable competitive advantage. It should therefore be implicit in the analysis that competitive advantage is better served by using a third-party provider, through either lower costs or increased value. The sustainable element means that the outsourcing arrangement must con-

tinue to deliver the intended benefits during and following implementation. Sadly, this understanding is often absent in many cost-driven initiatives to outsource. As an example, a company outsourcing on the basis of cost improvement must be clear that the revenue-earning potential is not affected adversely because the service becomes "commoditized." This may well have been the case in the financial services sector during the mass offshoring of call center services (certainly from the customer's viewpoint).

Many of the organizations involved have reverted to previous in-house arrangements at the behest of frustrated customers. There are also examples closer to home where outsourced arrangements have not delivered the anticipated benefits.

So how should companies with a choice make decisions on outsourcing? There is a very simple answer. If the service is critical to a business's strategy toward competitive advantage in chosen markets, it should not be outsourced.

As always, it seems to be the case that there are very clear areas at the extremes of business activities. The answer here is normally unambiguous.

Janitorial services are clearly obvious candidates, and product design teams are unlikely to be outsourced. In between, the choice becomes more challenging, and only the companies themselves can decide after careful consideration of their circumstances. There is, however, one golden guideline that I would like to propose: If a practical and enforceable contract cannot be devised that allows the outsourcing company to respond flexibly and cost-effectively to business pressures for change, it is a doubtful candidate for outsourcing.

9.5.2 NATURE AND CHALLENGE OF OUTSOURCED RELATIONSHIPS

An important consideration for outsourcing is the nature of the relationship involved compared to a traditional in-house approach. These are fundamentally contractual relationships and so are defined by preagreed terms set out in a contract. Although the supplying company may be willing to accommodate alternative arrangements, there is no obligation to do so. Any attempts at coercion would obviously be fruitless, and the only avenue for resolution would be renegotiation of the contract.

This could be a time-consuming process and ultimately end in the supplier not wishing to do business on the revised terms. What happens then? The competency set no longer exists in the organization, so where does a buyer of these services go for an alternative? Switching costs could be prohibitive, so there is a real dilemma here. Your business must either battle on against customer need or look for a longer-term resource, neither of which would be ideal.

This leads on to some "revealing" work carried out in the UK by Andrew Cox of Birmingham University and chairman of the advisory board of the international institute for Advanced Purchasing and Supply. Professor Cox received criticism from some sections of the purchasing fraternity, due to his forthright views on power and dependence in supply chains. At that time there was much interest in partnership sourcing and other shared relationship–based approaches. Many buying companies entered single-sourcing relationships with "partners" only to find that the benefits of "being in bed together" were not all they were cracked up to be.

Cox was, rightly in my opinion, focusing on the relative power differentials between buyer and seller as the basis for informing procurement strategy. Firms are distinct legal entities with boards of directors and pressures to perform and deliver shareholder value. Buyer–seller relationships are therefore certain to be formed and governed by these pressures. This reality is true throughout the procurement process, but whereas the consequences of a failed relationship in general procurement of goods are normally confined to certain transactions, poor outsourcing arrangements can cripple a business.

In a paper, Cox presented some remarkably incisive observations. The first point made is that buyers should have a methodology to ensure that strategically important resources are not outsourced to suppliers. Earlier in this section it was noted that outsourcing was not recommended for activities that were critical to competitive advantage and what Cox stresses as the ability "to earn above-normal returns."

The paper then goes on to examine the potential pitfalls once a decision to outsource has been made. The next section will consider the former point; here, the pitfalls are explored. Cox defines adverse selection as being where the buying company or outsourcing practitioner fails to realize that their relative power positions switch once the deal is done.

If they make a poor (suboptimal) selection, it is too late once the contact is signed. Inadequate due diligence and selection criteria can lead to a lifetime of regret. Believe it or not, there are suppliers out there who would claim competence in certain areas but actually possess little of it! The counter to that is to avoid the moral hazard by making suitable precontractual provisions in the agreement. The message in this is that buyers and suppliers must understand the fit between them. Put very simply, this means that (inexperienced) buyers can be seduced by suppliers who make promises they cannot keep.

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Meeting the Supply Management Challenge

To manage increasingly complex supplier networks, pharmaceutical companies must develop new capabilities, organizational structures and management tools.

By Ric Philips and Kevin Sachs, McKinsey & Co.

Pharmaceutical manufacturers have seized the opportunity to cut costs, improve flexibility, and reduce risk by expanding their use of third-party manufacturing partners. Between 2001 and 2008, the pharmaceutical contract manufacturing industry doubled in size and, according to Frost & Sullivan, it is forecast to continue growing at a rate of 11 percent per year and is expected to be worth more than $26 billion by 2012. As the external supply base has grown, however, managers are increasingly recognizing the true complexities of the process. Industry leaders we speak to highlight challenges across the key areas of quality, delivery and cost in managing their external supply relationships.

EFFECTIVE SUPPLIER MANAGEMENT MODELS EXCEL ACROSS FIVE CORE ELEMENTS

1 Strategic portfolio of external suppliers
Aligning supplier selection with overall business strategy. Segmentation of suppliers by strategic importance.

2 Commercial forecasting and supply planning
Adapting internal forecasting and supply planning approaches to match supplier capabilities and constraints.

3 Information sharing, performance management and issue notification
Processes for reporting supplier performance against expectations; and for raising, escalating and resolving issues.

4 Risk management
Proactive risk assessment to predict potential risks and apply appropriate risk management and mitigation techniques.

5 Supplier development
Processes for ongoing performance management and continuous improvement of supplier capabilities.

SOURCE: McKinsey

NEW GAME, NEW RULES

These challenges are not insurmountable. Companies in other sectors have built effective mixed models of internal and external manufacturing. Now pharma companies are beginning to apply some of the same techniques. Strong supplier management requires companies to have the right processes for selecting suppliers, for managing their performance, and for developing their capabilities over time. Companies with the most effective supplier management models do this by getting five core elements right (see image on previous page).

1. They create a strategic portfolio of external suppliers.

Most companies have allowed their external supply base to grow organically, selecting and qualifying suppliers on an ad-hoc basis for particular projects, products or markets. For some companies, this evolution has led to complex, expensive, and difficult to manage networks of more than 200 suppliers. The best firms, by contrast, take a much more rigorous approach. This starts by aligning the supplier selection process to overall business strategy. A company seeking cost leadership might aggressively seek low-cost country suppliers, for example, while another looking for technology leadership will want to forge collaborative relationships that give it access to critical skills and technologies.

Leaders also use sophisticated segmentation criteria when selecting and managing suppliers, including criticality of the product, supplier capabilities, the supply landscape and others. Firms apply these criteria rigorously to the full supply base and use them to stratify the supply base for selection and, later, improve prioritization for active supplier management.

2. They improve their forecasting and supply planning approach.

While outsourcing may offer a compelling solution to the problems associated with demand volatility and capacity constraints, companies that expect these issues to disappear altogether will be disappointed. Suppliers have some opportunity to offset demand fluctuations between customers, but still have constraints on equipment capacity, people, and materials availability. Compensating for this requires planning across multiple horizons, working closely with suppliers to understand their true flexibility and constraints, and adapting internal forecasting and supply planning approaches to respond. In industries where variability is particularly high, such as high-tech, the best performing companies hold quarterly (or longer) equipment planning reviews with their suppliers, design their forecast processes to eliminate unnecessary demand fluctuations, and then work together to develop inventory and production scheduling rules that are tailored to particular products based on their value and variability.

3. They implement rigorous procedures for information sharing, performance management and issue resolution.

Managing the performance of a supply chain becomes more difficult as more of it is outsourced. Companies frequently find that as they outsource manufacturing, for example, they lose sight of the vital production performance indicators that provide an early warning of potential supply issues. Likewise, their ability to rapidly resolve issues that do arise may be compromised because they lack the appropriate mechanisms for communicating and responding to them. Where an internal production manager would simply have picked up the phone to a colleague in logistics, for example, or discussed progress around the water cooler, a supplier may be unsure whom to call, and when.

Avoiding these issues requires companies to agree to an effective set of performance indicators with their suppliers — ideally the same ones they would have used when production was internal. It also requires them to implement formal protocols for the communication, escalation and resolution of issues.

One company in the high tech sector, for example, suffered from quality and reliability issues when it outsourced some critical assemblies to an external supplier. Identifying and rejecting substandard parts was expensive and threatened to disrupt production, so the company took steps to tackle the problem at the source. First, it designed a new set of daily, weekly and monthly reports with the supplier to ensure early identification and resolution of potential issues. Then the company worked with its supplier to identify the individuals within their two organizations who were best placed to take action to resolve issues. Finally, it established a cascading issue resolution and tracking system to ensure those people were brought together quickly when required, and to allow tracking of issues for ongoing supplier management and continuous improvement efforts.

As a result of the effort, delivery performance from the supplier improved by more than 9 percent, helping the company to accelerate sales growth. Within six months it had also achieved cost savings from the supplier of more than 5 percent, thanks to the reduced complexity of managing the program.

4. They take a proactive approach to risk management.

The best companies hold suppliers to a level of risk management equal to their internal production facilities. Rather than taking a reactive approach to supplier risk management, relying on reviews of batch records and infrequent formal audits, these companies adopt a proactive, on-site risk assessment and problem-solving approach.

Others are already adopting an approach pioneered in the automotive

sector to map the principal sources of quality risk in key suppliers. Risk "heat maps" use a company's own knowledge of process risks to predict the parts of a supplier's operation that have the largest potential to create problems. These heat maps can be used to identify critical criteria during supplier selection, and companies can engage directly with their existing suppliers to agree on appropriate risk management and mitigation techniques. For critical suppliers, top companies map the full operational taxonomy of past, current and future risk in detail and carefully manage to those risks. One pharmaco, for example, developed a detailed risk management heat map for its own plants, allowing it to focus quality improvement efforts precisely where the biggest risks arose. Having proved the technique in-house, the company is now rolling out the same management and mitigation approach to its most important suppliers.

5. They systematically improve performance and develop supplier capabilities.

Supply chains can't stand still. While outsourcing should deliver immediate one-off cost savings and performance improvements, companies must ensure they have mechanisms in place to drive further improvement over time. Simply placing suppliers under pressure to reduce their costs while increasing quality and delivery performance standards has proved frustratingly ineffective for many firms.

The best take a more collaborative approach. While they keep up the pressure for suppliers to improve their KPIs, they also work with them to identify ways in which the performance of the entire value chain can be lifted. Supplier development, in which engineers from the procuring organization spend time working on site with suppliers to fix problems and develop innovative new solutions, is common in the automotive and high tech industries. Now it is delivering benefits in pharma, too. A project at one large pharmaco, for example, focused on developing the skills of a select group of its own production engineers. Once they had gained considerable expertise in identifying and fixing production inefficiencies and quality issues, the company embarked on a program to share that expertise in a structured way with key suppliers. In this program, the company sends its engineers to work in supplier plants alongside supplier production staff, helping them to tackle specific issues and to build their own process improvement capabilities. So far, the project has been a considerable success, delivering 5 to 10 percent cost savings annually, together with improved supply reliability.

As they ramp up their use of outsourced manufacturing, pharmacos must be prepared to tackle new challenges. While it is still early days for the industry, those companies that are embracing the best practices developed in other sectors are finding that they can deliver big benefits in pharma, too.

Managing Supplier Quality, a Continuous Process

A proactive, collaborative approach is critical to success

By Parag Patel, Janice Pai, JehanZeb Noor, and Ramit Jain

While quality problems can be found in any industry, they are becoming a more pronounced problem in the pharmaceutical and medical device space. Over the last few years, supplier quality has become an increasing concern in the industry. Many regulatory agencies are holding pharmaceutical and medical device companies equally responsible for supplier related issues, affecting both companies' financial results and their reputations. As a result, more companies are focusing on addressing the challenges with a proactive, collaborative, and holistic approach to supplier quality management. Their goal is to manage and support suppliers in similar ways to their own production facilities, in an effort to reduce risk and build better partnerships with these suppliers.

Companies often tell us that they are struggling to master supplier quality — not due to a lack of effort, but because doing so is becoming more challenging. There are several reasons for this, notably:

- Product complexity is rapidly increasing, with the increased focus on lowering cost for small molecule solid dosage manufacturing, the increased usage of large molecule protein therapies, and the expanded market penetration of vaccine therapies. This increase in complexity is making supplier integration in product development, manufacturing, logistics and service operations more challenging and making the timely resolution of supplier quality issues more difficult.

- Globalization of the supply chain continues to increase complexity in the industry. For example, much of the world's active pharmaceutical ingredients (API) are now manufactured in low cost countries such as India, China and other south-Asian countries. This means companies must be able to manage supplier quality across physical, cultural and language borders. Seamlessly working on complex matters with best-cost-country suppliers far from home is obviously challenging, but

these far-away suppliers also use suppliers of their own. Pharmaceutical companies' visibility into the upstream supply chain is often limited to first tier suppliers, while significant risk of supplier quality incidents resides with their sub-suppliers further upstream.

- Regulatory demands continue to increase, with the FDA and other regulatory agencies increasing the expectations placed on pharmaceutical companies in managing their suppliers. For example, not only has there been an increased number of supplier related recalls (up around 16% year-on-year for the past five years), but there continues to be an increasing number of 483s, decrees, and forced plant shut-downs due to these issues. On top of this, today's fast moving media ensures widespread attention to any substantial quality issues, increasing the negative effects on the players involved.

With these increased challenges in managing supplier quality, we took a closer look at over 40 recent quality incidents (many of which were at pharmaceutical and/or medical device companies) to find common themes and identify a holistic approach to improving them. In this evaluation, we found that more than 40% of these incidents were actually due to supplier quality issues. An in-depth evaluation of these supplier quality issues found three main root causes: 1) lack of collaboration in the design phase; 2) lack of a robust quality system / KPIs at the pharmaco and/or the supplier; 3) lack of capabilities in supplier manufacturing facilities. This suggests that a robust supplier quality program is required in most companies to address and prevent these problems.

A HOLISTIC APPROACH TO SUPPLIER QUALITY MANAGEMENT

Best-practice in supplier quality is not a quick fix, but a multi-stage journey. It is our fundamental belief that successful supplier quality management requires a holistic approach. Based on our experience in multiple quality transformations, we have identified four essential cornerstones of such an approach:

- **Supplier strategy and KPI system:** Companies must ensure that their supplier quality strategy is aligned with their overarching corporate and purchasing strategies. They must focus their attention on strategically important suppliers, define clear targets and measure their progress against them. Often, companies fail to segment their supplier quality programs, spreading their effort too thinly as a result. This can leave them with only the resources to respond to day-to-day operational incidents, rather than the proactive and preventative actions that will drive deep improvements upstream.

- **Functional supplier quality processes:** Companies need to define and apply a structured set of standards and processes (advanced product quality planning, part approval processes and root cause analysis standards, for example), both internally for themselves and for their suppliers.

- **Supplier quality organization & governance:** Supplier quality requires an effective cross-functional approach,

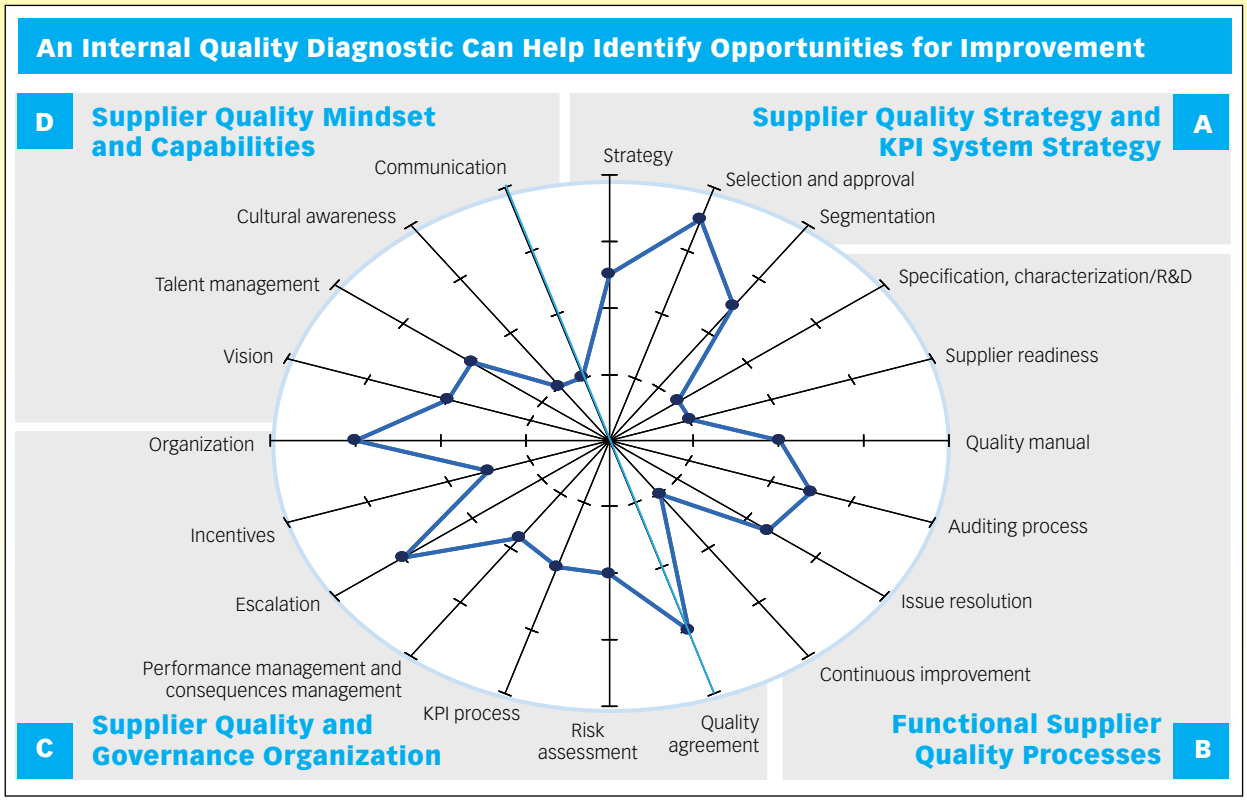

EXHIBIT 1: Example of supplier quality diagnostic across 20 dimensions

with the right organization structure, the right 'local' presence (e.g., at a supplier site or in the supplier's region) and smart performance management and incentives. Companies need to move away from an overemphasis on purchased cost and ensure that a holistic view of supplier performance is part of the agenda for their COO or CPO.

- **Supplier quality mindsets & capabilities:** Focused communication efforts with suppliers are required to maintain attention on quality issues. But it is equally important to invest in getting the right people with the right skills and expertise. Supplier quality results are strongly correlated with the competence level of the organization. The most effective supplier quality specialists have a combination of deep technical and quality expertise and strong business acumen in order to effectively drive change in their suppliers' operations and management practices.

SUPPLIER QUALITY MANAGEMENT APPROACH IN ACTION

One large medical device company applied many of the techniques outlined above to uncover and rectify many of their supplier quality issues. Along with organizational changes, the company followed a three-phased approach to improve supplier quality performance.

- **Diagnostic phase:** First, the company identified the sources of supplier quality risk by conducting a full

quality diagnostic across 20 critical dimensions of supplier quality. This company started with an internal diagnostic (see Exhibit 1) using these 20 dimensions to identify improvement opportunities and prioritize its areas of focus. This evaluation highlighted areas where the company needed to improve its internal approaches and capabilities as well as areas of focus for its suppliers.

- **Design phase / prepare for supplier assessment:** The company developed a supplier assessment approach to evaluate the operating systems, management systems and culture of its suppliers. The company's suppliers were also prioritized for evaluation based upon risk with the goal of balancing a reactive approach (i.e., address the recently "problematic suppliers) with a proactive approach (i.e., evaluate suppliers that could be "problematic" in the future). The company used criteria such as suppliers with recent recalls / complaints, suppliers linked to critical products, suppliers with highest spend, and other qualitative factors (based upon interactions, management and general understanding of suppliers riskiness) to rank suppliers and prioritize the evaluations. This helped to identify the first 15 suppliers to be assessed and improved. An in depth evaluation toolkit (with scorecards across operating, management and culture systems) was built to conduct the evaluation and a cross-functional evaluation team was selected and trained. Finally, the company proactively communicated to the suppliers so that evaluation could be collaborative to uncover "win-win" opportunities. For example, during the process, the first supplier the company worked with confirmed that a key issue for it was that control plans frequently did not capture the critical KPIs appropriately. As a result, the company was able to modify its CTQ cascade approach and control plan development to better ensure accuracy and therefore improve quality control.

- **Implementation phase:** Finally, to facilitate implementation, an 18- to 24-month roadmap was built to roll-out the assessments, build supplier capabilities and define the internal organizational requirements.

This new assessment approach was more actionable, holistic, and applicable across the company than the existing methodology. It allowed the company to go from a reactive, audit-based approach to a proactive assessment toolkit that could be applied across multiple franchises and products. The company has improved many of its internal practices, completed more than 15 supplier assessments with clear action plans to improve the suppliers' approach, and now is continuing to evaluate its other "high-risk" suppliers. Most importantly, there was a substantial improvement in the collaboration with suppliers that will continue to identify actions to reduce quality risks for both the suppliers and company itself in the future.

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Duke Fuqua Outsourcing Survey Results, 2012

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