

Bucking the Regulatory Affairs and Quality Outsourcing Trends

John Avellanet reports on a survey that highlights problems relating to the oversight of suppliers and outsourced contractors and explains how they can be avoided.

A survey of over 13,000 executives from medical device and biopharmaceutical industries has revealed surprising trends for outsourcing when it comes to regulatory affairs, quality and supplier oversight. Among the many findings, three stand out. Single-task focused roles within regulatory affairs and quality departments are being increasingly outsourced; supplier criticality is being based on risk to a company's quality system at the expense of risk to patient, product or profitability; and quality agreements are becoming change management control agreements between companies.

Given these findings, there should be little wonder then that US Food and Drug Administration enforcement actions around supplier management and control continue to strike a nerve in the industry. In 2009, the agency issued 16 warning letters solely on poor supplier and outsourcing oversight.

In the UK, a 2008-2009 review of inspectional findings by the Medicines and Healthcare products Regulatory Agency revealed that supplier and outsourced contractor oversight was the ninth most frequently cited issue.

Given this enforcement picture and the three findings from the survey, supplier oversight is not on the road to recovery. In addition, the results apply not just to US firms but to companies around the world too; while most of the companies surveyed were based in the US, a small fraction of firms were based outside the US and at least a quarter of the firms were multinational conglomerates such as Johnson & Johnson, Pfizer and AstraZeneca.

The survey

From November 2009 through February 2010, my colleague Nancy Singer (of US firm Compliance Alliance) and I queried over 13,000 executives in the medical device and biopharmaceutical industries, from tiny biotech startups to huge multinational device and pharma firms. We asked 17 questions covering a broad range of outsourcing and supplier management trends and kept all responses anonymous to ensure confidentiality and encourage full disclosure.

In addition to compiling and analysing respondent answers, we also reviewed and assessed individual comments. Respondents were encouraged to elaborate on their answers, especially on topics such as which sub-teams within departments they were outsourcing and why. When we discussed preliminary results in workshops and with clients in March 2010, we gained further feedback and insights. Throughout the process, our goal was to gain a clear understanding of the logic behind the various answers, so as to enable a better analysis of outsourcing trends and risks.

Bye-bye regulatory affairs?

Our findings showed that more than one-fifth of all medical device and biopharmaceutical firms surveyed now outsource significant components of their regulatory affairs departments. Those regulatory affairs functions most likely to be outsourced include:

- labelling;
- common technical document (CTD/eCTD) assembly;
- training; and
- submission tracking, indexing and archival.

Each of these functions represents, for the most part, a task-oriented activity or an easily defined set of work within regulatory affairs roles. In discussing the preliminary findings with one chief executive, he stated quite bluntly, "Look, if I can hire ten regulatory affairs people in India to do the same job as one guy here [in the US] and still save money and get ten chances to get it right – why wouldn't I do it?" This sentiment is eerily familiar to those of us who lived through the big information technology (IT/ICT) outsourcing push in the 1990s.

In the early 1990s, US companies began outsourcing many IT/ICT jobs. The first IT/ICT jobs to go were those that were narrowly focused, jobs that were, in the language of executives and management consultants at the time, referred to as "non-core" or "non-core business value added".

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More discrete IT tasks were more likely to be outsourced

Nice euphemisms for individuals whose skill sets were very technical, very narrow and often, very deep (eg those who just carried out software programming in a particular programming language, or those who worked only on desktop installation and repair, or those who just answered the phone and conducted initial, over-the-phone troubleshooting, etc). The more discrete the task, the more likely the activity was to be outsourced.

Is it possible that the outsourcing of the four very discrete, very task-focused regulatory affairs functions noted above represents the beginning of a tipping point for completely outsourcing regulatory affairs?

Implications

Almost 7% of device and biopharmaceutical firms now completely outsource their regulatory affairs departments (ie they have no regulatory affairs personnel on staff whatsoever). Can we, therefore, draw the conclusion that the traditional regulatory affairs team – oriented around tactical activities such as submissions, labelling and specific regulatory interpretations – may be on its way out? And if so, what is replacing the 20th century regulatory affairs professional?

Again, a look at the comments and preliminary feedback from the survey is revealing. Successful regulatory affairs professionals, according to one vice president of regulatory affairs, “can see all the unseen connections between regulations, product development, marketing, rules beyond just the FDA – those who can think broadly, critically, with an open mind”. Regulatory affairs professionals need to move beyond specific regulatory citations to a more strategic, more holistic compliance mindset focused less on “yes/no” and more on “how”. In other words, they need to act as navigators and architects, not rules-followers and enforcers. The regulatory affairs professional of the decade ahead must be able to adequately balance four concerns: patient safety, product efficacy, regulatory compliance and company profitability. From our survey and from comparison with historical patterns seen in other fields that have suffered through outsourcing, it appears that those regulatory affairs professionals who cannot demonstrate success at this strategic level will find their jobs at risk.

Regulatory affairs professionals must move to a more strategic, holistic compliance mindset

As with any support function, regulatory affairs needs to better demonstrate its ability to positively impact the bottom line. Delineating the myriad options is significantly beyond the scope of this or any one article and methods that have been shown to actually work are described in my book: *Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine*¹. However, as the remainder of this article makes clear, one area with direct financial impact in which regulatory affairs must play a stronger role is in supplier due diligence and oversight.

Quality's cart before the horse

Another revelation from the survey was the inadvertent perversion of risk-based decision-making when it comes to supplier selection, evaluation and qualification. Originally, the FDA – along with members of the International Conference on Harmonisation and its counterpart on the devices area, the Global Harmonization Task Force – argued that in the 21st century, a risk-based paradigm allowed companies to base the level of oversight of a vendor upon the risk that vendor and its supplies presented to patient safety, product safety and product efficacy. Thus, one would expect to see that risk to patient safety or product safety, or even product efficacy, would be the number one criterion underscoring a determination of vendor criticality.

And yet, when determining vendor criticality, 88% of respondents to the survey cited “risk to our company's quality system” as the key factor. Less than 75% of respondents identified “risk to product safety and efficacy” as even a factor in their decision-making and oversight – not precisely the intent behind risk-based purchasing and supplier control expectations espoused by the FDA or any of its international counterparts in the ICH or GHTF. In fact, when it came to specifically including risk to patient safety as a consideration in supplier criticality and level of control, less than 83% of firms said patient safety was factored into their supplier management programme. Instead, the number one driver of assessing supplier criticality was risk to the firm's quality system.

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The goal of any device or biopharma firm is to make money through selling and servicing consumers (ie patients) on its products. In order to do this, any device or biopharma firm must agree to abide by the regulations governing the regions wherein the firm conducts business. A quality system is only a means to this end. In other words, the quality system is the cart – not the horse (patient demand) or the market-bound cargo (device or drug).

So why then is risk to the cart the number one factor in determining whether the suppliers of the cargo are in a state of control?

Implications

Behind the numbers in the survey lie the real reasons why supplier criticality and control is largely only assessed through the lens of risk to quality system compliance: 93% of supplier due

diligence and qualification is conducted by the quality department. Quality departments dominate the discussion. Less than 73% of purchasing departments, 44% of regulatory affairs, and less than 10% of any other department (manufacturing, research and development, clinical, etc) play any role in supplier quality and oversight. In other words, supplier evaluation and control is not cross-functional, but is, instead, quality system focused.

Lest we run out and lambast quality managers, we should step back and remember that each of us is able to best control what we know and understand. If I only know about the ins and outs of quality systems, then that is what I tend to audit for, that is what I tend to select for and that is what, ultimately, I tend to control for. One answer may be to strengthen the cross-functional involvement of other groups such as regulatory affairs to add new perspectives and controls into any supplier selection, qualification and oversight process. Until this happens, though, it is likely that the industry will continue to stumble when it comes to supplier management.

This has further cascading implications. According to our survey, 96% of firms use onsite quality audits as the means by which they qualify vendors – far above other methods such as reviewing previous regulatory agency enforcement actions against a supplier (60%), financial and public record reviews (57%), personal references and previous experiences (35%) and reputation analyses (28%). Onsite audits are expensive, costing between \$5,000 and \$14,000 per person involved on the auditing team.

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If the need to conduct an onsite audit is based on risks to patient safety, product safety and efficacy, plus a host of other factors, then the potential exists to significantly save money by only conducting onsite reviews of suppliers deemed critical to patient safety and product safety and efficacy. Suppliers that pose a reasonable risk to patient safety and to product safety and efficacy should be in the minority, thus minimising qualification costs.

Unfortunately, when supplier criticality is predominately classified based on risk to a firm's quality system, not only do any potential savings opportunities evaporate, but because almost every supplier has a quality system and set of internal controls different to those in the hiring firm, a majority of suppliers can be viewed as posing a reasonable risk to the hiring firm's quality system. The result: more and more onsite supplier audits are "required" and supplier control costs skyrocket.

Sadly, if the increase in supplier-related FDA and MHRA enforcement actions is any indication, these increased costs do not translate into lower risk. To make matters worse, by failing to adequately incorporate consideration for patient safety into supplier management, firms have inadvertently placed themselves at increased vulnerability for product liability lawsuits.

Increased supplier control costs do not translate into lower risk

Such negative results to the bottom line are then dealt with in two ways: higher product pricing (a tactic that is rapidly running into healthcare reimbursement ceilings worldwide) and an increased impetus to outsource.

Change agreement or quality agreement?

When quality departments are asked to control for risk with suppliers, they inevitably turn to supplier quality agreements or addendums. Such contracts have a great potential to clarify accountabilities and delineate responsibilities. They also have potential to outline mutually agreed upon terms and conditions of working together as well as resolving product or service level discrepancies.

According to our survey, the number one condition placed in a quality agreement is a requirement that suppliers include the hiring firm in change management reviews and approvals (86%). This ranks above fixing identified deficiencies in supplied product or service (69%), a need for agreed upon timelines to fix any problems (39%), a provision of any type of guarantee or warranty that the supplied product will not be adulterated, misbranded or mislabeled (64%), or clarity of who is accountable for adulterated, misbranded or mislabeled product and the costs stemming from the supply thereof (56%). In other words, for one-third of companies, as long as the supplier provides them advance notice of changes, the supplier can send whatever product in whatever condition the supplier desires.

The number one condition in quality agreements is that suppliers include the hiring firm in change management reviews

When emphasis in supplier controls is on controlling risk to a quality system rather than risk to product safety or efficacy, then something has gone badly off track. This further compounds the triple jeopardy – regulatory agency enforcement, product liability lawsuits and negative bottom line impact – into which companies are constantly stumbling.

Implications

Controlling changes inside of suppliers can be a Sisyphean task, so where does one draw the line or measure success? To the FDA, changes that might impact product safety and efficacy and patient safety are the dividing lines against which supplier agreements should be measured. Focusing on supplier change control in a quality agreement rather than preventing the receipt of adulterated, misbranded or mislabeled product is a consequence of putting quality systems compliance first, rather than product safety and efficacy or patient safety.

It is better for firms to prioritise supplier criticality and quality agreements on ensuring clear accountability

Far better for firms to prioritise supplier criticality and supplier quality agreements on ensuring clear accountability and consequences for adulterated, misbranded or mislabeled product. Change management can be a method for avoiding misbranded or adulterated product, but should not come before agreement upon liability, accountability and acceptable levels of product quality.

By putting liability and accountability first in any legal agreement, proactively managing product quality and communicating change become vested interests for both supplier and the device or pharma firm. Firms and executives tend to follow their vested interests. Thus, with liability and accountability placed first, vested interest becomes the carrot that suppliers will chase. Without liability and accountability, there is no enforceability – and thus no real control.

Final thoughts

These trends, in and of themselves, are neither good nor bad. They simply reflect the ongoing transitions from one century to the next as executives struggle to adapt from an FDA-centric mindset to a broader context reflective of regulatory harmonisation, healthcare cost control and greater marketplace complexities. Vanishing are the days – if they ever truly existed – when quality and regulatory affairs could be judged solely on their own merits.

In an international marketplace of the 21st century – the so-called flattened world – quality and regulatory affairs professionals must find ways to add to the bottom line, or at least to avoid jeopardising it. To do otherwise is to risk becoming an outsourced statistic.

Quality and regulatory affairs professionals must find ways to add to the bottom line

References

1. Avellanet J, Get to Market Now! Turn FDA Compliance into a Competitive Edge in the Era of Personalized Medicine, May 2010, Logos Press

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