A QUICK Guide to Selecting a CMO

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In recent years, the pharmaceutical industry has increased efforts to outsource many previous in-house activities, such as manufacturing, testing, and packaging. Naturally, this means increased scrutiny on both sides of the outsourcing partnership to ensure proper compliance and robust business practices. Since release of the 2015 US FDA guidance, *Request for Quality Metrics*, many firms are using metrics as a tool for assessing a contractor's Quality Management System (QMS).

But numbers are only one factor when it comes to determining the amount of oversight needed to ensure cGMP compliance. Two questions remain: How should a firm evaluate whether a contract partner is the best fit for their intended needs? And, ultimately, how do they determine the correct level of involvement needed to guarantee a successful relationship? One way to make this determination is to use the QUICK method. It offers a thorough and systematic process to holistically gauge the attributes of a firm that are critical to creating an effective outsourcing relationship. What exactly is QUICK? It stands for:

Q — Quality Systems
U — Unparalleled Service and Performance
I — Innovative Technology and Facilities
C — Communication and Transparency
K — Knowledge and Reputation

Firms that analyze a contract partner using the QUICK indicators will be able to establish a mutually agreeable and successful relationship.

Quality Systems

The QMS of a firm is a key component on any auditor's checklist when performing an evaluation of a contract facility; however, procedures and policies only touch the surface of the underlying structure of the process. A thorough QMS evaluation must include a physical walkthrough of the contract facility to understand an organization's procedures as they occur in real time. While a desktop audit provides a high-level review of existing procedures, it does not show if those procedures are being followed. Onsite evaluations provide a wealth of information that may otherwise be missed using only a questionnaire. There is nothing more reassuring than walking onto a manufacturing floor or laboratory and observing the QMS in action. It also reveals one of the most important elements of QMS: the people. A solid foundation for any QMS lies within a company's quality culture. Interaction with the contract firm's personnel can demonstrate whether or not there is a strong commitment to quality.

Unparalleled Service and Performance

While quality remains a top priority, performance also plays an important role in determining the strength of a contract service provider. A manufacturer can have the most robust quality systems in place, but without a strong team of people to ensure that all regulatory and client requirements are met, critical projects risk falling short of expectations.

Before placing any work with a contract facility, a firm must ensure there is a strong performance management system in place as a guarantee that the contractor can provide unparalleled service. A contract facility does not merely manufacture a drug or provide laboratory results; it is a critical business partner, fully vested in the success of the client by maintaining an intimate business relationship. Routine business review meetings or steering committee meetings are key to keeping a pulse on a contractor's performance and service ratings. Without routine review of performance or service, critical problems in a relationship can escalate when preventative actions could have been taken to avert the larger issue.

Innovative Technology and Facilities

As mentioned previously, the onsite tour of a contract facility is a paramount activity in the contract partner relationship. Further, upon review of a facility, an auditor can immediately identify the state of the instruments, equipment, and buildings. Aging facilities, outdated instrumentation, or dilapidated equipment can point to potential cGMP problems. Investing in updated facilities and equipment displays that a contractor's senior management is committed to the success of the enterprise.

With release of the FDA data integrity guidance, industry has reacted strongly to comply, implementing more stringent controls of data. In particular, legacy systems in a contract facility pose a significant risk if not adequately controlled to produce quality data. For this reason, it is important that a potential client ascertain if the contractor has a continuous improvement plan to implement the guidance's data integrity recommendations across all systems.

Communication and Transparency

Too many firms focus on lengthy checklists and questionnaires to evaluate a potential contract partner. Yet two of the most vital fundamental measures of a relationship are communication and transparency. A healthy business affiliation cannot be managed without effective collaboration and open lines of communication. A contract facility is primarily—if not wholly—client driven, and therefore must provide a high level of cohesive correspondence. This goes beyond day-to-day status updates; instead, it should focus on building a partnership that can withstand any bumps in the road. A firm's worst nightmare is being left in the dark about a critical issue occurring at a contract location. The last thing they want is for a regulatory agency to uncover something that could have been addressed proactively. Preventive communications can avert disasters and build trust within a relationship.

Knowledge and Reputation

Contractor knowledge is pivotal in deciding the level of engagement a company's

product will receive. Merely manufacturing or testing a drug for many years does not necessarily equate to a strong knowledge base. A firm must ensure that contractors are continuously improving and building on their current body of knowledge. Ultimately, a company entrusts its most important asset—the product—with an outside vendor. Does the contractor have the competencies needed to provide the highest level of quality? Are they up-to-date with current regulatory and industry trends? Again, this is a great opportunity to seize the onsite audit and speak directly with the subject matter experts involved with the project. Another important question to pose is: What does the firm's regulatory history reveal? While this may not be an all-encompassing barometer of quality, it can demonstrate the frequency of inspections and results of regulators throughout the world. After all, would a company send a product for testing to a lab that has not been inspected by FDA in over five years.

The QUICK method can be used as a mechanism for identifying a core set of attributes that should be present within an outsourcing firm. As increased scrutiny is placed on contract vendors, firms must ensure they are using the most appropriate and comprehensive tools possible to demonstrate proper surveillance of all contract partners.

About the Author

As a Group Leader for Eurofins Lancaster Laboratories' Quality Compliance group, **Brittany Cloud** hosts client audits and agency inspections and provides quality oversight for the company.