Supplement to:
BioPharm INTERNATIONAL
The Science & Business of Biopharmaceuticals

Quality and Regulatory Leadership: Right-Sizing Need and Cost

This article examines the options to best match needs and spending for quality and regulatory leadership.

BRIAN MATYE, RICK DAVIS, AND FRANS DUBOIS

In today's competitive business environment, life-science companies run lean, particularly in terms of personnel. The regulatory affairs (RA) and quality assurance (QA) functions create extra complexity for pharmaceutical companies because needs vary greatly depending on the life cycle of the organization. An early-stage pharmaceutical manufacturer needs strategic RA leadership as the new drug is registered and filed with regulatory agencies. Once the RA strategy and filings are in place, the company's regulatory needs often transition to ascertain that the drug or product is kept up-to-date with the regulatory expectations, new requirements, and changes in the manufacturing process. The quality function typically sees a similar pattern of heavy strategic need followed by a maintenance need.

For a small- or mid-market company, this shift can create challenges for appropriate in-house staffing, particularly if the company has one or a limited number of products. It can mean an expensive hire early in the company's life cycle, followed by a period when the executive is too much horsepower for the maintenance needs of the company.

Outsourcing can provide a better match to changing RA/QA strategic needs through the company life-cycle. There are three major options commonly used: Sole RA/QA practitioner, enterprise consulting firm, or dedicated RA/QA consulting firm (see **Table I**).

SOLE PRACTITIONER CONSULTANT

With corporate downsizing, many executives with quality and regulatory expertise are establishing small consulting practices. With their long and accomplished resumes, they easily attract pharmaceutical clients. Sometimes, the clients are former employers and colleagues, who trust and value their expertise, but can't afford to have these sole practitioners on the full-time payroll. This arrangement enables the pharmaceutical company to hire RA/QA staffers as needed, while using the outsourced QA/RA executive on an as-needed basis for strategy and major projects.

Problems can arise with this model when the pharmaceutical company changes scope or scale beyond the consultant's capabilities, or when the sole practitioner finds a full-time job and decides a steady paycheck with benefits is better than consulting. So, while using the sole-practitioner model, the pharmaceutical company may be best served by maintaining a rolodex of multiple subject-matter experts in case backfilling is needed.

ENTERPRISE CONSULTING FIRM

Enterprise consulting firms offer services in more than one functional area, typically operations and financial areas. These firms can be ideal for early- and mid-market pharmaceutical companies because they represent one-stop shopping for executive leadership in multiple areas. Often these firms are large and can attract the best talent, which the pharmaceutical company can access as needed.

Problems can arise with this model when the consulting firm lacks a deep stable of RA and QA talent, but rather brings in executives as needed. This arrangement can mean delays in getting help and also can mean a higher price tag when the firm outsources QA/RA talent and adds a markup. So the pharmaceutical company may be best served by validating the talent they receive, and by communicating their QA/RA needs well in advance to their enterprise consultants.

FOCUSED QA/RA CONSULTING FIRM

The focused QA/RA consulting firm is a blended solution. Because quality and regula-

BRIAN MATYE is the general manager for the Southeast division, b.matye@rcainc.com; **RICK DAVIS** is the director, ASQ CQA,r.davis@rcainc.com; and **DR. FRANS DUBOIS** is a management consultant for biotech companies, f.dubois@rcainc.com; all at Regulatory Compliance Associates, Kenosha, WI.

tory is their only business, these firms generally provide good talent at a fair price. Because they have multiple consultants, they should be able to scale or change direction, unlike sole practitioners.

Outsourcing can provide a better match to changing RA/QA strategic needs through the company lifecycle.

Problems can arise in identifying and vetting the QA/RA firm because there are few large players with national reputations. The pharmaceutical company may be best served by establishing a due diligence process that matches their needs to the consulting firm's strengths.

The following cases illustrate several approaches that provide QA/RA expertise while saving money.

COMPANY BENEFITS FROM OUTSOURCED QA/RA INSIGHTS

One established pharmaceutical company evaluated its product lifecycle and decided to implement a series of changes surrounding the API. Retiring the old API, transitioning to the new API, and the related activities were simply beyond the bandwidth of the quality and regulatory team in place. It's not uncommon for consultants to be called upon for projects like this, but the pharmaceutical company recognized there would be economies of scale by using the same team of outside experts over the course of multiple projects, avoiding the ramp-up time and discovery fees that would be associated with multiple consulting engagements. Additionally, the pharmaceutical company found that having local experts not only saved on travel costs, but also allowed the consulting firm to become part of the team, adding value to *ad hoc* meetings, and integrating into their quality and regulatory functions without being on the payroll.

Table I: Outsourcing options.

Model	Pros	Cons
Sole practitioner	• Often a known and trusted colleague • Cost effective—high expertise but not on the payroll	• May lack bandwidth or specific skills • Not as stable as larger consulting firms. May close the practice
Enterprise consulting firm	• One-stop-shopping for multiple functional needs • Can attract high caliber talent	• May not truly have QA/RA talent • May outsource RA/QA talent, costing additional markup • May focus on their larger clients over your needs
Focused QA/RA consulting firm	• Value—high expertise at a fair price • Deep QA/RA knowledge that can scale or change scope	• Few large players, lacking national reputations • May be more difficult to vet, requiring a due diligence process in vendor selection

OUTSOURCED QA/RA ACCELERATES NEW PRODUCT DEVELOPMENT

A Fortune-500 company was planning a new drug/device product development using a disruptive technology. Recognizing that risk insulation and speed-to-market would be crucial for early adoption and success, the company decided to create a new subsidiary to develop and launch the product.

The seasoned QA and RA management decided to stay with the Fortune 500 enterprise instead of joining the subsidiary, whereas some of the early- and mid-careerists were attracted to the startup venture. The subsidiary realized they had staff to implement but lacked QA/RA leadership and deep expertise.

The RA/QA consulting firm was brought in to complete product development, direct regulatory filings and compliance activities, and to set up a quality-management system (QMS). The subsidiary had originally planned to adopt the QMS of the parent company but the consulting firm pointed out the need to right-size the legacy QMS for the new start-up subsidiary. With ongoing outsourced QA/RA expertise and their implementation staff, the subsidiary was able to launch the product, comply with all regulations, and implement their QMS systems without hiring expensive executives. Additionally, some of their staff used the consulting firm as their mentors and used this opportunity to step up. Over time, there were some internal promotions within the QA/RA team because the subsidiary had created a culture of grooming and promoting from within.

EXAMPLES OF BENEFITS FOR EARLY-STAGE COMPANIES

Example one

A biotech startup was in a Phase II clinical trial and struggling

with its cash-burn rate. They had a four-person quality team in place in anticipation of future needs. Their QA/RA consulting firm recommended managing work more efficiently, scaling back to two analyst-level personnel and augmenting with occasional consultation by outsourced quality experts. This model was possible, because the quality systems were already in place but didn't need such heavy staffing. By transferring expense away from the quality function, they were able to deploy additional resources to the scientific and product development area, their greatest need.

Example two

Another early-stage company engaged a consulting firm because the owners were not familiar with the regulations surrounding their medical device. The team had a business plan in place, a solid IP platform, and a distribution plan, but the company lacked a regulatory and quality pathway.

A consulting firm provided the company with an overview of the RA and QA requirements. Because the leadership team was bootstrapping the company, they decided to purchase off-the-shelf quality documents, and asked the consultants to fill the gaps. The consulting firm began a steady process of backfilling where the firm needed help, such as matching the purchased standard operating procedures with the business needs and remediating the product development in accordance with the developing QMS. As the launch date for the new product approached, the consulting firm helped the company implement corective and preventive actions and a complaint system, along with an internal audit plan.

The consulting firm performed all this QA/RA oversight and backfilled the firm's gaps while working within a fixed monthly fee, helping the firm's cash flow requirements.

The product has since launched and is a commercial success. As the company continues to grow and scale, the consulting firm continues to provide ongoing support as the outsourced QA/RA manager, working hand-in-hand to augment the firm's capabilities, while keeping their expenses to a manageable level.

CONCLUSION

Outsourcing quality and regulatory expertise can bring needed experience while saving costs. As companies grow and scale, they need flexible models for meeting their evolving compliance needs, and outsourcing can provide value. **BP**

By transferring expense away from the quality function, they [the biotech] were able to deploy additional resources to scientific and product development.

Recommendations

1. Determine your needs and examine the skill levels needed.
   - For start-ups, focus on the right systems and controls, while keeping staff to the bare minimum. Right-size the QA/RA organization to the stage of the company.
   - For many organizations, much of the quality and regulatory work is implementation and can be accomplished with less experienced personnel or contract staff. Right-size the skill set to the needed work, but do not forget the appropriate amount of oversight, mentoring, and management.
2. Consider using experienced QA/RA experts to determine the strategy and guide the implementation. Consider the breakeven level between hiring and outsourcing.
3. Consider matching the size of your organization to the consulting firm.
   - While the mega-sized consulting firm has depth and multiple subject matter experts, it's more likely that your small business will take the backseat to their major clients. Small life-science companies may receive better service from smaller consulting firms.
   - Local QA/RA experts save on travel expenses and may have more flexibility for impromptu meetings.
4. Seek flexibility in billings that best match the firm's needs.
   - Some QA/RA consultants can be handled in a monthly retainer that's easy to forecast into your cash flow.
   - Some life-science firms may benefit from fixed-price consulting agreements or time and materials contracts with QA/RA consultants.