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Outsourced Quality & Regulatory Leadership:

Right-Sizing Need and Cost

Small or emerging life science organizations often put off hiring Quality and Regulatory executives, exposing the company to risk or worse. Other organizations add full time leaders before they have full time needs, resulting in over-spending. This article suggests another model: variable outsourcing of Quality and Regulatory leadership to best match needs and spending.

In today's competitive business environment, life science companies run lean, particularly in terms of personnel. However, the complexities of the regulatory (RA) and quality (QA) functions in pharmaceuticals, biotech and medical devices require levels of expertise and leadership. In our compliance consulting practice, it's not uncommon for life science companies to engage our services for special projects. However, we're increasingly seeing client organizations seek on-going compliance counsel from us after the special project is completed. This enables them to maintain a baseline level of QA/RA expertise without the hefty price tag of a full time equivalent. The following four cases illustrate various approaches that provide QA/RA expertise while saving money.

Pharma Company Benefits from Outsourced QA/RA Insights

One established pharmaceutical company evaluated its product life cycle and decided to implement a series of changes surrounding the Active Pharmaceutical Ingredient (API). Retiring the old API, transitioning to 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 pharma 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 pharma company found that having local experts not only saved on travel costs, but also allowed us 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.

Outsourced QA/RA Accelerates New Product Development

A fortune 500 company was planning new product development using a disruptive technology. Recognizing that risk insulation and speed to market would be critical for early adoption and success, they decided to create a new subsidiary to develop and launch the product.

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

RCA was brought in to complete product development, direct regulatory filings and compliance activities, and to set up a quality management system (QMS). See Figure 1 below. The subsidiary had originally planned to adopt the QMS of the parent company but we pointed out the need to right-size the legacy QMS for the new start-up subsidiary. With our 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 saw us as mentors and used this opportunity to step up their contributions. Over time, there were some internal promotions within the QA/RA team as the subsidiary had created a culture of grooming and promoting from within.

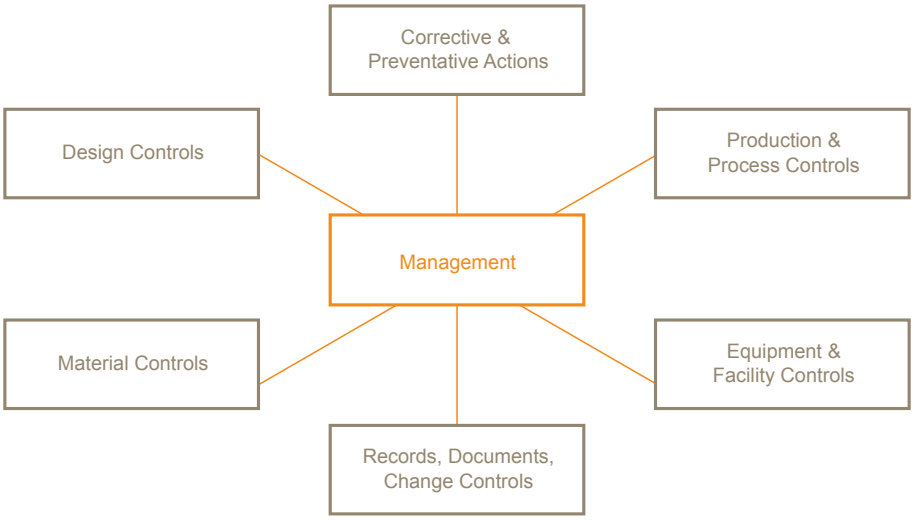
Outsourced QA/RA Benefits Early Stage Companies

A biotech start-up was in stage II clinical trial and struggling with its cash burn rate. They had a four person quality team in place in anticipation of future needs. We recommended that they manage 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.

Another early stage company approached our firm because the owners were not familiar with the regulations surrounding their medical device. The

FIGURE 1

Quality Management System



savvy team had a business plan in place, a solid IP platform and a distribution plan, but they lacked a regulatory and quality pathway.

Our firm provided them with an overview of the RA and QA requirements. Since they were bootstrapping the company, they decided to purchase off-the-shelf quality documents, and asked us to fill the gaps. We began a steady process of backfilling where they needed help, such as matching the purchased standard operating procedures with their business needs and remediating their product development in accordance with the developing QMS. As the launch date for the new product approached, we helped them implement CAPA and a complaint system, along with an internal audit plan.

We performed all this QA/RA oversight and backfilled their gaps while working within a fixed monthly fee so they could meet their cash flow requirements.

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

Outsourcing Quality & Regulatory Leadership: Recommendations

1. **Determine your needs and examine the skill level 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.
2. **Consider using experienced QA/RA executives to determine the strategy and guide the implementation. Consider the breakeven level between hiring and outsourcing.**
3. **Compliance consulting firms are a good source for outsourced managers.**
   - The local temp agency typically does not have access to seasoned quality and regulatory leaders, whereas consulting firms attract top talent who are used to juggling multiple priorities.
   - While it's tempting to work with sole practitioners who are between full-time jobs, you need a new QA/RA manager when they land a full-time job.
4. **Consider matching 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 mega-sized clients.
   - A local QA/RA manager saves on travel expenses and may have more flexibility for impromptu meetings.
5. **Seek flexibility in billing.**
   - Some outsourced QA/RA arrangements can be handled in a monthly retainer that's easy to forecast into your cash flow.
   - Or you might want to ramp up slowly with the outsourced leader.

Regardless of the size of the life science company, we've seen situations where outsourcing quality and regulatory management brings needed expertise while saving costs. As companies grow and scale, they need flexible models for meeting their evolving compliance needs, and outsourcing can provide value.