



Outsourced Quality & Regulatory Leadership

Interim Management: Outsourcing Quality and Regulatory Management

Outsourcing has become an increasingly common practice in the life science industry. The quality assurance (QA) and regulatory affairs (RA) functions create extra complexity for large and small life science companies because needs may vary greatly depending on the life cycle of the organization. These companies turn to outsourcing to manage operations and tactical skills, and also help adopt best practices.

Early in the company life cycle, strategic leadership is needed for product filings, regulatory pathway, setting up manufacturing, and creating quality management systems. As the company matures, these functions often transition to a maintenance mode.

Outsourcing strategic management can provide a better match to changing QA/RA strategic needs through the company life cycle. RCA's interim management brings needed expertise while saving costs.

RCA can assist in the following situations:

- Strategic leadership and management of the QA/RA functional area
- Staff transitions or augmentation
- Special projects lacking internal bandwidth
- Early stage companies needing strategic QA/RA insights, but not ready for full-time headcount

RCA can provide needed expertise while saving costs in areas including:

- Quality
- Regulatory
- Operations
- Medical Affairs
- Product Development

***“RCA is a great mentor to the R&D team”
-Director Engineering Services***



RCA Case study: Benefits for Early-Stage Biotech Company

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. RCA recommended managing work more efficiently, scaling back to two analyst-level personnel and augmenting with occasional consulting through RCA. 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, the company was able to deploy additional resources to the scientific and product development area, their greatest need.



RCA Case study: Company Benefits from Outsourced QA/RA Insights

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 implementation staff, 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). The subsidiary had originally planned to adopt the QMS of the parent company but RCA pointed out the need to right-size the legacy QMS for the new startup 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 RCA 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.



RCA Case study: Benefits for Early-Stage Medical Device Company

Another early-stage company engaged RCA 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.

RCA provided the company with an overview of the QA and RA requirements. Because the leadership team was bootstrapping the company, they decided to purchase off-the-shelf quality documents, and ask RCA to fill the gaps. RCA 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, RCA helped the company implement corrective and preventive actions and a complaint system, along with an internal audit plan.

RCA 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.



RCA Case study: Benefits for Early-Stage Medical Device Company Continued...

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



RCA Case study: 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 RCA's 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 consultancies.

Additionally, the pharmaceutical company found that having local experts not only saved on travel costs, but also allowed RCA to become part of the team, adding value to ad hoc meetings, and integrating into the quality and regulatory functions without being on the payroll.



Recommendations

1. Determine your needs and examine the skill levels needed. 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. Match the size of your organization to the consulting firm
 - While the large-sized consulting firms have depth and multiple subject matter experts, it's more likely that your small business will take the backseat to their major clients. Smaller 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.
 - Local solo consultants often have deep expertise, personal flexibility and can save on travel costs. Problems can arise with this model when the life science company quickly scales or when the sole practitioner consultant opts for a full-time job.
4. Seek flexibility in billings that best match the firm's needs
 - Some QA/RA consultants will work within 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.

****Note:** The recommendations and case studies cited in this paper originated from RCA'S "Outsourced Quality & Regulatory Leadership: Right Sizing Need and Cost" White Paper and was authored by Brian Matye, Rick Davis and Frans Dubois.