



In Action

QLEAR ADVISORS IN ACTION: QC EXPERTISE AND EMPATHY

Quickly Build Competency and Confidence
Following Major Layoffs

THE SITUATION

A drug development and manufacturing company, having recently hired the Director of Quality Control (QC), implemented significant layoffs due to its financial situation, reducing the workforce of the QC Department by 50%. One issue also identified by the QC Director was that many SOPs needed major updates and revisions to reflect actual processes.

“The layoff affected a large swath of the company—from QC to QA and Operations,” the Director said. Along with a serious morale issue, the remaining employees lacked practical support to help with labor-intensive tasks such as writing investigations, change controls, and notebook reviews. Furthermore, the leadership expected the company to continue at the original pace of business with significantly reduced staff numbers.

THE CHALLENGE

The QC Director needed to quickly assess the situation and create a plan to meet milestone goals and keep operations moving. The remaining staff were required to handle more responsibility in terms of writing investigation reports, so he wanted to ensure that they were properly trained and mentored.

“For many of the remaining employees, it was their first time working in such a highly regulated industry; they lacked outside industry experience, so they also needed an appreciation of that to understand the importance of their work.”

THE SOLUTION: OUTSIDE RESOURCE WITH DEPTH OF KNOWLEDGE AND EXPERTISE

Following the layoff, the QC Director hired Jackie Torfin to determine how best to restructure and maintain performance. After one call, the Director knew that Jackie would be the right partner.

“JACKIE HAS SIGNIFICANT DEPTH OF QC EXPERIENCE, IS ORGANIZED, AND SEES THE BIG PICTURE,” THE DIRECTOR SAID. “SHE ENGAGED WITH PEOPLE INCREDIBLY WELL. FROM WHAT I HEARD FROM MY STAFF, JACKIE CALMED PEOPLE DOWN AND BUILT UP THEIR CONFIDENCE. HER EXPERTISE AND EMPATHY ALLOWED HER TO CREATE THE RIGHT STRATEGY AS WELL AS A STRONG TRAINING PROGRAM QUICKLY.”

The Director also noted that Jackie was the fresh change needed to help people understand the situation and gain perspective. “She took on the role of the ‘QC Therapist’ and helped all of us feel heard and valued. She assured us that the staff would get the training and resources needed to be successful. Jackie built up significant credibility in a short time; it was quite impressive.”



LEADERSHIP AND CULTURAL ASSESSMENT LEADS TO ACTION

Jackie conducted an assessment of the QC organization's leadership and department with an organizational tool developed using the Baldrige Excellence Framework and Performance Excellence Tool that involved surveying 22 individuals across the company—from chief compliance officer to scientists, stability coordinators, administrators, and lab members.

The organizational tool helped identify areas within the QC organization for improvement. The review also assessed the competencies of personnel to identify ways to improve the work environment and create growth opportunities to ensure industry best practice performance.



THE KEY POINTS

- The QC Department leadership was well regarded and valued, and provided a stabilizing factor in its operation, although the QC Director was seen as overtasked.
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- The lack of automated processes and tools—a well-known deficiency—and the lack of acknowledgment and or/communication about potential improvements exacerbated issues.

While they recognized the need for process improvements, the staff felt overwhelmed with routine work and were unable to see a clear plan for tackling the issues.



THE FINDINGS

The findings provided a clear starting point from which Jackie created a tailored, appropriate action plan that included an investigations training program, so the team could confidently and competently handle additional responsibilities. The goal was to engage people in training that had an immediate impact. The nine-hour training was broken up over three days, to be sensitive to people's time.

“JACKIE BROUGHT TOGETHER REPRESENTATIVES FROM DIFFERENT DEPARTMENTS AND HAD THEM WORK ON REAL-WORLD INVESTIGATION SCENARIOS,” NOTED THE DIRECTOR. “THERE WAS NO LECTURING. IT WAS ‘HANDS-ON’ TRAINING. PEOPLE COULD BRAINSTORM AND PROBLEM SOLVE TOGETHER—AS THEY WOULD DURING ACTUAL INVESTIGATIONS.”



POSITIVE OUTCOMES

Feedback on training was overwhelmingly positive:

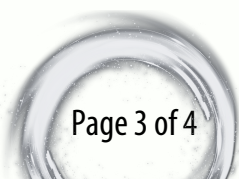
- Survey quotes included that having a “planned, systematic approach towards lab investigations” was the best/most valuable skill gained during the training.
- Participants noted how the training helped them to “better brainstorm the root causes of a problem and narrow it down...” and also offered tactics “... to write a good problem statement.”
- 62% of those surveyed rated the training course as “excellent.”
- The majority noted that the “trainer was knowledgeable,” content was “organized and easy to follow,” and people “... will be able to apply the knowledge learned.”



AS A RESULT

The QC Director noted two positive outcomes:

- Jackie helped to stem the attrition from the QA and QC teams.
- Following the training, the QA and QC teams felt more confident and capable when thinking about and writing up investigations reports.





ABOUT QLEAR ADVISORS: PRODUCING RESULTS FAVORABLE TO YOUR BUSINESS

At QLeaR Advisors, we like to exceed expectations. We don't just fix problems, we enable quality teams with information to help them successfully implement intelligent ways to meet the regulatory hurdles without breaking the bank or the spirit of those involved.

We thrive on working across functions to obtain optimal business outcomes that meet regulatory requirements, and we have fun doing it. We are experts in compliant and efficient solutions and can provide invaluable regulatory leadership skills and coaching.

Why "QLeaR," you ask? There's more to a name than may first appear. Our chosen spelling highlights our areas of focus: Q for Quality, L for Leadership, and R for Regulatory.

To be QLeaR, we love our work. We love to provide QLaRity. And we value honesty, directness, integrity, accountability, and mutual respect.

We're fun but also prioritize efficiency, professionalism, and personalization of each project with each client, every time. We pride ourselves on our relaxed and informal, yet conscientious, approach, and our strengths of using creativity and critical thinking to find solutions and create efficient processes.

CONTACT US

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