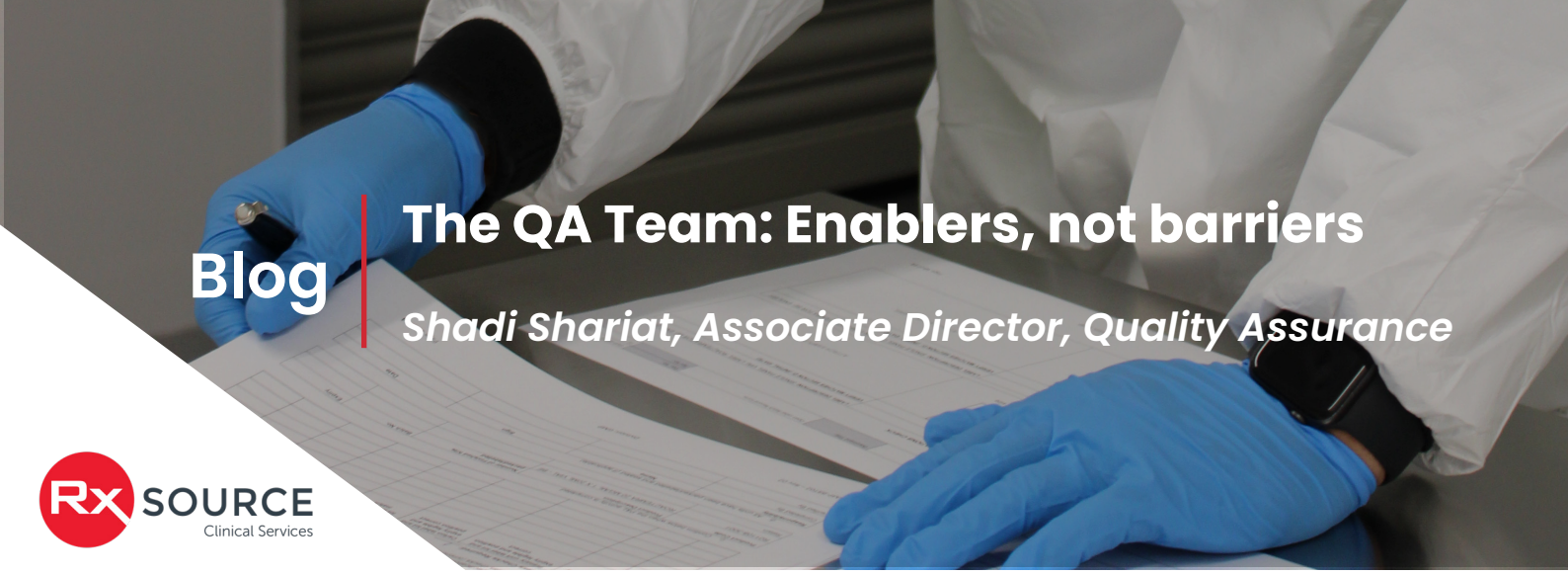

Blog

The QA Team: Enablers, not barriers

Shadi Shariat, Associate Director, Quality Assurance

Quality plays a pivotal role in the pharmaceutical industry. Many organizations underestimate the value of involving quality team members in the development of processes to ensure they understand the intricacies of a new procedure before inviting Quality Management to review and (hopefully) approve. All too often new 'groundbreaking' processes are developed by Operations or Business functions first, then presented to Quality teams in the hope they will simply sign-off. Significant delays to the roll out of new processes can result if the Quality team highlights process changes needed to make the process compliant with local and global regulations, after a process has been developed. Much of this could have been avoided by viewing the Quality team as a partner in process development, as opposed to a final approver.

Challenges & Solutions

Quality's primary challenge lies in achieving full compliance with both regional regulations and global standards, while also maintaining a practical approach internally and externally. This is particularly challenging for global organizations like ours involved in clinical trials worldwide where regulations can vary significantly by region and by country. As a smaller, flexible company RxSource Clinical Services constantly strives to develop better ways of delivering clinical trial supplies to our customers and their patients, and the early involvement of our QA team is key to successful development of new offerings.

An example of this was a request to support a Special Access Program in Canada for one of our clients. Our client was planning a compassionate use program to continue to supply Canadian patients with investigational medication to bridge the time between their participation in a clinical trial ending, and the new product becoming available commercially. In the absence of clear regulatory guidance on the client's specific scenario, our Project Management team brought our Quality team into early discussions with the client. As a result of our early involvement, the Quality team was able to engage promptly with the Regulators (Health Canada) for guidance. We were then able to collaborate closely with our client to ensure the correct documents were submitted to support approval of the program. In parallel with this, the Quality team worked with our Operations team to ensure our labelling strategy complied with the regulations. By working as a team, both internally at RxSource, with the Regulators, and with our client, we were able to support this program without disruption to

patients' treatment schedules. We recently posted a detailed article on our website "How to Run a Compassionate-Use Program in Canada," that provides comprehensive insights into our learnings from this case study, click here for article.

More recently, we have been seeking to further develop our demand-led and just-in-time packaging services to ensure we can scale our service to match growing client demand, improve our efficiency and turnaround times, while maintaining the quality of our offering. Our Operational and Business teams presented our current approach, and their suggested modifications. We were able to highlight areas of quality risk with the proposals and suggest modifications, ensuring that these can be accommodated into our new processes. This is far more efficient than simply sending everyone back to the drawing board after weeks/months of hard work developing a process our (clients') QA team is not comfortable with.

RxSource puts Quality at the heart of everything we do. I do not view my team as a 'team apart', whose only function is to review and approve/reject new initiatives. I want us to be a part of developing these initiatives in our growing organisation. Personally speaking, it was only by actively participating in day-to-day operations that I gained valuable insights about the organization and the industry, which I been able to blend with my regulatory knowledge to support continuous improvement. As a part of this growth process, I realised that the most efficient approach involves gaining familiarity with floor-level processes and understanding the challenges faced by various departments. Knowing these processes and adhering to regulatory guidelines for full compliance is the linchpin. Over a decade of being a member of RxS global family, I've grown alongside the company, celebrating numerous achievements as part of the team.

Everyone at RxSource is committed to continuous learning, collaborating with industry partners to grow together. We view customer audits and regulatory inspections as prime opportunities for improvement and expanding our knowledge. While regulations and guidelines may share similarities worldwide, there is no one-size-fits-all approach, and we value the insights gained from our industry peers.

We are fully dedicated to quality, and within our organization, a commitment to quality is ingrained in every function, department, and individual. Our perspective at RxSource is that each of us is a member of the quality team, and we all bear responsibility for the safety and well-being of patients. This shared passion and vision are what drive us to achieve exceptional results.

Conclusion

In conclusion, I'd like to encourage my fellow quality professionals to consider spending time on the shop floor and collaborating with colleagues from other departments. This approach has personally contributed significantly to my growth. We, as quality professionals, always prioritize quality above all else, and understandably so, as it's non-negotiable in our world. However, by maintaining our commitment to quality while remaining receptive to the perspectives of other departments and individuals, we can achieve remarkable outcomes. Our role primarily is to guide and support, not to create barriers to progress.

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