

Quality: Biopharma's New Secret Weapon

Today's Senior Quality Executives are Strategic Operators, Enabling the Safe Introduction of Novel Solutions to Help Consumers Lead Healthy Lives

By Andrea Kilpatrick



Quality executives used to be the in-house police; internal affairs officers investigating production errors and mishaps and reporting them up the chain of command. The quality teams of yesterday were often outsiders, reacting to problems. Today, as biopharmaceutical companies launch revolutionary and life-changing solutions from around the world, the role of the senior quality executive has evolved into the one of the most important leaders at biopharma firms.

The reasons that CEOs are looking for new quality leadership are many. Regulators in North America, Europe and Asia are flexing their muscle, and threatening costly penalties and fines to firms with poor quality controls—not to mention dangerous pharmaceuticals. Complicating matters further is the global nature of production, with quality assurance needed to span international boundaries. As former FDA Commissioner Margaret Hamburg recently wrote:

“Today’s medical-product landscape blurs the line between domestic and foreign production, drawing attention to the need for global quality and safety oversight to prevent patient exposure to falsified products.”

Consumers and healthcare providers can exact even higher tolls on companies by instantly eliminating poor-quality product lines in the span of a bad Internet news cycle. Today, the competition for quality superiority and safety rivals the importance of price competition.

The Skills of Tomorrow's Quality Leaders

The best quality executives possess a range of skills including, first and foremost, technical expertise, usually with a degree in sciences or engineering. Educational achievement brings credibility inside the company and to outside stakeholders. Yet, this is merely the first requirement of successful business-focused quality leaders. When working at the highest levels, these executives also need a strategic mindset with the ability to identify potential revenue-loss pitfalls, coupled with the ability to increase a product's safe speed to market, all while partnering with regulators to guarantee confidence.

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Today, quality leaders must work across departments with excellent abilities to collaborate, communicate and influence. These executives must possess the ability to work across multiple departments including manufacturing, regulatory affairs, commercial and research and development. They must also be able to use these skills externally by working closely with outside experts. They must cultivate an understanding of regulators' goals, policies and points of view. The ability to work and collaborate with the Food and Drug Administration, and other regulatory agencies, is essential. Finally, these leaders can no longer work in isolation—an internal affairs group—but instead must be able to motivate their large teams to work independently while collaborating globally.

Where they Lead

At Egon Zehnder we've worked with multiple leading organizations to build superior quality teams. There is no one archetype for a successful quality leader, as organizations operate with unique strategies, cultures and business models. A few recent assignments highlight the range of skills required at different organizations. A leading generics and specialty pharmaceuticals company was in search of a senior leader to lead a global quality function based out of India. South Asia has become a robust center of global pharmaceutical production, and regulators around the world are intensely scrutinizing quality issues. The successful candidate had deep experience working across departments and geographic regions at large organizations and also had proven success working with multicultural and multinational colleagues. We also recently partnered with a leading global biotechnology firm to place an executive overseeing a team of 850 individuals across quality management, technical operations, R&D and regulatory affairs.

Far different from these established organizations with wide product lines, we also partner with a range of companies focused on a single breakthrough solution to drive results. One example is a highly innovative startup with positive Phase III results. With the company's long-term viability dependent on the success of this blockbuster treatment it needed a Global Head of Quality to ensure the smooth transition from development to commercialization. The successful candidate brought the requisite technical and scientific background, but also had experience helping startups navigate the regulatory challenges that come with new product launches.

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