Back to Basics for Biotech

Driving a Culture of Quality and Compliance with Practical Communication Techniques

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The robust regulatory environment surrounding biotechnology and bioprocessing demands a comprehensive current good manufacturing practice (CGMP) culture of quality, compliance, and absolute adherence to policy. Employees need to be engaged in their work, with a laser focus on meeting stringent specifications and operating under tight controls. A misstep in quality or compliance can lead to hefty fines, legal concerns, regulatory retaliation, and reputational damage.

Communication and stakeholder engagement are critical to aligning organizations and driving the right culture in highly regulated environments. This is essential during times of rapid change such as when systems, processes, and technologies are evolving and when organizations are expanding into new and emerging markets, integrating new employees, and implementing productivity initiatives. Research has shown that effective communication is a vital part of project management, technology adoption (1) and merger and acquisition (M&A) integration (2), all of which are ubiquitous in the biotechnology industry.

Unfortunately, during times of change — when communication is most critical to ensure consistency in quality and compliance — many biotechnology companies eschew communication and stakeholder engagement and consider them “distractions” or “unnecessary expenses.” This is a reasonable position, considering that return on investment (RoI) for some communications activities can be difficult to quantify (e.g., sharing updates with key audiences through meetings or electronic communications, measuring performance, collaborating across functions), and fewer than four in 10 businesses employ executive-level communications professionals (3). However, a mentality that refrains from communication during times of change simply will not do nor will disruptive communications programs that require heavy investments in staff, high-priced agencies, or complex collaboration technologies.

A communications model is needed to ensure that biotechnology companies continue to engage their stakeholders and drive cultures of quality and compliance as these companies change, grow, and adapt to evolving business realities. This model is both relevant and practical. It relies on repeatable and scalable communication methods that can be implemented quickly. Such methods empower executives, managers, and communications and human resources professionals to engage key stakeholders (e.g., employees, customers, suppliers, and investors) and galvanize them around change initiatives and organizational objectives.

When implemented consistently, the five practical communication techniques below can drive performance, promote collaboration, and build cultures in highly regulated environments such as those in biotechnology and bioprocessing.
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**Connect the Dots for Employees**

It’s clear that having an engaged workforce — employees who are aligned behind an organization’s strategic imperatives and willing to go above and beyond to meet critical objectives — is essential to performance. In fact, organizations with highly engaged employees have an average three-year revenue growth of 20.1% (compared with the average 8.9% rate) (4).

One of the most essential elements of employee engagement is pride in work and a feeling that work is meaningful. This is particularly true for up-and-coming millennial employees, more than 70% of whom expect employers to focus on “societal or mission-driven problems” (5).

The need to have engaged employees who find meaning in their everyday work is even more necessary in the quality-driven world of biotechnology. Employees need to be “on their games” always, monitoring for impurities, ensuring consistent service delivery, and operating safely.

The good news is that in the biotechnology industry, it’s relatively simple to connect daily work and meaning. After all, drug products are developed to save or improve the lives of patients — who may well be the family members, neighbors, and friends of employees themselves. Further, connecting those dots and communicating meaning is far less expensive and disruptive than the Silicon Valley–style perks (e.g., fancy employee events, gym memberships, and snack bars) on which too many companies rely to enhance engagement.

**Example:** This practical method was implemented at a global life sciences industry supplier of excipients and materials, where a low-cost internal campaign galvanized employees around the true meaning of their work. This company was going through significant changes, including M&A integration, a corporate rebrand, issues with technology adoption, and changes in ownership and leadership. Those changes were wearing on employees, and morale was slipping, as evidenced by erosion in quality, service delivery, and safety performance — all essential elements of the company’s value proposition.

Focus groups and in-depth interviews with global employees showed that most had very little understanding of the ultimate end use of materials they manufactured and purified. That translated to a transactional workforce that valued salary, paid time off, and benefits over quality, service and safety.

For employees to address the question of meaning and “connecting the dots,” a comprehensive communication program was implemented. It used existing staff resources and relied on company leaders to serve as messengers. No additional communications staff members were hired, nor was a high-priced agency involved.

Through posters, articles, and information sessions, the program shared real-world stories about the end uses of the manufacturer’s products. Employees could see and hear how the basic chemicals with which they worked were transformed into vaccines and drug therapies to treat societal banes such as cancer, heart conditions, and other diseases. Key pharmaceutical customers also were invited to visit with employees and discuss the end uses of the company’s products, underscoring the importance of delivering quality materials to specification and on time.

Within weeks, the program moved the dial, as key quality metrics began to improve, and integration efforts were expedited. A year after the program was launched, employee focus groups showed a significant increase in overall understanding of the company’s mission and strategic objectives. This the program set the stage for significant (>100%) improvements in on-time-in-full (OTIF) delivery performance and accelerated growth.

**Empower Employees to Stop the Process**

When employees notice potential quality or safety issues (e.g., black specks, inaccurate certificates of analysis, or debris causing safety hazards), they must feel empowered to stop a process and make their concerns known. This is easier said than done, particularly in environments where financial or efficiency performance is paramount and employees are incentivized to hit production targets at all costs. To instill a sense of empowerment in employees, organizations can take two practical steps, neither of which involves heavy investment.

**Rhetorically prioritize quality and safety.** Profit and productivity are essential to a company’s ability to succeed and thrive, and both must be measured, tracked, and incentivized accordingly. However, the order in which an organization discusses key metrics can have an implicit effect on employee behavior.

When reporting metrics at organizational or investment meetings, executives should lead the conversation with issues relating to quality and safety. Similarly, corporate scorecards and other reporting tools should be designed to emphasize those metrics that are most important from an organizational culture standpoint. Although financial or productivity results must not be ignored, they should be positioned as subordinate to the core issues of quality, service, and safety.

**Recognize employees who speak up.** When an employee does the right thing and stops a process because of quality or safety concerns — even at the expense of production time or operational efficiency — leadership needs to recognize that behavior. Recognition can take different forms and need not include bonuses or financial recompense.

For example, one quality program started at a life sciences global manufacturer recognized employees by using simple techniques at no cost to the company. Employees who stopped a process due to potential quality concerns were honored with certificates presented by site leadership at standing employee meetings. The story behind each honoree’s quality achievement was shared on the company’s intranet, and particularly illustrative stories were highlighted by the CEO in all-staff emails and at global leadership gatherings.
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Such practical recognition activities, when incorporated into existing processes, provided enough of an intrinsic boost that they encouraged others to follow their colleagues’ leads. Major quality complaints and recordable injuries both declined following program implementation, and key customers lauded the program during audits and meetings with executives.

**TALK THE TALK, EVERY TIME**

Every touchpoint with every critical stakeholder (e.g., employees, customers, suppliers, investors, key community influencers, and the media) is an opportunity to emphasize the core value generators for a company. For biotechnology companies, that means quality, service, and safety. By leveraging every contact point, manufacturers can multiply the impact of key messages without requiring extensive investment in tactical mass communication such as advertising, digital marketing, and public relations. This is an inexpensive, practical way to reinforce brand identity inside and outside an organization and to build the right culture.

Consistency is key. To leverage messaging effectively in this way, every meeting with every stakeholder must include and preferably begin with a discussion of quality, service and safety. By leveraging every contact point, manufacturers can multiply the impact of key messages without requiring extensive investment in tactical mass communication such as advertising, digital marketing, and public relations. This is an inexpensive, practical way to reinforce brand identity inside and outside an organization and to build the right culture.

To ensure that the appropriate messaging is reinforced, biotechnology companies should consider developing key organizational message frameworks that can be shared with internal and external influencers, including employees, channel partners, and outsourced sales teams. That will ensure that all parties are “reading from the same script” and reinforcing the right messages across stakeholder groups and interactions.

**COMMUNICATE CLEARLY**

Compared with average companies, high-performing organizations are twice as likely to keep their language clear and jargon free (6). This is not a surprise because jargon-laden “business speak” creates confusion, builds barriers, and erodes trust between managers and employees.

In a biotechnology environment where regulatory changes and shifts in customer requirements need to be communicated clearly and quickly, ambiguous language and complex acronyms can be disastrous. If communication is replete with jargon and other industry lingo, messages may not get through to your entire audience. This means that employees, suppliers, and customers might misinterpret messages and misunderstand required changes, leading to poor change adoption and regulatory risk.

Communicating otherwise simple messages in opaque terms also is a productivity waste because stakeholders spend time deciphering terms and decoding language at the expense of getting things done. To communicate clearly (both in writing and verbally), follow the tips below, all of which cost nothing and require no marginal investment.

**Be honest.** When communicating a difficult message or new requirement, be blunt and straightforward. Leave nothing to your audience’s imagination, and be clear about action items, training requirements, and mandatory aspects of the change.

**Be specific.** Ensure that all messages are specific. Details matter.

**Be concise.** Keep messages as streamlined as possible while ensuring that pertinent details, actions, and questions are clearly defined.

**Eliminate business jargon.** Do not use acronyms, jargon phrases, and complex language. This mitigates the risk of misinterpretation, confusion, and inaction.

**Eliminate hyperbole.** Go light on flowery adjectives. They can be met with skepticism and incredulity. Do not exaggerate claims or requests.

**RELY ON MIDDLE MANAGERS**

As we’ve noted, employee engagement is critical in the highly regulated biotechnology industry. Practical communication and stakeholder outreach techniques can improve engagement levels without requiring significant investments. One way to enhance engagement is to rely on individuals who have the most direct impact on employees: middle managers.

Research shows that an employee’s relationship with his or her immediate supervisor is a key driver of employee engagement (7). This relationship becomes even more vital during times of change. Good managers model the right behaviors; work with employees to demonstrate quality, safety, and service performance; and advocate for regulatory compliance. And managers who can communicate effectively can build trust within their teams while leveraging other communication touchpoints. Respected managers who cascade and reinforce the right messages can supercharge communication within a company and multiply the effect of every word, detail, and request shared by executives, the communications and human resources departments, and even customers.

Although managers are extremely important to sharing communication and building cultures, in reality many such people are ill-equipped to adequately capitalize on their positions. Many individuals rise to middle management because of their technical expertise, but they can lack the managerial capabilities to help their teams maintain quality and compliance standards while navigating major change (8).

Biotech companies must build middle management communication capabilities through training. To reduce cost, communications or human resources staff may be able to offer those development opportunities. Low-cost online training alternatives are available, as are myriad books and articles that can improve managerial communication performance quickly. Through consistent performance management, managers must be held
accountable for communicating with their teams and acting as positive-change agents.

These low-cost communication techniques transcend enterprise-level utility. They can be incorporated into daily activities by individual managers and technologists, and they can be implemented immediately, helping to drive cultures of quality and compliance without delay.

References:

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