

# Become a Regulatory Leader

By Paul Gil, PhD, RAC

The pharmaceutical industry has evolved from a stable, industrial structure, dominated by large, vertically integrated firms and an innovative but maturing technological environment, to a radically new knowledge base that has created great potential for new economic activities and induced important changes in industrial organization. Given this shift, it is more critical than ever to find ways of facilitating the transfer of knowledge and enhancing performance and effectiveness. Within a large pharmaceutical organization, the key is interpersonal interactions, personal rapport and collaborative relationships.

Nurturing relationships and building a reputation with colleagues, agency reviewers and agency inspectors are worthwhile activities that rarely receive enough attention. Honesty and trust go a long way in any work environment. Regardless of the size of the organization, being sensitive to the needs and interests of others, fostering a sharing environment, being socially skilled, and openly acknowledging the contributions of others are essentials to success.

Following are important steps to take in becoming a regulatory leader in a large pharmaceutical organization.



## Step 1—Share Experiences and Connect Emotionally

The first step is to share regulatory experiences and build trust in the work environment. Leaders with high self-awareness are able to recognize how their feelings relate to themselves, others and their job performance. Self-awareness is associated with emotional awareness, accurate self-assessment and self-confidence. Leaders can promote honesty and trust in the organization through being introspective, aligning goals with



values and being candid about feelings.

If a team is seeking advice about a particular regulatory strategy, be open and honest. Discuss realistic timelines and expectations, and be prepared to present alternatives. Invite dialogue and questioning to teach organizational members about their thinking to solve complex problems. Be honest and genuine. Authenticity will be gained by allowing heartfelt emotions to guide personal interactions and convey the truth about personal feelings and values. Voice, tone, gestures

and eye contact are visual clues that can indicate believability and trustworthiness. A focus on the feelings and perceptions of others that are beneath the words will help to establish an emotional connection and evoke a sense of trust.

### **Step 2—Resist Impulses and Suspend Judgments**

Leaders with high self-regulation are in control of their feelings and create an environment of trust and fairness. Self-regulation is associated

with self-control, trustworthiness, conscientiousness, adaptability and innovation. By suspending judgments, seeking out information and mastering their emotions, leaders are able to adapt to changes and build integrity. Resisting impulsive urges, choosing words carefully and developing a propensity for reflection will mitigate frustration. A good regulatory leader perceives and manages emotions. Regulatory affairs should set the example and focus the team to think critically, deconstruct problems and reach conclusions. Uncertainty and disorderly situations can be significant and have huge costs associated with mishandling.

### **Step 3—Empower and Motivate Others**

Learning is the foundation of effective leadership and a regulatory leader who continually develops employees helps to ensure organizational success. Large pharmaceutical companies tend to have more funds available for personnel development, technical seminars and symposia. Seize this opportunity. Invite staff to lead projects—teach and mentor them.

Motivation refers to achievement, drive, commitment, initiative and optimism. Motivated leaders have a passion to go beyond the minimum requirements and are driven by the desire to achieve. Communication, in terms of a leader's ability to relate to others, is a key element in the leader's ability to motivate. Complacency causes poor performance and sustained motivation requires periodic renewal. Continually raising the performance bar and tracking results will increase optimism and commitment to the organization. Effective leaders motivate, influence and inspire others.

### **Step 4—Listen Carefully With Focused, Genuine Interest**

Empathy refers to understanding and developing others. In large pharmaceutical organizations, formal systems, layers of bureaucracy and barriers may slow or inhibit communication. Regulatory leaders should turn away from organizational positions and politics toward attentiveness and genuine concern for others. Work closely with your colleagues and listen to them carefully. They may have concerns about data, a particular submission or global strategy. Listening with empathy shows genuine concern. Hearing others' perspectives and different experiences shows support and boosts their self-esteem. Showing genuine interest and enthusiasm builds employee morale and commitment. Empathetic leaders sense the viewpoints of others and consider employees' feelings and

other factors when making decisions. Practice listening skills and focus on the emotional makeup of others to enhance empathy. Mentoring can also build closer relationships that provide the opportunity to exercise more empathy.

### **Step 5—Network and Recognize the Contributions of Others**

Social skill is associated with influence, communication, conflict management, leadership, change, bond building, collaboration and cooperation and team capabilities. Social skill is about managing relationships with others. In a large company, regulatory leaders with social skill realize the importance of networking and getting work done through others. Interact frequently and build relationships and rapport widely across the organization. The key to successful organizational leadership centers on being sensitive to others. Large organizations usually have many lucrative and creative means to reward and recognize others. Personally delivering recognition and rewards also shows respect and gratitude and helps to solidify relationships.

### **Conclusion**

Effective organizational leadership calls for a dialog between leaders and their constituents to share knowledge and find meaning. Because the involvement of regulatory professionals transcends the product lifecycle, leadership opportunities are abundant. By building relationships, mentoring and collaborating, regulatory leaders play a key role sharing values, gaining understanding and expressing the organization's culture. ■

#### **Author**

**Paul Gil, PhD, RAC**, is Deputy Director, Regulatory Affairs for Bayer HealthCare in Berkeley, CA. He has been in the pharmaceutical industry for more than 30 years and with Bayer Global Regulatory Affairs for the past 10 years. Paul holds Master's degrees in science and business and recently earned a doctoral degree in management and organizational leadership from the University of Phoenix. He can be reached at [paul.gil.b@bayer.com](mailto:paul.gil.b@bayer.com)