



ANALYSIS



CRITICAL  
THINKING



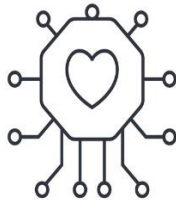
CREATIVITY



TEAM  
BUILDING



DECISION  
MAKING



EMOTIONAL  
INTELLIGENCE



RISK  
MANAGEMENT



RESEARCH

# The leadership role in regulatory affairs

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**Abstract** The global regulatory affairs (RA) profession is facing a shift in the definition of leadership success. This article aims to shed some light on important aspects of leadership. In the context of the article, leadership is defined by the power of making a difference. It explains why critical thinking, business acumen, emotional intelligence, team building, influence and mentorship plays a vital role in building leaders and why RA professionals today should use these tools to evolve into successful leaders. **Keywords** – business acumen, critical thinking, emotional intelligence, leadership, regulatory affairs

## Introduction

The regulatory profession was created with the desire of government health agencies to protect public health by ensuring control over safety and effectiveness of marketed products. With technological innovation (including the internet), globalization, and most recently, the COVID-19 pandemic

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experience, this profession has grown organically into a science where leadership needs have evolved. Regulatory knowledge is a must-have in today's leaders, but there are other traits, discussed elsewhere in this article, that set great regulatory leaders apart from the pack.

Leadership is very much related to change. As the pace of change accelerates, there is naturally a greater need for effective leadership.<sup>1</sup>

– John Kotter

Leonard Sayles, in writing on leaders, has addressed several relationship skills vital for leadership position, including motivating staff, supervisory behavior, problem-solving, communication, discipline, and performance appraisal.<sup>2</sup> Besides those skills, today's regulatory leaders are highly accountable for both the public's safety and the business, brand, and revenue. They may lead teams of a hundred or more professionals and have a long-lasting impact on the careers of many aspiring future leaders. In that context, technical skills alone do not make effective leaders. Effective regulatory leaders today are relying more than ever on skills from other functional areas (e.g., research and development, compliance, and marketing, among others) and on relationship skills they have developed over time with critical experiences. Today's regulatory leadership needs to have a multifaceted skillset to distance itself from the norm.

### Critical thinking

In 1910, John Dewey coined the term *critical thinking* as an educational goal that identifies a scientific attitude of mind.<sup>3</sup> Since its first setting, critical thinking has branched out from the educational setting and is now considered an essential skill for many working professionals, especially organizational leaders. Critical thinking is a crucial skill, or tool, for effective leadership. In today's competitive landscape, critical thinking is recognized at all levels of employment and can be the distinguishing factor that propels an individual upward in a company's hierarchy. The rising rate of complexity and ambiguity caused by rapid changes and developments in the industry has made it more essential than ever for leaders to be flexible in comprehending the competitive landscape and ever-changing regulations. For example, regulatory professionals are witnessing a perfect storm of complexity and uncertainty because of the COVID-19 pandemic attention and changes in regulations such as the EU Medical Device Regulation and In Vitro Diagnostic Regulation. More than ever, critical thinking is vital in dealing with global supply chain, personnel shortages, and the US food and Drug Administration's prioritizing of COVID-19—related medical therapeutics.

For leaders, asking a string of questions about a given problem is only the initial step in the critical thinking process. The regulatory leader must develop a robust process that goes beyond identifying the best subsets of solutions and considers the implementation of solutions with an equally robust execution strategy. An execution strategy must factor in current global regulations and standards and strategic path to be in compliance with regulatory bodies as well as for postmarket product sustenance. A critically thought-out and developed plan for global regulatory compliance can better position the organization to respond to unforeseen circumstances. For example, identifying and including global

regulatory requirements for new markets earlier in the product-development plan would eliminate country-specific requirements after the early design is completed. This would save valuable time and resources that can be allocated elsewhere to expedite time to the global market. The process should be concluded with a well-thought-out communication strategy to the rest of the leadership teams. As regulatory teams need to work cross-functionally with other stakeholders, communications must be critically planned and executed because a simple miscommunication can result in extended time to market and drive up costs.

It is a challenge to ferry many therapeutic product types through the regulatory trajectory the requirements can sometimes be difficult to interpret and relate to the business. Regulatory leaders need to have appropriate regulatory knowledge and experience that can be leveraged to achieve a desired solution with a less-than-desirable situation. For this, a good leader needs to draw on previous experience and conduct a retrospective analysis of the situation to be able to steer of potential pitfalls – for example, incorporating extra time at the start of a project to account for last-minute testing delays, properly documenting changes to avoid noncompliance, and having a robust, sustaining strategy in place to avoid any compliance gaps after approval.

A leader must have a great understanding of self-awareness and awareness of a company's culture to ensure their thinking is not influenced by biases. This can be achieved by learning from past mistakes and admitting any shortcomings. An effective leader should avoid jumping to any unfounded conclusions and instead ensure that any critical decision is based on careful and considerate scrutiny. For example, if a leader is influenced by confirmation bias, they will actively try to seek information that proves their point of view or placing greater emphasis on facts that benefit their argument rather than using all the known facts to make a sound decision. The latter could at times mean making an unpopular choice, that in the moment will go against the majority's opinion. However, the ultimate goal of the leader is not instant gratification, but the proper completion of the project with fewer obstacles.

### **Beyond business knowledge**

To understand what makes business acumen essential for leaders in today's global market, we must first understand what the term means. The word "business" in the collective word denotes the business literacy, which is to say a leader should have knowledge and understanding of various functions and departments within an organization. "Acumen," according to the Merriam-Webster dictionary, is "keenness and depth of perception, discernment, or discrimination, especially in practical matters."<sup>5</sup> Summed up, *business acumen* is the understanding a leader should have about how their business operates and how it is acquiring market share in the competitive landscape.

Powerful global economic trends are [. . .] converging in such a way as to increase the importance of business acumen in leadership-development approaches.<sup>4</sup>

– E. Ted Prince

A key component of business acumen skills is to have in-depth knowledge of the industry in which one operates. A leader needs deep insight into business space and the organization's portfolio to have clear visibility of product lines in jeopardy of losing market share or introducing a new product that acquires market shares from competitors. A regulatory leader needs to have well-developed business acumen skills to deal with the complexities faced in the regulatory development path, as many business factors drive ultimate development strategy design. Since regulatory decisions have a direct impact on business outcomes, a regulatory leader needs to have strong business acumen skills to comprehensively understand the business. The need for these in-depth skills is crucial in all aspects of the product life cycle. The importance of business acumen for regulatory leaders can be best exemplified by examining the complex decision-making that takes place in product development from initial stages of development to product discontinuance.

A regulatory leader must understand the business implications of choices made during the early stages of product development (i.e., nonclinical and clinical studies). Special attention should be paid to the clinical study endpoints as they will directly affect the product's label claims and competitive advantage in the marketplace. By combining the understanding of the business space and good regulatory decision making, a superior product that maximizes the therapeutic value to patients and market success can be introduced.

Even after product approval, regulatory intelligence and business acumen are needed to understand the business aspects of postmarket regulatory decisions. As the need increases for a company's medical products increases in the market, one of the first changes that will need to be considered is expansion of the manufacturing facility, whether that entails buying new equipment for existing manufacturing facilities or transferring manufacturing to a newer facility. In either case, a regulatory leader needs to evaluate the implications of the requested change(s) from both the regulatory and business aspects. From a regulatory perspective, a few considerations must be considered, for example, regulatory submissions and supplements, potential time interacting with the regulatory authority, and any applicable filing fee. From a business perspective, risks such as a potential line situation must be considered when evaluating a proposed manufacturing change. Having a strong understanding of regulatory knowledge coupled with a core competency of business acumen, a regulatory leader will have a comprehensive understanding of any given situation that would help in making the right decisions.

In today's competitive environment, it is important that smart decision making is not limited to organizational leaders who head up departments – business acumen needs to be more pervasive across all corporate levels. To achieve that, leaders should mentor those they supervise in the art of business and provide adequate opportunities for on-the-job training, professional development programs, or formal business training. This will help individuals step outside their specialized functions and comfort zones to gain a deeper understanding of how the organization operates and they will come to better understand the impact of their role in achieving the company's goals. In turn, this also

underscores the importance of teamwork and discipline and a deeper understanding and appreciation of the interdependence of different functional areas. To achieve this level of success, a leader must have a good aptitude for emotional intelligence, discussed in the next section, as they need to gauge and cater to the needs of their superiors, their subordinates, and the company.

### **Self-awareness and emotional intelligence**

While the regulatory workforce is still dealing with the stress and social isolation associated with COVID-19, delays in communications with health agencies, and internal pressures to deliver, the ability to recognize and manage emotions is more important than ever. According to the International Chamber of Commerce's Workforce Trends Survey of 2020, emotional intelligence, otherwise referred to as emotional quotient, is among several must-have skills a successful leader should have.<sup>6</sup>

The ability to monitor and discipline oneself is one of the most important traits of an effective leader. Fundamentally, emotional intelligence is rooted in the concept of self-awareness and executed through self-discipline. There are four elements to emotional intelligence: self-management, self-awareness, social awareness, and relationship management. Leaders with a high emotional quotient are aware of how their emotions affect their work, relationships, communication skills, and empathetic attitude toward others. Emotional intelligence can be difficult to acquire if it is not innate because it is multifaceted, but it is an important trait in successful leadership.

Within internal teams, harnessing emotions is crucial when applying them to tasks that involve critical thinking and problem-solving within regulatory affairs. Regulatory leaders are required to understand internal and regulatory health agency processes to strategize for market approval. Emotionally intelligent leaders are able to understand and analyze the process, as well as understand how the health agency regards certain issues at hand. Emotionally intelligent leaders will know that the agency reviewers are their advocates in advancing the product to approval. Catering to agency requirements while simultaneously navigating the dynamics of a business requires the ability to control one's emotions in times of stress or conflict while empathizing with colleagues. Emotionally intelligent leaders are adept at navigating such fluid situations and better achieve positive outcomes.

### **Building strong regulatory teams**

According to US Bureau of Labor Statistics, about 4 million people quit their jobs in October 2021, and US companies had a total of 11 million open positions by the end of 2021.<sup>7</sup> Today's leaders are seeing high turnovers of employees, which is placing stress on their teams. When employees leave, productivity can sink, morale suffers, and those left behind struggle with increased workloads until new personnel can be hired and brought up to speed. To avoid high employee turnover, it is important to build strong teams that foster belonging and provide adequate growth and development opportunities to team members with varied professional goals.

Regulatory affairs comprises many closely related groups within a company, such as clinical, quality, and manufacturing, which means there is a huge potential for people with different backgrounds and expertise to contribute to the regulatory side of emerging technology. Essentially, regulatory leaders need to embrace the catch-all mentality to create an environment in which all team members can realize their potential. This can be achieved by clearly defining current roles and responsibilities across the organization so that teams understand the current scope of their roles and determine appropriate growth pathways to achieve professional goals.

Diversity unlocks innovation by creating an environment where ‘outside the box’ ideas are heard.<sup>8</sup>

– *Harvard Business Review*

Companies with effective diversity programs are 70% more likely to capture a new market. A good regulatory team needs good diverse collaborators. Effective execution of strategies can be achieved through highly engaged, diverse, and collaborative team members with a strong sense of teamwork. The regulatory function continues to be an interface between different business areas to put together a convincing story for the regulatory agencies or between the agency and business, to be the catalysts for collaboration and problem solving. Collaborative problem solving occurs as people work together to exchange information, ideas, or perspectives. A collaborative culture may not occur if people do not feel empowered, and empowerment does not occur unless people trust that they are valued, appreciated through adequate performance appraisals, feel safe to give their opinions, and are able to be the unique individuals they are. Regulatory leaders are required to create an empowered culture in which people constantly share and work out problems and solutions, leading to an increased knowledge gain of the entire team, which can then be shared to avoid future pitfalls and lead to greater performance of the team.

Finally, leaders also need to be cognizant of the hurdles of remote work and aim to ensure that their teams can maintain a sufficient work-life balance. This work-life balance is particularly important for larger companies with a global presence, for example, where team members need to be in meetings at the same time but are in different time zones. Providing adequate secondary support for such team activities should be prioritized and can be achieved through modeling culture of collaboration, trust, and awareness of colleagues.

### **Leading by influence and mentorship**

Effective leaders are inspiring and influential and have an impact on individual performance by drawing on their emotional intelligence and business skills and fostering collaboration and trust at both the individual and team levels. Different ideas motivate different people, so it is important for leaders to get to know their team members and understand what motivates them. The assumption that influence is synonymous with authority is no longer valid. Fortune magazine’s annual issue of the 50 Greatest World Leaders<sup>9</sup> is a good example of influencing leaders. The accolades are not limited to CEOs and industry leaders. Instead, it celebrates individuals who are doing groundbreaking work with, or without, formal authority.

## Shared leadership

Regulatory organizations are increasingly adopting a model of shared leadership. The workload today is usually too large for a single influencing leader and is better managed by multiple leaders at different levels displaying similar confidence and influence. This also provides multiple opportunities for undesignated leaders to shine and demonstrate their abilities.

Train people well enough so they can leave, treat them well enough so they don't want to.

– Sir Richard Branson

LinkedIn's 2020 workplace learning report shows that 94% of employees stated they would stay at a company for longer time if they were offered opportunities to develop and grow within the company and their careers.<sup>10</sup> Also, 9 out of 10 workers with a mentor say they feel happier within their career, according to a survey on workplace happiness.<sup>11</sup> In contrast, 4 out of 10 workers who do not have a mentor admit that they have considered quitting their job every 3 months.<sup>11</sup> Leadership is often reduced to titles, positions, and day-to-day workplace tasks. These are important aspects of leadership, but a leader's success can and should be defined by their ability to make a positive impact on others.

## Mentorship

In particular, leaders should consider being mentors. Effective mentoring can contribute to achieving business goals. However, mentoring also increases job satisfaction and could enhance the leadership and team experience. Mentoring and career progression go hand in hand, with mentoring now considered one of the top strategies for career and leadership development. Whether you are a mentor or a mentee, it can greatly benefit your career. The merits of a good mentoring program were demonstrated in a 5-year study in 1,000 employees at Garner, which found that mentees are five times more likely to be promoted than those without a mentor.<sup>12</sup> A compilation of mentoring statistics, updated in early 2022, established a similar trend for mentors who were six times more likely to be promoted compared with their coworkers who were not mentors. In addition, the statistics indicated that 25% of employees in a mentoring program had a salary increase, compared with 5% who were not in the program.<sup>13</sup>

## Conclusion

An individual with strong leadership skills is more capable of making sound judgments, creating successful business strategies from a regulatory standpoint, and being self-aware and emotionally intelligent. The leadership skills discussed in this article are not quickly or easily acquired and need to be taught and honed over time.

The key to strong leadership skills is the ability to learn how to be a better leader and to share the acquired experience with those who are less experienced. It is equally important to understand as much as possible about the specific organization, regulations, and market space, as it is to understand and the people you work for and, more importantly, those who work for you. A



leader needs to have solid business acumen skills to ensure they do not implement strategies purely on a regulatory basis, but also consider the impact of regulatory decisions on the overall business and future operations.

Like all important skills in life, it takes time to acquire leadership skills and longer to perfect them. The art of being a great leader is always finding new ways of self-improvement and influencing others along the way. If there can be one takeaway from this article it is that there is no one person that is a perfect leader, but it is this realization that leads to people becoming great leaders.

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