

Quality Culture: Charting the Path

to an Organization-wide Commitment to Quality,
Compliance and Right-1st-Time Performance



Rapid and significant global growth for the biologics division of a major pharmaceutical manufacturer brought a dramatic increase in regulatory inspections – and deficiencies in quality. Expecting unprecedented growth in number and types of new products in the coming five years, the division wanted to become best-in-class in overall quality in order not to jeopardize its operating license or its future. For help, they turned to **Tunnell Consulting** for an assessment of all aspects of quality across multiple sites and corporate headquarters.

The result: The organization now has a comprehensive roadmap for creating a sustainable Quality Culture, which will allow it to:

- Improve operating performance and productivity while reducing compliance risk
- Maintain a reliable state of quality and compliance in all company activities at all levels
- Grow the business significantly without disruptions to quality

Tunnell assembled a team . . . and it facilitated the shared perspectives that are essential for creating a Quality Culture in which everyone . . . thinks and lives Right-1st-Time.

Tunnell was engaged to assess global quality and GMP compliance challenges and help create a sustainable quality-based culture.

The biologics organization had faced multiple pressures in many parts of the business, and rapid growth in the vaccines business had brought increased regulatory inspections. Expected growth in several products promised even more change ahead. And, like many companies, the division faced the inherently more complex challenges of compliance. In response, the division established a cross-functional Quality Improvement Team. Chartered to assess global quality and GMP compliance issues and recommend remediation strategies – with particular emphasis on prevention – they turned to Tunnell for assistance.

Tunnell assembled a multi-functional team of highly experienced consultants in quality/compliance, biopharmaceutical manufacturing, lab operations and OpEx/OD/HR to conduct on-site evaluations at the company's vaccine manufacturing sites as well as their corporate headquarters. This single, integrated team conducting the assessment across all global sites ensured a consistent approach and evaluation across the organization. And it facilitated the shared perspectives that are essential for creating a Quality Culture in which everyone, at all levels and in all functions, thinks and lives Right-1st-Time and

maintains a reliably high state of quality and compliance in all activities.

Our assessment comprehensively addressed the process and people issues that together make up organizational culture.

Because culture is constituted of the complex interaction of activities, attitudes, and processes, we undertook a comprehensive evaluation of the organizational, procedural, staffing, and other parameters that impact quality within the organization. The assessment included:

- Interviews with site management
- Group polling sessions with site personnel across functional areas
- Review of site staffing and staffing ratios for quality-critical functional areas
- Assessment of impact of seasonal staffing at those sites where applicable
- Review of quality and compliance organizational and governance structures
- Review of current quality culture and practices and their impact on morale and behavior
- Evaluation of the impact of management style and behavior on the organization's quality culture
- Analysis of the impact of HR systems such as rewards and recognition on the quality culture

Defining & Creating a Quality Culture



- An effective and sustainable **Quality Culture is characterized by employees who are motivated** to consistently strive for the highest level of quality.
- **Achieving and sustaining a Quality Culture is an ongoing process** of continuous improvement – a mindset shared by all where everyone understands the organization's objectives, policies and procedures and their individual roles in helping to achieve them.
- **A Quality Culture is led by example.** Leadership at all levels is visibly engaged in supporting the development of a Quality Culture and effectively engages and motivates others to do the same, resulting in self-motivated accountability and sustainability.
- **An effective and sustainable Quality Culture is the sum of all the parts** of the organization, and must be continually monitored and fine-tuned as the organization grows.

- Review of quality- and compliance-based metrics
- Review of training and training effectiveness of full-time and seasonal employees

Our assessment uncovered people strengths that could be leveraged and culture challenges that needed to be fully understood and tackled.

The assessment found broad agreement across the organization about many of the aspects that bear on Quality Culture. Employees felt good about what they do; they recognized the high level of scientific and technical expertise throughout the company, and they felt that it manufactured high-quality products. Overall, they viewed their direct managers and supervisors favorably; they knew how their work affected the quality of their products, and they felt comfortable bringing attention to potential non-compliant activities.

However, in a number of critical areas, challenges that get in the way of an integrated, organization-wide Quality Culture emerged, including widely divergent views from site to site and to headquarters about the state of that culture. Among other things, the assessment found:

- Teams believed that they did not function effectively
- Employees had unfavorable perceptions of leadership above their direct managers and supervisors
- The manufacturing sites felt that they were micromanaged by headquarters
- Rewards and recognition programs for individuals and teams were regarded unfavorably and personal development opportunities were felt to be unavailable
- The organization was viewed as focusing on short-term fixes rather than long-term resolution of quality issues and engaging in reactive rather than proactive behavior
- Seasonal staffing issues were also seen to be a concern

Strikingly, barely a third of the polled staff at corporate headquarters and at all but one of the manufacturing sites responded positively when asked whether the right behaviors were encouraged for sustaining a Quality Culture.



Tunnell developed recommendations to help the company transform its disparate cultures into a powerfully integrated Quality Culture.

On the basis of the assessment, Tunnell developed an actionable set of prioritized recommendations for improvement, including quick wins and goals for the short, medium, and long terms. These recommendations encompassed highly detailed and specific action steps in these key areas:

- Leadership and Leadership Development
- Strategic Planning
- Organizational Structure
- On-boarding and Training
- Succession Planning and Career Development
- Rewards and Recognition
- Process Improvement
- Metrics

Based on Tunnell's input, the client has begun implementing many of the recommendations that were made and has recently reported successful outcomes in each area including successful restructuring of their Quality organization and improved Quality Culture across the organization.

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