

Quality Culture and its Measurement

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The Pharmaceutical Quality System (PQS) is composed of interlinked processes, such as the production process, the supplier process, supporting processes (validation, training, change control, investigation of nonconformances, audits, etc.) and management processes (review and ownership of the PQS, etc.). Underlying the PQS, and critical for its success, is the culture of the company, i.e., the quality culture.

The culture or values of an enterprise serve as a guide to decisionmaking. They indicate what is important to the enterprise and are largely attributable to the organization's leadership. Culture can be defined as the behaviors and beliefs characteristic of a social group.

More often than not, when a thorough root cause analysis of failures is done, the root cause is a problem with the culture. Another consequence of deficiencies in the culture is lack of continuous improvement of operations, and thus, of the PQS.

Today, the U.S. FDA is concerned about drug shortages caused by process and product failures in the industry. In response, FDA is pushing for quality metrics, and industry groups, such as PDA, are responding to this interest. Unfortunately, the metrics being considered—batch rejection rate, OOS, complaints, etc.—are all lagging indicators and do not address the root causes of these process and product failures.

Components of the Quality Culture

What are the desired components of the quality culture? Below are some things to consider.

1. Customer focus

The patient, the recipient of our products is the primary customer, not the regulatory authorities. The product must be safe, effective, available and affordable. All employees must understand what they are doing from the customer's point of view. For most employees, the immediate beneficiary of their work is a group or person inside the company, i.e., an internal customer. They need to understand the needs of their internal customers and assure that these needs are being met right first time and every time. This would apply to several QA-owned processes such as auditing, change control and documentation. Remember that only the production process provides an output used by the patient, the external customer.

2. Quality is the responsibility of every employee

Every employee is responsible for the quality of their work. It should be done right first time with no errors. Senior management is responsible for the PQS, compliance with it and its continuous

improvement, as per ICH Q10. They are the owners of the PQS. Production is responsible for the production process and the quality of its output, the drug product.

The quality department works with process owners and subject matter experts in production, R&D, engineering, etc., to assure that processes are well designed for their purpose. It periodically provides data to senior management on process performance through analysis of the quality metrics and through audits. It provides expertise and facilitation, when needed, for preventive and corrective action to improve processes. It promotes and sells good quality practices by example, shares best practices and rewards good performance.

3. Quality before cost

Although the cost of the drug product is important to both the patient and the company, quality must never be compromised for the sake of money. On the other hand, all processes should be designed to be efficient as well as effective. Waste, in all its forms, should be ruthlessly eliminated.

4. Employee empowerment

All employees should be given power and responsibility as well as held accountable for the quality and efficiency of their work in proportion to their capabilities.

The goal of the company is to increase each employee's capability through training and experience.

5. Continuous improvement

For continuous improvement to be more than a wish or a slogan it must be driven by senior management; and the employees need the skills and the time for improvement activities. Improvement activity should include preventive actions not just corrective ones. Periodically, processes need to be completely redesigned; i.e., they require breakthrough or radical improvement. All processes should be measured as right first time. Aim for at least 95% right first time; critical processes should approach 100%. Six Sigma should be the long term goal.

6. System approach to management (ISO 9000)

A system is a group of parts, components or departments/people working together to achieve a common goal. The PQS is a system composed of various processes. Interrelated processes are managed as a system. Processes are well designed, capable, fail-safe and controlled. We manage processes not departments.

7. Scientific approach

Use good scientific principles. Decisions, specifications and limits are based on data. If data does not exist, experiments are performed to obtain the data.

Use statistical and quality tools as needed. Statistical tools are used for validation and process control.

8. Emphasis on prevention, not appraisal

Shift from quality by inspection to Quality by Design. Focus on process understanding so that processes can be designed that are robust and fail-safe. Balance the "CA" in CAPA with more "PA."

9. Balance between the short term and the long term

Excellence requires years of consistent effort. The winners of the Malcolm Baldrige National Quality Award speak of a ten-year journey. Achieving Class A certification for Operational Excellence usually takes at least three years.

This requires a strategic improvement plan for the PQS which should be a part of the company's strategic plan.

10. Teamwork

As was said above about a system, all departments need to work together, openly and honestly, to achieve common objectives. Cross-department communication, respect and trust are essential. Understand that all important processes are cross-functional which requires interdepartmental cooperation in their design, control and continuous improvement.

11. Integrity

This should be an obvious requirement. At the end of the day we must be proud, not ashamed, of what we have done. Management must hold themselves and their employees accountable for their actions.

12. Drive out fear (Deming's 14 points)

Perhaps this should be at the top of the list. Fear can be the most pernicious and deadliest cultural disease; in particular, fear of saying the truth.

An aspect of this is the need for a communication path for all employees directly to senior management for all high risk quality problems.

13. Risk Management

Risk analysis and risk thinking permeates all processes and decision making. The concern is to minimize risk to the patient, to the employee and to the company. Priorities and resource allocations should be made based on a risk analysis.

Risk management is a skill the quality department should provide if it does not exist elsewhere in the organization.

14. Give priority to learning — individual and organizational

Benchmark and learn from other more advanced industries. Make training more effective. Training should result in change and improved performance, otherwise it is a waste. Allocate sufficient time for training in the weekly schedule. WHO recommends 3–5% of available time for skilled and experienced individuals. Training needs to exist at all levels from senior management down. Continuous improvement requires continuous learning.

Measurement of Culture

A positive culture change requires active involvement of management. It must be measured and planned. Culture or values are usually measured by employee surveys. There are many companies that provide this service. These companies can design a valid survey based on your specific desired culture.

Figure 1 for an example of a simple survey with scaled responses.

For example, an employee would rate the following statement: “Employees are empowered to take direct action whenever they encounter a problem that is likely to impact customer satisfaction, product or service quality, cost and/or schedule,” with a rating of Excellent, Very Good, Fair, Poor or Not Doing **(1)**.

The self-assessment maturity scale in Table A of ISO 9004-2009 provides a long list of key elements many of which relate to culture. For each element it provides a description for each level, 1-5.

Figure 1 Here on this continuum line, employees can rate their perception of the relative importance in the company of cross-functional teamwork



Change of Culture

It is inevitable that a company will want to change or improve some aspects of its culture. As with any improvement, there needs to be an assessment of the current reality, a vision of the desired state, a concrete plan to achieve the desired state and a way to measure progress. This is obviously a responsibility of senior management. They must model the desired behavior by their actions and also reward behavior consistent with the company’s values, refusing to tolerate behavior inconsistent with

the values. In the latter case, sometimes it may be necessary to terminate the employee. Some companies as part of their hiring process give “value” tests. These companies recognize that it is easier to train an employee technically than to change the employee’s values. Personal values become more important the more senior the position.

The company culture or values—which should not be distinguished from quality culture—is critical to product and service quality, for consistent compliance and the long term success of the company. And it can, and should be, measured and managed.

References

1. Oliver Wight International, Inc. *The Oliver Wight ABCD Checklist for Operational Excellence*. John Wiley & Sons, Inc: Hoboken, NJ, 2000.

About the Author

Robert Kieffer is an authority on quality management and on quality system design.

Hear more about this topic from Robert at the new PDA Education course, “The Quality Culture and its Measurement,” following the 2015 PDA Annual Meeting, March 19. To learn more, visit www.pda.org/2015-pda-annual-meeting-course-series.