

## Quality culture: A top-down culture

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Establishing a quality culture from the top of an organization down to each and every employee ensures a safe and effective product, and saves costs.

Quality culture is a patient-focused approach to quality that is proactive not reactive or procedural, according to Rick Friedman of FDA, in a conference presentation. When an organization is focused on quality, it can detect problems earlier, experience fewer deviations and costly remediations, and protect its brand, according to Friedman. Creating a quality culture means an investment in quality including organizational structure, actions, quality standards, support for all levels of the company, and having quality be a part of business decisions. And the quality culture starts at the top.

“Companies with good quality cultures usually have transparency and collaboration between departments,” says Susan J. Schniepp, distinguished fellow at Regulatory Compliance Associates. “This is critical when there are problems that impact manufacturing. Companies with a robust culture usually solve the problem faster, which helps them maintain high productivity rates,” she says.

### Quality culture is not just the quality department

The quality department in a bio/pharmaceutical company plays a critical, but not exclusive, role when it comes to ensuring that biologics and drugs are safe and effective. The entire organization, however, must be involved in ensuring quality is built in.

“Let’s clear up one issue right away,” says Schniepp. “When we refer to quality culture, we are referring to the culture of the company and not the culture of the quality department. Having an established quality department does not mean a company has a culture of quality. In a robust culture, the attention to quality is a responsibility of all employees, not just those who work in the quality department. In a robust quality culture, the quality department is a partner with operations, it’s a policing function,” she stresses.

“Quality culture is an all-pervading attitude and sense of purpose in which quality is foremost in everybody’s activities. A quality department is a part of the organization that monitors quality, (e.g., by end-product testing). However, quality cannot be tested into the product, it is inherent, and has to be built in—by design,” agrees Chris Moreton, PhD, vice president of pharmaceutical sciences at Finnbrit Consulting.

According to Friedman, “senior management has a critical ongoing oversight role to ensure suitability of operational design, control, and maintenance.” Friedman points to behaviors that can lead to the development of quality culture that include shared accountability, teamwork, listening, continual improvement, coaching, and integrity.

Moreton agrees. “In my opinion, a quality culture means that everyone from the CEO down to the most junior staff put quality (and patient safety) at the top of their agendas. Quality requires ‘top-down’ and ‘bottom up’ approaches. If senior management are not committed/interested, then the junior staff will find it difficult to implement and maintain quality activities. Similarly, if the junior staff are not properly trained and committed to and interested in quality, then quality will not be properly implemented. I have seen organizations where the commitment to quality was lacking, and there was, in effect, a lack of a quality culture,” says Moreton.

### Creating a quality culture

Creating a quality culture starts with the head of the organization, according to Moreton. “The CEO has to be committed in both words and deeds. [The CEO] has to hire people who will help shoulder the burden while maintaining the business. This then goes on down through to the most junior staff. People also have to be prepared to enforce the rules. (There is a line beyond which an individual must not step, because once they have stepped over it, they will be asked to do so again and again—to thine own self be true!),” he says.

Communication is key, says Schniepp. “Robust quality cultures have open communication and welcome feedback from all employees regardless of position within the company. When a company has a poor culture, the communication is top down, and employee opinion and input [are] not valued.”

### Measuring quality

How does one take stock in the robustness of quality culture in a bio/pharmaceutical company? “There are studies and data that suggest you can measure the quality culture of an organization by looking at the maturity level of the attributes in their quality management system,” says Schniepp. “The premise is if you can measure a company’s attributes (CAPA [corrective action and preventive action] system, communications), you can measure the quality culture of an organization.”

Regulatory agencies may take the organization’s history into consideration when assessing the effectiveness of a company’s quality practices, especially during an inspection. “How many FDA 483 observations have there been, and how efficiently did they respond and rectify the issues? The inspector will also take note of how people are working, etc. during an inspection. In some ways, it all comes down to the inspection process and the inspector,” says Moreton. “[Regulators] want quality (and patient safety) to be taken seriously, and not simply paid lip-service to. They will look to see who makes the decisions affecting quality. The general state of the facility and the attitude of staff (both senior and junior) during on-site inspections. They will also look at how complaints are handled and recall-readiness—how the organization would cope in the event of a recall,” says Moreton.

“Regulators have linked the lack of a quality culture with data integrity issues. Guidance documents released from the Pharmaceutical Inspection Co-operation Scheme, the UK’s Medicines and Healthcare products Regulatory Agency, the World Health Organization, and FDA all stress the link between a robust quality culture and reliable and consistent data. One thing they all stress is an open culture that embraces employee feedback and values employee contributions. They also stress that senior management must be involved and must fully participate in establishing a culture of quality,” says Schniepp.

### Poor quality leads to problems

Is the investment in creating a company-wide culture of quality worth the time and effort? It seems the alternative is worse; the repercussions of not having a robust quality culture include higher costs and increased scrutiny by regulators. “Ultimately, [the impact] is likely to be financial because there will be FDA 483 observations to remedy, possibly product recalls, and ultimately the possibility of a consent decree. These all take time and money. (If people think quality is expensive, try a long FDA 483 list, a product recall, or a consent decree). The company’s stock price will also likely take a hit,” stresses Moreton.

“Companies that lack a good quality culture usually have high deviation/investigation rates, which impact their ability to provide safe and effective medicine to patients. It also costs them more money to perform the investigations making them less efficient,” agrees Schniepp. And, in the end, the safety of the patient is what matters most.