Culture and Medical Device Quality

Introduction

Providing a quality product while meeting all quality standards set by regulatory bodies can often prove to be a challenge even to the most seasoned organizations. When an inspection occurs receiving a demerit can deal a blow to an organization, not only to their regulatory standing but to the organization’s morale and reputation as well. Some organizations have chosen an approach to inspections called Just-In-Time Readiness. This approach has organizations preparing for an audit in the weeks or months leading up to when they know the audit will occur. Basically, not caring about quality until it is time for the inspection. This leaves the organization scrambling and places a considerable amount of stress on everyone involved.

This, however, is not the only approach to preparing for an audit. A way to constantly be prepared for audits is to promote a culture of quality within the organization. Having everyone within the organization dedicated to and constantly working towards quality will mean that the organization is always ready for an audit. Additionally, the organization will continually be producing high-quality work and have reduced need for crisis management and corrective and preventive actions (CAPAs).

The FDA requires the quality systems for products they regulate to be aligned with current good manufacturing practices or cGMPs¹. Medical device cGMPs are listed under the FDAs regulation 21 CFR part 820¹. Part 820 details what the FDA expects out of a quality management system for medical devices. Other regulations provide similar outlines of what they require from quality management systems. However, simply following these outlines will not be enough to create a culture of quality within an organization. That being said, incorporating the practices from these regulations, like those in part 820, into everyday work is a good first step for medical device manufacturers.

Consequences of Poor Quality

Having poor quality products can have disastrous results even outside of inspections. When an organization lets quality fall by the wayside until it is time for an inspection it is an example of a culture of low quality. Among medical device manufacturers, poor quality can have many consequences. Continuous low-quality work can put the company in bad standing with both regulatory bodies and customers.

A recall is one consequence that a manufacturer could face. An organization with a culture of low quality will most likely produce a product that is low-quality. A low-quality product released can result in the need to perform a recall. While larger multimillion-dollar organizations can easily deal with the ramifications of a recall, for smaller organizations even one recall can prove fatal. Whether it is a voluntary or involuntary recall the cost will likely be great, both monetarily and otherwise. The sheer number of resources needed to go through a recall can cripple an organization. A recall can take months with the FDA requiring an update every 2 to 4 weeks.

A culture of low quality can also cause damage from within the organization. Constant recalls and demerits on audits can cause morale among employees to drop significantly. While quality is everyone’s responsibility, mistakes and defects in products will most likely come from employees not following procedures correctly or following procedures that were made without quality in mind. This means that the employees will ultimately be reprimanded in some way. Being reprimanded in this way will also decrease morale, especially if the employee had followed the procedure correctly.

Low morale and high stress can lead to higher turnover rates. Losing employees in high numbers will, once again, damage the organization, costing even more resources to hire and train new employees. A culture of quality can help prevent this issue and even increase employee morale. Quality built into the organizational culture will allow organizations to actively prevent the worst-case scenarios and be prepared for those inevitable instances when disaster does strike.

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Starting a Culture of Quality

To create a culture of quality several different factors will need to be considered. Leadership, teamwork, process and process improvement, and the values of the organization should all be looked at. When the push towards the new culture begins every person within the organization would be playing an active role in creating the new culture.

Figure 1: Consequences of Poor Quality

Creating a culture of quality starts from the top. Leaders and those in positions of power must not only be dedicated to quality but demonstrate that commitment on a regular basis. Having leaders who believe that quality should be a part of everyday life in the work environment can inspire employees to integrate quality practices into their everyday tasks as well. This creates a ripple effect, with employees continually striving towards quality, audits will become significantly less stressful, customers will be happier, and the organization's reputation will be greatly increased as well.

The total quality management (TQM) approach is a well-known approach to quality improvement. While the approach is popular and respected, it has been observed that without support from an organization's leadership many TQM initiatives fail\(^5\). This failure to implement the initiative demonstrates just how vital a role leaders play in quality. Even highly respected approaches to quality, like TQM, can fail if senior leaders are not behind them or actively working towards them with the rest of the staff.

Leaders who are active supporters of quality have a much higher chance of creating a culture of quality within their organization. Senior leaders should come together to create a


united and clear message about quality within the organization. Inconsistent messaging can lead to confusion among employees which could have negative effects on quality instead of positive ones. Clear messaging will lay the foundation needed for the culture of quality.

To be an active supporter means leaders need to do more than simply voice their desire for a culture of quality. Being active means doing things such as providing employees with any resources or tools they would need to build the quality culture, ensuring that quality improvement initiatives are a part of the organization's strategic plan, providing guidance on what exactly the organization means when they say quality, and more. Leaders should also be setting the example, practicing quality methods in their work.

Additionally, leaders should encourage employees to pursue quality. Outside of providing resources, as stated above, recognition and praise of those employees who demonstrate their commitment to quality is also important. However, being too heavy-handed can lead to the opposite effect. Leaders need to apply the right amount of guidance and encouragement to effectively promote quality among employees. Too many rules can end up preventing employees from thinking of creative solutions and creative quality improvement initiatives. The balancing act can be challenging but if done properly it will allow employees to take charge of the quality of their work. Employees will begin to actively and happily pursue quality instead of just seeing quality as another mandate from the senior leaders.

Maintaining a Culture of Quality

Senior leadership promotion lays the foundation for the culture of quality; however, it is employees who will ultimately maintain it. Employees can make or break the push towards a sustained culture of quality. Engagement is a key factor for employees to want to pursue quality. As stated previously, leaders encouraging employees that show their commitment to quality is a step toward creating a culture of quality. To maintain the culture, however, even those employees who seem to not be committed must be engaged and encouraged.

Employees being resistant to any kind of change can have a negative impact on the push for quality. Often, these employees can cause a toxic environment to be created that will result in other employees resisting the change as well. There could be any number of reasons why an employee may not want the change towards quality to occur. Giving these employees the chance to voice their grievances and make them feel heard will reduce their resentment. Allowing employees at all levels to participate and be active in the change will reduce employee resistance as well as have a positive impact on employee satisfaction.

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Reinforcement of desired behavior from those committed to quality while helping those who are scared or resistant to change understand why it is needed will help maintain the culture. Harsh discipline towards an employee who is not actively participating in or even voicing discontent with the culture of quality can have the opposite effect. Seeing disciplinary action taken can make other employees fearful and see the new culture as a negative thing instead of the positive one it is meant to be.

While employees are the key to maintaining the culture, leadership must still be taking an active role. Setting the foundation for the culture is not the end of their job. To maintain the culture of quality leadership should be working on building quality into the organization's core values and mission. Strategic planning should be done with quality in mind as well and processes should be made to produce a quality product. Quality is something that must be constantly strived towards, and it is the leader’s role to set the next goal.

Once again balance is imperative. Setting unrealistic quality goals can frustrate employees and lead to dissatisfaction. Realistic goals, even if they are challenging, can motivate employees to pursue quality even harder than before. Leaders need to understand their employees and pursue quality in a driven yet realistic fashion.

Conclusion

Quality is everyone’s responsibility. Initiated by senior leaders and maintained by employees, quality improves the overall state of the organization. Poor quality can have serious negative ramifications for an organization, but a culture of quality can have a substantial positive impact. A culture of quality is hard to achieve but the benefits are well worth it. EMMA International can help develop a culture of quality by establishing a well-made Quality Management System tailored specifically to companies and capable of growing with those companies. EMMA International helps companies improve quality, give us a call at 248-987-4497 or email info@emmainternational.com to get in touch with our team of experts today.