Essential Steps for Implementing A Quality System

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Implementing a comprehensive quality system is more difficult than most people anticipate because most companies start with two fundamental gaps in the implementation process. The first gap is a lack of objective information assisting in truly understanding the resources, time, and eventual rewards required for implementation of the quality system. The second gap is a failure to recognize adequately the amount of training required to support the culture change required for creating a sustainable culture for the quality system. Resolution of these gaps can readily be resolved by including an in-depth comprehensive compliance audit at the beginning of the process to provide management with an objective evaluation of the gaps, resources that will be required, and potential rewards to be realized. The second gap can be resolved by including key training on critical topics to support the implementation process periodically throughout the process.

To understand fully the reasons underlying this problem it will be helpful to ensure we all understand the scope of a quality system. A comprehensive quality system is the aggregate of all the organizational activities, incentives, plans, policies, procedures, processes, resources, responsibilities, and the infrastructure required in formulating and implementing a Total Quality Management (TQM) approach. Simply reviewing the definition emphasizes that implementing a comprehensive quality system is an activity that involves every person within the organization and the development of a culture of continuous improvement to achieve consistent quality in everything the organization does.

Research performed by leadership guru Dr. John Kotter© has proven that 70% of all major change efforts in organizations failed to meet their objectives. His research suggests that this failure arises because the organizations do not take a holistic approach required to see the change through. A critical step in developing a holistic understanding of the resources required to implement a quality system is often simply obtaining an objective third-party audit of the existing quality system to allow the organization to understand fully what is involved to implementing a more comprehensive quality system. This objective third-party audit should be performed by a certified auditor familiar with the pharmaceutical industry. The American Society for Quality (ASQ) provides independent testing and certification of auditors. ASQ also provides independent testing and certification for GMP professionals. An auditor certified by ASQ as a Certified Quality Auditor (CQA) and as a Certified GMP Professional (CPGP) can provide the objective in-depth audit that is required to provide the company with a thorough understanding of their current quality system and any gaps to be resolved as they move to a comprehensive quality system. An experienced quality auditor can also serve as a resource to help identify approaches helping to resolve gaps, when this information is included in the contract for the audit process.

When this in-depth, objective, quality system audit is complete, the organization needs to build a team for implementation of the change effort. This team will be comprised of staff members throughout all levels of the organization and will be charged to create and implement the change effort. This team needs to be carefully selected to include respected staff members and opinion leaders that will help convey the importance of this change. This team will work with management to communicate the new vision and the strategies required to implement the total quality management process within the organization. An essential

component of this team's function is to identify projects that provide visible performance improvements and to prioritize these projects so that success can be demonstrated rapidly, recognized, and rewarded early to support later and more difficult projects.

Implementing a quality system requires that the organization communicates that quality – and everything associated with the achievement of quality – is the main driver of the business, and that without quality, the business won't succeed! A corollary of this communication of quality is the development of a deep understanding that there is always more to learn about the company's processes and products. A culture of continuous improvement is uncomfortable for many people who have developed a sense of satisfaction in their understanding of their work. This very sense of satisfaction may be detrimental to the development of a culture of continuous improvement because it may fail to encourage people to see all opportunities for improvement. A company that is comfortable with its operations often fails to see opportunities for improvement or relegates some potential opportunities for improvement to some distant future because they failed to evaluate properly the cost of implementation and the impact of the potential profit.

One area that is frequently overlooked for improvements includes the testing and release procedures used within a company. These test and release procedures are embedded in the regulatory filings submitting the company's product approvals. Especially when a company is using pharmacopeial procedures, these procedures are considered almost etched in stone with substantial psychological barriers to change. Considered objectively, compendial procedures are consensus methods developed to a historically low technical level while still supporting product safety and are based on materials and techniques that are frequently a decade old if not older. Since the innovator is required by law to assist the United States Pharmacopeia (USP) by submitting a validated method, the productivity of these methods is frequently intentionally low. In fact, most pharmacopeial procedures provide for defined improvements of these procedures, such as USP General Chapter <1225> and <621> that can provide twofold or greater improvements in productivity over legacy or compendial methods with minimal cost of regulatory filings. Since product testing and release is direct overhead, failure to consider implementation of these allowable adjustments in test methods to improve productivity is effectively ignoring one significant area of improvements in productivity and profitability.

Communication of the message of continuous improvement of quality requires that everyone within the organization understands that quality and good manufacturing practices are synonymous. Good manufacturing practices are exactly what the words mean. Good manufacturing practices are those practices that support doing everything right the first time to minimize waste, maximize productivity, and maximize profitability.

As the quality system is being implemented, the organization needs to identify obstacles to change and change systems or structures that undermine the implementation of the vision. The organization needs to communicate an openness to risk taking and nontraditional ideas, recognizing the opportunity to learn more about their processes and products. An additional component of this openness to risk-taking and nontraditional ideas is communicating the concept that all avenues to improving operations will be evaluated holistically.

An example of this openness to careful consideration of all opportunities may be provided by the example of a company that had successfully implemented a total quality management system emphasizing the culture of continuous controlled improvement. This company manufactured aluminum vial seals. An operator on the floor offered a suggestion that would reduce operating cost for a single aluminum seal by approximately 1/10 of a cent. At first glance, this suggestion seems to be such an insignificant improvement that is easy to discount it. When the production capacity of the company was considered in addition to the cost improvement for the item the return on investment changed markedly. For this company, the normal production of aluminum seals was about 1 billion seals a year! Combining a rather minor cost improvement for each item coupled with such a high production volume provided an increased profit of $1 million a year!

Throughout this process, the successful organization will recognize that staff will have to adapt to a culture of continuous improvement rather than one of stability and absence of change and support them in this change. A successful company will provide additional training resources at key points throughout the implementation of the quality system to support the culture change. Management of the company can select key topics that are identified as hampering the implementation of the quality system and develop targeted training to help facilitate the transition. Common topics that facilitate an understanding of a quality system include GMP documentation procedures, change control procedures, and investigation procedures. Proper training on these topics helps the staff recognize that each of these procedures provides critical support to the ongoing quality of products and to the culture of continuous improvement.

The successful organization will have to work to celebrate growth both as an organization and for the individuals that contribute to it. The successful organization will recognize that there is always more to learn about our product and our processes.

By including a comprehensive in-depth audit of the existing quality system at the start of the process of updating the quality system and including systematic targeted training at key points throughout the implementation process the company has a markedly better chance of achieving the goal of a successful culture change in implementation of an improved quality system supporting GMP operations.

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[1]John P. Kotter, Leading Change