A company facing a laundry list of observations at the end of any regulatory inspection will likely react with great energy and purpose to fix each one. This reactionary approach will likely lead to disappointment when the next regulatory inspection reveals additional examples of the same or similar problems. It can rapidly become a repetitive cycle of failures resulting in chronic quality system/GMP non-compliance. This happens when the company focuses on the symptoms rather than the underlying causes, i.e. the systems. If the underlying systems are not corrected, inspection after inspection will identify examples of the same system weaknesses.

Strategic well-planned remediation is paramount to long-term sustainable corrections and corrective actions. Following a systems approach to remediation, combined with some fundamental key success factors, will ensure success. The value of a systems approach to corrective actions is recognized globally; MHRA and FDA recommend a quality systems approach. Correcting specific findings without correcting the underlying causative system is analogous to treating symptoms rather than curing the disease. A systems approach is not a controversial concept and many who are caught up in the “findings/company fix/findings/company fix…cycle” from one inspection to the next believe they are taking a systematic approach. In reality, they focus on fixing specifics or elements of underlying systems without regard to the causes for the problem. This superficial approach assures failure.

A robust quality system, first and foremost, provides assurance of high quality products. An additional benefit is assurance of regulatory compliance. A company that prides itself in having a comprehensive, sustainable quality system distinguishes itself from one whose objective is to be in compliance. The latter fails to capitalize on the business advantages deriving from a quality system. Creating a compliant quality system can be achieved by addressing the subsystems of the quality systems.

KEY TO SUCCESS FACTORS: COMPANY CULTURE, COMMUNICATION AND COLLABORATION

Over years of performing a variety of large to small-scale remediation projects, we have found a number of key success factors. We are highlighting three factors that will almost always assure a positive, successful and sustainable outcome -- the “Cs to success” or Company Culture, Communication and Collaboration.
These three key indicators are not easy to implement, but they should always be factored in early on and as part of the remediation plan. The analogy is a three-legged stool: If the stool loses one of its three legs, it will not stand properly. Likewise the three Cs are equally important to the success of the remediation and without all three in place, the likelihood of success is marginal.

A remediation plan that applies a systems-based team approach with collaboration and communication can itself have a positive affect on culture, but a concerted effort must be made by management to assure alignment of values with the remediation activities. This can be very difficult.

**Company Culture**

At the heart of any successful remediation should be the requirement to align a company’s organization to a common vision from which it can establish a robust remediation that meets regulatory requirements and is in support of the company’s business strategy. The values reflected in the company’s organization and support systems impact behaviors that ultimately influence the manner in which the remediation activities are executed.

However, if organizational values are not in sync with the vision, remediation plan and principles, then the remedial solutions (such as establishing, revising and modifying procedures) and in some instances processes may get changed. But, the behaviors of personnel may not, resulting in a compliant system on paper but not in actual practice. In this situation, any remediation/system corrections that are made will likely not be sustainable.

In addition, how employees are incentivized, rewarded, compensated, promoted, etc. influences behaviors. Sometimes little attention is given to the behavioral impacts and how they can affect remediation efforts. Management must lead by example. If they do something different from what they say, this sends clear messages to the organization that certain behaviors are tolerated, expected and/or permitted. During any remediation this will result in an organization at odds and in conflict.

Before remediation activities commence, personnel must understand the significance of the issues with respect to the regulation. They must first learn about basic regulatory terminology, requirements and expectations. Personnel should receive comprehensive training on regulations, requirements and approaches for personnel. The training should include an introduction to pharmaceutical law, management responsibility and basic pharmaceutical GMP/quality systems requirements and the fundamentals of building a quality system. The structure of the training should highlight the regulatory expectations, current industry practices (i.e. “best practices”) and address domestic and international regulatory requirements. The program should be structured to ensure that employees absorb the material and incorporate the trainings into their responsibilities.
Communication

Communications must be planned, measured, consistent and managed to assure clarity, effective conveyance of key ideas and consistent support of ongoing development. Providing the necessary attention to organizational culture can speed the process of remediation, as well as assure its ultimate success.

To implement sustainable organizational improvements, communication is required so that members of the organization have a common understanding of why change is required of them and the organization. Both initial and ongoing communication should convey the remediation plan and the strategy for the remediation, what it will entail and the expectation for the personnel directly impacted as well as those support functions sitting on the periphery. To help communicate the plan, a charter and a remediation playbook should be developed. The charter defines roles and responsibilities, team structure and scope of work. The remediation playbook establishes a common understanding and agreement among the team involved in the remediation and the standardized approach of how to conduct the work required in the remediation. The playbook also provides the general parameters and structure for the remediation, including:

> Core project team structure and membership

> A kick-off meeting with the teams to provide an overview of the core team process and all the phases of the project.

  • Define overall project goals, scope, and critical success criteria
  • Define key project, phases, deliverables and milestones
  • Define the project team organization and governance structure

Overseeing the entire project is the Steering Committee which may be called the leadership team, management team, etc. It consists of the senior managers representing the various functional areas of the company along with a third-party senior management expert for objective regulatory assistance. This team sets the vision, provides the necessary resources and commitment, assures linkages between the various teams, serves as the change agent for cultural and system issues, and resolves issues that invariably surface during the course of the project. It also affords visibility of senior management’s quality commitment.
Collaboration

Collaboration is essential for any organizational change. Building the relationship with team members and the client is paramount to a successful remediation outcome. Establishing a quality system that meet a company’s regulatory and business needs is challenging enough and in most instances requires a third-party expert to help companies address the quality systems issues. The quality system itself can take months if not years to remediate and a company in such a situation can develop a successful approach if it recognizes the value of a collaborative systems approach. This will ultimately have an impact on the organizational culture and lend itself to a group of people who constructively explore ideas to search for effective, efficient and compliant solutions. A company that does not embrace collaboration puts the organization at a disadvantage and at risk. The more a team collaborates toward a common goal, the better the working relationship, resulting in open sharing, discussion and consensus on solutions.

ABOUT THE AUTHOR

Maxine Fritz has 25+ years of combined FDA, industry and consulting expertise and is responsible for overseeing the Pharma Biotech practice at NSF Health Sciences, serving in both a technical and management role. Ms. Fritz works with clients in the pharmaceutical, biologics, biotech and medical device industries to develop quality assurance, manufacturing and regulatory strategies for compliance with FDA regulations. She conducts and oversees regulatory gap analyses, assists with the development and implementation of quality systems, and develops and implements corrective action plans to address deficiencies identified by regulatory agencies. Ms. Fritz has successfully managed, resolved and consulted on large complex compliance projects including corporate warning letters, mass seizure, consent decree(s), Application Integrity Policy (AIP) prosecution and import detentions.

For additional information about our remediation services, please contact Maxine Fritz at healthsciences@nsf.org.