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 upon the next regulatory inspection when the 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. 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. The value of a systems approach to corrective actions is recognized globally, with MHRA and FDA recommending 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 of 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 of 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 three key success factors that will almost always assure that the outcome will be positive, successful and sustainable. The three key indicators are known as the “Cs to success” or company culture, communication and collaboration. These three key indicators are not always easy to implement and must be factored in early on and as part of the remediation plan. Like a three-legged stool that will not stand properly if it loses one of its legs, all three Cs are equally important to the success of the remediation and without all three, 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 effect 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 to establish a robust remediation that meets regulatory requirements and supports 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. For example, see the case study, Remediation Done Right, on page 6.

However, if organizational values are not in sync with the vision and the remediation plan and principles, the remedial solutions – such as establishing, revising and modifying procedures or processes – may change, but the behaviors of personnel may not, resulting in a compliant system on paper but not in actual practice. For example, see the case study, Remediation Done Wrong, on page 7. In this situation, any remediation/system corrections 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 impact the remediation efforts. Management must lead by example and when in conflict with its words, this will send 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. Education and training should be comprehensive on regulations, requirements and approaches for personnel. Training should include an introduction to pharmaceutical law, management responsibility, basic pharmaceutical GMP/quality systems requirements and the fundamentals of building a quality system. The structure of the training should highlight regulatory expectations and current industry best practices, and address domestic and international regulatory requirements. The program should be structured to assure that employees absorb the material and incorporate it 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 and 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. Initial and ongoing communication should detail the remediation plan and strategy and what is expected from personnel both directly and peripherally impacted. To help communicate the plan, a charter and remediation playbook should be developed. The purpose of the charter is to define roles and responsibilities, team structure and scope of work. The remediation playbook establishes a common understanding among the team players involved in the remediation and standardizes the 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 the membership
- Structure of the kick-off meeting to provide an overview of the core team process and all the phases of the project, including:
  - Overall project goals, scope and critical success criteria
  - Key project, phases, deliverables and milestones
  - Project team organization and governance structure

A steering committee (also called the leadership or management team) oversees the entire project. It consists of the most 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 and for building the relationship with team members, and the client is paramount to a successful remediation outcome. Establishing a quality system that meets a company’s regulatory and business needs is challenging enough and in most instances requires third-party experts to help companies address the quality systems issues. The quality system can take months if not years to remediate and a company can achieve success if it recognizes the value of a collaborative systems approach. It will ultimately impact the organizational culture and allow a group of people to constructively explore ideas for effective, efficient and compliant solutions. A company that does not embrace collaboration puts the organization at a disadvantage and risk. The more a team collaborates toward a common goal, the better the working relationship, resulting in open sharing, discussion and agreement of solutions.

**A TALE OF TWO REMEDIATION PROJECTS**

These two case studies illustrate the points in this article.

**REMEDIATION DONE RIGHT**

– AN OPTIMAL MIXTURE OF THE THREE CS

Company A is a large multinational company with over 50 locations, various product lines and a strong drive for continuous improvement. The company proactively reached out to NSF for help with a number of quality system-related issues. More remarkably, the company was not under any kind of regulatory action and was in good standing with regulators. Instead, executive management recognized a quality system that was overly complex, had systemic issues and was not in line with industry best practices.

Senior management’s drive to initiate this remediation effort was indicative of the company’s culture, one of continuous improvement driven internally and not through an external regulatory action.

The remediation effort started under ideal circumstances with strong sponsorship from executive management and effective communication throughout the organization of the ultimate goal of the project. A project steering committee was formed to ensure that the project remained a top priority for the organization and to demonstrate executive ownership of the project.

Project teams were established consisting of NSF subject matter experts and cross-functional client team members. This composition helped create a team mindset that the project was a collaborative effort with both the client and NSF working together to provide the optimal solution. This spirit of collaboration ensures that a solution is achieved that not only reflects industry best practices but is also an ideal fit for the client and ensures sustainability since the client is part of the solution.

As part of the project governance, weekly meetings were held at the project team and project oversight levels. Meetings were well attended and issues were promptly escalated for resolution. The project was an overall success resulting in a less complex quality system that incorporated industry best practices throughout the system.
REMEDIATION DONE WRONG
– A SYSTEMIC BREAKDOWN OF THE THREE Cs

Similar to Company A, Company B is a large company with many locations worldwide and a number of product lines. However, that is where the similarities end. Company B engaged a number of consulting firms after facing significant regulatory action. The engagement was a knee-jerk reaction to a regulatory action and was not well orchestrated.

Communication with the senior management was strained as a multitude of events were competing for senior management's time. A project steering committee was not formed due to client time restraints and executive sponsorship was spread thin throughout the organization. This resulted in the remediation effort being one of many competing priorities which did not get the full support of the organization. The culture of the organization was not one of continuous improvement but one of fear and an overriding theme was “what do we need to do to get out of trouble.”

Without executive sponsorship and open lines of communication, the project suffered and timelines were extended, resulting in more knee-jerk reactions to get a quick fix in place. Weekly meetings were set up but poorly attended by both senior leadership and client project team members. Senior leadership did not make the remediation effort a priority and sites followed their lead.

Collaboration was limited and the client was content to have the consulting firms fix the issues independent of active client participation. The result is a solution that is done to the client as opposed to the client being part of the solution. The sustainability of these efforts is dubious as the client is not intimately familiar with the new system and processes that it must now operate within.

ABOUT THE AUTHOR

Maxine Fritz has over 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.

Follow Maxine on LinkedIn.

For more information, contact healthsciences@nsf.org or visit www.nsfhealthsciences.org

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