CASE STUDY

A TALE OF TWO PHARMACEUTICAL REMEDIATION PROJECTS

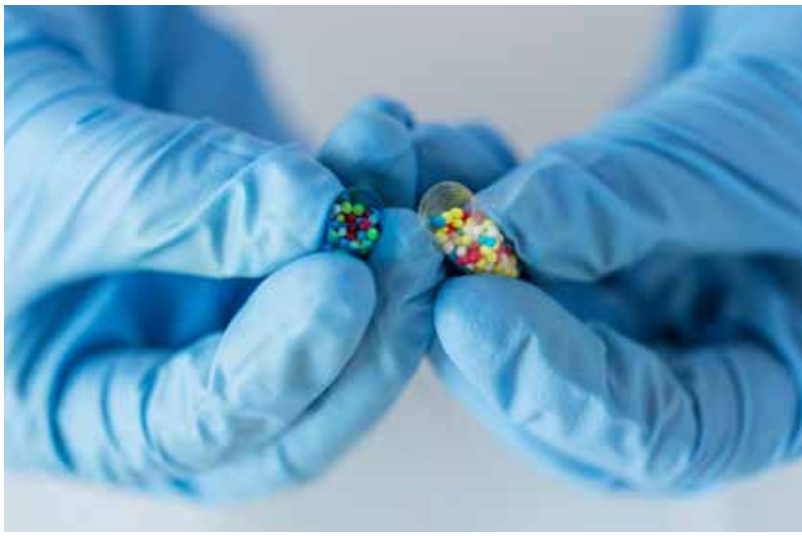
Over years of performing a variety of large and small-scale remediation projects, we have found a number of key success factors. We are highlighting three key factors that will almost always assure a positive, successful and sustainable outcome -- the "Cs to success" or Company Culture, Communication 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.

So let's look at two similar companies and the divergence of how they addressed quality issues.

Remediation Done Right - An Optimal Mixture of the Three Cs

A large multinational company with over 50 locations, various product lines and a strong drive for continuous improvement 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 its regulators. Executive management at the company realized the quality system 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, not through an external regulatory action.



The remediation effort started under the ideal circumstances with strong sponsorship from executive management and effective communication of the ultimate goal of the project throughout the organization. A 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 level and at the project oversight level. Meetings were always 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.

Remediation Done Wrong - A Systemic Breakdown of the Three Cs

A similar large, global company with a number of product lines engaged a number of consulting firms after facing significant regulatory action. The engagement was a knee-jerk reaction to a regulatory action that was not well orchestrated.

Communication with senior management was strained as a multitude of events were competing for their time. A project steering committee was not formed due to client time restraints and executive sponsorship being 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 therefore sites followed their lead.

Collaboration was limited and the client was content to have the consulting firms involved fix the issues independent of active client participation. The result is the solution was something "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 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.

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LMD-793-1219