GxP Quality – Building a Culture of Compliance

Establishing a "culture of compliance" is not a "paint-by-numbers" exercise; it must be injected into the DNA of a company. In our experience, many companies strive to create a "culture of compliance" but few approach it from the perspective of a mindset of "shared attitudes, values, goals and practices that characterizes an institution or organization," which is the essence of a "culture." The ideas that follow are intended to provide roadmap and practical steps towards implementing a company-wide "culture of compliance" in the life science industry, across any GXP area.

1. Develop a quality policy statement and quality objectives

Every company should set quality-related expectations for its employees and contractors. The policy that establishes an environment where employees and contractors are made knowledgeable of, and held accountable for, good quality practices pertinent to the company's business should not only be visibly displayed but also discussed with/explained to those parties who will be required to adhere to it. Company management should emphasize the details of the quality policy that are outlined in item number 2.

2. Identify and document quality criteria

Company management should identify and document the criteria for "good quality practices." These components may include, but may not necessarily be limited to, adherence to written policies and procedures, exercising good documentation practices (e.g. initialing and dating cross-outs, using a single line to for corrections), promptly bringing any deficiencies and/or deviations to the attention of company management, documenting unplanned deviations, providing explanations/justifications when planned deviations occur and correcting them in a timely fashion.

To successfully implement staff adherence to the company's quality policy, it may be beneficial for a company, in part, to tie staff members' annual reviews, promotions and/or salary increases to the effectiveness of the adherence to, and application of, good quality practices. In other words, it should be made clear to the employees that everyone, including those responsible for a given department/operation where a quality deficiency is identified, will be held tangibly accountable.

3. Establish a robust quality baseline

Through performing internal audits and assessing CAPAs, the company's Quality function (e.g., Quality Assurance) should identify quality-related issues based on the criteria regarding the components of "good quality practices" outlined in item number 2.

While performing the internal audits and through capturing the findings in the CAPA system, the Quality function should focus on identifying trends and themes related to non-compliance. In order to achieve this objective, the company's CAPA system should be such that it allows the company to collect information regarding appropriate metrics to assess the success of the "culture of compliance" initiative.

Lack of compliance should be tracked not only on an issue-by-issue basis, but also across departments, individuals and operations/processes. Collecting information on these items will help to identify the root cause of the issue, which may stem from a larger issue related, but not necessarily limited to,

1. *Cumbersome and, therefore, ineffective processes*

2. *Lack of appropriate supervision*
3. *Procedures that lack clarity (e.g., poorly worded documentation; lack of guidance, contradictory information)*
4. *Lack of documented procedures*
5. *Lack of an individual's attention to detail and common sense*
6. *Lack of effective training*

The list of potential root causes of the deficiencies encountered is limitless, but one thing always remains clear: unless quality-related issues are addressed and remedied at the root cause level, the fix to compliance issues will not be permanent, nor will the company be able to create and maintain the "culture of compliance."

4. Maintain a robust quality baseline

Every internal audit should focus on the effectiveness of the established CAPA system. Specifically, the Quality function should determine whether

1. *The nature and impact of the deficiency on data has been properly identified*
2. *Effective corrective and preventive actions have been implemented*
3. *Appropriate follow-ups have been performed*
4. *The system is robust enough to trend and track quality-related issues accurately and completely*
5. *The system is robust enough to identify weaknesses with processes, documentation practices, personnel, etc.*

The company's Quality function should investigate all instances where the above has not been achieved for improvements within the quality system. This includes the defined metrics of the CAPA system.

In conclusion, we would like to emphasize that many factors, including but not limited to, new staff, acquisitions/mergers, new lines of business, staff reductions and/or new management have impact on the "culture of compliance." Therefore, in order to be successful, a "culture of compliance" should be a "living" initiative, which is constantly assessed for its effectiveness in light of changes that every company experiences during the normal course of events.