Expect More from your Quality Assurance Group

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There is much to be desired regarding the general quality of the Quality Assurance groups that we have assessed or observed. In all too many instances, the companies' Quality Assurance groups (1) do not address a business or regulatory need, (2) focus on regulatory compliance issues of marginal importance while missing significant operational root causes of regulatory compliance problems, and/or (3) try to implement solutions with minimal or no common sense. We contend that it is the responsibility of those of us who are responsible for the overall success of the company to know what is needed for its continuing benefit and to ensure that it is being delivered.

To survive, the pharmaceutical, biotechnology, medical device industries and their support organizations (e.g., CROs, CMOs, software companies) in general have had to adapt to a new value proposition - do more, do it faster, and do it with fewer resources. To achieve this objective, companies try to invest their efforts into "doing it right the first time" in order to increase operational efficiency. While this model has been implemented within many companies' departments, the same often does not hold true for the Quality Assurance group: the group is still expected to focus only on regulatory compliance issues and nothing else.

So what can and should be done to maximize the value of what Quality Assurance brings to the company? In the context of the Quality Assurance group, this means that the personnel should be expected to identify not only regulatory compliance deficiencies, but also to be savvy and competent enough to be able to 1) assess, where necessary, the company's operational and technical capabilities and challenges, 2) recognize potential underlying operational problems which result in the regulatory compliance deficiencies, and 3) as appropriate, recommend practical and efficient solutions for both. We are surprised and disappointed that company management, by and large, does not expect this from their Quality Assurance Group, be they internal resources or external Quality Assurance consultants.

If the model of "faster, better, and more efficient" would be practiced by Quality Assurance groups, companies would benefit in a number of ways. First, due diligence activities could be performed with fewer people while meeting the same end-goal of establishing whether a potential partner is suitable. Secondly, by focusing on operations as well as on the regulatory

compliance piece, Quality Assurance would bring true business value to management. Thirdly, if Quality Assurance is encouraged to provide acceptable-to-all resolutions to their concerns, companies would be able to integrate quality with operations in a much more streamlined and facilitated fashion.

To ensure efficiency of, and to maximize on value from, the Quality Assurance group, we suggest that company management hires professionals who are technically competent in the areas they assess for regulatory compliance. Furthermore, company management should expect the following from their Quality Assurance group:

- An understanding that a "one size fits all" regulatory compliance audit approach/checklist is not an effective way to address the myriad business relationships that a company may have. For example, an initial due diligence assessment to determine if a new vendor/supplier should even be considered (e.g., does the vendor have sufficient capacity and does the vendor comply with the regulations?) is far different from the assessment of a vendor/supplier with whom the company has worked for several years (e.g., have business conditions changed (e.g., more services due to merger/acquisition) and whether these changes may potentially affect regulatory compliance).
- An intuitive grasp of the highest risks applicable to the given situation. For example, the existence of data integrity problems should indicate to Quality Assurance that a prudent place to start the assessment would be performing an appropriate investigation if one has not been done rather than determining whether there is a current SOP on SOPs in place.
- An ability to view regulatory compliance issues through the larger operational prism and business context. For example, a lack of current SOPs may be indicative of too cumbersome of an SOP system that a company has difficulty maintaining and managing.
- A practical, common sense approach with respect to recommendations. Recommendations should aim to keep the company in regulatory compliance without increasing operating costs and/or delaying timelines.
- A demeanor and communication style that is professional and respectful to those who are being assessed by Quality Assurance. An "I know your process better than you do" or "This is not acceptable because I have not seen it done before" attitude has stifled many potentially beneficial business relationships. In other words, the Quality Assurance group should not use its independent power and authority to hinder appropriate operational innovation and creativity.

Regulatory compliance is a business issue first and foremost. Therefore, if the Quality Assurance group provides a regulatory observation without the business context, it will be like serving coffee without a cupSM. Whoever is paying for the Quality Assurance services should expect the most business value for the money. This, by default, will also position the Quality Assurance group within the "faster, better, and more efficient" model. **GXP**

ABOUT PSG

PSG focuses on creating an environment which helps companies to improve operational efficiency, productivity and profitability while maintaining regulatory compliance. The areas of core expertise include GXP audits; assessments; due diligence (including selecting and managing outsourcing partners for GXP activities); QA/QC consulting (building a quality infrastructure and processes for GXP activities); system validation; 21 CFR part 11 compliance; and software commercialization.

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