Quality: a means for Value Creation

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Pharmaceutical firms and contract manufacturers that supply into the firms are regularly challenged with balancing the need to bring cutting edge and innovative medicines quickly and cost effectively to the patients, with the need to ensure that there is no compromise on their quality and safety. In a highly regulated industry such as pharma, quality assumes significant implications since sub-standard medicines can jeopardize human life.

40% of the finished pharmaceuticals that are consumed in the US are imported; this figure is close to 80% for active and bulk pharmaceutical ingredients. As per the FDA Safety and Innovation act, GDUFA, signed in July 2012, the agency has to inspect global plants on the same schedule as it does the ones in the US. The FDA has also been tasked with clearing the backlog of drug applications seeking approval within five years. These factors, coupled with some high profile compliance failures, have triggered increased vigilance over the past few years.

Among the multitude of factors cited for non-compliance, two common issues have emerged and have been highlighted by the regulatory agencies: Data integrity (DI) and cross contamination, which affects product quality.

Data integrity issues arise when regulators are not convinced of the data based on which the products are launched in the market. In 2015, 74% of the total warning letters issued by US FDA were linked to DI and the number increased to 79% in 2016.

Compliance derailment can cause value destruction; an import alert or warning letter may trigger significant decline in stock prices of a firm. Moreover,, it results in a delay or unavailability of drugs to patients. For drug manufacturers, recent events have underscored the importance of managing regulatory risk in order to remain a viable business.

CDMOs supply drug substances and drug products to various countries across the globe; as a result they are audited by both the respective regulatory agencies from the country of launch, and by their customers. For CDMOs, customer audits are as critical as regulatory audits as they ensure that the manufacturing sites are perpetually audit ready. The good service providers usually lever this and adopt best practices in Quality and Compliance through engagement with their global customer base. CDMOs must view the current regulatory landscape as an opportunity to provide a differentiated and sustainable advantage in a competitive market. The regulatory landscape is also quite dynamic and is evolving rapidly. At Piramal, we have an internal cell that tracks all regulatory updates including 483s, observations, and new regulations in the industry on a daily basis. Existing practices can be evaluated vis-à-vis these events to identify possible deficiencies.

The nature of regulatory inspections has also undergone significant changes. Earlier, regulators scouted for evidence of non-compliance, whereas they now have a perception of non-compliance and leave it to the firms to demonstrate otherwise. This shifts the onus of proof to the CDMO or the pharmaceutical firm. Until recently, citing deficiencies used to be the norm, however lately regulators have started citing improvement opportunities during inspections. To help reduce the challenges inherent to inspections, it is essential to continuously remain in contact with regulatory authorities. Collaborating with FDA by participating in meetings concerning quality metrics is crucial.

Quality has been long viewed as a means to successfully clear regulatory audits and obtain product approvals. This approach could be attributed partly to the quality issues at the manufacturing sites. Firms must shift focus from Quality for Compliance to Quality as a Culture by keeping the end patient in mind.

Finally, it is our belief that Quality is a collective responsibility and must be woven into the fabric of any organization. Foremost of all, Quality must be aligned as a business strategy within the organization. A strong governance and escalation mechanism is the foundation of any quality organization and it must exercise autonomy and have a reporting structure independent of operations. A robust review process should employ various tools including data integrity calculations and drive towards an audit readiness scorecard that can quantify the quality health of sites within the organization, and potentially, predict quality outcomes. Stringent internal audits at manufacturing sites by the Corporate QA team are a means to proactively identify risks and mitigate them.

"A strong quality culture is best indicated by what is done when nobody is looking. Culture is the cornerstone of Quality"