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# "Quality focus could make Indian firms favorites of global regulators"

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**"Quality focus could make Indian firms favorites of global regulators"**

**Q: Please tell us in brief about the major insights from the recent EY report on data frauds? Are Indian firms among most affected?**

EY's Fraud Investigation & Dispute Services team recently conducted a survey on 'Analysing the state of Data Integrity Compliance in the Indian Pharmaceutical Industry'. Some of the highlights of the survey are, 30 percent of respondents' received inspectional observations by global regulators in the last three years; 57 percent of the employees agreed to have seen work pressure on the manufacturing personnel to meet KPIs; 28 percent of respondents indicated that their organisations did not have a whistle blowing mechanism in place; 18 percent do not have adequately staffed Quality Assurance to witness and review the manufacturing and testing of all the products independently; 72 percent users in the Quality Control (QC) department have IT administration rights for laboratory systems such as HPLC, GC, etc., (This enables QC personnel to create, delete or modify data at their discretion) and 25 percent were unaware of the 21 Code Federal Regulation (CFR) Part 11 standards prescribed by the US FDA. I am sure such issues are present outside India as well.

**Q: Why does data integrity remain a challenge even now for the drug discovery companies? Is the GMP compliance really so tough or there are other factors involved?**

Nothing is tough or impossible; and challenges faced by the pharmaceutical sector are not unsurmountable. However, one issue seen when conducting data integrity reviews is the lack of understanding among people at the ground level. While companies often have extensive training programs, measuring the efficacy of those trainings is often missed. For example, did the machine operator (local language specialist) clearly understand the training consultant (an English speaking, a former regulatory inspector) about the importance of equipment validation? How well did he comprehend the concept and the requirement?

It is important to bring in a cultural and monitoring change which emphasizes on quality and compliance. It should also remind the sector about the presence of proactive periodical data integrity reviews, which like an industry watchdog can detect any data integrity issues.

**Q: What can be the possible solutions? Has technology yet not been able to create effective tools to tackle this issue?**

As mentioned before, engaging in proactive periodical data integrity reviews will enable companies to identify any potential problems quickly. For instance, is the problem due to the product's formulation; is analytical testing method not appropriate for the test; the trials need to be performed only when a certain equipment is in use etc. These are some of the questions which data integrity reviews can help to answer.

Once the problem is identified, companies can focus their efforts on investigating the root cause, followed by putting an effective Corrective Action Preventive Action (CAPA) in place. Post implementation of a CAPA, it is also important to conduct a follow-up data integrity review after 75 to 90 days to gauge its effectiveness. Adding a robust and effective technology enabler for instance, ensuring that the required equipments are 21 CFR Part 11 compliant and are regularly monitored for anomalies, if any, will additionally act as a strong door keeper.

**Q: Report says, funding a major challenge for the government regulator such as CDSCO. What kind of adverse impact can it have on the product quality?**

Industry sources say that the CDSCO has asked the Indian health ministry to release the USD 2.9 billion which has been allocated to the department of pharmaceuticals under the Twelfth Five Year Plan. This was to fortify its regulatory mechanism at the Central and State level regulatory bodies.

Any investment made into the sector will be beneficial to the industry and the harmonization of global regulatory requirements will take place sooner or later. The industry should also maintain highest levels of quality and compliance at all times - this way, companies will continue to be favorable in the eyes of global regulators.

**Q: Where does the future lie and what is the way forward on the issue?**

The pharmaceutical industry acknowledges the issues around data integrity and is dealing with it proactively. Several companies are upgrading the technical systems in Quality Control laboratories and are investing in employee trainings. In fact, over one third of the data integrity reviews done by EY Fraud Investigation & Dispute Services are now proactive. So it is only a matter of time, a few years of continuous change and hard work on this commitment to quality and compliance, by when the industry will emerge successful.