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Data integrity concerns still prevalent among pharma companies: EY survey

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One third of pharmaceutical companies have not conducted reviews to assess potential gaps in data integrity, according to an EY survey, 'Analysing the state of Data Integrity Compliance in the Indian Pharmaceutical Industry'.

Data integrity reviews are conducted to evaluate if data records are accurate, complete, attributable, legible and maintained within their original context in electronic or paper form. Over 30 percent of the respondents stated that they have received inspectional observations by regulators. This was despite signing off their understanding and compliance with Good Manufacturing Practices (GMP) norms.

Mr Arpinder Singh, partner and national leader, Fraud Investigation & Dispute Services, EY said, "The pharmaceutical industry has been a buoyant sector in the eyes of domestic as well as foreign investors. But at the same time, the industry is still struggling to deal with challenges around pricing in domestic market, increased regulations as well as data integrity. Companies need to take these issues seriously, especially those around data integrity as it is a critical aspect within the overall compliance framework."

"Maintaining data integrity is crucial for the pharmaceutical sector. Today, companies with existing or anticipated concerns around data integrity should initiate regular proactive data integrity assessments. This will be beneficial even for companies that enjoy a good reputation in the market. These periodic assessments provide assurance to all stakeholders involved - customers, investors, regulators as well as reaffirm the management's commitment toward highest standards of quality." adds Rajiv Joshi, Partner, Fraud Investigation & Dispute Services, EY.

Dr Ajaz S. Hussain, advisor, EY and Former Deputy Director, Office of Pharmaceutical Science, US Food and Drug Administration (US FDA) added, "Integrity of data is the foundation on which we make decisions on quality, safety and efficacy. Recording of data and information with accuracy protects life; without it, we cannot differentiate between counterfeit and authentic medicines. At the end, any lapse in the assurance of data integrity is a serious deviation from expected practices and can have adverse repercussions. The EY survey is an apt reminder - a means to improve awareness and to

communicate this important message."

EY's Fraud Investigation & Dispute Services team conducted the survey to assess the state of compliance related to Data Integrity Compliance faced by pharmaceutical companies. Some key highlights of the survey are:

Technology upgrade is the need of the hour

25 percent were unaware of the 21 Code Federal Regulation (CFR) Part 11 standards prescribed by the US FDA which establishes the criteria to record data in electronic form. 33 percent mentioned to have shared employee login ids and passwords for laboratory systems such as High Performance Liquid Chromatography (HPLC), Gas Chromatography (GCs). This shows that organizations still need to make a significant headway for being compliant with global standards. It is important that the management pays more attention to these requirements, as failure to do so can invite regulatory and/or penal consequences.

Work pressure and shortage of manpower affects quality compliance

Over 57 percent of the employees agreed to have seen work pressure on the manufacturing personnel to meet Key Performance Indicators (KPIs) such as volume of output, low rejection ratio and overall equipment effectiveness. 18% did not have adequately staffed Quality Assurance teams to review the manufacturing and testing of all the products independently. This indicates that shortage of manpower or excessive work pressure can lead to inaccurate or incomplete documentation, and eventually could impact the product quality.

Absence of quality process and procedures

33 percent respondents did not conduct reviews to assess potential gaps in assurance of data integrity. It has been observed that regular and proactive data integrity reviews can ensure accuracy and consistency of GMP data. 13 percent respondents did not have clearly documented Standards Operation Procedures (SOP) on backup and deletion of laboratory data files generated by HPLC or GCs.

Lapses in data integrity continue to rise

More than 30 percent of respondents had received inspectional observations such as Form 483s, warning letters, import alerts, Statement of non-compliance with GMP etc. issued by global regulators. 21% stated that audit trails on laboratory equipment are not always enabled in their organizations. Absence of audit trails can be a serious problem as there would be no records of data captured which could lead to severe action by regulators.

Setting up whistle-blowing frameworks, still work in progress

28 percent of respondents indicated that their organisations did not have a fraud reporting mechanism in place. In such a guarded industry, lack of whistle-blowing policies means individuals who genuinely want to help their organizations by flagging any unethical acts or wrongdoings may be forced to report such issues externally.