

Data integrity issues continue to haunt pharma sector: EY

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Hyderabad: Despite being saddled with warning letters from several global drug regulators, one-third of the Indian pharmaceutical companies are yet to conduct reviews to assess potential gaps in their data integrity issues, according to an Ernst & Young (EY) survey titled 'Analysing the state of data integrity compliance in the Indian pharmaceutical industry'.

Data integrity reviews are conducted to evaluate if data records maintained by a pharma company are accurate, complete, attributable, legible and maintained within their original context in electronic or paper form. Even United States Food and Drug Administration (USFDA) had earlier suggested that Indian pharma players can seek expertise of third party auditors and consultants to resolve data integrity issues and ensure compliance. EY advisor and former deputy director, office of pharmaceutical science, USFDA, Ajaz S Hussain, pointed out that integrity of data is the foundation on which regulators make decisions on quality, safety and efficacy. "Recording of data and information with accuracy

'Life sciences sector growth outpaces compliance mgmt processes'

Hyderabad: The fast pace of growth in the life sciences sector in India appears to have outpaced compliance management processes, revealed Deloitte India's latest survey report -- 'Managing growth through better compliance management'. According to the report, the rise in regulatory non-compliance in the sector may be attributed to the evolving changes in regulatory standards, which have resulted in limited availability of compliance management professionals equipped to manage these requirements. About 55% of survey respondents have indicated that their compliance teams were not adequately trained to address regulatory requirements. Around 61% of respondents felt that there was a lack of internal controls and compliance processes to proactively manage and mitigate the risk of non-compliance. The report was developed on the basis of responses from 33 leading organizations in the sector. TNN

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," he said.

"Companies with existing or anticipated concerns around data integrity should initiate regular proactive data integrity assessments. These periodic assessments provide assurance to all stakeholders involved - customers, investors, regulators as well as reaf-

firm the management's commitment toward highest standards of quality," EY partner (fraud investigation and dispute services) Rajiv Joshi explained.

EY partner (fraud investigation and dispute services) Sandeep Balajava said, data integrity issues are not new for the pharmaceutical industry but the seriousness with which the regulators look at these has changed in recent times. "Regulators now expect companies to undertake independent audits to address data integrity issues and im-

prove overall compliance. These audits are expected to adopt a detective approach to proactively identify and address potential data integrity issues," he added.

Dr Reddy's Laboratories chief financial officer Saurabh Chakraborty said, ensuring data integrity was an integral part of ensuring high quality standards in an organization and money pumped into this area must be seen as an investment and not costs.

According to the report, 33% of the respondents shared employee login IDs and passwords for laboratory systems, which shows that organizations still need to make a significant headway towards being compliant with global standards. It said 28% of respondents indicated that their organisations did not have a fraud reporting mechanism in place, which means individuals who genuinely want to help their organizations by flagging any unethical acts or wrongdoings may be forced to report such issues externally. This report was prepared based on the responses received from over 170 respondents from the pharmaceutical industry during the period January-March 2015, it added.