

## Image of Indian pharma industry tarnished: EY

Drug exports to the US have gone up from \$1.25 b in FY10 to \$3.45 b in FY14

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The increase in foreign regulatory inspections has marred the image of the Indian pharmaceutical industry, according to a survey by EY.

Out of 19 US Food and Drug Administration's (USFDA) warning letters issued in 2014, eight were issued to Indian companies, EY said in its latest survey analysing the state of data integrity compliance in Indian pharmaceutical industry. India has the second largest number of manufacturing facilities outside of the US (523 as on March 2014) registered with the USFDA.

There has also been a steady rise in drug exports to the US from India. It has gone up from \$1.25 billion in FY10 to \$3.45 billion in

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FY14. "With the growing importance of the Indian pharmaceutical industry in the global market, the number of foreign regulatory inspections has also increased considerably," the survey said.

Referring to the data integrity issues in the industry, EY said shortage of staff and excessive work pressure can lead to inaccurate documentation.

"Even companies with a good track record with regulators, regardless of existing or anticipated Good Manufacturing Practices (GMP) compliance, should initiate periodical and proactive data integrity assessment to assess their state of quality compliance," it said.

Industry