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LOST IN TRANSLATION

USFDA Inspectors, Indian Drugmakers Face Language Gap

Shop floor operators, not used to US accent, find it difficult to understand US drug inspectors' questions

ON VACANCIES
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New Delhi: A lot is lost in translation and cultural gap between the shop floor operator in a drug making facility in a remote corner of the country and a visiting US drug inspector, Indian drugmakers have told the government, urging it to request the US Food and Drug Administration to fill the positions of drug inspectors lying vacant here.

Not being able to understand the American accent of the drug inspectors, usually sent on short-term visas is proving to be a serious handicap for workers handling FDA approved facilities, the drugmakers have said.

"The shop floor operators, not used to American English, find it difficult to understand their (US drug inspectors') questions or observations and likewise the inspectors, not used to Indian English; do not fully grasp the explanation provided by the operators. These cultural differences act as barriers to communication," Indian Pharma Alliance (IPA), a grouping of leading domestic drug firms, has told the government here.

India has sanctioned 19 posts for the USFDA drug inspectors. "Several of these posts, particularly of the drug inspectors, are lying vacant. Instead, the drug inspectors come on short-term visa," the industry body said, adding that such a practice leads to cultural differences resulting in "inadequate appreciation of the cGMP (current good manufacturing practices) and other measures for compliance with the FDA standards and practices". Over 30 India-based drug making units have been banned from shipping to the US in the last two years. These include units belonging to Sun Pharma, Ranbaxy Labs (in the process of getting acquired by rival Sun) and Wockhardt. "Goals of Indian manufacturers and the FDA are congruent. While Indian drug makers want to meet US prescribed norms all the time, the US regulator wants Indian companies to export safe medicines. This can be better achieved if drug inspectors, instead of being perceived as 'investigators' assume the role of 'enablers'," said DG Shah, secretary-general of IPA. A total of seven Indian facilities were put under import alert (ban on drugs from a plant) by the US regulator in 2011, a number that had risen to 32 by March 2014, reckons an India Ratings & Research estimate of May 2014.

INDIAN PHARMA ALLIANCE

In 2013 alone, the FDA banned 21 Indian manufacturing facilities from shipping, the highest ever for India in any single year. It also constituted half of all such import alerts the US drug regulator issued globally that year. But that is mainly because outside of the US, India has the largest number of facilities (523 as of March 2014) registered with the FDA and is source to 40% of generic drugs consumed there.

Global safety consultancies called such cultural barriers more of a "nuance" and said Indian drug makers have to train their staff better if they want to serve highly-regulated markets like the US.

"For the FDA, the means to achieve an end is as important as the end, if not more and so they are hawks in scanning documentation processes. For them, if something hasn't been documented, it hasn't happened. And this is where Indian companies have to learn a lot," said Suresh Sugavanam, managing director of the South Asian arm of UL, a global safety consultancy.

Regulatory