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# When it comes to USFDA probes, India is ahead of China

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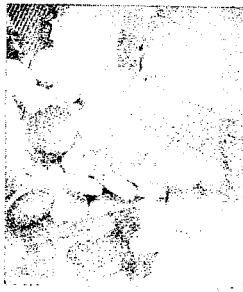
Mumbai, Jan 2

CHINA may have many more US Food and Drug Administration-approved drug manufacturing units than India does, but the US regulator inspects more Indian units, the trend in the last three years shows. For instance, in the year to September 2012, 22.6% of the 624 inspections worldwide (outside of the US) were conducted in India and just 10% in China. In the previous year, the gap was somewhat narrower — of the 558 inspections, India's share was 18% and China's 16% while in 2009-10, India accounted for 16.4% and China just 11%. India has 526 USFDA-approved units while China is home to over 960 such sites.

Media reports say the regulator raised its American staff in India to 19 from 12 last September, with 10 people dedicated to medical products. Of late, Indian drug makers have been pulled up for violating current good manufacturing practices (CGMP) — a set of regulations enforced by the USFDA that ensure proper design, monitoring and control of manufacturing processes and facilities. Recent Indian recipients of warning letters are Wockhardt's Waluj and Chikalthana units.

Typically, deficiencies spotted during such inspections are usually identified via a Form 483, an inspection report issued to the firm's management at the conclusion of an inspection. A Form 483 may or may not be made public by the regulator. If the problems identified in the Form 483 are not addressed to the satisfaction of the USFDA, the agency will escalate it to a warning letter, which details the issues observed during the inspection and have remained unaddressed. An unresolved warning letter may result in an import alert under which products made at the particular manufacturing site will not be allowed to enter continental US.



**BITTER PILL**

USFDA inspections of approved establishments outside US

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|---|---|---|---|---|---|
| 2007 | 333 | 64 | 19 | 19.22% | 5.71% |
| 2008 | 324 | 64 | 36 | 19.75% | 11.11% |
| 2009 | 424 | 59 | 52 | 13.92% | 12.26% |
| 2010 | 440 | 72 | 48 | 16.36% | 10.91% |
| 2011 | 558 | 98 | 89 | 17.56% | 15.95% |
| 2012 | 624 | 141 | 61 | 22.60% | 9.78% |

Source: USFDA

The USFDA issued 11 observations after inspecting KKR-backed Gland Pharma's manufacturing unit based in Hyderabad in September 2012, according to its own data. The inspection revealed deficiencies such as inadequate control procedures, steps to prevent contamination of drug products not established and followed and incomplete laboratory records. "Employees engaged in the processing and packing of a drug product lack the training required to perform their assigned functions... Protective apparel is not worn as necessary to protect drug products from contamination," the USFDA report said.

The USFDA was also concerned about a field alert report not submitted to it by Gland Pharma. The USFDA field alert programme is created to quickly identify drug products that pose potential safety threats. All drug manufacturers, whether innovators or generic drug makers, have to submit field alert reports if they find any significant problems with an approved drug within three days of a problem being identified.

Gland Pharma declined to respond to queries on whether the USFDA-identified issues have been resolved. On November 27, private equity firm KKR acquired a minority stake in the privately-held Gland Pharma for about $200 million or Rs 1,243.1 crore, according to the exchange rate on that day.

Mumbai-based Unichem Laboratories' plant in Ghaziabad in Uttar Pradesh was inspected in June 2012 with four observations.

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# USFDA...

The regulator identified issues in documentary procedures and drug quality check in the company. "GMP training is not conducted on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them," the USFDA report said. "There were certain observations in June 2012 which duly taken care of by Unichem. The plant got re-certified by US FDA in October 2012," Unichem vice-president K Subharaman said.

German company Fresenius Kabi Oncology's Baddi facility in Himachal Pradesh got 11 citations from the USFDA after an inspection conducted in August 2012. The Gurgaon-based company is in the news for its attempts to delist from the Bombay Stock Exchange.

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