USFDA to step-up unannounced Inspections on Indian Pharma Plants

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India will be a dominant part of planning the resilience of supply chains, United States Food and Drug Administration (US FDA) Commissioner Robert M Califf said.

The US drug regulator has declared that there will be more unannounced inspections at the pharmaceutical plants in India.

“A mixture of announced and unannounced inspections is important, and you will see more unannounced (inspections),” said United States Food and Drug Administration (US FDA) Commissioner Robert M Califf in an exclusive interview with CNBC-TV 18 on September 29. "More inspections are to develop a system where there are no surprises.".

Califf said the US FDA plans to reward those who display a commitment to quality and integrity. Also, a bottom-up approach was important with the staff having deep integrity and honesty even if that hurts.

During the course of the Covid-19 pandemic, inspections of pharmaceutical manufacturing facilities in India by the US FDA turned fewer. In July, a US House panel tasked with examining the FDA's foreign inspections expressed apprehension about the regulatory agency's actions pertaining to manufacturing facilities in India and China, as well as its reliance on foreign drug manufacturers. Since then, there has been a rise in the number of inspections conducted by the FDA in India.

Califf added that he expected India to continue being a dominant supplier to the US, which is world's largest drug market. Speaking on the country's over-reliance on China, he noted that nations must be self-reliant in the matter of producing their own drugs.

Source: U. S. Food & Drug Administration (USFDA)