PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Economic Times , Delhi
Friday 29th January 2016, Page: 7
Width: 8.59 cms, Height: 15.79 cms, a4, Ref: pmin.2016-01-29.43.52

MANUFACTURING NORMS FOR DRUG MAKERS

Onus on Top Deck to Maintain Quality

Divya.Rajagopal
@timesgroup.com

Mumbai: Indian drug companies battling the stringent rules of the US Food and Drug Administration might have to make additional commitment to prove that they are compliant with the good manufacturing guidelines of the regulator.

The USFDA has proposed a new system that will evaluate the health of the quality culture of drug companies.

In a draft report on quality metrics, the USFDA suggested various quantifiable parameters with an attempt to manage its inspection schedule and identify possible situations where there is a risk of drug shortage, among other issues. With that intention, the regulator wants to measure the commitment of senior management to quality.

"A corporate commitment to quality has been identified in multiple public forums as a strong indicator of a robust Pharmaceutical Quality System," the USFDA wrote in its draft guideline. "While it may be difficult to measure this factor objectively between different companies, the agency is committed to a dialogue with industry to consider benchmark standards that could provide acceptable metrics that specifically demonstrate senior management's commitment to a culture of quality."

This idea, according to FDA is to identify whether senior management with resources and authority to implement changes is engaged in the assessment of product quality as well as whether this information is shared with quality and manufacturing organisations.

The USFDA has proposed a new system to assess corporate commitment to a culture of quality

More than 40% of the drugs consumed by US patients is manufactured by Indian drug makers. The US is also one of the largest and profitable markets for Indian drug companies. However, post the debacle of Ranbaxy's quality issues and stringent action by the US regulators, Indian companies have been feeling the heat of the increased surveillance by the USFDA. In the last three months alone, Sun Pharma, Dr Reddy's and Zydus have faced USFDA flak for not complying with good manufacturing practice.