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[Pharma](#) > [A Case of Slipping Quality](#)



## A Case of Slipping Quality

01 August 2023 | [Features](#) | By [Sanjiv Das](#)

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Touted as the Pharmacy of the World, Indian pharma is on a spree to launch new drugs and supply them globally. However, amidst launching new drugs, companies are failing to adhere to norms when it comes to maintaining the quality of the products where The United States Food and Drug Administration (US FDA) is keeping a hawk's eye on the drugs being manufactured. Stringent regulatory measures and keeping an eye on bribery/corruption are likely to have a positive impact on the quality measure being followed without fail.

### Digital innovation

Digital tracking of products is possible to ensure that the products are distributed under the required conditions of temperature and humidity. Any deviation can result in potential deterioration of quality and is subject to recall. One can also build a mechanism to ensure that counterfeits are tracked and appropriate action is taken against them. All this of course comes at a cost and the pricing mechanism should be considered. All wholesale and retail outlets are subject to not only self-regulation but regular inspection and certification by the regulatory authorities appointed by the government.

The Indian pharmaceutical industry is a global supplier of high-quality, affordable medicines throughout the world. This is well-recognised and respected globally. There are a few who do not follow the standards required in this industry. Such companies must be taken to task.

A database with the list of accredited vendors should be developed and manufacturers can use them for procuring the raw material. Implementation of automation has been shown to reduce the potential breach of data integrity as data trails are meticulously captured and any wrongdoing can be detected.

**Manoj Saxena, President-elect, Organisation of Pharmaceutical Producers of India (OPPI) and Managing Director, Bayer Pharma,** says “Prioritising patient safety and product quality is the prime objective of pharma manufacturers, which requires investing in robust quality management systems and conducting thorough risk assessments. Promoting a culture of compliance with global best practices such as Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) is important to ensure that manufacturing and distribution processes meet the required quality and safety regulations. The use of emerging technologies such as AI can enhance transparency, traceability, and accountability throughout the supply chain. In addition, continuous training and education, and proactive monitoring of manufacturing processes can help prevent issues and maintain high-quality standards. The sector must collaboratively work towards strengthening the ecosystem to ensure we continue to deliver high standards of quality.”