Veterans Spot Gold in Drug Cos' FDA Mess

Look to help pharma cos comply with global manufacturing quality standards

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Mumbai: A group of Indian pharma veterans, who had hung up their boots after successful careers, have smelled an opportunity in helping domestic drug companies comply with strict manufacturing quality standards set by regulators overseas and save on their legal costs.

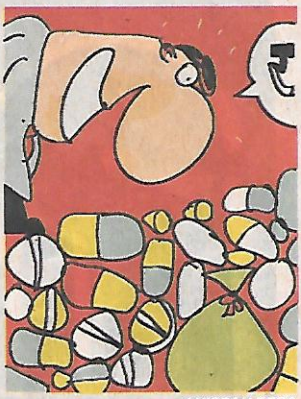
A six-member team led by Satish Khanna, formerly with Lupin, and Anand Venkatrao, who was most recently with Dr Reddy's Laboratories, has floated a 'knowledge' venture called Qualiminds, which aims to address the Indian pharma industry's dealings with the US Food & Drug Administration (USFDA).

The consultancy offers to help Indian companies that have got entangled in manufacturing quality issues with the FDA over the past few years. The firm has pulled senior representatives from top drug companies and aims to become the Indian version of large pharma consultancy firms such as Lachman Consultants and Quintiles Inc.

There are almost 100 drug companies in India that export medicines to the US. In some cases, stringent scrutiny of manufacturing facilities by the FDA has led the regulator to issue warning letters to companies or impose import bans. Such steps have drained out about ₹5,000 crore in legal costs for such companies, according to an **ET** report based on the annual reports of 2016 of these companies.

Qualiminds, based in Mumbai, says it will offer services at one-fourth of the cost of hiring an international quality consulting firm, which charges $400-500 per hour per person. The founders say they can generate revenue of ₹20 crore by 2017. Besides cost, it's their understanding of typical Indian pharma shop-floor behaviour that sets them apart from most international consultancy firms.

"We understand where the quality team deters because we are from that side," said Venkatrao. "In our long career, we have had close interactions with the FDA and we understand what they are looking for in terms of quality."



ANIRBAN BORA

Venkatrao spent about 22 years leading the compliance functions of companies such as Lupin, Glenmark and Dr Reddy's. In his assessment, there are communication gaps in the manufacturing chain and cultural issues such as being non-critical of seniors and eagerness to appease them by not reporting anomalies.

A 6-member team has floated a 'knowledge' venture to address the industry's dealings with USFDA

A key issue for the Indian drug industry is that officials responsible for quality are stuck between dealing with incompetent junior-level staff and high expectations of promoters and this is what compromises quality, according to Venkatrao.

"We understand the supervisor's point of view and are able to look at broader issues that are India-specific, which an international firm might not understand," he said.

Khanna, who branched out into investing in startups after retiring, said there is a need for a 'quality' institution in India. The billionaire promoters need to create a culture of quality bottom-up that becomes the operational DNA of companies.