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'Drugmakers need to learn to comply with FDA rules not once, but every time'

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A rush to hit the market, culture-mismatches, blind spots in senior management, lack of training... Pharma industry representatives are reeling out a host of reasons for drugmaker Ranbaxy's woes. One after another, the company's Indian plants have been banned from selling to the US by that country's regulator, the FDA.

Wockhardt has faced similar troubles. However, companies such as Lupin and Sun Pharma, which have got warning letters from the US regulator in the past, have managed to resolve its concerns.

So, why do different firms have different outcomes in their problems with the FDA?

Amit Chander, Partner with Baring India, says Ranbaxy's problems are internal and not systemic to the industry. He believes parent Daiichi Sankyo may have focussed on leveraging Ranbaxy's distribution skills and paid less attention to its manufacturing processes.

The hurry to get to the market could be the other reason companies are tripping, he adds, pointing to the race to file applications and sell first in the US market.

At one time, companies were filing applications in the US "at an unrealistic pace" to get a slice of the commercial opportunity. And if there are instructions from the top to speed things up, employees got the message, says Chander.

In a blog post last September, Ajaz S Hussain, a former US FDA official and founder of US-based consultancy Insight, had expressed concern that "blind spots" in senior management may be hindering the change in attitude among employees.

Ranjit Kapadia, VP, Centrum Broking, says that in Ranbaxy's case, there seems to be a lack of training and understanding on the criticality of current Good Manufacturing Practices.

Companies need to understand that it is not about getting it right once but about getting it right every time, says Suresh Sugavanam, MD and VP (South Asia) of US-based safety sciences company UL. And that requires a change in DNA to understand the importance of manufacturing processes and quality control.

It is better that companies invest in doing things right rather than doing them fast, adds Chander. Some years ago, Lupin looked like a slow starter, when it was in its investment phase. But the approach paid off, he points out.

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