



## Indian companies need to develop a quality culture for patient safety

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US Food and Drug Administration (FDA) Commissioner Dr Margaret Hamburg in her talks with Indian regulatory experts have advocated the need for a quality culture to be developed in Indian pharma companies.

Ellen Leinfuss, senior VP, UL EduNeering and an expert on global regulatory compliance echoed the sentiments of Dr Margaret and said that quality is linked to product safety and without focus on quality, the potential for patient harm increases significantly.

In an email interview with Chronicle Pharmabiz, Dr Margaret says, "I am pleased that, as a global leader in the pharmaceutical sector, India will continue partnering with us to ensure that the companies exporting products to the US are adhering to established quality standards. On the home front, we at the FDA will also continue to increase our focus on quality. One way we are doing this is through the creation of a new Office of Pharmaceutical Quality that will create one voice for drug quality at the FDA and improve our oversight of quality throughout the lifecycle of a pharmaceutical product."

Quips Leinfuss, "As the practice leader for UL EduNeering's life science business, commitment of the US and India's pharmaceutical community is encouraging as it will help pharma companies foster a "quality culture." Dr Hamburg stated, "In my talks with regulators and companies here in India, I have placed a great deal of emphasis on why quality matters."

Elaborating on the quality aspect, Leinfuss further says that the work done by compliance and regulatory learning solutions companies with the US FDA over the past 14 years can help develop training and educational programmes around cGMP and other key quality topics for safe delivery of drugs to global patients.

Echoing his views Scott Barnard, Quality, Compliance and Learning, expert says, "Considering the demand and importance of meeting the quality and compliance expectations of the FDA, my experience of working with Life Science clients says that development of quality and compliance culture comes from education and training. We have had tremendous success helping clients use cGMP training and systems to build a strong quality foundation for their organizations."

Reiterating the point that India pharma industry need to reclaim its position in a global market, Kavita Mehrotra, global strategic alliances head, UL EduNeering concludes, "It is clear that India, the second largest exporter of over the counter and prescription drugs to the US is in the news because it is very important to the global market. In the upcoming conference on the 20th of February, 2014 between Indian pharma companies and compliance experts in Mumbai, we will help carve a roadmap for the Indian companies to become compliant to global norms."

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