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FDA to India: Regulatory compliance a must

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FDA to India: Regulatory compliance a must

Bangalore: "Make quality the top priority," was the clear message from the FDA officials to Indian Pharma companies. A two day meeting, conducted by the Central Drug Standards Organisation (CDSCO) and Indian Pharmacetical alliance (IPA), was held in Hyderabad on May 5, followed by workshops in Goa, Ahmedabad, and Chandigarh for the Indian drug industry and the regulators from CDSCO.

The meeting and workshops that marked the beginning of a one-on-one discussion with the FDA, saw huge participation from the industry. Ms Leslie Ball, assistant commissioner and deputy director, Office of International Program at the FDA said that the workshop was an excellent opportunity to for the FDA to put forth their expectations and receive feedbacks. She further said that the companies must have quality culture and should be doing what they say, saying what they do and seek improvement.

Since the beginning of last year, there's been a spike in "violations" at India-based drug plants, according to data from FDA's Centre for Drug Evaluation and Research. In its latest word on Indian drug makers, the US top drug regulatory agency, the Food and Drug Administration (FDA) has said that the industry needs to continuously upgrade and strengthen their facilities to uphold quality and safety of pharmaceutical products.

Mr Howard Sklamberg, deputy commissioner, USFDA, Global Regulatory Operations and Policy, emphasized on the role of senior management in ensuring a quality culture within a company. He highlighted that the six elements inspected by the FDA were materials, equipment and facilities, production, laboratory, packaging and labeling.

Dr Satish Reddy, chairman of the Dr Reddy's Laboratories and the president of the Indian Pharmaceutical Alliance commended the workshops as the efforts in the right direction to enhance quality standards.