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US FDA collaborates with Telangana Drug Control Administration

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Ensuring the quality and safety of pharmaceutical products in Telangana and beyond



In a significant development in the realm of pharmaceutical regulation, officials from the United States Food and Drug Administration (US FDA) recently paid a visit to the Drug Control Administration (DCA) of Telangana, located in Vengal Rao Nagar, Hyderabad.

The meeting revolved around discussions on various initiatives aimed at ensuring the stringent implementation of regulatory standards to safeguard the quality and safety of drugs and medicines produced by the pharmaceutical, biotech, and related industries.

Among the US FDA delegation were notable figures such as Dr Sarah McMullen, Country Director of US FDA's Indian Office; Dr Phil Nguyen, an International Relations Specialist, and Dr Sudheendra Kulkarni, a Senior Technical Advisor. The Director General of Telangana DCA, V.B. Kamalasan Reddy, extended a warm welcome to the US FDA regulatory authorities and outlined the recent regulatory measures undertaken by Telangana DCA.

During the discussions, Director General Kamalasan Reddy shed light on the adoption of risk-based sampling techniques and the issuance of advisories to the industry regarding the testing of raw materials, specifically Glycerin and Propylene Glycol, to monitor DEG and EG content. He also provided a comprehensive overview of the vigilance cell's operations, emphasizing the department's commitment to ensuring the quality of raw materials used by pharmaceutical companies in drug production.

Kamalasan Reddy expressed his satisfaction with the visit, noting that the DCA's efforts were well-received by the US FDA officials. He disclosed that the US FDA authorities proposed the establishment of a 'US FDA and Telangana DCA Regulatory Forum' to foster future strategic collaboration and initiatives. The primary objective of this proposed regulatory forum would be to explore elements of observed inspections, with the intent to involve DCA Telangana inspectors as observers in US FDA-led inspections.

This collaborative endeavor underscores the commitment of both US FDA and Telangana DCA to strengthen the regulatory framework, ensuring the quality and safety of pharmaceutical products in Telangana and beyond. It marks a significant step towards the shared goal of safeguarding public health and bolstering the pharmaceutical industry's integrity.