GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION

Press Release

The US drug regulator, USFDA, collaborates with Drugs Control Administration, Telangana for future strategic initiatives.

'First Annual Regulatory Forum' between USFDA and Drugs Control Administration, Telangana held on 31st January at Hyderabad.

Drugs Control Administration, Telangana continues its combat against spurious drugs and is making every effort to uncover a web of illegal activities including unlicensed manufacturing of drugs in chemical factories, unlawful stocking and sale of drugs, manufacturing of drugs in guise of food products etc. that put public health at serious risk.

As the State Regulatory Authority of Telangana, which contributes to more than 35 percent of 'pharmaceutical production' in India, Drugs Control Administration, Telangana has taken several regulatory initiatives viz. Risk-based inspections, Risk-based sampling, stringent testing guidelines to the industry regarding testing of raw materials Glycerin and Propylene Glycol for DEG and EG content for assuring safety of cough syrups, creation of vigilance cell for detection of clandestine activities, unannounced inspections of chemical/intermediate units, stringent review for approval of licences to the manufacturers etc., thus creating a stringent regulatory environment and better oversight with respect to the medicines manufactured in the State of Telangana.

In this context, a team of USFDA officials led by Dr. Sarah McMullen, Country Director, USFDA India Office, who visited Drugs Control Administration

office at Vengalrao Nagar, Hyderabad on 2nd November, 2023 proposed for "US FDA – Telangana DCA Regulatory Forum" for future strategic collaboration and initiatives, as Telangana State has more than 214 USFDA registered manufacturing sites i.e. pharmaceutical companies that manufacture, export medicines to USA.

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Dr. Sarah McMullen, Country Director, US FDA Indian Office, Dr. Phil Nguyen, International Relations Specialist, Mr. Yvins Dezan, Consumer Safety Officer & Drug Investigator, Mr. Guerlain Ulysse, Consumer Safety Officer & Drug Investigator, Dr. Sudheendra Kulkarni, Senior Technical Advisor and Mr. Dhruv Shah, Senior Technical Advisor are among the USFDA officials who participated in the 1st Annual Regulatory Forum with DCA Telangana held on Wednesday.

During the Annual Regulatory Forum, Drugs Control Administration, Telangana has given presentation on regulatory program overview, current operations and initiatives taken by DCA Telangana.

Dr. Sarah McMullen, Country Director, US FDA presented an overview of their recent initiatives, USFDA inspection trends in India. US FDA officials have given presentations on USFDA Medical Products Program Overview and their mechanisms related to manufacturing facility oversight and regulatory actions, approaches to the Pharmaceutical Quality System and Risk-based approach for GMP Inspections.

USFDA officials also discussed about ‘Observed Inspection SOP’, for future participation of DCA, Telangana inspectors as ‘observers’ in the US FDA led inspections.

This annual regulatory forum between the USFDA India Office and Drugs Control Administration, Telangana is designed to identify best practices for future strategic collaboration and initiatives.

The forum also provided an opportunity for USFDA and Drugs Control Administration, Telangana to provide an overview of operations and learn about one another’s current practices for further engagements.

Date: 31-01-2024 **V.B. KAMALASAN REDDY, IPS**

DIRECTOR GENERAL

Photographs


U.S. FOOD & DRUG
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DCA
1st Annual Regulatory Forum
INDIA OFFICE
and


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