GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION

Press Release

U.S. Food and Drug Administration (USFDA) announced that Drugs Inspectors of Drugs Control Administration, Telangana are eligible to observe USFDA inspections conducted in Telangana State as part of collaboration.

Telangana has now become the fourth state in India to reach this milestone.

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The details are as follows:

The **U.S. Food and Drug Administration (USFDA)**, the U.S. drug regulator, announced in its **"Global Update Newsletter"** from its Office of Global Policy and Strategy (OGPS), issued in February 2024, that officers of the Drugs Control Administration, Telangana, have joined the group of eligible states to observe inspections conducted by the USFDA in India.

The 'First Annual Regulatory Forum' between the USFDA and Drugs Control Administration, Telangana was held on 31st January, 2024, in Hyderabad. After the joint regulatory forum, the USFDA made this announcement through its official newsletter, USFDA 'Global Update', on 14th February, 2024.

This allows Drugs Inspectors of DCA, Telangana, to be invited to observe select USFDA medical product inspections, which is one of the activities planned and performed under a 'Memorandum of Understanding' that the USFDA signed with India in 2020.

Telangana has now become the fourth state in India to reach this milestone, joining Gujarat, Karnataka, and Goa.

Telangana State, often referred to as the 'Bulk Drug Capital of India', accounts for more than 35% of the total pharmaceutical production in India. Telangana State has more than 214 USFDA-registered manufacturing sites, i.e., pharmaceutical companies that manufacture and export medicines to the USA.

As the State Regulatory Authority of Telangana, the **Drugs Control Administration, Telangana**, has taken several new regulatory initiatives, thus creating a stringent regulatory environment and better oversight with respect to the medicines manufactured in the State of Telangana.

The joint regulatory forum with USFDA was designed to share inspectional best practices for medical products and served as an opportunity for the USFDA and DCA Telangana to provide an overview of regulatory operations and learn about one another's current compliance practices to better inform future engagements.

Collaboration between the U.S. Food and Drug Administration (USFDA) and Drugs Control Administration, Telangana, can be beneficial for ensuring the safety and quality of pharmaceutical products. Allowing Drugs Inspectors from the Drugs Control Administration to observe USFDA inspections in Telangana State can provide them with valuable insights into international regulatory standards and practices.

This collaboration could potentially lead to enhanced regulatory harmonization, improved compliance with global standards, and better oversight of pharmaceutical manufacturing processes in Telangana.

It can also facilitate knowledge sharing and capacity building among regulatory authorities, ultimately benefiting public health by ensuring the availability of safe and efficacious medicines.

The link to the Global Update Newsletter of USFDA is as follows:

https://content.govdelivery.com/accounts/USFDA/bulletins/389b745

Date: 17-02-2024

V.B. KAMALASAN REDDY, IPS

DIRECTOR GENERAL

USFDA – Global Update – News Letter

Photograph: USFDA-DCA Telangana Regulatory Forum

Presenters from the FDA's India Office at the forum in Telangana (left to right, top row then bottom): Dr. Sarah McMullen, Dr. Phil Nguyen, Yvins Dezan, Dr. Sudheendra Kulkarni, Guerlain Ulysse, and Karthik Siva Chaitanya.