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No plans to expand in other Indian cities: US Pharmacopeia

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A part of this investment will be made in India. It aims to execute multiple activities in the country including medical monograph modernization, increasing resources, building manpower, and expanding technology-related activities.

In 2005, USP opened its first office and collaborative testing laboratory facility outside of the United States, near Hyderabad.

"Since USP India's opening, India's pharmaceutical industry has continued to grow rapidly, resulting in an increased demand for USP standards and services," said Dr K V Surendranath, SVP, International Site Operations, USP-India.

The USP India facility works to create standards for medicines ensuring full safety and quality of medicines, and brining international standards in drug manufacturing to India.

The not-for-profit organization develops reference standards to ensure the quality of Active Pharmaceutical Ingredients (APIs) and supports government's initiatives to strengthen domestic manufacture of intermediaries and APIs.

$20 mn in 4 years

In 2011, USP expanded from 14,000 square feet to more than 100,000 square feet in a new facility.

It has spent over US $20 million over the past 4 years to improve its infrastructure and capacities.

This allowed the organization to increase its capacity for analytical chemistry and microbiological testing, and as well as to explore new initiatives in bioanalytical chemistry and testing, and synthetic chemistry.

Added Dr Surendranath, "The expansion has been integral to the collaborative testing needed to develop reference materials for the United States Pharmacopeia and the National Formulary (USP-NF)."

$200 mn investment

Currently USP Hyderabad has a head count of 150 employees, and it plans to expand its capacity, and grow its activities based on local requirements and demands from the industry.

".... As the industry grows and drug testing activities increase, we will continue to increase our capacity and facilities accordingly," pointed Mr Surendranath.

Furthermore, in the next 5 years, it plans to spend US $200 million to notch-up its operations across the globe.

"This investment will be used to revise at least half of USP's drug testing monographs using the latest technology and drug testing procedures," voiced Dr Surendranath.

Working with USFDA

Manufacturers that market drug products and their ingredients (active and inactive) in the US are expected to comply with USP's quality standards, and the standards are enforced by the US Food and Drug Administration (USFDA).

USP's process for developing and updating standards include incorporating inputs from experts in the industry, academia, and the government, and the USFDA.

"In addition, scientific experts from USFDA regularly participate in USP's workshops, forums and related meetings," revealed Dr Surendranath.

India site's uniqueness

According to USP India, the Hyderabad site is largely involved in activities similar to those at USP's US and other sites, such as collaborative studies for development of reference standard, education, and training programs.

Some of the activities which are unique to the India site are the synthetic laboratory, industry support programs, and the site serving as a global hub for tests conducted for USP's verification programs.

As of now, the organization does not have any plans in expanding further to other Indian cities.

USP and its stakeholders

ï‚§ USP works with USP India to improve quality and reference standards for pharmaceutical ingredients
ï‚§ It also works with Indian manufacturers on collaborative testing, verification testing, pharmacopeial education, customer support, and sourcing of written and physical standards for drugs
ï‚§ The organization educates local companies on reference standards besides supporting existing customers
ï‚§ The Hyderabad facility has been working in collaboration with various labs for developing reference standards in India