Letitia Robinson, Director, US FDA, India Office

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Dr. Letitia Robinson, Director of the US FDA India Office, provides insights into the main goals and responsibilities of the FDA in India and documents the US FDAâ??s collaboration efforts with its Indian regulatory counterparts.

Could you introduce to our international readers the US FDAâ??s Office of International Programs and the Indian Office in particular?

The FDAâ??s Office of International Programs (OIP) works with governments, industry and academia in foreign countries, as well as with multilateral organizations, to help assure that food and medical products exported to the United States meet U.S. standards. Today, with 300,000 foreign facilities from more than 150 countries exporting FDA-regulated products to the United States, FDA works beyond U.S. borders to ensure that products coming into the United States are safe and effective.

All products regulated by the Food and Drug Administration must meet the same requirements, whether imported from abroad or produced domestically.

The FDA opened the India Office in 2008, to ensure that food and medical products exported from India to the U.S. are safe, are of good quality, and are effective.

What are the main goals of the FDA in India as well as the main responsibilities and priorities of the Indian office?

FDAâ??s goals in India are to obtain information to help make better regulatory decisions about the products from India that are being developed and exported for the U.S. market. This includes medical products being reviewed for marketing authorization in the U.S., and the safety assessment of products that are already on the U.S. market. In addition, the India Office helps verify that foods being imported into the U.S. are safe.

FDA activities in India include conducting inspections of medical products and foods facilities that export to the U.S. We also engage with Indian regulatory authorities to build confidence in each other and develop quality standards as well as bilateral initiatives. Finally, we assist and train Indian regulators, Indian pharmaceutical and foods industries and stakeholders on developing and maintaining the quality, safety and effectiveness of medical products and foods. The India Office also aims at building and strengthening relationships with the government of India by supporting the mission of the U.S. Embassy

Could your elaborate the US FDAâ??s collaboration efforts with its Indian regulatory counterparts?

India is a significant player in the global marketplace, representing an important source of FDA-regulated products. Indian regulators have become important strategic partners for FDA. Today, we regularly engage with them on everything from sharing information on FDA guidance and regulations to collaboratively addressing product safety issues.

The FDA India Office seeks to engage proactively and consistently with Indian regulatory counterparts and industry representatives to facilitate FDAâ??s domestic mission of assuring the safety, efficacy, and quality of FDA-regulated products. This includes managing the sharing of information and addressing regulatory compliance issues, some of which have a global impact. FDAâ??s communication with its foreign regulatory counterparts seeks to share technical expertise that enhances the countryâ??s ability to produce safe foods and quality medical products. These information sharing and capacity building activities strengthen the ability of India to provide exports that meet the FDA standard and allow FDA to fulfill its mandate of consumer protection for Americans.

Over the past four years, there was a surge in the number of US FDA warning letters issued to India-based manufacturers and companies. What are the problems encountered by the FDAâ??s investigators in India?

The problems encountered by the FDAâ??s investigators in India are similar to those seen around the world in manufacturing. Common issues include inadequate or poor quality systems implementation, data integrity issues, inadequate validation of various processes used in manufacturing or testing, and product contamination. While some Indian companies meet U.S. product quality standards, others do encounter problems and operational challenges.

FDAâ??s risk-based site selection model focuses on drug manufacturing establishments, rather than countries. Indian regulators have become important strategic partners for FDA.

What will be your final message to our international readers?

FDAâ??s India Office engages with its government counterparts and industry to learn more about Indiaâ??s regulatory environment and practices. We strive towards communications that help one another understand each otherâ??s approach to issues identified across the wide range of products we each have responsibility for. The common mission of protecting the health of our citizens binds us together. Our responsibilities may differ in scope or emphasis, but our practices are based on similar foundations of good manufacturing or other good practices; we engage to ensure that we understand one anotherâ??s approaches towards the common goal: safe, quality and effective products for our citizens.

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