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DBT, CDSCO address regulatory concerns of innovators

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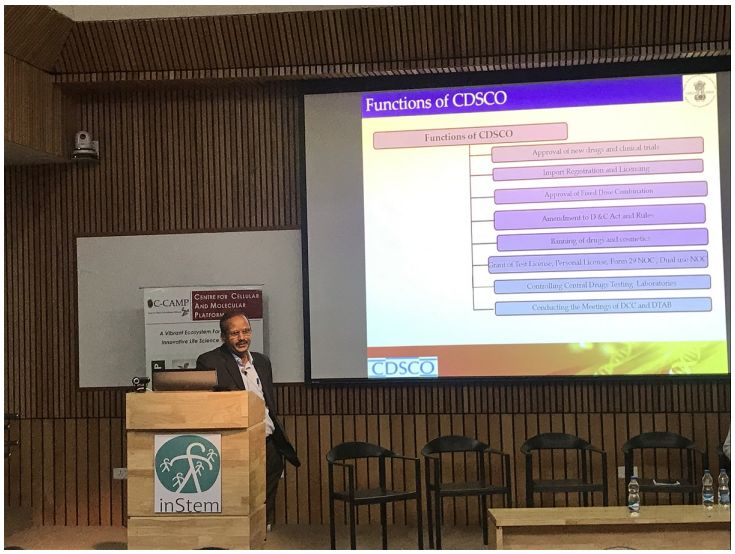

Department of Biotechnology (DBT) jointly with Central Drugs Standard Control Organisation (CDSCO) is organizing a national series of six regulatory workshops across the nation on facilitating resolution of regulatory concerns faced by the innovators in India.

This workshop series is being conducted by the Biotechnology Industry Research Assistance Council (BIRAC) and Clinical Development Services Agency (CDSA).

Two workshops in the series were conducted in New Delhi in December 2018 and Pune in February 2019. The third in this series was recently organised at the Centre for Cellular and Molecular Platforms (C-CAMP), Bengaluru.

“C-CAMP is providing the necessary platform to the innovators so that they can share their doubts and questions directly with the regulators. We plan to start a portal soon where the innovators can drop in their questions for the regulators and we can mediate it further”, said Dr Taslimarif Saiyed, CEO & Director, C-CAMP.

The workshop offered an opportunity to the innovators to interact with the regulators to resolve their regulatory issues thereby facilitating them to seek market authorization. Deliberations were done on various regulatory pathways applicable for the development of the new drugs, biopharmaceuticals, vaccines, medical devices & IVD kits, phytopharmaceuticals from discovery to commercialization.

“The regulatory system is very much supportive towards the innovators. The regulatory pathways have been simplified and made clear. We are always open in addressing people’s doubts and concerns. The government is taking all possible measures for strengthening the regulatory system both at the central and state levels. A lot of questions are being asked nowadays about the regulations for e-pharmacies. The draft is ready from our side but the final decision is yet to be taken since the IDMA is not in favour ”, mentioned Dr B Kumar, Deputy Drugs Controller India, CDSCO, Sub Zonal Office,

Bengaluru.

During the workshop, Dr Sucheta Banerjee Kurundkar, Director Training, CDSA shared her views on how a communication gap at times exists between the innovators and regulators. “The government is keen on understanding the various concerns of the innovators. As a result, we are conducting these regulatory workshops through government organisations such as C-CAMP, ICGEB, Venture Center in order to reach out to the researchers and innovators. We have three more workshops lined up which are a part of this series. There are two sessions being organized at NIPER in Hyderabad and Guwahati, and one most probably in Baroda at MSU. We plan to do much more in this regard”, she said.

The workshop was attended by a number of innovators, personnel working in the government national laboratories, academics and research institutions, participants from non-governmental institutions, startups, SMEs, MSMEs, industry, researchers.