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Venture centre organizes workshop on Regulatory Compliance for Medical Products

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The Department of Biotechnology (DBT) and Central Drugs Standard Control Organisation (CDSCO) alongwith Biotechnology Industry Research Assistance Council (BIRAC) and Clinical Development Services Agency (CDSA) has organised with Venture Center, Pune a one-day interactive program,'**National workshop on regulatory compliance for accelerating innovations".** This is one of the 6 national programs being planned across the nation. CDSA is a DBT organisation and it

works with regulators (CDSCO) and innovators to facilitate the journey from *'bench to bed side*' faster. Venture Center is working with various innovators, start-ups by providing all assistance like incubator facility, mentorship, funding support etc.

Prime Minister had launched the **Make in India** initiative on September 25, 2014, with the primary goal of making **India** a global manufacturing hub. There are 25 sectors assigned in *'Make in India'*, biotechnology being one of them. This workshop aimed to facilitate "*Make in India*" drive by helping the innovators and offer an opportunity to the innovators to interact with the regulators to resolve their regulatory issues thereby facilitating them to seek market authorization.This series is planned as per the one of the recommendations of the inter-ministerial meeting at the NITI Aayog. First workshop of this series was organized on December 10, 2018at ICGEB, New Delhi.

The workshop was attended by senior representatives from Government organizations, academia, medical device industry,*in vitro* diagnostics, new drugs, biopharma, phytopharma representing various start-ups, hospitals, institutes etc. There were total 96 participants representing 67 institutes who attended this interactive meet. The faculties included senior experts, present and former regulators from CDSCO (Central Drugs Standard Control Organisation); BIS (Bureau of Indian Standards); CDSA, THSTI (Translational Health Science & Technology Institute); and NIB (National Institute of Biologicals). There were 3 major themes (medical devices; new drugs & phytopharma and biopharma) and all questions were addressed by the regulators.

The other 4 programs in this national workshop series are envisaged at Bengaluru, Hyderabad; Guwahati and Vadodara in 2019.Such an attempt by various stakeholders to bring in facilitative platforms *where innovators can meet regulators* was hugely applauded by the attending participants.