



National workshop on regulatory compliances for accelerating innovations
ICGEB, New Delhi
December 10, 2018

Program Agenda

09:00 – 10:00	Welcome Address	Dr. Dinakar Salunke Director, International Centre for Genetic Engineering and Biotechnology (ICGEB)
	Workshop Background and Mandate	Dr. Alka Sharma Adviser, Medical Biotechnology Division, Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India
	Partnerships for regulatory pathways for innovation / The Importance of partnerships in regulatory Compliances for accelerating innovations	Dr. S. Eswara Reddy Drugs Controller General of India (DCGI), Central Drugs Standard Control Organization (CDSCO)
		Secretary, Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India
	Note of Thanks	Dr. Mohd. Aslam , Adviser, DBT; MD, BIRAC Dr. P. K. S. Sarma , Head, Technical Discovery & Product Development, BIRAC
10:15 – 11:00	Overview of regulations in India <ul style="list-style-type: none"> • CDSCO Structure • Regulatory pathways • Approval Process, Sugam Portal • Things to know before application • Fee Structure, Public Relations Cell 	CDSCO (Faculty to be nominated) Dr. V. G. Somani Joint Drugs Controller (India), CDSCO
11:30 – 12:00	Regulatory Pathway of <i>In-vitro</i> diagnostics in India	CDSCO (Faculty to be nominated) Mr. Senthil & Dr. Reba Chhabra (I/C, DDQC Diagnostics, NIB)
12:30 – 13:00	Regulatory pathway of New drugs and phyto-pharmaceuticals in India	CDSCO (Faculty to be nominated) Mr. A. K. Pradhan/ Mr. Patil/ Mr. Kanan

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Time	Title	Faculty
14:00 – 15:30	Medical devices <i>In-vitro</i> diagnostics	Panel Members: 1. CDSCO (Faculty to be nominated) 2. Mr. Malay Mitra , Former Deputy Drugs Controller (India), CDSCO 3. Dr. Reba Chhabra (Scientist Grade -I, I/C, DDQC Diagnostics, NIB) 4. Mr. Kalyan Verma , VP, Business Stream Products, TUV
14:00 – 15:30	Bio-pharmaceuticals	Panel Members: 1. CDSCO (Faculty to be nominated) 2. Mr. A.B. Ramteke , Former Joint Drugs Controller (India), CDSCO; Consultant Regulatory Affairs, CDSA 3. Prof. Anuraq S. Rathore , Professor of Chemical Enqg.
Conference Hall (Second floor), ICGEB		
14:00 – 15:30	Phyto-pharmaceuticals	2. Prof. Y. K. Gupta , Principal Adviser (Projects), THSTI 3. Dr. Geetanjali Uppal , Consultant, Regulatory & Clinical Development
15:30 – 17:00	Experience and regulatory challenges sharing by participants in the areas of • Medical devices • <i>In-vitro</i> diagnostics • Bio-pharmaceuticals • New drugs • Phyto-pharmaceuticals	Dr. Alka Sharma , Adviser, Medical Biotechnology Division, Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India Dr. P. K. S. Sarma , Head, Technical Discovery & Product Development, BIRAC CDSCO Nominated Faculty Moderator: Prof. Y. K. Gupta , Principal Adviser, (Projects), THSTI
	Distribution of <i>'Certificate of participation'</i>	

Happy Learning

