National workshop on regulatory compliances for accelerating innovations

ICGEB, New Delhi

December 10, 2018

Program Agenda

Time	Title	Faculty
Auditorium, ICGEB		
08:30 – 09:00	Registration	BIRAC & CDSA
Inaugural session		
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)
	Keynote Address	**Dr. Renu Swarup** Secretary, Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India
	Inaugural Address	**Prof. Vinod K Paul** Member, NITI Aayog
	Vote of Thanks	**Dr. Mohd. Aslam,** Adviser, DBT; MD, BIRAC **Dr. P. K. S. Sarma,** Head, Technical Discovery & Product Development, BIRAC
	Moderator – Dr. Sucheta Banerjee Kurundkar, Director Training, CDSA **Rapporteur –** Ms. Sonia Gandhi, Senior Manager - Investments	
10:00 – 10:15	**Group Photograph followed by Networking tea**	
Overview of Regulatory Pathways		
10:15 – 11:00	Overview of regulations in India • 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
11:00 – 11:30	Regulatory Pathway of Medical devices in India	**CDSCO (Faculty to be nominated)** Mr. Ravi Kant Sharma/Mr. Arvind Hiwale
11:30 – 12:00	Regulatory Pathway of *In-vitro* diagnostics in India	**CDSCO (Faculty to be nominated)** Mr. Senthil & Dr. Reba Chhabra (I/C, DDQC Diagnostics, NIB)
12:00 – 12:30	Regulatory Pathway of Bio-pharmaceuticals in India	**CDSCO (Faculty to be nominated)** Mr. R. Chandrashekhar/ Mr. Jayant Gangakhedkar
12:30 – 13:00	Regulatory pathway ofNew drugs and Phyto-pharmaceuticals in India	**CDSCO (Faculty to be nominated)** Mr. A. K. Pradhan/ Mr. Patil/ Mr. Kanan
13:00 – 14:00	**Lunch**	

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Resolution of regulatory concerns in different product categories (Parallel Sessions)		
Auditorium, ICGEB		
14:00 – 15:30	Medical devices *In-vitro* 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
Seminar Room (Ground floor), ICGEB		
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. Anurag S. Rathore**, Professor of Chemical Engg, IIT Delhi
Conference Hall (Second floor), ICGEB		
14:00 – 15:30	New drugs Phyto-pharmaceuticals	**Panel Members:** 1. **CDSCO** (Faculty to be nominated) 2. **Prof. Y. K. Gupta**, Principal Adviser (Projects), THSTI 3. **Dr. Geetanjali Uppal,** Consultant , Regulatory & Clinical Development
Valedictory Session		
Auditorium, ICGEB		
15:30 – 17:00	Experience and regulatory challenges sharing by participants in the areas of • Medical devices • *In-vitro* 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
	Open Forum for Q & A	**All Faculty & Moderator** **DBT/BIRAC/CDSA**
	Distribution of '*Certificate of participation*'	
17:00 onwards	**Tea/Coffee**	

Happy Learning