

## National workshop on regulatory compliances for accelerating innovations

**ICGEB, New Delhi**  
**December 10, 2018**

### Program Agenda

Time	Title	Faculty
<b>Auditorium, ICGEB</b>		
08:30 – 09:00	Registration	BIRAC & CDSA
<b>Inaugural session</b>		
09:00 – 10:00	Welcome Address	<b>Dr. Dinakar Salunke</b> Director, International Centre for Genetic Engineering and Biotechnology (ICGEB)
	Workshop Background and Mandate	<b>Dr. Alka Sharma</b> 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	<b>Dr. S. Eswara Reddy</b> Drugs Controller General of India (DCGI), Central Drugs Standard Control Organization (CDSCO)
	Keynote Address	<b>Dr. Renu Swarup</b> Secretary, Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India
	Inaugural Address	<b>Prof. Vinod K Paul</b> Member, NITI Aayog
	Vote of Thanks	<b>Dr. Mohd. Aslam</b> , Adviser, DBT; MD, BIRAC <b>Dr. P. K. S. Sarma</b> , Head, Technical Discovery & Product Development, BIRAC
<b>Moderator</b> – Dr. Sucheta Banerjee Kurundkar, Director Training, CDSA <b>Rapporteur</b> – Ms. Sonia Gandhi, Senior Manager - Investments		
10:00 – 10:15	<b>Group Photograph followed by Networking tea</b>	
<b>Overview of Regulatory Pathways</b>		
10:15 – 11:00	Overview of regulations in India <ul style="list-style-type: none"> <li>• CDSCO Structure</li> <li>• Regulatory pathways</li> <li>• Approval Process, Sugam Portal</li> <li>• Things to know before application</li> <li>• Fee Structure, Public Relations Cell</li> </ul>	<b>CDSCO (Faculty to be nominated)</b> <b>Dr. V. G. Somani</b> Joint Drugs Controller (India), CDSCO
11:00 – 11:30	Regulatory Pathway of Medical devices in India	<b>CDSCO (Faculty to be nominated)</b> Mr. Ravi Kant Sharma/Mr. Arvind Hiwale
11:30 – 12:00	Regulatory Pathway of <i>In-vitro</i> diagnostics in India	<b>CDSCO (Faculty to be nominated)</b> Mr. Senthil & Dr. Reba Chhabra (I/C, DDQC Diagnostics, NIB)
12:00 – 12:30	Regulatory Pathway of Bio-pharmaceuticals in India	<b>CDSCO (Faculty to be nominated)</b> Mr. R. Chandrashekar/ Mr. Jayant Gangakhedkar
12:30 – 13:00	Regulatory pathway of New drugs and Phyto-pharmaceuticals in India	<b>CDSCO (Faculty to be nominated)</b> Mr. A. K. Pradhan/ Mr. Patil/ Mr. Kanan
13:00 – 14:00	<b>Lunch</b>	

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<b>Resolution of regulatory concerns in different product categories (Parallel Sessions)</b>		
<b>Auditorium, ICGEB</b>		
14:00 – 15:30	Medical devices <i>In-vitro</i> diagnostics	<b>Panel Members:</b> 1. <b>CDSO</b> (Faculty to be nominated) 2. <b>Mr. Malay Mitra</b> , Former Deputy Drugs Controller (India), CDSO 3. <b>Dr. Reba Chhabra</b> (Scientist Grade -I, I/C, DDQC Diagnostics, NIB) 4. <b>Mr. Kalyan Verma</b> , VP, Business Stream Products, TUV
<b>Seminar Room (Ground floor), ICGEB</b>		
14:00 – 15:30	Bio-pharmaceuticals	<b>Panel Members:</b> 1. <b>CDSO</b> (Faculty to be nominated) 2. <b>Mr. A.B. Ramteke</b> , Former Joint Drugs Controller (India), CDSO; Consultant Regulatory Affairs, CDSA 3. <b>Prof. Anurag S. Rathore</b> , Professor of Chemical Engg, IIT Delhi
<b>Conference Hall (Second floor), ICGEB</b>		
14:00 – 15:30	New drugs Phyto-pharmaceuticals	<b>Panel Members:</b> 1. <b>CDSO</b> (Faculty to be nominated) 2. <b>Prof. Y. K. Gupta</b> , Principal Adviser (Projects), THSTI 3. <b>Dr. Geetanjali Uppal</b> , Consultant, Regulatory & Clinical Development
<b>Valedictory Session</b>		
<b>Auditorium, ICGEB</b>		
15:30 – 17:00	Experience and regulatory challenges sharing by participants in the areas of <ul style="list-style-type: none"> <li>• Medical devices</li> <li>• <i>In-vitro</i> diagnostics</li> <li>• Bio-pharmaceuticals</li> <li>• New drugs</li> <li>• Phyto-pharmaceuticals</li> </ul>	<b>Dr. Alka Sharma</b> , Adviser, Medical Biotechnology Division, Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India  <b>Dr. P. K. S. Sarma</b> , Head, Technical Discovery & Product Development, BIRAC  <b>CDSO Nominated Faculty</b>  Moderator: <b>Prof. Y. K. Gupta</b> , Principal Adviser, (Projects), THSTI
	Open Forum for Q & A	<b>All Faculty &amp; Moderator</b> <b>DBT/BIRAC/CDSA</b>
	Distribution of ' <i>Certificate of participation</i> '	
17:00 onwards	<b>Tea/Coffee</b>	

**Happy Learning**

