National workshop on regulatory compliances for accelerating innovations

National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad

May 29, 2019

Program Agenda

Time	Title	Presenter
Venue 1: NIPER, Hyderabad Auditorium		
08:30 – 09:00	Registration	**Ms. Vandana Chawla** (Manager Training, CDSA); **Shri. Jitender Ahuja ;** (Training Coordinator, CDSA); **Ms. N. Haritha** (NIPER); **Shri. G.C.B. Reddy** (NIPER)
Inaugural session		
09:00 – 10:00	Welcome address	**Dr. Shashi Bala Singh** Director, NIPER, Hyderabad
	Workshop background and mandate	**Dr. Alka Sharma** Adviser & Scientist 'G', Medical Biotechnology Division, Department of Biotechnology (DBT), New Delhi
	BIRAC overview	**Dr. Hardeep Vora** and **Dr. Shikha Taneja Malik** Program Manager(s), National Biopharma Mission, BIRAC
	Keynote Address	**Dr. S. Eswara Reddy*** Drugs Controller General (India), Central Drugs Standard Control Organisation, New Delhi
	Objective and expectations	**Dr. S. Rajesh** Director (Health), NITI Aayog, New Delhi
	Vote of thanks	**Dr. Sucheta Banerjee Kurundkar** Director Training, CDSA, THSTI, DBT
	Organising Team: (NIPER, Hydearbad)	**Dr. G. Chandraiah,** Assistant Professor, Regulatory Toxicology **Dr. D. Nandkumar**, Veterinary Scientist
Overview of regulatory pathways		
10:00 – 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	1. **Ms. Annam Visala,** Deputy Drugs Controller (India), CDSCO, Zonal office, Hyderabad 2. **Shri. Bikramaditya Chowdhury**, Drugs Inspector, CDSCO, Zonal office, Hyderabad
11:00 – 11:30	**Group photograph followed by networking tea**	
Resolution of regulatory concerns in different product categories (Parallel sessions)		
Venue 2: Hall 1, NIPER, Hyderabad		
11:30 – 12:30	Regulatory pathway of medical devices and *in vitro* diagnostics (including the role of NIB) in India	**Shri. Vinod Kumar,** Assistant Drugs Controller (India), CDSCO, Zonal office, Hyderabad **Dr. Reba Chhabra,** Scientist Grade-I, I/C, DDQC Diagnostics, NIB
12:30 – 13:00	Standards applicable for instrumentation and medical devices	**Shri. Prakash Bachani** Scientist E & Head, Medical Equipment & Hospital Planning Department, BIS
13:00 – 13:30	Validation and certification for new medical devices under IC-MED	**Shri. M. G. Sathyendra** Technical Expert, NABCB, QCI
13:30 – 14:30	**Lunch**	

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Venue 2: Hall 1, NIPER, Hyderabad		
14:30 – 16:00	Experience and regulatory challenges sharing by participants in the areas of • Medical devices • *in vitro* diagnostics	**Panel members:** **1. Shri. Malay Mitra**, Former Deputy Drugs Controller (India), CDSCO HQ, New Delhi **2. Shri. Vinod Kumar,** Assistant Drugs Controller (India), CDSCO, Zonal office, Hyderabad **3. Dr. Reba Chhabra**, Scientist Grade-I, I/C, DDQC Diagnostics, NIB **4. Shri. Prakash Bachani**, Scientist E & Head, Medical Equipment & Hospital Planning Department, BIS **5. Shri. M. G. Sathyendra**, Technical Expert, NABCB, QCI
		1. Sh. R Dharmraj, Assistant Drugs Controller (India), Krishnapatnam Port, Krishnapatnam **2. Smt. K. Bhuvaneshwari,** Drugs Inspector, CDSCO, Zonal office, Hyderabad **3. Sh. Narendra Kumar,** Drugs Inspector, CDSCO, Zonal office, Hyderabad
Rapporteur – Dr. M. Mallika, Lecturer, NIPER, Hyderabad		
16:00 onwards	Distribution of '*Certificate of participation*'	
	Tea/Coffee	

Time	Title	Presenter
Venue 3: Hall 2, NIPER, Hyderabad		
11:30 – 13:30	Regulatory pathway of Bio-pharmaceuticals in India • Biosimilars, Vaccines • Regenerative medicines • Blood products	**1. Ms. Annam Visala,** Deputy Drugs Controller (India), CDSCO, Zonal office, Hyderabad **2. Smt. Suganthi,** Drugs Inspector, CDSCO, Zonal office, Hyderabad **3. Shri. Naveen,** Drugs Inspector, CDSCO, Zonal office, Hyderabad
13:30 – 14:30	**Lunch**	
14:30 – 16:00	Experience and regulatory challenges sharing by participants in the areas of • Biosimilars, Vaccines • Regenerative medicines • Blood products	**1. Shri. A. B. Ramteke,** Former Joint Drugs Controller (India), CDSCO; Consultant Regulatory Affairs, CDSA, THSTI, DBT **2. Shri. R Srinivasan,** Assistant Drugs Controller (India), Visakhapatnam **3. Smt. Sunita Seerapu**, Drugs Inspector, CDSCO, Zonal office, Hyderabad
Rapporteur – Dr. V. Swapna, Lecturer, NIPER, Hyderabad		
16:00 onwards	Distribution of '*Certificate of participation*'	
	Tea/Coffee	

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Venue 1: NIPER, Hyderabad Auditorium		
11:30 – 13:30	Regulatory pathway of new drugs and phyto-pharmaceuticals in India	1. **Ms. Annam Visala,** Deputy Drugs Controller (India), CDSCO, Zonal office, Hyderabad 2. **Dr. Jay Jyoti Roy,** Drugs Inspector, CDSCO, Zonal office, Hyderabad
13:30 – 14:30	**Lunch**	
14:30 – 16:00	Experience and regulatory challenges sharing by participants in the areas of • New drugs • Phyto-pharmaceuticals	**Panel Members:** **1. Sh. Vanam Anjaneya Mitra,** Drugs Inspector, CDSCO, Zonal office, Hyderabad **2. Sh. Bikramaditya Chowdhury**, Drugs Inspector, CDSCO, Zonal office, Hyderabad **3. Dr. Jay Jyoti Roy,** Drugs Inspector, CDSCO, Zonal office, Hyderabad
Rapporteur – Dr. T. D. Neelima, Assistant Professor, NIPER, Hyderabad		
16:00 onwards	Distribution of '*Certificate of participation*'	
	Tea/Coffee	

*** Confirmation awaited**

Happy Learning