NATIONAL GLP COMPLIANCE MONITORING AUTHORITY SENSITIZATION WORKSHOP ON GLP

(May 17&18, 2018)

<u>Venue</u>: Sangam Hall, National Productivity Council, Lodhi Road, New Delhi- 110002

PROGRAMME

May 17, 2018 Thursday (Day 1)

09:00 - 09:30 hrs.	Registration	QCI
Time	Topic	Speaker
09:30 – 10:10 hrs.	Introduction to GLP, Genesis of NGCMA & Achievements made	Dr. Ekta Kapoor
10:10 – 10:50 hrs.	Expectations from a GLP Test Facility vis-à-vis compliance to OECD principles of GLP	Dr. Vinita Sharma
10:50 – 11:10 TEA		
11:10 - 11:50 hrs.	OECD Principles of GLP	Prof. Bikash Medhi
11:50 – 12:30 hrs.	Key players in GLP Set-up	Dr. Ekta Kapoor
12:30 – 13:00 hrs.	Discussion	All
13:00 – 13:45 LUNCH		
13:45 – 14:30 hrs.	Resources & Documentation in GLP Environment	Dr. K. Sadasivan Pillai
14:30 – 15:15 hrs.	Application of GLP Principles to Testing of Medical Devices	Prof. Bikash Medhi
15:15 – 15:35 TEA		
15:35 – 16:20 hrs.	GLP Requirements for submission of Safety Data for Regulatory purposes of Agrochemicals	Dr. Sandhya Kulshreshtha
16:20 –17:05 hrs.	Computerised systems in a GLP Environment	Dr. K. Sadasivan Pillai
17:05 – 17:30 hrs.	Discussion	All

May 18, 2018 Friday (Day 2)

Time	Topic	Speaker
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09:30 – 10:15 hrs.	Road Map towards GLP certification	Dr. K. Sadasivan Pillai
10:15 – 11:00 hrs.	Application for GLP Certification to NGCMA	Dr. Ekta Kapoor
	11:00 – 11.20 TEA	
11:20 – 12:05 hrs.	Test Facility Management: Roles and Responsibilities	Prof. K.B. Tikoo
12:05 – 12:45 hrs.	Quality Assurance Unit: Roles and Responsibilities	Dr. K. Sadasivan Pillai
12:45 – 13:15 hrs.	Study Director: Roles and Responsibilities	Prof. K.B. Tikoo
	13:15 - 14:00 LUNCH	
14:00 –14:45 hrs.	Archiving in a GLP Environment	Dr. K. Sadasivan Pillai
14:45 –15:15 hrs.	Overview of Quality Council of India and partnership between NGCMA & QCI	Dr. Manish Pande
	15:15 – 15:30 TEA	
15:30 – 17:30 hrs.	Panel Discussion	
16:15 – 17:30 hrs.	Feedback/ Short presentation from participants : Expectations & Suggestions	All