GOOD CLINICAL PRACTICE

Lecture Room, Venture Center, 100, NCL Innovation Park, Dr. Homi Bhabha Road, Pune
February 11-12, 2020

Program Agenda

February 11, 2020 (Day 01)

Time	Title (Learning Objectives)	Presenter
08:30 – 09:00	Registration and ice breaker Pre-assessment	**Ms. Vandana Chawla & Mr. Jitender Ahuja** Training Manager & Training Coordinator, CDSA, THSTI
09:00 – 09:15	Welcome address	**BIRAC-NBM/BCIL/CDSA/Venture Center**
09:15 – 10:00	Overview of GCP	**Dr. Sucheta Banerjee Kurundkar** Director Training, CDSA, THSTI
10:00 – 10:30	**Group photograph followed by networking tea**	
10:30 – 11:30	Ethical considerations	**Dr. Nandini K. Kumar** Former Deputy Director General Sr. Grade, ICMR; Vice President FERCI; Adjunct Faculty, CDSA, THSTI
11:30 – 12:15	Roles and responsibilities of an Investigator	**Dr. Sudha Basnet** Professor, Dept. of Child Health, Institute of Medicine, Tribhuvan University, Kathmandu, Nepal
12:15 – 13:00	Roles and responsibilities: Sponsor, institution, and monitor	**Ms. Ruteja Joglekar** Senior Manager, Clinical Operations & Start up management, Covance; ISCR Representative
13:00 – 13:45	**Luncheon**	
13:45 – 14:45	Current challenges in clinical trials/research: GCP implementation	**Dr. Cristina E. Torres** FERCAP Coordinator, Forum for Ethical Review Committees in Asia & Western Pacific, Thailand; Adjunct Professor, National Institutes of Health, University of Philippines, Manila, Philippines **Ms. Abhidnya V. Desai** IRB Administrator, Tata Memorial Hospital, Mumbai
14:45 – 15:30	<u>Panel discussion</u>: Addressing queries related to ethical considerations	**Dr. Nandini K. Kumar (Moderator)** **Dr. Cristina E. Torres** **Dr. Sudha Basnet** **Dr. Sanish Davis/Ms. Ruteja Joglekar**
15:30 – 15:45	**Tea/Coffee break**	
15:45 – 16:30	Clinical trial documents	**Dr. Monika Bahl** Director Clinical Portfolio Management, CDSA, THSTI
16:30 – 17:30	Role-play and case studies Quiz: Semi-final	**Ms. Vandana Chawla** Training Manager, CDSA, THSTI
>17:30	**Open forum for Q & A**	

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Program Agenda

February 12, 2020 (Day 02)

Time	Title (Learning Objectives)	Presenter
09:00 – 09:30	Recap	**Participants**
09:30 – 10:15	Record keeping and data handling	**Dr. Sucheta Banerjee Kurundkar** Director Training, CDSA, THSTI
10:15 – 10:30	**Tea/Coffee break**	
10:30 – 11:15	New Drugs and Clinical Trials (NDCT) Rules, 2019: Salient features	**Dr. Rubina Bose** Deputy Drugs Controller (India), CDSCO West Zone
11:15 – 12:00	Panel discussion: Addressing queries related to NDCT Rules, 2019	• **Shri. A. B. Ramteke (Moderator)** Former Joint Drugs Controller (India), CDSCO HQ; Consultant, Regulatory Affairs, CDSA, THSTI • **Dr. Rubina Bose** Deputy Drugs Controller (India), CDSCO West Zone
12:00 – 13:30	Quiz: Final Exercises: Individual/group	**Ms. Vandana Chawla** Training Manager, CDSA, THSTI
13:30 – 14:15	**Luncheon**	
14:15 – 16:00	Role-play and case studies Post-assessment	**Ms. Vandana Chawla** Training Manager, CDSA, THSTI
	Tea/Coffee break	
16:00 – 16:45	**Exit assessment**	**Participants**
>16:45	Closing remarks	**BIRAC-NBM/BCIL/Venture Center** **Dr. Sucheta Banerjee Kurundkar** Director Training, CDSA, THSTI
	• Feedback from participants • Vote of thanks	**Ms. Vandana Chawla** Training Manager, CDSA, THSTI
	• Open forum for Q & A • Distribution of certificates	

Happy Learning