# GOOD CLINICAL PRACTICE

**Seminar Hall 1, CDSA, THSTI, NCR Biotech Science Cluster, Faridabad**
**January 28-29, 2020**

**Program Agenda**

**January 28, 2020 (Day 01)**

| Time | Title (Learning Objectives) | Presenter |
|---|---|---|
| 08:30 – 09:00 | Registration and Ice breaker | **Ms Vandana Chawla & Mr Jitender Ahuja**<br>Training Manager & Training Coordinator, CDSA |
| 09:00 – 09:15 | Welcome Address | **BIRAC-NBM**<br>**BCIL**<br>**CDSA** |
| 09:15 – 10:00 | Overview of GCP | **Dr. Sucheta Banerjee Kurundkar**<br>Director Training, CDSA, THSTI |
| 10:00 – 10:30 | **Group photograph followed by networking tea** | |
| 10:30 – 11:15 | New Drugs and Clinical Trials (NDCT) Rules, 2019: Salient features | **Shri. A. K. Pradhan**<br>Deputy Drugs Controller (India), CDSCO New Delhi<br>Or<br>**Dr. Dhananjay Sable**<br>Assistant Drugs Controller (India), CDSCO New Delhi |
| 11:15 – 12:00 | Panel discussion:<br>Addressing queries related to NDCT Rules, 2019 | • **Shri. A. B. Ramteke**<br>Former Joint Drugs Controller (India), CDSCO HQ; Consultant, Regulatory Affairs, CDSA, THSTI<br>• **Dr A. K. Pradhan**<br>Deputy Drugs Controller (India), CDSCO New Delhi<br>• **Dr. Dhananjay Sable**<br>Assistant Drugs Controller (India), CDSCO New Delhi<br>• **Prof Y. K. Gupta (Moderator)**<br>Principal Adviser (Projects), THSTI; Former Dean (Academics), AIIMS, New Delhi |
| 12:00 – 13:00 | Ethical considerations | **Dr. Nandini K. Kumar**<br>Former Deputy Director General Sr. Grade, ICMR; Vice President FERCI; Adjunct Faculty, CDSA, THSTI |
| 13:00 – 14:00 | **Luncheon** | |
| 14:00 – 14:45 | Roles and responsibilities:<br>Sponsor and Institution; Monitor | **Ms Shubhra Bansal**<br>Director Clinical Portfolio Management, CDSA, THSTI |
| 14:45 – 15:30 | Roles and responsibilities:<br>Investigator | **Dr. Nitya Wadhwa**<br>Assistant Professor, THSTI; Faculty In-Charge, CDSA, THSTI |
| 15:30– 15:45 | **Tea/Coffee break** | |
| 15:45 – 16:30 | Challenges of collaborative clinical trials: IRB operations and implementing GCP in letter and spirit | **Dr. V. Koneti Rao (Online)**<br>Staff Clinician, National Institutes of Health, Bethesda, USA |
| 16:30 – 17:30 | Exercises: Individual/group | **Ms Vandana Chawla**<br>Training Manager, CDSA, THSTI |

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| 17:30 – 18:00 | Addressing queries related to current ethical considerations | **Dr Nandini K. Kumar**<br>Former Deputy Director General Sr. Grade, ICMR; Vice President FERCI; Adjunct Faculty, CDSA, THSTI |
| >18:00 | **Open Forum for Q & A** | |

# GOOD CLINICAL PRACTICE

**Auditorium, THSTI, NCR Biotech Science Cluster, Faridabad**
**January 28-29, 2020**

**Program Agenda**

**January 29, 2020 (Day 02)**

| Time | Title (Learning Objectives) | Presenter |
|---|---|---|
| 09:00 – 09:30 | Recap | **Participants** |
| 09:30 – 10:15 | Clinical trial documents | **Dr Monika Bahl**<br>Director Clinical Portfolio Management, CDSA, THSTI |
| 10:15 – 10:30 | **Tea/Coffee break** | |
| 10:30 – 11:15 | Record keeping and data handling | **Dr Sucheta Banerjee Kurundkar**<br>Director Training, CDSA, THSTI |
| 11:15 – 13:30 | Quiz and exercises | **Ms Vandana Chawla**<br>Training Manager, CDSA, THSTI |
| 13:30 – 14:15 | **Luncheon** | |
| 14:15 – 16:00 | Role play and case studies | **All Faculty and participants** |
| | **Tea/Coffee break** | |
| 16:00 – 16:45 | **Exit assessment** | **Participants** |
| >16:45 | Closing remarks | **BIRAC-NBM**<br>**BCIL**<br>**CDSA** |
| | Feedback from participants<br>Vote of thanks | **Ms Vandana Chawla**<br>Training Manager, CDSA, THSTI |
| | • Open Forum for Q & A<br>• Distribution of Certificates | |

**Happy Learning**