The New Drugs and Clinical Trials Rules 2019 have been notified on March 19. Clinical Development Services Agency (CDSA), an extramural unit of Translational Health Science & Technology Institute (THSTI), DBT, GoI jointly with Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, GoI organizing an 'Interactive meet on 'New Drugs and Clinical Trials Rules 2019; It's understanding and impact'. The interactive session has been planned to discuss and address issues/concerns pertaining to new clinical trial rules and remove any ambiguity. Further, Good Clinical Practice (GCP) guidelines are in the final stage of revision aligning with the New Drugs and Clinical Trials Rules and national ethical guidelines. This platform will also give an opportunity for inputs from various stakeholders.

**HIGHLIGHTS:**

- Presentation on salient features of New Drugs and Clinical Trials Rules 2019
  - **Prof. Y. K. Gupta,** Principal Adviser (Project), THSTI, DBT
- Panel discussion and question answer session
  - **Prof. Y. K. Gupta,** Principal Adviser (Project), THSTI, DBT
  - **Dr. S. Eswara Reddy,** DCGI, CDSCO
  - **Shri. A. K. Pradhan,** DDCI, CDSCO
  - **Prof. Gagandeep Kang,** ED, THSTI, DBT
  - **Prof. Y. K. Gupta,** Principal Adviser (Projects), THSTI, DBT
  - **Prof. Shinjini Bhatnagar,** Dean, Clinical Research, THSTI, DBT
  - **Prof. Usha Menon,** Strategy Lead, CDSA, THSTI, DBT
- Representatives from AYUSH, BIRAC, CSIR, CDSCO, DBT, DST, ICMR, ISCR, IPC, WHO will also attend

**WHO SHOULD ATTEND?**

- Clinical research investigators
- Members of ethics committee
- Faculty and staff from academic/medical institutions other institutes with interest in clinical trials
- Professionals working in drug research and development laboratories
- Professionals from pharmaceutical industry /industry association/CRO
- Any other stakeholder

**ONLINE REGISTRATION**

Interested personnel can apply through the online registration link given below. Registration is on first come first serve basis.

Online registration link:
https://forms.gle/UreppNFzVDvuaUZM6

**NO REGISTRATION FEES . NO TA/DA SUPPORT.**

**OTHER DETAILS**

- Timing of the program: 9:00 -13:30 Hrs
- Seats available: 150
- Last date of registration: May 14, 2019
- Final list: May 15, 2019

**CONTACT**

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**Organizing team**

- **Shri. A. B. Ramteke** Former Joint Drugs Controller (India), CDSCO; Consultant, Regulatory Affairs, CDSA
- **Dr. Nitya Wadhwa,** Faculty In-charge, CDSA & Assistant Professor, THSTI, DBT
- **Dr. Sucheta Banerjee Kurundkar,** Director Training, CDSA, THSTI, DBT
- **Mr. Prashant Bhujbal,** Manager Admin & Finance, CDSA, THSTI, DBT
- **Ms. Vandana Chawla,** Training Manager, CDSA, THSTI, DBT
- **Mr. Jitender Ahuja,** Training Coordinator, CDSA, THSTI, DBT