CURRENT REGULATORY REQUIREMENTS FOR CONDUCTING CLINICAL TRIALS IN INDIA

MULTIDISCIPLINARY

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TYPE OF COURSE : New | Elective | UG/PG
INTENDED AUDIENCE : Personnel working in new drug development
COURSE DURATION : 4 weeks (25 Feb 19 - 22 Mar 19)
EXAM DATE : 28 April 2019
PRE-REQUISITES : MBBS/BDS//BSc/B.Pharm and PG in said degrees, who are engaged in drug research, regulatory affairs.

INDUSTRIES APPLICABLE TO : Pharmaceutical Companies, Research Institutions, Biomedical research organizations, Drug regulators

COURSE OUTLINE :

Demonstration of safety and efficacy of the drug product for use in human being is essential before the drug can be approved for import or manufacturing and marketing in the country. The Rules 122A, 122B and 122D, 122 DA, 122DB, 122DAA, 122 DAB, 122 DD, and 122E of Drugs and Cosmetics Rules and Appendix I, IA and VI of Schedule Y, describe the information/data required for approval of clinical trial and/or to import or manufacture of new drug for marketing in the country. Recently, there are few amendments made related to the new drug rules. and " New Drugs and ClinicalTrial Rules, 2018. (Draft) published by the CDSCO.

ABOUT INSTRUCTOR :

Shri. Arunkumar B. Ramteke retired as a senior drugs regulatory officer (Joint Drugs Controller, India, CDSCO) with 31 years of experience in drug regulatory aspects in the office of the Drugs Controller General of India (DCGI).

Dr. Sucheta Banerjee Kurundkar joined CDSA as Director Training in 2012. She has 20+ years of experience in research and CRO Industry. Prior to this, she was Chief Scientific Officer at a multinational Clinical Research Organization. She is involved in training, quality assurance (pre-clinical, clinical & medical labs) and regulatory affairs at CDSA.

Dr. Nandini K. Kumar completed her MBBS and Post Graduate Diploma in Clinical Pathology from GMC, Trivandrum, and is a Fogarty Fellow graduate in Bioethics from University of Toronto. She worked as a researcher in the Gastroenterology Dept. of GMC, Trivandrum and in the Liver Clinic of Madras Medical College, Chennai.

COURSE PLAN :

Week 01 : Introduction, Definitions, Drug Regulatory Authorities

Week 02 : Drugs & Cosmetic Act & Rules (Relevant Act and Rules), Drugs & Cosmetics Rules (Relevant Guidelines issued by CDSCO), Drug development Overview

Week 03 : Good Clinical Practice (Indian), Schedule Y: Overview, Schedule Y: Appendices

Week 04 : Ethical considerations, Recent amendments, Special concerns (Approval procedure for Medical device, Biologicals, Phytopharmaceuticals, r-DNA derived products)