REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVD (IN VITRO DIAGNOSTIC) KITS IN INDIA

MULTIDISCIPLINARY

DR. MALAY MITRA
Former Dy.Drugs Controller
CDSCO

DR. ARUN B. RAMTEKE
Regulatory Affairs
CDSA, THSTI, DBT

TYPE OF COURSE : New | Elective | UG
EXAM DATE : 27 April 2019
COURSE DURATION : 4 weeks (25 Feb 19 - 22 Mar 19)
INTENDED AUDIENCE : Personnel working in medical device industry, Investigators, Regulatory Affairs personnel
PRE-REQUISITES : MBBS/BDS/ BE /ME/MSc/M.Pharm and above

INDUSTRIES APPLICABLE TO : Medical device companies, Research Institutions, Biomedical research organizations, Drug regulators, etc.

COURSE OUTLINE :

Demonstration of safety and efficacy of medical device and in vitro diagnostic (IVD) kit for use in humans is essential before the product can be approved for import or manufacturing and marketing in the country. Medical devices are currently regulated under the definition of DRUG. The Rules are :- Rules 109-A - Labeling of medical devices, Rule 125-A - Standards for medical devices, Schedule M III - QMS requirements, Schedule R- Standard for mechanical contraceptives, Schedule R1-Standards for medical devices, Schedule DII -Annexure B - IVD

ABOUT INSTRUCTOR :

Shri. Mitra completed his Pharmaceutical education from Jadavpur University, Calcutta in 1974. He worked in the area of pharmaceutical manufacturing in various capacities up to 1982. He joined Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, Ministry of Health & Family Welfare, Govt. of India in 1982. He has audited around 1500 institutions till date including China. He was an active member during the formation of Schedule M (GMP, Drugs and Cosmetic Rules, 1945).

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). He has in-depth knowledge of Indian Drugs & Cosmetics Act, Rules and of regulations of Global Drug Regulatory norms. He started his career at Central Research Institute, Kasauli, as Deputy Assistant Director, BSQC Division and faculty for B.Sc. (Microbiology) H.P. University. As Drug Regulator he has extensive experience with new drugs, vaccines and biotech products/pharmaceuticals, medical devices regulatory approvals and development experience.

COURSE PLAN :

Week 01 : Introduction, Classification of medical devices, Types of medical devices including combination device
Week 02 : Standards of medical device and testing, How to obtain a license to manufacture a medical device, Technical personnel required for manufacturing
Week 03 : Import and export, Local manufacturer: How to apply?, Schedule M-III and other standards like ISO 13485
Week 04 : Quality Assurance, Inspection and fees, Inspection before licensing