



REGULATORY REQUIREMENTS FOR MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS IN INDIA (VERSION 2.0)

Prof. Aseem Sahu

CDSCO, Ministry of Health & Family Welfare

Prof. Malay Mitra

Former DDC(I), CDSCO

Prof. Arun B. Ramteke

Consultant Regulatory Affairs, CDSA, THSTI, DBT; Former Joint Drugs Controller, CDSCO

TYPE OF COURSE : New | Elective | UG/PG

COURSE DURATION : 4 weeks (27 Jan' 20 - 21 Feb' 20)

EXAM DATE : 29 Mar 2020

PRE-REQUISITES : There is no pre-requisite to undertake this course.

INTENDED AUDIENCE : • Medical device industry • in vitro diagnostics (IVD) manufacturers • Innovators or start-ups involved in either medical device or IVDs • Regulatory affairs personnel • Human ethics committee members • Clinical trial/research team members • Any person interested to acquire knowledge in this area

INDUSTRIES APPLICABLE TO : Medical devices & IVD companies, Research/Academic Institutions, Biomedical research organizations, Regulatory authorities, Medical colleges, Contract research organizations

COURSE OUTLINE :

Demonstration of safety, efficacy, and performance of the medical device and in vitro diagnostic (IVD) kit for use in humans is essential before the product can be approved for import or manufacture and marketing in the country. Medical devices are currently regulated under the definition of 'drug'. Recent amendments made in the Rule by incorporating specific rules i.e., "Medical Devices Rules 2017" [G.S.R. 78 (E) dated the 31st January 2017] are published and are mandatory with effect from 1st January 2018. These rules provides requirements for import, manufacture, clinical investigation, medical device and in vitro diagnostics. All these had been effectively addressed in this course.

ABOUT INSTRUCTOR :

Prof. Aseem Sahu, Deputy Drugs Controller (India), CDSCO North Zone.

Prof. 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).

Prof. 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.

COURSE PLAN :

Week 1: Introduction: Medical device and in vitro diagnostics, Types of devices including combination devices and Drug Vs device Vs IVD, Medical Device Rules, 2017: Implications on medical devices, Classification. Labeling of medical devices.

Week 2: Standards of Medical Device, Quality Assurance, and Testing, Biocompatibility Studies on Medical Devices, Clinical Investigation of Medical Devices

Week 3: Quality Assurance and Quality Management System, Manufacture of Medical Devices and IVDs. How to obtain a license to manufacture a medical device?, Risk Management System for medical devices (ISO 14971)

Week 4: Inspection of medical device and IVD establishments, Import and export of medical devices and IVDs, Medical device regulation: International practices