

**Bhaujbal Knowledge City,
MET's Institute of Pharmacy,
Adgaon, Nashik-03**

Report on Certificate Course in Pharmacovigilance

MET's Institute of Pharmacy have conducted a short term certificate course in Pharmacovigilance in academic year 2017-18. The course was conducted in association with Inclination, Mumbai. InClinition is a pharmaceutical and clinical research organization. InClinition provides domestic and international pharmaceutical, biotech and, nutraceutical, food, beverage, cosmetics companies with reliable, cost-effective, value-added service, to advance their goals and objectives. Dr. Amrit Karmarkar, Director, Inclination, Mumbai had coordinated the course along with Dr. Deepak Bhambere, MET's Institute of Pharmacy.

There is huge potential for indigenous and outsourced clinical research in India. Such knowledge resides with specialists, such as clinical research associate, clinical team leader, project manager, clinical supply manager, quality assurance manager, medical and regulatory affairs manager, data manager and head of clinical operations. Training of these professionals in GCP standards would go a long way to strengthen the CR industry. Specialized training requirements may include, training on clinical trial process, development of standard operating procedures and GCP and applicable regulatory guidelines. Only few of the present requirement of the trained persons presently required in the healthcare industry are trained and certified annually. As there is no certificate course available in Nashik region about pharmacovigilance and hence the awareness of this course is concealed from the mind of students. There are some course running in Mumbai and Pune but the cost of course is not affordable to students which belongs to poor financial background or from rural region.

In order to bridge this gap MET's Institute of Pharmacy had taken initiative in collaboration with Inclination, Mumbai in order to sensitize the student with this untouched field and conducted a Certificate Course in Pharmacovigilance very affordable fees. The fees for course was decided Rs. 4720/- per student including GST. The tenure of course was decided 3 months. The class room sessions were conducted on every odd Saturday. The syllabus was designed as per the Inclination and some suggestions from PV Scientist working with renowned companies like TCS, Cognizant. The demonstrative/promotional lecture was arranged on 12th Aug. 2017. Total 36 students

enrolled for course from MET's Institute of Pharmacy, Sandip Institute of Pharmaceutical Sciences, R. G. Sapkal College of Pharmacy, Sir Dr. M.S. Gosavi College of Pharmaceutical Education and Research. Along with class room sessions, students were familiarized with some important aspects of PV including ADR and Drug Dictionaries, Signal detection, strengthening and analysis and software Safety databases - ARGUS and ARISG along with live demonstration. Students were provided with free login id and password in order to access Inclination Android App for study material, E-learning portal to access study material.

The course coordinator had conducted weekly assignment from MOODLE App, group discussions, case studies and case presentation from students as a part of course. The examination pattern was decided as MCQs, Problem Solving, Formative Assignments, Written Test, Viva Voce and Case Studies. The final examination was conducted on 3rd June 2018. The certificate distribution ceremony of first batch of certificate course in Pharmacovigilance is organized on 18th Aug 2018.



Dr. S. J. Kshirsagar
Principal

Dr. D. S. Bhambere
Course Coordinator