

MGM INSTITUTE OF HEALTH SCIENCES

(Deemed University u/s 3 of UGC Act, 1956) **Grade 'A' Accredited by NAAC** Sector-01, Kamothe, Navi Mumbai - 410 209 Tel 022-27432471, 022-27432994, Fax 022 - 27431094 E-mail : <u>registrar@mgmuhs.com</u> |Website : <u>www.mgmuhs.com</u>

Value Added Course

Clinical Research

Dr. Rajesh B. Goel MGM INSTITUTE OF HELATH SCIENCES (DEEMED UNIVERSITY u/s 3 of UGC Act,1956) NAVI MUMBAI- 410 209

Dr.Shashank D.Dalvi Vice Chancellor MGM INSTITUTE OF HEALTH SCIENCES (DEEMED UNIVERSITY ufs 3 of UGC Act, 1956) KANOTHE, NAVI MUMBAI

Annexure-52D of BOM-62-2020

<u>Item 10 F: Title of the Course</u> –*Clinical Researc* h(Pharmacology, Navi Mumbai and Klintec Academy, Mumbai)

<u>Course objectives</u>: Candidate will understand whole canvas of clinical research in short so that he/she is job ready for a Clinical Research Organisation or a Pharma company research department

Course content:

•	Introduction to Clinical Research 2 hrs	
•	Process of drug development	2 hrs
•	Clinical research methodology & study designs	4 hrs
•	Ethics in Clinical research	2 hrs
•	Clinical trial regulations India and international	4 hrs
•	Good Clinical practice guidelines	2 hrs
•	Clinical Trial operations	4 hrs
•	Quality in clinical trials	2 hrs
•	Clinical data management 2 hrs	

Eligibility:Final year MBBS, BHMS, MD/MS, BAMS, BDS, Nursing and BPT, Graduates in Life Sciences, Pharmacy, Biotechnology, Bio-Sciences, Bio-informatics, Paramedical and Allied Health Sciences

Duration of the course: 12 weeks

Expected hours of teaching: $24 \sim 26$ hours (4 hrs over alternate weekends)

<u>Coaching methodology</u>: In classroom lectures by faculty

Assessment mode: Written exam/s (MCQs) of 100 marks across topics taught in the course. A minimum 50% marks required for candidate to pass the exams and be awarded the 'certificate'. Written exams with a minimum 50% marks required for candidate to pass the exams and be awarded the 'certificate'