

**Maharashtra University of Health Sciences,**

**Nashik**

# **Syllabus**

**Fellowship Course in Advanced Clinical  
Research**

## Speciality wise Course Details

### 1. Curriculum

I. Title of the Course – **Fellowship Course in Advanced Clinical Research**

II. **Aims/Objective & Desirability –**

Obtain a clear understanding of Good Clinical Practice and Standard Operating Procedure for Clinical Research and Clinical Data Management.

Provide Individuals / Students / Professionals from Pharmacy, Medical, Nursing, Life Sciences, Research & Development, Clinical Research, Allied areas and Academic fields, a basic to advanced level understanding of various clinical trial processes.

Enable participation in design, conduct and management of global clinical trials, conducted at multi-centric sites in India and overseas.

Acquire an understanding of evolving regulatory processes, standards and practices of ICH GCP in the conduct of different therapeutic trials and in the preparation of submissions to be made to regulatory authorities in India and overseas.

Support overall clinical trial process electronically by implementing Electronic Data Capture (EDC) system and Project Monitoring. Course

To accomplish these goals, fellows are supported for 1 year.

III. Duration – 1 year

IV. Eligibility Criteria for admission –

Graduates in Life Sciences, Pharmacy, Biotechnology, MBBS, BHMS, BAMS, BDS and BPT, Paramedical and Allied Health Sciences.

Entrance Test : Theory- MCQ of 50 marks without negative marking,

Shortlisting - 3 times of the number of seats.

Final selection by interview.

V. **Intake Capacity** – 1 per Teacher

#### **Selection Criteria for candidates:**

Fellows should be selected in a fair and non-discriminatory manner in accordance with the Equal Opportunities. The selection process will be according to MUHS guidelines.

The candidate is expected to appear for the multichoice(MCQ) written examination of 100 marks. Selected candidates will be called for the interview. Ultimately, selection of a candidate for a fellowship will be done by an interview with panel of faculties constituted by the MUHS.

#### **Examination paper for selection of candidates for Fellowship:**

Three sets of MCQ paper will be set by the committee of the faculties approved by MUHS & only one paper will be selected by random process on the day of examination.

Evaluation of the examination conducted will be done by a committee of faculties

Merit list & Successful candidates name will appear on the WEB site of MUHS

Syllabus / Course contents –

- **Module-I: Introduction to Clinical Trials**
  1. Introduction to Clinical Research
  2. Definition, History
  3. Drug Discovery and Drug Development
  4. Pharmacology- PK, PD
  5. ICH, GCP
  6. Schedule-Y
- **Module-II: Clinical Trials**
  1. Clinical Trial Designs and Phases
  2. Informed Consent [Main, Children, Geriatric, Special Population]
  3. Source Documentation
  4. CRF Design, CRF Entry, CRF Types
  5. Protocol Design and Development
  6. Source data verification, monitoring, Inspection, Audit
  7. Data Management
  8. Pharmacovigilance - AE, SAE, ADR
- **Module-III: Pretrial and Trial Related Discussions**
  1. Pre-trial activities
  2. Essential Documents
  3. Standard Operating Procedures
  4. Quality Control and Quality assurance, Monitoring role & responsibility, monitoring plan and implementation
  5. Monitoring visit type, monitoring activities
  6. Scientific paper writing, publishing a research paper
- **Module-IV: Regulatory**
  1. Drug Regulatory Authorities- US-FDA, EU, DCGI, ICMR, ICH-GCP, SCHEDULE-Y, IPR, HIPPA, Patent
  2. IND,NDA- Submission forms, submission process
  3. Pre and post drug approval
  4. Inspection and Audits-Regulatory Overview
  5. Ethics Committee, IRB, DSMB
- **Module-V: Miscellaneous**
  1. Biostatistics
  2. GMP & GLP
  3. BA/BE Studies
  4. Role of Central lab
  5. IMP handling
  6. Communication skills
  7. Collaborative research-National/International
  8. Funding agencies
  - I. Teaching Scheme
    - i. Lectures
    - ii. Surgical
    - iii. Practical
    - iv. Presentations

- v. Publications
  - vi. Other – As per speciality
- II. Mentorship required -- yes
- III. Evaluation/Examination Scheme
- i. Attendance
  - ii. Log book
  - iii. Publications
  - iv. Credit hour system
    - i. Didactic lectures
    - ii. Surgical work
    - iii. Clinical work
    - iv. Practical
    - v. Research work/publications
    - vi. Assignment
    - vii. Portfolio
    - viii. Presentations
    - ix. Lab rotation
    - x. Seminar
    - xi. Log book
    - xii. Any other – As per speciality
    - xiii. Conferences/Workshop of that speciality attended

**1. No. of teaching / non teaching staff required**

**A. Teaching**

- i. Professor
- ii. Associate Professor
- iii. Lecturer
- iv. Tutor

**B. Non Teaching**

- i. Nurses
- ii. Technicians
- iii. Clerical :
- iv. Counselor
- v. Social worker :
- vi. Attendant
- vii. Any other – As per speciality

**2. Eligibility criteria for teaching staff at each level**

- i. Minimum 10 years teaching experience and minimum including at least 3 years of postgraduate teachership.
- ii. Minimum experience of teacher in the speciality of course applied for :  
Research experience 3 years.

## **Scheme of Evaluation**

The entire course is Credit System based. For each Module, the candidates will be assigned credits for their work by respective Faculty/Institute.

**Total Credits: 300**

**Minimum Number of Credits for successful completion of programme:-240 credits**

Transfer of Credit to and from other Universities: Not at present but will be informed once broad consensus among other universities is established.

Breakup of credits

- **For each Module (or week) 20 credit points (Total of 100 credits)**

Throughout the course student will be evaluated through questions, observing the understanding, etc. Credits will be allotted at the end of each module.

- **Research Project work ( 100 credit point)**

Fellow has to design and conduct a research/study project on a research question under faculty guidance and present/publish and submit it to MUHS.

- **Theory: (50 Credit points) MCQs**

- **Practicals (50 credit points)**

1. Exam on Biostatistics. **(25 credit points)**
2. Discussion on journal article **(10 credit points)**
3. Viva **(15 credit points)**

**15. Announcement of results**

Results will be announced on the website and notice board within one week of the conclusion of the examination.

**16. Award of Fellowship**

Certificates will be awarded by the MUHS after the results will be sent to the MUHS.

**Standards & Information required for Recognition of Hospital/Institute to start Fellowship/Certificate Course**

**1. Hospital/Institute**

- i. Building ( Hospital building should be own)
- ii. The Hospital should be minimum 03 years old (Audited Budget Statement for last 03 years)
- iii. No. of beds in the same Unitary Campus (for multispeciality hospital minimum 200 beds required, for monospeciality minimum 50 beds required, for subspeciality like Ophthalmology, ENT, Dermatology, Psychiatry etc., minimum no. of hospital beds will depend upon workload, Volume of patient services)

**2. Infrastructure for teaching**

- i. Lecture halls/ teaching space – minimum 02 areas for teaching
- ii. Laboratory
- iii. Anesthesia facility
- iv. Blood bank facility
- v. Radiology/Imaging facility
- vi. Operation Theatre
- vii. Library Facility
  - A. No. of books
  - B. No. of journals (National/International)

**3. Workload Facility**

- i) IPD (Average for last 03 years)
- ii) OPD (Average for last 03 years)
- iii) Bed occupancy for last 3 year
- iv) ICU patients
- v) Operations – total and speciality-wise (Average for last 03 years)
- vi) Lab investigations
- vii) Radiology/Imaging Investigation
- viii) Blood Bank

**4. Teaching/ nonteaching Staff (Speciality wise)**

Name	Designation	Speciality	Qualification	total experience		Research	Full time/part time	
				Teaching				Clinical
				UG	PG			