

Clinical Research - Total

Background Information:

S. P. Mandali's **Therapeutic Drug Monitoring Laboratory (TDML)**, now identified as **Institute for Advanced Training and Research in Interdisciplinary Sciences (IATRIS)** is a premiere research institute and was one of the first laboratories in India to conduct Bioequivalence studies on modern drugs. One of the salient features of this laboratory is its strength in industrial research. The laboratory has the recognition and approval from Drug Controller General of India (DCGI) to conduct clinical studies on healthy human volunteers.

IATRIS is part of S. P. Mandali, a Charitable Trust which runs 40 educational institutions across Mumbai, Pune, Solapur, Chiplun, and Bangalore, of which the renowned Ruia College is one such institution.

EnvisBESM Solutions Pvt. Ltd. is a Business and Education Solutions Provider registered under the Companies Act, 1956 (No. 1 of 1956) as Private Limited Company. The Company has been founded by experts in the field of Cosmetics, Pharmaceuticals, Foods, Household and Fabric Care as well as Clinical Research with a Number of years of experience behind them.

EnvisBESM Solutions possesses collective exposure to various aspects of Product Development, Product Evaluation, Intellectual Property, Techno-Legal, Regulatory, Quality Management Systems & Knowledge Management.

Together, **IATRIS** and EnvisBESM Solutions possess all the necessary skills, infrastructure and expertise to provide comprehensive education in the field of Pre-clinical and Clinical Research.

Course Details:

The course is a unique programme designed to provide comprehensive education and training in the field of Pre-clinical and Clinical Research.

Highlights of the Programme

- Lectures by Experts in the field
- Adequate Practical Training for Hands-on Exposure
- In-House Library facility
- In-house preclinical & clinical facilities
- Small batch size for one to one attention

Course Curriculum

The Course Curriculum is designed by an **Expert Panel** comprising members from the **Education Field, Medical Practitioners, Clinicians and Industry Experts** to provide comprehensive and relevant coverage.

The following provides a brief idea on the coverage of the course.

- Definition, Type and Scope of Pre-Clinical & Clinical Research including Careers in Clinical Research
- Drug Development Process
- Science of Skin & Hair
- Introduction to Regulatory Toxicology & Related Guidelines
- Preclinical Studies – including Introduction to Toxicology, Toxicology in regulatory process, Methods of toxicity evaluation, Animal to human extrapolation, etc.
- GCP Guidelines, OECD Guidelines, ICMR Guidelines, Schedule Y, BIS Guidelines, etc.



- Design and conduct of Clinical Study
- Design and conduct of studies for Cosmetics and Foods including Cosmeceuticals,

Nutraceuticals and Functional foods

- Study Documentation and Study Audits
- Biostatistics and Electronic Data Management

There would be adequate practicals to provide hands-on exposure to the various topics.

Assessments

During the entire course there would be adequate opportunity for the students to work in teams as well as to interact with the faculty.

Overall assessments would be based on-

1. Completion of Project Assignment
2. Practical assessment
3. Theory examination

This would provide for a comprehensive overall evaluation of the candidates knowledge and expertise while also providing the industry adequate confidence in the candidate's capabilities.

Why a Career in Clinical Research?

Clinical research and more particularly Human Participant Research is today accepted as an essential part of New Product Development in Pharmaceutical, Cosmetic, Personal Care and Foods industry and is here to stay. Also, comprehensive Pre-clinical evaluation is very important in order to establish preliminary safety of the product or ingredient prior to conducting research on human participants.

Consumers, Medical Practitioners as well as Regulators are becoming increasingly aware of the science behind clinical research and are demanding sound clinical data in support of product claims.

Since registration of clinical trials on the CTRI Registry has been made mandatory around mid-2009, more than 1500

trials have already been registered and the number will keep increasing.

So it is evident that growth in this industry is going to increase significantly in future.

Job Opportunities

Knowledge in Pre-Clinical and Clinical Research provides a knowledge intensive career unlike the routine run-of-the-mill job options.

Some of the options include:

Clinical Research Associates (CRA): Entry level position in CRO's and provides a link between CRO, Sponsor and Investigator.

Principal Investigator / Co-Investigator: Medical Practitioner responsible for conducting Clinical Investigations on site.

Clinical Research Manager (CRM): Oversees entire Clinical Research Operations.

Regulatory Manager: Oversees documentation for regulatory submissions.

Auditors and Inspectors: Oversee compliance with regards to ICH/GCP and ICMR Guidelines.

Medical Writers: Specialists in designing Protocol, IC, CRF, Study Reports and various study related documents.

Clinical Research knowledge thus provides a variety of openings based on one's aptitude and liking.

Besides CRO's, Pharmaceutical and FMCG industry is today continuously on the lookout for candidates with clinical research background since they could add value to their product development team or become part of the in-house

team handling pre-clinical and clinical research for the company. Subsequent growth in the industry is a function of the candidates desire to learn and adopt the latest skills and techniques in a field that is continuously evolving.

Course Programme: (6 months -)
Theory: Three days a week (6.30pm to 8.30pm)
Practicals: 4 hours on Saturdays

Eligibility:

- Graduate / Post Graduate in Chemical / Biological / Pharmaceutical / Medical Science
- Graduate with at least 2 years industry experience in Clinical Research

Admissions to be completed at:
IATRIS, Plot No. 194, Scheme No. 6, Road 15, Sion-Koliwada, Sion (E), Mumbai 400022
Timings: 10.30am to 5.00pm

Kindly Note:

1. Admissions after scrutiny of biodata and personal interview.
2. Admissions are completely at the discretion of the course management.
3. Payment by DD only. DD in favour of 'S. P. Mandali's IATRIS'
4. No Donation / Capitation fee

Contact for further information, Admission Forms & Prospectus:

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S. P. Mandali's
INSTITUTE FOR ADVANCED TRAINING AND RESEARCH IN
INTERDISCIPLINARY SCIENCES
(Therapeutic Drug Monitoring Laboratory)



S. P. Mandali's

Institute for Advanced Training & Research in Interdisciplinary Sciences (IATRIS)
(Therapeutic Drug Monitoring Laboratory)
in collaboration with
EnvisBESM Solutions Pvt. Ltd.

CLINICAL RESEARCH - TOTAL
(Post-Graduate Diploma in Pre-Clinical & Clinical Research)



Comprehensive Training for Excellence in Pre-Clinical and Clinical Research