Why LEO?

We offer a complete learning experience featuring online classes, on-site tours, and a broad range of necessary resources and tools, allowing you to connect with biopharmaceuticals and medical device companies worldwide.

Leo Clinical RESEARCH

Our Curriculum includes:

- Access to online databases
- Instructions by Industry Experts
- Participation in ongoing clinical research studies across globally located hospitals
- Assistance with CV preparation and mock interviews
- Networking opportunities with industries
- Job opportunities in partnered CROs

Our courses offer the unique opportunity to join live sessions with experts and engage in collaborative exercises with a global community of learners.

Our institute is committed to supporting lifelong learning, providing professionals worldwide with dedicated staff and access to advanced databases throughout their careers.

Learning Outcomes:

- Good Clinical Practice (GCP)
- Good Manufacturing Practice (GMP)
- Regulatory Guidelines
- Ethics Committee Purpose
- Clinical Trial Process
- Informed Consent Procedures
- Pharmacovigilance
- Patient Safety and Risk Management
- Clinical Data Management
- SAS Programming

Clinical Research Management

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease. Clinical research is different from clinical practice. In clinical practice, established treatments are used, while in clinical research evidence is collected to establish a treatment. It therefore becomes necessary to understand how to manage them, audit & monitor them at the same time.

In a world facing significant disease challenges and rising healthcare needs, developing new drugs is essential. Clinical research is the only way to introduce safe and efficacious molecules in the market, hence clinical trials are an essential part of drug development. Hence there is a growing need for medical professionals, biomedical and biological scientists in the pharmaceutical and medical device industry.

Topics covered in the course:

- Introduction to Clinical Research and Research Methodology
- Ethical Considerations
- Feasibility and Site Management
- Ethics Committee Management
- Screening, Randomization and Enrolment procedures
- Informed Consent Process
- Clinical Trial Monitoring and Auditing
- Data Collection and Quality Control
- Assessing and Reporting Adverse Events
- CRF (Case Report Form) Management
- Source Documentation and TMF (Trial Master File) Management

Career Avenues in Clinical Research:

Clinical Research Associate – Level I/II/III
Clinical Research Coordinator/Clinical Trial Associate
Clinical Trial Administrator
Clinical Trial Documentation Specialist (Records Management)
Manager - Quality Assurance
Clinical Project Manager/Trial Manager

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Drug Regulatory Affairs

Regulatory Affairs departments are on the rise within companies. Due to the ever-changing resource requirements to fulfil regulatory obligations, some companies also opt for outsourcing or delegating regulatory affairs to external service providers. Remarkably, the Regulatory Affairs department is constantly evolving and growing and that remains least impacted during acquisitions, mergers, and economic recessions.

Global harmonization in standards has led to a consistent approach in regulatory submissions and hence its review. The companies responsible for the discovery, testing, manufacture, and marketing of these products also want to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare.

The regulatory professional's roles and responsibilities often begin in the research and development phases, moving into clinical trials and extending through premarket approvals, manufacturing, labelling, advertising and post-market. The role involves monitoring the constantly evolving regulations in all the regions where the company intends to distribute its products.

Topics covered in the course:

- Introduction to Drug Regulatory Affairs
- Introduction to International Drug Regulatory Authorities
- Introduction to ICH GCP Guidelines
- Overview of Drug Discovery & Development Process
- Regulatory Control in Clinical Trials
- Drug Regulatory Applications
- Introduction to CMC Section
- Licensing Authorisation Process
- IPR in Pharma Industry (Overview)
- Drug Regulatory Affairs in USA
- Drug Regulatory Affairs in European Union
- Drug Regulatory Affairs in Australia and Canada
- Drug Regulatory Affairs in India

Career Avenues in Regulatory Affairs:

Compliance Officer
Regulatory Officer Specialist
Regulatory Medical Writer
Regulatory Associate
Regulatory Executive/ Research Scientist

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Pharmacovigilance and Medical Writing

Pharmacovigilance is a vital scientific discipline that supports the improvement of clinical practice and contributes to the enhancement of public health. The national pharmacovigilance centres have gained significant influence over drug regulatory authorities, especially during a time when drug safety concerns have become more prominent in both public health and clinical practice. Pharmacovigilance is rooted in scientific principles and essential for clinical practice. However, it must evolve to meet public health expectations.

The pharmaceutical industry established medical writing as a distinct function in response to the realization that generating well-structured documents, which effectively convey information with clarity and brevity, necessitates specialized skills. With the intricate journey of clinical trials and regulatory protocols leading to market approval for new drugs, there is a growing need for precisely articulated medical science, driving the demand for meticulously crafted, compliant documents that can be readily comprehended by healthcare professionals.

As a result, there is a growing need for adequately trained pharmacy/medical professionals, biomedical and life-science professionals with relevant experience in the pharmaceutical and biotechnology industry. We realize how important it is for you to place yourself in good company after spending a considerable amount of your time and effort studying for your respective biomedical degrees.

Topics covered in the course:

- Overview of Pharmacovigilance
- Preparation of Investigator's Brochure (IB)
- Preparation of Clinical Study Report (CSR)
- Interpretation of Clinical and/or Scientific Data
- Medical Editing of Prescribing Information /Patient Information Leaflet/Periodic Safety Update Report (PSUR), Individual Case Safety Reports (ICSR)
- Common Technical Documentation (CTD)
- Standard Operating Procedures (SOPs) on Protocol and Related Documents (i.e. ICD/CRF/IB) for Regulatory Submission
- Writing of Protocol, Informed Consent Document and Case Report Form
- Writing for Publication of Scientific/Medical Findings
- Documents for Medico-Marketing

Career Avenues in Pharmacovigilance and Medical Writing:

Medical Writer
Scientific Editor
Drug Safety Associate
Safety/Operational Specialist
Aggregate Report Scientist
Clinical Team Leaders

Clinical Data Management

Clinical Data Management (CDM) is an increasingly vital profession within the realm of pharmaceutical research and development. Over the past decade, CDM has made substantial advancements, evolving into a well-established discipline in its own regard. It has emerged as a recognized field where individuals can cultivate their expertise and advance their professional trajectories.

CDM plays a pivotal role in clinical research, ensuring the production of high-quality, reliable, and statistically sound data from trials. This significantly accelerates the drug development-to-marketing timeline. CDM team members are actively engaged throughout the clinical trial process, necessitating robust process knowledge to uphold quality standards. Current industry demands highlight the need for enhanced CDM standards to meet regulatory requirements and expedite product commercialization. Regulatory-compliant data management tools are crucial for this purpose. Furthermore, electronic data submission is becoming mandatory, requiring CDM professionals to uphold data quality standards and adapt to evolving technology.

As a result, there is an increasing demand for well-trained pharmacy and medical professionals, as well as biomedical and life science experts with pertinent experience in the pharmaceutical and biotechnology sectors.

Topics covered in the course:

- CRF Design and Development (Paper/e-CRF)
- Database Build and Testing
- Edit Checks Preparation and Testing
- Data Entry, Discrepancy Management
- Data Coding (MedDRA and WHODDE)
- SAE Reconciliation
- Database Lock

Career Avenues in Clinical Data Management:

Clinical Data Manager
Database Administrator
Database Programmer/Developer
Clinical Data Associate - Level I/II/III

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Schedule - **April / July / October / January**
Length and Hours - 8-**12 weeks and 8-10 hours/week**
Duration for all courses - **3 Months**
Duration for an individual course - **2 months**

- The course schedule includes 3 days of theoretical classes per week.
- Practical sessions are conducted for 2 working days each week.
- The last 1-2 weeks are reserved for CV preparation, mock interviews, and networking with companies.
- We provide comprehensive placement assistance through our industry connections with pharmaceutical and biotechnology firms.

Why Choose Us?

Practical Experience

Affordable Training

Expert Instructors

Real-world Application

Job Preparation

Industry Placements

Eligibility

- Students currently enrolled or about to graduate from the following programs: BPharm/M Pharm, BSc/MSc in Life Science Disciplines (e.g., Pharmacology, Physiology, Biochemistry, Microbiology, Biotechnology); MBBS/MD; BDS; BAMS; BUMS; BPT; Certification in Medical Laboratory; Nursing.
- Practicing Pharmacists and Medical or Healthcare Professionals seeking career advancement opportunities

Teaching Faculty

Our faculty comprises experts from top multinational pharmaceutical companies, ensuring students receive the best technical exposure.

Examinations/Certifications

There will be periodic assessments of your lectures through Multiple-Choice Questions (MCQ) Examinations. Upon successful completion of the course, a Certificate will be awarded.

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