

# CLIN BIOSCIENCES



# Campus Seminar Session





# University of Technology and Applied Sciences - Muscat



# Dubai- Dubai Pharma College, Campus Seminar Session







# **Welcome to CLIN BIOSCIENCES Institute**

## **Join the 100% Recession Proof Industry**

CLIN BIOSCIENCES is one of India's premier institutes in the field of Clinical Research, committed to developing highly skilled professionals for the industry. With a strong focus on quality education, our comprehensive curriculum integrates core scientific knowledge with practical exposure, soft skills training, and hands-on internships in leading Clinical Research Organizations (CROs). Over the years, students and professionals from Allied Health Sciences and Life Sciences backgrounds have greatly benefited from our industry-aligned training approach, paving the way for successful careers in Clinical Research and related domains.





### Eligibility for the Course

Candidates with the following academic backgrounds are eligible to apply:

**B.Sc / M.Sc** in: Botany, Zoology, Chemistry, Biochemistry, Biotechnology, Microbiology, Genetics, Nursing

**B.Tech** in Biotechnology

**Medical & Allied Health Degrees:** M.B.B.S, B.D.S, B.A.M.S, B.H.M.S, B.V.Sc, B.S.M.S

**Pharmacy:** B.Pharm / M.Pharm

This course is ideal for:

Fresh graduates

Professionals seeking a **mid-career shift**

Individuals aiming for **better career growth** in the clinical research domain

### Course Outcomes

**PG Diploma in Clinical Research & Pharmacovigilance**

Awarded to candidates who complete **Classroom** or **Virtual Training**.

**Certification in Clinical Research**

Granted to candidates who complete our **Online** or **Direct Clinical Research** programs.

## Placement & Internship Assistance – Guaranteed\* 100% Placement & Internship Support

At CLIN BIOSCIENCES, we are committed to your career success.

After completing the training program, we provide:

**Interview opportunities** with reputed employers

**End-to-end interview support** until the candidate is placed

**Internship opportunities** for fresh graduates upon successful completion of the 3-month classroom training

\*Terms & conditions apply.



## Market Leaders in Innovation

At CLIN BIOSCIENCES, we take pride in being recognized as market leaders through our **self-designed, industry-integrated curriculum** that is continually updated to meet evolving global standards.

Our programs combine **cutting-edge technical training, soft skills development, and hands-on experience with modern technology**, ensuring our students are fully prepared for real-world challenges in Clinical Research and related fields.







## **Best Placement Record in the Industry**

At CLIN BIOSCIENCES, our commitment to students goes beyond delivering industry-relevant skills and high-quality training—we are equally dedicated to launching their careers with top-tier organizations.

It is no surprise that we hold one of the best placement records in the Clinical Research industry. Our alumni are successfully placed in renowned CROs (Clinical Research Organizations), pharmaceutical companies, and biotech firms across India and abroad

## **The CLIN BIOSCIENCES Culture of Growth**

At CLIN BIOSCIENCES, one of the leading Clinical Research institutes, we foster a culture of continuous growth, innovation, and professionalism. Our programs are delivered in a dynamic learning environment supported by state-of-the-art facilities and experienced faculty.

We ensure that every aspect of our online, direct, and classroom training in Clinical Research and Pharmacovigilance is handled with the utmost quality and care—equipping students with the skills they need to thrive in the healthcare and life sciences industry.



# **JOIN OUR 7,00,000+ CLIN BIOSCIENCES ALUMNI THRIVING IN THE CLINICAL RESEARCH INDUSTRY SINCE 2011!**

Become part of a growing global network of professionals trained at CLIN BIOSCIENCES — one of India's most trusted names in Clinical Research education.



## **Aspiring to Build a Career in Clinical Research?**

### **Explore Our Industry-Focused Programs:**

- ✓ Advanced PG Diploma in Clinical Research & Pharmacovigilance
- ✓ PG Diploma in Clinical Research & Pharmacovigilance
- ✓ Diploma in Clinical Research & Pharmacovigilance (CR & PV)
- ✓ Certification in Clinical Research & Pharmacovigilance (CR & PV)

Whether you're a fresher or a professional seeking career growth, our programs are designed to equip you with the skills and practical exposure needed to excel in the Clinical Research industry.

# Join Our 7,00,000+ CLIN BIOSCIENCES Alumni Thriving in the Clinical Research Industry Since 2011!

Pharmacovigilance is widely recognized as an **evergreen industry**, playing a vital role both in **new drug development** and in the **post-marketing evaluation of approved drugs and medical devices**.

It is a scientific discipline focused on **identifying, validating, quantifying, evaluating, and improving drug safety** to protect public health.

During this course, you will gain knowledge and hands-on skills in the core activities of pharmacovigilance, including:

- \*Providing end-to-end **medical, safety, and analytical services**
- \***Medical review** and **expectedness assessment**
- \***Causality assessment** and preparation of **case narratives**
- \*Case **processing and coding** using medical dictionaries (e.g., *MedDRA*)
- \***Data mining** and **signal detection** for emerging safety issues
- \*Handling **medication error-related activities**
- \*Delivering specialized **regulatory services** required for compliance

Upon completion, you will be prepared to contribute effectively to this critical field within the clinical research and pharmaceutical industries.





## ICH Guidelines

Q

- Stability
- Impurities testing
- GMP

S

- Carcinogenicity
- Genotoxicity
- Reprotoxicity

E

- Clinical trials
- Pharmacogenomics

M

- MedDRA
- CTD
- Electronic Standards



## Eligibility & Program Overview

### Eligibility:

Candidates should hold an undergraduate or graduate degree in Human Medicine (MBBS, BDS), Veterinary Medicine (BVSc), Ayurveda/Unani (BAMS, BUMS), Pharmacy (B.Pharm/M.Pharm), Nursing (B.Sc), or Allied Health/Life Sciences (B.Sc Biotechnology, Microbiology, etc.).

### Program Highlights:

Our Post Graduate Diploma in Clinical Research & Pharmacovigilance offers industry-approved training in core pharmacovigilance principles and regulatory practices. It's ideal for fresh graduates and professionals seeking to enter or switch to the pharmacovigilance and clinical research fields.

# PG Diploma in Clinical Research & Pharmacovigilance

The **PG Diploma in Clinical Research & Pharmacovigilance** is designed to equip graduates from life sciences and health sciences with a comprehensive understanding of the entire drug development lifecycle—from laboratory research (bench side) to patient application (bedside). This program provides an in-depth insight into the processes involved in clinical trials, including clinical trial approvals, marketing authorization procedures, and the roles of various regulatory authorities worldwide responsible for product registration and compliance.

## Is this program right for you?

If you have a keen interest in working with clinical data and aspire to build a career in the pharmaceutical and healthcare sectors, this program is an excellent choice. It is specifically tailored for candidates aiming to work in Site Management Organizations (SMOs), Contract Research Organizations (CROs), pharmaceutical companies, and multinational corporations (MNCs). The course prepares you to handle clinical research activities effectively and supports your professional growth in this dynamic industry..

## Who can apply?

This program is open to graduates and postgraduates from the following disciplines:

**Medical and Health Sciences:** MBBS, BHMS, BAMS, BPT, MPT, BDS, BMLT, Bachelor in Naturopathy, Veterinary Science, MD/MS

**Pharmacy:** Graduate/Postgraduate degrees in Pharmacy and Pharmaceutical Sciences

**Life Sciences:** Graduate/Postgraduate degrees in Botany, Zoology, Biochemistry, Microbiology, Genetics, Biotechnology

**Other Relevant Fields:** Graduate/Postgraduate degrees in Chemistry, Biostatistics, Bioinformatics

**Nursing and Allied Health:** Graduate degrees in Nursing and Allied Health Sciences

**Final-Year Students:** Students in the final year of graduation in any of the above-mentioned disciplines are also eligible to apply







## What are the job opportunities for clinical research?

The **PG Diploma in Clinical Research** opens doors to a wide range of career opportunities, especially in multinational pharmaceutical companies, Contract Research Organizations (CROs), and healthcare institutions.

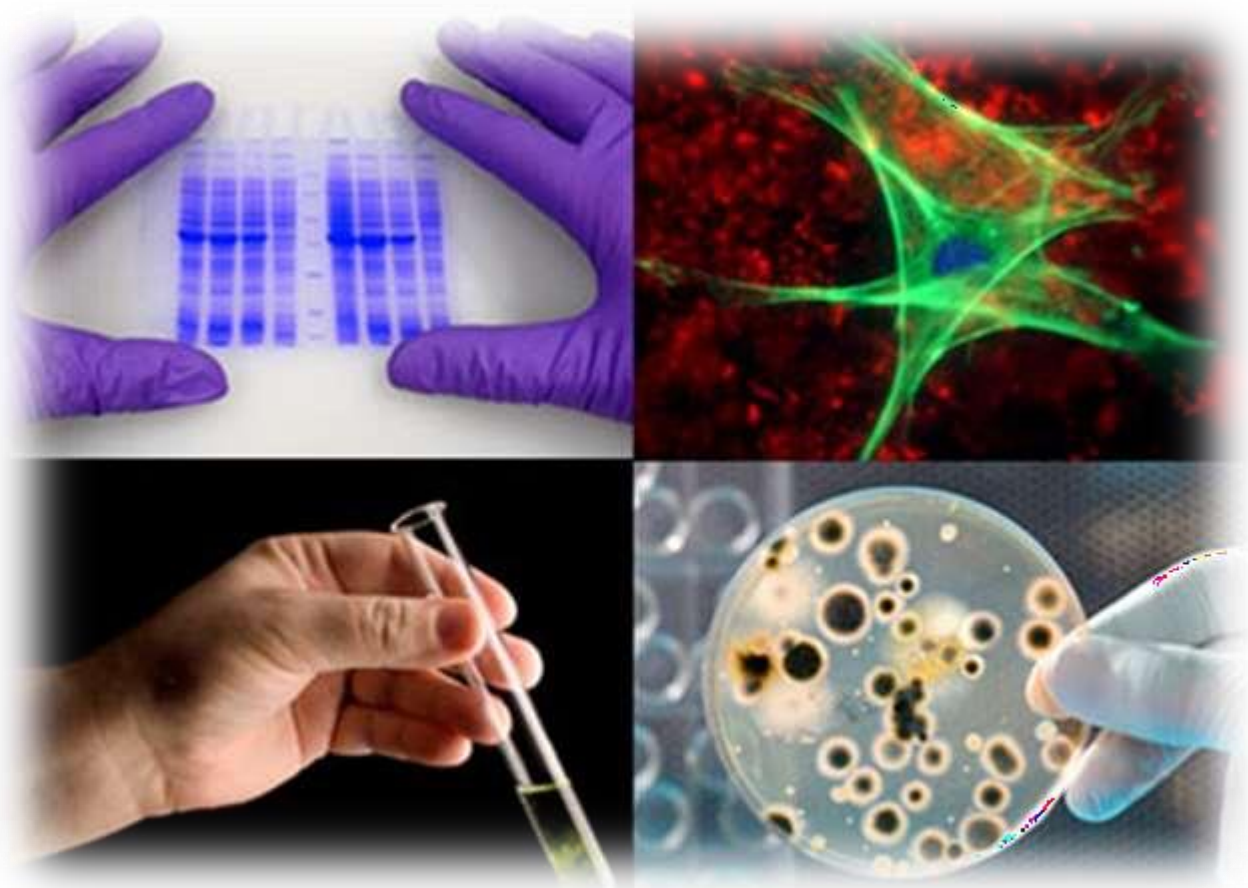
Graduates of this program can pursue various roles, including but not limited to:

- \***Clinical Trial Analyst**
- \***Clinical Trial Assistant**
- \***Clinical Research Coordinator**
- \***Clinical Research Associate**
- \***Quality Control Specialist**
- \***Quality Analyst**
- \***Principal Investigator**
- \***Sub-Investigator**

These positions offer a dynamic and rewarding career path, contributing to the development, management, and monitoring of clinical trials and ensuring compliance with regulatory standards.

# What are the job opportunities for Clinical Data Management?

- ✓ Data Entry Operator
- ✓ Associate Clinical Data Co-Ordinator
- ✓ Data Validator
- ✓ Medical Coder
- ✓ Data Manager
- ✓ Clinical Data Analyst
- ✓ Clinical Data Programmer
- ✓ Clinical Data Manager I
- ✓ Clinical Data Manager II
- ✓ Principal Clinical Data Manager
- ✓ Manager, Clinical Data Management
- ✓ Group Manager, Clinical Data Management
- ✓ Associate Director, Clinical Data Management







Registration

# **Master's Programms in Clinical Research and Pharmacovigilance**

6 month of training + Years

Hands on Training of

Paid internship with Package

with Guidelines Course: Dubai,  
United Arab Emirates

Website:

[www.clinbiosciences.in](http://www.clinbiosciences.in)

Ph: 9342735755





# Careers In Clinical Research

**Clinical Research Associate (CRA)** is a healthcare professional responsible for managing and monitoring clinical trials. CRAs play a pivotal role in clinical research, often regarded as the backbone of the field. They work across diverse organizations, including pharmaceutical companies, medical research institutes, and government agencies. Depending on the organization's policies, specific educational qualifications and certifications may be required to qualify as a CRA.

**Clinical Data Management (CDM)** is a crucial phase in clinical research that ensures the generation of high-quality, reliable, and statistically valid data from clinical trials. The primary objective of CDM is to maintain data integrity and accuracy, which supports valid research conclusions. By achieving this, CDM safeguards public health and fosters trust in therapeutic innovations.

**Clinical Research Organisation (CRO)** landscape is extensive and varied. Leveraging the expertise of a CRO can significantly enhance the efficiency and success of clinical trials. However, selecting the right CRO tailored to the specific needs of a project is essential to maximize outcomes and maintain regulatory compliance.



Typically, a CRO will organize and conduct clinical trials to check the test molecule in humans. As independent companies, they offer an objective assessment of a new drug in the clinical setting and since they partner with many companies, typically provide broader experience.

## Careers In Clinical Research

Key Cities in India for Clinical Research

Delhi & NCR Region

Mumbai

Pune

Ahmedabad

Vadodara

Hyderabad

Bangalore

Chennai

Chandigarh, Bhopal, Indore, Coimbatore and Vizag are emerging as new centres for clinical trials.



## **Career options after BVMS / BSMS / BAMS / BPT / MBBS/BDS**

Clinical research refers to the process, which is basically the evaluation of how effective or useful a new drug, vaccine, diagnostic test, new device or surgical technique, can be in humans.

### **Advantages of doing a CR course**

The number of trials approved by the Drugs Controller General of India is on the rise, with India becoming a one-stop destination for many disease indications, and both MNC and Indian companies eager to conduct multinational multi-centric trials here.

CROs, as the name suggests, offer a wide range of “outsourced” pharmaceutical research services to pharmaceutical industries and hence are the next big employers of clinical research professionals.

India is the second largest pharmaceutical market in Asia growing by more than nine per cent annually. According to a report, there are more than 50,000 jobs in clinical research in India.

### **Various job roles available**

- ❖ As Principal Investigator
- ❖ As Co-investigator
- ❖ As Medical Advisor
- ❖ As Drug Developer
- ❖ As Clinical Research Physician
- ❖ Technical writer
- ❖ Protocol Development
- ❖ Pharmacovigilance dept. in pharma companies
- ❖ As Regulatory Affairs Manager
- ❖ As Clinical Research Physician



# Career options after M.pharm / B.pharm

Clinical Research has emerged as a popular career choice in India and abroad. Holding a strong growth potential, a clinical research profile has become a calling for many. India being a land known for Ayurveda, Unani, Siddha, and Homeopathy besides allopathy, India is growing as the preferred destination for global clinical trials.

Clinical research is a multinational, multi-billion and multidisciplinary industry.

After MPharm there are various opportunities for students, if one wishes to pursue a career in Clinical research, he/she can undertake programs like PG Diploma in Clinical Research, PG Diploma in Clinical Data Management, PG Diploma in Pharmacovigilance.

## Advantages of doing a CR course

Many allied sectors offer opportunities after completing a course in clinical research and the numbers are on the rise. “The employment of manpower is the highest in the R&D at biopharmaceutical companies, which are always on the lookout for pharma candidates.

With operational players including some of the top Indian Pharmaceutical companies, such as Ranbaxy, Dr. Reddy's Labs, Biocon, Dabur, Wockhard, Merck, Astra Zeneca, a clinical research profile offers a plenty of job opportunities.  
Job profiles

## Clinical Research Coordinators:

Their duties include recruiting, studying the site, enrolling participants for trial, follow-ups, maintaining and dispensing drugs, performing experiments, testing accuracy and creating the reports etc.

## Clinical Data Manager:

It involves data entry and data validation the way the client (CRO, pharma, Biotech Company) requires it.

**Protocol Development:** It is more knowledge-driven and requires an understanding of medical terms.





## **Regulatory department personnel:**

It involves liaising with regulatory authorities with respect to approval applications and other types of license/permit requests, handling in-house regulatory documentation and playing an advisory role to provide country-specific regulations for clients outside India.

## **Pharmacovigilance dept. in pharma companies:**

This involves monitoring, researching, assessing and evaluating information from health care providers and patients on the adverse effects of medications



## Technical writer:

This professional is responsible for writing and editing standard operating procedures, clinical study protocols, laboratory procedure manuals, and other related documents in the field.

There are various job profiles available in clinical research field like clinical research associate, clinical pharmacist, data managers, pharmacovigilance case processor, project managers, regulatory affair publishers, biostatisticians, etc.

MPharm / B. pharm graduates can find jobs in following sectors after completing Clinical Research course

- Clinical Research Organizations.
- KPOs like Accenture & Quintiles.
- Regulatory Agencies like DCG (I) & CDSCO
- Pharmacovigilance units in Medical colleges & Hospitals

# Types of Research





Career options after M.Sc. For any M.sc life science students after completing their academics they have to go for further studies or they have to choose the research field. Even after entering the research field they have to look for the fellowships and they have to gain experience if they want to go for the industry jobs.

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use.

Clinical research industry is an ever growing and recession proof but at the same time very challenging and dynamic. Post graduate diploma in clinical research is a comprehensive course offering candidate with knowledge and practically important information about the industry type, working modalities and the methodologies used.

### **Job Prospects:**

This course is meant for all those keen on being a part of clinical Research industry, so all graduates, post graduates and even working professionals can apply for the course.



This course is meant for graduates and post graduates, employed plus yet to be employed candidates keen on taking regulatory affairs as their career choice. By doing this course they are exposed to Clinical Research, Regulatory, Clinical data management, Pharmacovigilance and Medical writing. They can get placed in any one of the various job profiles. Basically the entry level job for a diploma holder will be as **Clinical research coordinator**.

**You will be placed in any one of the following:**

Site Management Organisations (SMOs)  
Contract Research Organisations (CROs)  
Pharmaceutical Companies  
KPOs and MNCs





### **Various Profiles:**

Clinical Trial Analyst, Clinical Trial Assistant, Clinical Research Coordinator, Clinical Research Associate, Quality Control, Quality Analyst, Principal Investigator, Sub-Investigator, Data Entry Operator, Associate Clinical Data Coordinator, Data Validator, Medical Coder, Data Manager, Clinical Data Analyst, Clinical Data Programmer, Clinical Data Manager Clinical Data Manager II, Principal Clinical Data Manager, Clinical Data Management Group Manager, Clinical Data Management, Associate Director, Clinical Data Management, Project Manager, Biostatistician, Clinical Data Auditor, Clinical Applications Programmer, Database Administrator, Outcome Evaluators, Principal Investigators, Health Policy Analyst, Data Manager, Clinical Trial Reports (CTR)/ CSR, New Drug Applications (NDA), Investigational New Drug Application (IND), Protocol and its Amendment, CTD Journal articles, Medical coder, Narrative writer, submission to journals



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# MEDIA ACCREDITATIONS of CLIN BIOSCIENCES





Business Woman Mrs.Alamelu Murali - how to improve business? 19/05/2017





# **Programme - Arab Pharmacovigilance Guidelines Course**

## **An introduction to the PV structure**

Overview of the modules

The interaction of the modules

A comparison to the EU modules

## **Module I - quality management systems**

Quality control, quality assurance, and quality management

Quality management of PV systems

QPPV and quality management

Quality and training

QA and quality management and internal audits

## **Module II - the pharmacovigilance system master file (PSMF)**

The content of the PSMF

Licence submissions and the PSMF

The QPPV and the PSMF

Control/management of the PSMF

## **Module III - pharmacovigilance inspections**

The purpose of the inspection

Types of inspection

Inspection findings

Re-inspections

## **Module IV - pharmacovigilance audits**

The purpose of company audits

Audit scheduling and risk

Audit outputs and findings

Audit findings and their corrections - root cause analysis, corrective action plans, completion and re-audits



## **Module V - risk management plans (RMPs)**

ICH E2E - pharmacovigilance planning

The RMP purpose

The RMP format

Updating the RMP

RMPs and REMs

## **Module VI - adverse reaction reporting (part 1)**

Definitions

Special situations

Triage - seriousness

Expectedness and causality

Expedited reporting

## **Module VI - adverse reaction reporting (part 2)**

Electronic ADR reporting - local and international

Follow-up of cases

ICH E2D - post-marketing safety

Literature ADR reporting

Case closure

## **Module VII - periodic safety update reports (PSURs)**

ICH E2F and ICH E2C (R2) - DSRRs and PSURs/PBRERs

Objectives of the PSURs

Risk-benefit analyses in PSURs

The format of the PSUR

Mapping signals and risks to the PSUR

## Module IX - signals and their management

What is a signal?

Signal validation

Signal analysis and prioritisation

Signal assessment

Actions to be taken



An Opportunity for students and fresher's, to clear all doubts Regarding Clinical Research & PV. We are Offering In House training for the college students with scholarship in the Training Programme Clinical Research & Pharmacovigilance.

If your college Don't delay! Secure your Seat today..... REGISTER NOW for Admission call to us: 9342735755 .