



QUISCON BIOTECH



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Dubai- Bits Pilani, Campus Seminar Session



University of Technology and Applied Sciences - Muscat



Dubai- Dubai Pharma College, Campus Seminar Session





Welcome to **QUISCON BIOTECH** Institute

Join the **100% Recession Proof Industry**

Quiscon Biotech is one of the most premier Clinical Research institutes of India, dedicated to providing excellent Clinical Research Professionals to its field. Numerous students and professionals from Allied Health Science/Life Science streams have benefited from our robust curriculum, coupled with training in soft skills and internships in leading Clinical Research Organizations.





ELIGIBILITY FOR COURSE:

B.Sc/M.Sc (Botany, Zoology, Chemistry, Biochemistry, Biotechnology, Microbiology, Genetics, Nursing), B.Tech (Biotechnology), M.B.B.S / B.D.S / B.A.M.S / B.H.M.S / B.V.Sc. / B.S.M.S, B.Pharm / M.Pharm.

This course is best suited for Freshers/Mid-term career change/Better career growth.

COURSE OUTCOMES:

PG Diploma Clinical Research & Pharmacovigilance is awarded to candidates who take up Classroom or Virtual Training.

Certification in Clinical Research is awarded to candidates who take up our **online/ Direct clinical research courses.**

PLACEMENT & INTERNSHIP ASSISTANCE GUARANTEED

100% Placement & Internship Assistance

Guaranteed. **Conditions Apply*

After the training, we arrange interviews with the employers. We provide interview support to the student till the time they are placed. Internships are provided to the fresh graduates after completion of the 3 months class room program.



WHY OMASY RESEARCH

MARKET LEADERS IN INNOVATION

We are clearly the market leaders in terms of our self-designed, up-to-date industry-integrated curriculum, as well as the technical and soft skills we impart our students, while making them adept at the use of modern technology.





BEST PLACEMENT RECORD IN THE INDUSTRY

Our commitment to our students does not just end with providing them the best skills and training possible, but also to helping them start their career with the best names in the industry. No wonder, we have the best placement record for Clinical Research professionals and our previous batch students are placed with top CROs, Pharmaceuticals and Bio-tech companies.

THE OMASY RESEARCH CULTURE OF GROWTH

At **QUISCON BIOTECH**, one of the **top clinical research institutes**, we have established a culture of constant growth, innovation and enterprise in a professional environment aided with state-of-the-art facilities, led by our supportive staff who teach professionally every aspect of **online/ Direct clinical research & pharmacovigilance courses**.

**JOIN OUR 7 LAKHS + QUISCON BIOTECH STUDENTS
WORKING IN THE
CLINICAL RESEARCH SPACE SINCE 2011!**



**If you are aspiring to enter into Clinical
Research.**

You Can opt for Courses

- ADVANCE PG DIPLOMA IN CLINICAL RESEARCH & PHARMACOVIGILANCE
- PG DIPLOMA IN CLINICAL RESEARCH & PHARMACOVIGILANCE
- DIPLOMA IN CR & PV
- CERTIFICATION IN CR & PV

What will I learn if I take up this course?

Adv. PG Diploma in Clinical Research & Pharmacovigilance

Pharmacovigilance is regarded as an evergreen industry. It is at the center stage of new drug development as well as post marketing evaluation of approved drugs and devices. Pharmacovigilance is a scientific discipline which is mainly concerned with identifying, validating, quantifying, evaluating and increasing their safety.

The main activities in a pharmacovigilance involve providing end to end medical, safety and analytical services which include medical review, expectedness, casualty assessment, case narratives and processing, coding using medical dictionaries (e.g, MedDRA), data mining and signal detection, medication error related activities and finally some specialized regulatory services.



ICH Guidelines

Q

- Stability
- Impurities testing
- GMP

S

- Carcinogenicity
- Genotoxicity
- Reprotoxicity

E

- Clinical trials
- Pharmacogenomics

M

- MedDRA
- CTD
- Electronic Standards



The basic minimum qualifications for fitting to a pharmacovigilance career include undergraduate and/or graduate degrees in human (MBBS, BDS) and veterinary (BVSC) medicine, BAMS, BUMS, pharmacy (B.Pharm), nursing (BS) or allied health sciences (BSc); after which a course in **Post Graduate Diploma in Clinical Research & Pharmacovigilance** can be applied for.

The professional **clinical research & pharmacovigilance diploma courses** in pharmacovigilance will provide a foundation in pharmacovigilance principles and operations. The curriculum is fully reviewed by the industry professional and is relevant to aspirants who want to join the pharmacovigilance sector from both within and outside the pharmaceutical industry.

PG Diploma in Clinical Research & Pharmacovigilance

The **PG Diploma Clinical Research** programme will help the life science and health science graduates to learn about the life cycle of a drug and provide an understanding on the process involved in the movement of a drug from the bench side to the bedside.

It will also give an insight into clinical trial approval processes, marketing approval processes and about the different regulatory authorities pertaining to product registration across the globe.

Is this program right for me?

If you are passionate about working with clinical data and looking forward to work in Site Management Organisations (SMOs), Contract Research Organisations (CROs), Pharmaceutical Companies and MNCs **PG Diploma Clinical Research** course is the right choice.

Who can apply?

MBBS/BHMS/BAMS/BPT/MPT/BDS/BMLT/
Bachelor in Naturopathy &
Veterinary Science /MD/MS.

Graduate/Postgraduate degree in Pharmacy/
Pharmaceutical Sciences.

Graduate/Postgraduate degree in Life
Sciences (Botany, Zoology, Biochemistry,
Microbiology, Genetics, Biotechnology).

Graduate/Postgraduate degree in Chemistry/Biostatistics/
Bioinformatics.

Graduate or equivalent degree in Nursing/Allied Health. Students in their final year of graduation for the above courses may also apply.





What are the job opportunities for clinical research?

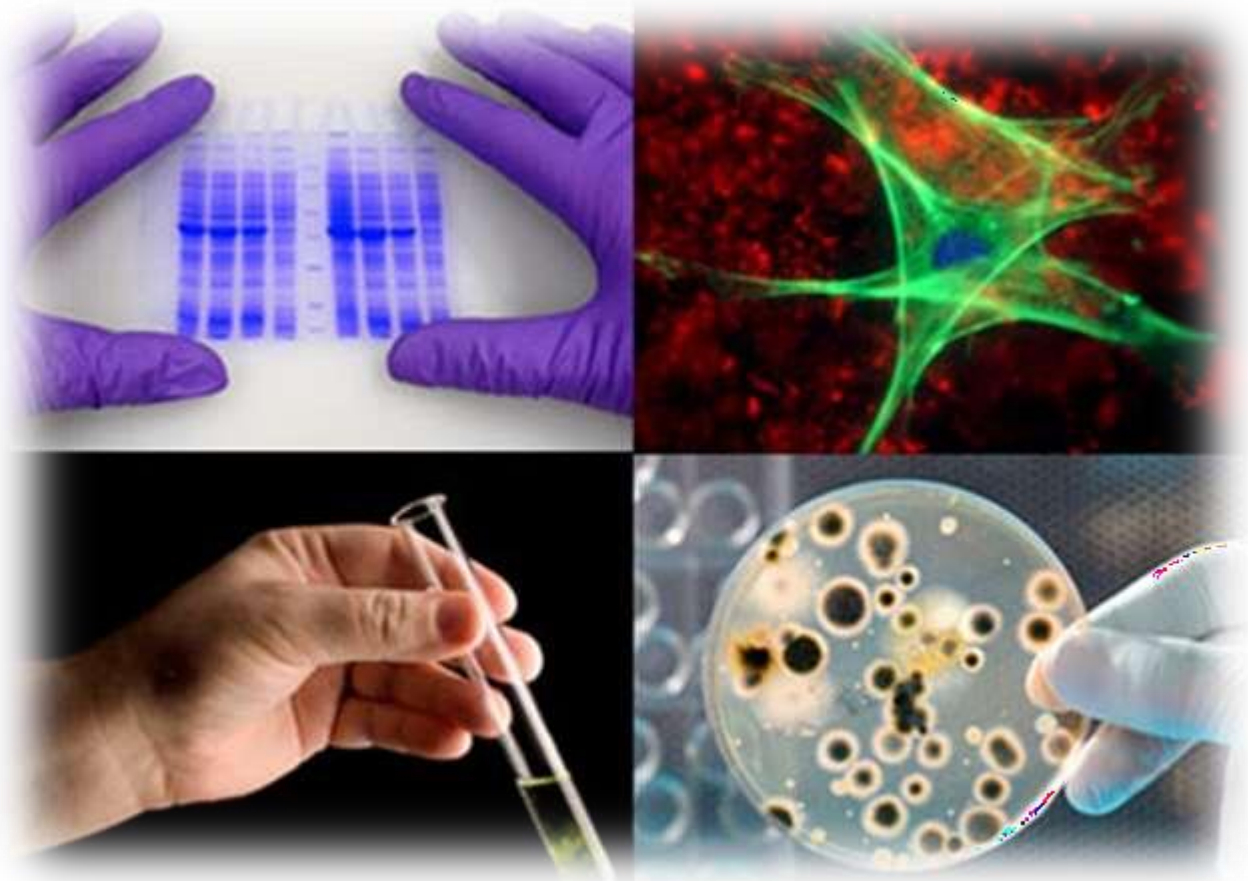
The **PG Diploma Clinical Research** programme will give an opportunity to work in Multinational Companies.

Students can get engaged in different profiles like

- ✓ Clinical Trial Analyst
- ✓ Clinical Trial Assistant
- ✓ Clinical Research Co-Ordinator
- ✓ Clinical Research Associate
- ✓ Quality Control
- ✓ Quality Analyst
- ✓ Principal Investigator
- ✓ Sub-Investigator

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:

info@quisconbiotech.com

Ph: 7200192275





Careers In Clinical Research

Clinical Research Associate (CRA) is a health-care professional who performs activities related to clinical trials. They are the soul in the field of Clinical Research. The experts find their place in various organizations such as pharmaceutical companies, medical research institutes and government agencies. Depending on the organization's policies different education and certification requirements may be necessary to practice as a Clinical Research Associate.

Clinical Data Management (CDM) is a critical phase in clinical research. CDM leads to generation of superior quality, dependable, and statistically well informed data from clinical trials. The ultimate goal of CDM is to assure a well maintained data support conclusions drawn from research and thus achieving this goal protects public health and creates confidence in the world of therapeutics.

Clinical Research Organisation (CRO) A CRO landscape is vast; using a CRO's expertise you can maximize the efficiency of your clinical trials, but only if you choose the right one for the project at hand.

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



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

Career options after M.Sc / B.Sc Life Science

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QUISCON BIOTECH

Arab Pharmacovigilance Guidelines Course



**Don't delay! Secure your
Seat today..... REGISTER NOW.**

**Call to us: 7200192275 & for Admission/
Mail your Cv to info@quisconbiotech.com**



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: 7200192275.