CHITKARA UNIVERSITY

2-YEAR MASTERS (M.Sc) IN PHARMACOVIGILANCE & CLINICAL RESEARCH

FUTURE READY PHARMA COURSES

2-YEAR MASTERS (M.Sc) IN PHARMACOVIGILANCE & CLINICAL RESEARCH

INTRODUCTION TO PHARMCOVIGILANCE

One sector that would always boom and is recession proof is healthcare and pharmaceuticals. With many drugs hitting the market, there is a growing need for vigilance to prevent and monitor the adverse effect of drugs. There is a complete science to it. It is called Pharmacovigilance.

Pharmacovigilance also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. As such, pharmacovigilance focuses on adverse drug reactions, or ADRs, which are defined as any response to a drug which is noxious and unintended, including lack of efficacy. Medication errors such as overdose, misuse and abuse of a drug, as well as drug exposure during pregnancy and breastfeeding, are also of interest, even without an adverse event, because they may result in an adverse drug reaction. Simply put, Pharmacovigilance, is drug safety. It can be defined as the study and prevention of adverse effects caused by pharmaceutical products.

Pharmacovigilance is the reason because of which many drugs are withdrawn from or are not even brought into the market at times. The government supports and helps to implement courses in pharmacovigilance as their primary goal is to ensure students of medicine are aware of the adverse effects of certain drugs.

Pharmacovigilance makes it possible to implement quality systems in all pharmaceutical companies that manufacture large amounts of medicine. Information received from patients and healthcare providers via Pharmacovigilance agreements (PVAs), plays a critical role in providing the data necessary for Pharmacovigilance to take place. In fact, in order to market or test a pharmaceutical product in most countries, adverse event data received by the license holder must be submitted to the local Drug Regulatory Authority. Ultimately, Pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimising the risk of any harm that may come to patients. Companies must conduct a comprehensive drug safety and pharma audit to assess their compliance with worldwide laws, regulations, and guidance.

PROGRAM OVERVIEW

The 2-year Masters program in Pharmacovigilance is aimed at creating skilled and competent Pharmacovigilance professionals who can work effectively at different levels in Pharmacovigilance departments of leading Pharma companies and Clinical Research Organizations (CROs) worldwide. This program lets the students learn from industry experts to get Internationally Compliance Pharmacovigilance training based on defined Pharmacovigilance Competency Frameworks (PCF).

The curriculum includes in-depth study of Pharmacovigilance related processes, complimented with hands-on training on ICSR processing, quality management, aggregate report (PSUR/ PBRER/ PADER etc.) writing and compliance management, and in turn help students develop internationally accepted competencies to become world-class Pharmacovigilance Professionals.

CAREERS IN PHARMCOVIGILANCE

The field offers a great career scope for Life Science and Pharmacy graduates. It is a scientific discipline that is primarily concerned with reporting and analysing of drug side effects. It is primarily due to the work of these professionals that the drugs in the market that we consume are mostly safe, and those that are found harmful are taken off the market.

After a drug side effect is reported, these professionals enter the event in relevant databases, follow up with the case to gather more information and forward these reports to regulatory authorities and other applicable bodies. Pharmacovigilance professionals identify signals in data that may point towards a potential side effect and probe the case further.

JOB RESPONSIBILITIES

- Recording and reporting adverse reactions received from healthcare professionals and consumers.
- Conducting in-depth interviews with patients and healthcare professionals.
- Developing a thorough knowledge of products.
- Completing periodic safety update reports on drugs and other treatments.
- Writing and reviewing serious adverse effects report and forms.
- Flagging early warning signs of adverse effects of drugs.
- Minimising the risk of serious side effects.
- Completing safety audits.

OUTCOMES

- You can make a career in creating Individual Case Safety Reports (ICSRs), PSUR (Periodic Safety Update Reports), Signal Detection, Risk Management, Medical Coding, and Medical Writing.
- An entry-level job in this field is DSA (Drug Safety Associate). DSAs are mainly involved in case creation, checking for MSI (Minimum safety information — a patient, a reporter, a suspect drug and an adverse event), reconciliation and follow-up process, data entry of all information available in the document and medical coding.
- Once a candidate has 2-3 years' experience and builds required skill sets (medical coding, narrative and scientific writing, good understanding of medical terms and basic understanding of regulatory affairs, ICH-GCP and compliance) he can go on to become a DSS (Drug Safety Scientist).
- At present, India is the fourth largest producer of pharmaceuticals in the world, with more than 6,000 licensed drug manufacturers and over 60,000 branded formulations. India offers unique advantages for the growth of Pharmacovigilance that include rapid induction of New Chemical Entities (NCEs) and high technology pharmaceutical products in the market, an abundance of patients with genetic diversity, presence of lakhs of formulation in the domestic market and a large world-scale Adverse Drug Reaction (ADR) database. All this makes it a thriving platform for a career in Pharmacovigilance.

PROGRAM HIGHLIGHTS

For the current academic year, we are offering the following 2-Year Masters program in Pharmacovigilance with specializations in:

- Advanced ICSR Processing
- Pharmacovigilance Quality
- Pharmacovigilance Medical Safety Writing
- Pharmacovigilance Compliance Management

ELIGIBILITY

Working on clinical trials of new drugs, candidates of Pharmacovigilance can pursue both certificate and diploma courses. In order to pursue a career in this field, the minimum eligibility criteria to apply for the course is:

- A PG or graduate degree in Bioscience/Life Sciences (with any of the following subjects - Botany, Zoology, Biochemistry, Microbiology, Genetics, Biotech) with at least 50 per cent marks in aggregate.
- A PG or graduate degree with Chemistry as a subject with at least 50 per cent marks in aggregate.
- A postgraduate or graduate degree in Pharmacy.
- A postgraduate or graduate degree in Medicine. (Till a few years ago, BSc and MSc graduates were hired for Pharmacovigilance. Soon, companies started roping in BPharm students on the same pay scale as BSc and MSc, hence started hiring Pharmacy graduated and postgraduates.)
- Candidate has to appear for the Entrance Exam
- Personal interview

FEES

Per Semester	ERP^	CAS^^
Rs. 75,000	Rs. 6,000	Rs. 10,000

CHITKARA UNIVERSITY

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