Career Scope in Pharmacovigilance

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The Pharmacovigilance industry has been gaining a lot of attention in recent years. The global rollout of COVID-19 vaccines, and the extensive media coverage of their potential side effects, has brought the issue of drug safety into limelight. The public has been encouraged to report any side effects experienced after receiving coronavirus jabs, and therefore have become familiar with regulatory and drug safety monitoring processes that, previously, many may not have been aware of.

To achieve well-balanced health, the treatment of disease is primary. Such treatment demands the unequivocal necessity that the drug used to treat the disease does not harm the patient in such a way that quality of life is further diminished, or results in death. This vigilance in finding out all aspects of a drug, positive and negative, has led to the evolution of a new branch of pharmacological science, known as Pharmacovigilance.

What is Pharmacovigilance?

The origin of the word Pharmacovigilance can be traced to the words pharmakon (Greek for "drug") and vigilance (Latin for "to keep watch"). Pharmacovigilance (PV), also known as drug safety, is one of the fundamental wings of the healthcare system and pharmaceutical companies. It is the sub-field of pharmacy that includes research, detection, assessment, analyzing of drugs - both new and existing ones. As such, Pharmacovigilance heavily focuses on adverse drug reactions (ADR).

According to the World Health Organization (WHO), Pharmacovigilance is a branch of pharmacological science comprising the activities related to the detection, assessment, understanding, and prevention of adverse effects of any drug. Fundamentally, it is aimed to ensure guaranteed patient safety and is considered an arm of patient care.

Pharmacovigilance is also extended to vaccines, biological, medical devices, herbal drugs, veterinary medicines, blood, and blood-related products. Without Pharmacovigilance, there would be no way to assess the effectiveness of drugs in comparison to their side effects. It is designed to protect patients and enable the dissemination of knowledge among professionals to minimize the risk of adverse events. Pharmacovigilance is the reason that many drugs are withdrawn from the market.

Courses and Eligibility

In order to pursue a career in Pharmacovigilance, the minimum eligibility to apply for the course are:

- A postgraduate or graduate degree in Bioscience/Life Sciences (with any of the following subjects: Botany, Zoology, Biochemistry, Microbiology, Genetics, Biotech) with at least 50% marks in aggregate.
- A postgraduate or graduate degree with Chemistry as a subject with at least 50% marks in aggregate
- A postgraduate or graduate degree in Pharmacy or Pharmaceutical Sciences.
- A postgraduate or graduate degree in Medicine.

Specialisations in Pharmacovigilance

A pharmacy graduate can directly join this profession, if a person wants to strengthen his/her resume, there are specialised diplomas available like a Professional Diploma in Pharmacovigilance & Pharmacoepidemiology, PG Diploma in Clinical Research & Pharmacovigilance, PG Diploma in Pharmacovigilance & Regulatory Affairs, PG Diploma in Pharmacovigilance & Medical Writing to grab good opportunities.

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Students pursuing Pharmacovigilance can take one of the following specialisations:

- Data collection and organisation
- Safety administration and evaluation
- Regulatory submissions
- Data mining & toxic sample identification

Pharmacovigilance Career Trajectory

A typical entry-level management position may include that of an Assistant Manager progressing into Associate Manager and Senior Manager. This is followed by a few leadership roles such as Associate Director, Director, and Senior Director. These roles may further progress into executive roles such as Vice President and Executive Vice President. Several roles are evolving in the future of PV. These roles are influenced by technological enhancements, business development, and regulatory changes. Some of these roles include business process analyst, benefit-risk management specialist, project or program manager, PV systems expert, and PV vendor management specialist.

Main Areas of Pharmacovigilance?

Pharmacovigilance is a huge and encompassing discipline, beyond core functions, the PV department is empowered and supported by management, regulatory affairs, clinical research, legal department, medical affairs, medical information, literature search and review, information technology and information services, training team, quality control/assurance, project management, manufacturing operations, supply chain, product security, sales, and marketing, and external partners liaison team. The three main sub-specialisations are:

a) Operations

This sector is where many life science professionals interested in drug safety jobs will begin their careers. Typical jobs within drug safety operations include case processor, Drug Safety Officer/Associate and Drug Safety Manager, and of course team lead and directorships. These professionals will collect and record information during pre-clinical development and clinical trials, in addition to gathering real-world evidence (RWE) of adverse events reported by doctors and patients post-market. Operations are also usually responsible for creating standard operating procedures (SOPs), individual case study reports, literature screening, and regulatory expedited reporting.

b) Surveillance

Professionals who focus more on surveillance tend to look towards risk management and signal detection jobs. This also involves performing an analysis of the data collated by the wider division. Professionals in this area can hold an array of titles, the most common of which are *Pharmacovigilance Scientist and Drug Safety Physician. These professionals perform analysis of the drug safety information* gathered by the wider department and assist with the creation and review of aggregate reports. They also create development safety update reports for drugs in clinical research and periodic benefit-risk evaluation reports (PBRER) for post-market drugs. These reports ultimately help the team in drawing conclusions about the safety and efficacy of a drug or candidate molecule.

c) Systems

This division is concerned with the building and ongoing development of a fully robust and innovative system, charged with the responsibility for housing and allowing access (in various forms) to vast quantities of safety data. This safety data is usually collated by those working in operationally focused roles but is accessed by all. The systems division constantly needs to improve, and stay in line with changing regulations and requirements for the business/health authorities, making this a very challenging and vital aspect of drug safety.

Pharmacovigilance Officer Job Profile

The role of a Pharmacovigilance Officer, also known as Drug Safety Officer, is to ensure the safety of the drug when administered. Duties include:

- Collecting and recording the adverse effects of the product received from health care professionals (Doctors, Dentists, Nurses, Pharmacists, and other health workers) and consumers.
- Analysing the recorded reports.
- Writing and reviewing serious adverse effects reports.
- Completing the Periodic Safety Update Reports (PSUR) of the product.
- Assessing the risk-benefit ratio of the drug.
- Conveying the reports to the regulatory authorities.
- Working on clinical trials of new drugs.

Pharmacovigilance: What Does the Future Hold?

The COVID pandemic and surge in lifestyle-related disorders such as diabetes, and hypertension propel the Pharmacovigilant demand. The clinical trials of new drugs involve closely monitoring their efficacy, immediate adverse effects, and general safety among a limited population. However, all other details like the long-term effects of the drugs, effects on the various ancestral ground, drug-drug interactions, and effects of high doses / irrational use of the drugs are essential to ascertain patient safety. This extensive safety profile can be generated by closely monitoring the effects of drugs for a longer period in the actual patient population. This is known as post-marketing surveillance and is carried out by the Pharmacovigilance wing of the pharmaceutical companies, and marketing authorities. Many pharmaceutical companies have their in-house Pharmacovigilance system or rely on outsourcing firms to carry out post-marketing surveillance to monitor the safety profile of their products. As regards India, the sector holds immense potential for employment owing to the following facts:

- India is the third-largest producer and exporter of pharmaceutical products in the world and supplies 62% of the global demand for medicines and vaccines.
- The Indian domestic pharmaceuticals market turnover reached US $20.03 billion in 2019 and is expected to reach US $130 billion by 2030.
- There are more than 3,000 pharma companies with a strong network of over 10,500 manufacturing facilities.
- India becomes a favorite destination for clinical trials and PV outsourcing because of its low set, high degree of compliance with international guidelines, high skill set, and English language literacy.
- In India, IT firms such as Cognizant, Tata Consultancy Services, Accenture, Oviya, Medsafe, and Wipro Limited, extend their PV-related services to their global pharma clients.

Who Hires Pharmacovigilance Professionals?

People trained in Pharmacovigilance can find excellent employment opportunities in the following types of organisations:

- Pharmaceutical companies.
- Biotech companies.
- Medical Devices companies
- Regulatory agencies such as DCG (I), CDSCO.
- PV units in medical colleges and hospitals.
- Knowledge Process Outsourcing (KPOs) such as Accenture, Cognizant, Sciformix Corporation, iGATE, etc.

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