INTERNATIONAL EDUCATED BIOTECHNOLOGIST PURSUING A PHARMACOVIGILANCE CAREER IN BC

OVERVIEW

Pharmacovigilance is the branch of science relating to the discovery, estimation, understanding and avoidance of adverse effects, mainly long- and short-term side effects of medicines. In general, it deals with compiling, monitoring, investigating, estimating, and analyzing data from healthcare service providers and patients on the adverse effects of biological, allopathic medications, herbals, and alternative medicines

A pharmacovigilance associate or drug safety associate (DSA) works in the medical industry to monitor the safety of pharmaceutical drugs and to evaluate and prevent adverse reactions in patients. A DSA is responsible for assessing the safety of pharmaceuticals drugs once they're on the market, meaning they are involved with drug safety management in clinical trials and post marketing surveillance (PMS). Using standardised guidelines, the DSA determines whether the medication causes any adverse reactions in patients and report their findings back to the pharmacovigilance department.

The work for a DSA begins after a drug has been launched and as soon as an alert of a serious adverse event (SAE) is raised it sets into motion the necessary tasks that need to be completed to process the events. A DSA requires resilience, adaptability, excellent time management and the ability to prioritise and tackle high workloads.

A career in drug safety, also called pharmacovigilance, can include work with clinical research organizations that conduct trials, biotechnology firms, pharmaceutical companies, or government agencies like Health Canada). Drug safety associates need excellent research skills, a strong background in medical or biological science, and in-depth knowledge of the federal food and drug regulations. Responsibilities include analyzing clinical trial data, writing reports, and determining whether specific pharmaceutical drugs are safe.

WORKING TO TIGHT TIMELINES

In a life-threatening case, or in the case of death, DSAs are given 1-2 business days to process the necessary information and pass it onto other teams. Other medical cases including hospitalisation, significant disability, congenital anomaly, or other medically important events require this process to be completed in 2-7 days. The DSA classifies the case, ensures all the key information is present, enters the information in the database and sends the case to quality review. They then proceed to the medical review stage and create queries to obtain as much information as they can to accurately

assess the role of the study drug on the event. This information must be passed along to entities such as relevant authorities, review boards, investigators, and drug producers.

ROLES AND RESPONSIBILITIES

DSAs review and evaluate adverse events related to use of pharmaceutical drugs, serve as a point of contact for stakeholders on safety activities, and identify safety signals. They answer questions from health workers, partners, and others, and ensure compliance throughout the program with reporting requirements related to adverse events.

The major functions or actions of a drug safety associate are as follows:

1. Needs to ensure that most of the safety reports that are received from the investigational sites or from the post- marketing sector must be identified; reported in accordance to established standards and also by the standard operational procedures.
2. Reports collected must be prioritized based on the seriousness or effectiveness of the drug initially.
3. Consistency in assessing the adverse reaction reports must be accurate and legible.
4. Use judgment in decision-making by applying their knowledge of standard regulations.
5. Communicate with clinical physicians in drug safety and assess case report forms.
6. Able to distinguish and analyze the ratio of risks and benefits of a drug that is marketed.

Primary responsibilities will be following up Adverse Events Reports, preparation of Safety Reports as per the guidelines mentioned by the regulatory authority of that particular country, to generate clear, concise and comprehendible CRFs, maintenance of safety databases, coding of diseases, ADRS and medications, reconciliation of SAEs in accordance with specific guidelines, review trial protocol on a periodic basis, generation of PSURs, etc.

EDUCATION, TRAINING AND QUALIFICATIONS

A bachelor's degree in Life Sciences, Medicine, Pharmacy, Nursing. Specialized degree or training in Pharmacovigilance an asset
Experience working in a medical setting such as a hospital, physician's office, or pharmacy an asset

Detail oriented, strong knowledge of medical terms and terminologies

An understanding of regulatory requirements from Health Canada, EU, US, WHO.

Experience liaising with Regulatory Authorities, i.e., US FDA, Health Canada, Notified Bodies is an asset.

EDUCATION PROGRAMS

There are no specific education programs offered in BC for this profession.

AAPS, located in Toronto, offers an on-campus post degree diploma program - *The* Clinical Research, Drug Safety and Pharmacovigilance Post-Graduate Diploma Program that enables graduates to develop the specialized knowledge and skills required to; write study protocols, monitor and manage clinical trials, and to conduct drug safety and pharmacovigilance activities. The program uses a hands-on approach to learning. Graduates of the program qualify for Certified Clinical Research Professional - CCRP Certification awarded by Society of Clinical Research Associates (SOCRA).

AAPS also offers an on campus certificate in Drug Safety and Pharmacovigilance. Also designed as a hands-on program, graduates learn to write study protocols, monitor and manage clinical trials, and to conduct drug safety and pharmacovigilance activities.

The Global Health Network provides pharmacovigilance-related courses online as well as a list of available e-learning resources from other organizations internationally. Eu2P offers a range of courses, some of which pertain to pharmacovigilance. All courses are delivered online.

DIA Global offers a competency-based Safety and Pharmacovigilance certificate. Once enrolled students work through a 'learning path' to meet the competencies and can acquire the knowledge and skills through attendance at live training courses, online and blended learning courses. Upon completion of the required credits, students write an exam, designed to measure achievement of the competencies and on which they must score at least 75%.

Temple University, located in Pennsylvania, offers both a Pre-Master's and Post-Master's Certificate in Global Pharmacovigilance: Benefit-Risk Assessment through its Department of Pharmacy. Both programs are delivered on campus.

RESOURCES

Careers ICON PLC - https://careers.iconplc.com/blog/what-does-a-drug-safety-associate-dsa-do--blog-91981795662#:~:text=A%20Drug%20Safety%20Associate%20is,back%20to%20the%20pharmacovigilance%20department.

James Lind Institute - https://www.jli.edu.in/blog/roles-responsibilities-of-a-drug-safety-associate/

Payscale.com - https://www.payscale.com/research/CA/Job=Drug_Safety_Associate/Salary

Society of Clinical Research Associates (SOCRA) - https://www.socra.org/

Sollers College - https://www.sollers.edu/roles-and-responsibilities-of-a-drug-safety-associate/

Zip Recruiter - https://www.ziprecruiter.com/e/What-Does-a-Drug-Safety-Associate-Do

JOB BOARDS

Indeed.ca - https://ca.indeed.com/jobs?q=Drug+Safety+Associate&l=British+Columbia

Glassdoor - https://www.glassdoor.ca/Job/british-columbia-drug-safety-associate-jobs-SRCH_IL.0,16_IS4075_KO17,38.htm

LinkedIn https://www.linkedin.com/jobs/search/?geoId=100216049&keywords=drug%20safety%20associate&location=Greater%20Vancouver%2C%20British%20Columbia%2C%20Canada&originalSubdomain=ca