



Major Need and Importance of Pharmacovigilance

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DESCRIPTION

The WHO Pharmacovigilance Team works to ensure the reliable and timely exchange of information on safety issues, promote pharmacovigilance activities across the organization, and encourage participation in WHO's international drug surveillance programmes, to ensure the safety of pharmaceuticals and to ensure vaccine safety.

Pharmacovigilance is a vast and comprehensive field, but it can be broadly divided into six main subspecialties:

Operations

It is in this field that many life sciences professionals interested in working in drug safety start their careers. Typical drug safety jobs include case workers, drug safety officers/employees, drug safety managers, and of course team leaders and directors. Collect and record information during preclinical development and clinical studies, in addition to collecting Real-World Evidence (RWE) of reported adverse events. Operations are also typically responsible for preparing Standard Operating Procedures (SOPs), individual case study reports, literature reviews, and rapid reporting by regulatory agencies.

Surveillance

Professionals with an emphasis on surveillance tend to look for jobs in risk management and signal detection. This includes analysis of data collected from broader departments. Experts in this field may hold a variety of titles, the most common being Pharmacovigilance Scientist and Drug Safety Physician, but like all teams there are many seniority levels and duties. These experts analyse drug safety information collected by the broader department and assist in overall report preparation and review. We also prepare Development Safety Update Reports (DSUR) for drugs under clinical investigation and Periodic Benefit Risk Evaluation Reports (PBRER) for post-marketing drugs. These reports ultimately help the team to draw conclusions about the safety and efficacy of the drug or candidate molecule.

Systems

This division is concerned with building and on-going development of a fully robust and innovative system responsible for providing access (in various formats) to residential and vast amounts of security data. This security data is typically collected by people working in operations-focused roles, but is accessible to everyone. Systems departments must constantly improve and adapt to changing regulatory and business/health authority requirements, making this a very challenging and critical aspect of drug safety. Pharmacovigilance is arguably the most important function of Life's science company. In order to develop, manufacture and market pharmaceuticals, companies must comply with strict regulations. Many of these regulations focus on patient safety and the additional patient benefits of drugs. In short, this is the mission of drug safety and highlights why this field plays a central and important role in pharmacy.

Patient safety and continuous vigilance

By definition, drug safety is about ensuring patient safety and well-being are maintained throughout the drug development life cycle, including the time it takes to reach the market. In fact, the drug is continuously monitored for other side effects in patients and any new data are collected and reported regularly to health authorities. While other departments are committed to improving patient lives, no other department puts more emphasis on patient safety as an endpoint.

Power and authority

This constant vigilance means that senior officers of the drug safety team, along with other members of the industry, have the responsibility and authority to recommend that the development process be halted or that approved drugs be withdrawn from the market. Means that there is The EU QPPV is of particular importance in this process, again demonstrating the importance and centrality of drug safety.

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Keeping it moving

Drug safety helps to keep the wheels of drug companies spinning in many ways. The safety nature of a drug means that it

works very cross-functionally. As such, the impact and value that departments have on other aspects of the business is immense.