Pharmacovigilance

Naik, J Pharmacovigilance 2015, 3:1
http://dx.doi.org/10.4172/2329-6887.1000159

Short Communication Open Access

The Future of Pharmacovigilance

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Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. It is an important part of the drug development process as it looks into the safety profile of a drug and helps analyze the risk-benefit ratio of a new drug. A new drug gets approved by FDA when its benefit outweighs risks.

Companies that manufacture new drugs can either carry out pharmacovigilance activities in-house or outsource it to vendors who perform any number of activities that fall under the purview of drug safety. Companies may either outsource ad hoc activities or all of their drug safety needs to a vendor. Outsourcing companies cater different services such as conducting audits, development of product information, standard operating procedure, designing processes etc. Key benefits of outsourcing include flexibility of resources, minimization of upfront investments and overhead costs. As per Cutting Edge Information's latest study, Benchmarking Drug Safety and Pharmacovigilance (http://www.cuttingedgeinfo.com/drug-safety/), it was found that as companies grow in size, they take on more Pharmacovigilance responsibility in-house [1]. Their data also shows that it is largely a matter of the companies' individual preference, infrastructure and skill sets which decide about when to outsource certain activities and when to keep them in house.

Medicines Healthcare products Regulatory Agency (MHRA) of UK has undertaken a novel initiative by investing in a three year project 'WEB –RADR' [2]. In this project, a mobile app will be manufactured for healthcare professionals and patients to report suspected ADRs to national EU regulatory bodies. Such initiatives are expected to drive growth of pharmacovigilance market in the near future.

US Food and Drug Administration and European Medicines Agency have recently intensified the regulations related to drug safety monitoring. With these recent developments, there is a growing demand for professionals in this field as companies boost their pharmacovigilance departments. Companies that hire for drug safety positions are pharmaceutical, biotechnology, contract research organizations (CRO), consulting companies, regulatory organizations and service providing/BPO/ vendor companies. Positions usually start as drug safety associate, officer or coordinator and then progress on to managerial or specialist positions with experience.

Most Pharmacovigilance professionals have a life science degree such as either a medical, nursing or pharmacy degree. Besides having a life science degree, it is essential for these professionals to have sound basic knowledge of the drug development processes and the ability to constantly update themselves with the changing regulatory requirements in drug safety [3]. Some of the prerequisites for advancement in a career in pharmacovigilance are a clear understanding of the activities of drug safety assessment, knowledge and understanding of the stringent regulations governing this process and industry practices. There are also postgraduate and other training courses in Pharmacovigilance offered through various universities and training institutes. Most people attain a lot of on-the-job training and enhance their skills as they advance their career. Previous Pharmaceutical/ Biotechnology or CRO experience and experience or training in MedDRA Coding, drug safety softwares like ARGUS and ARISg and medical writing are valuable attributes.

With the advent of more stringent regulations in drug safety and rise in health conditions arising from drug side effects, this field is predicted to progress and grow in the new few years creating more demand for professionals with expertise in pharmacovigilance.

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Received February 03, 2015; **Accepted** February 17, 2015; **Published** February 21, 2015

Citation: Naik P (2015) The Future of Pharmacovigilance. J Pharmacovigilance 3: 159. doi:10.4172/2329-6887.1000159