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Pursuing pharmacovigilance career in the industry

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Review Article

Pursuing pharmacovigilance career in the industry

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Abstract

Pharmacovigilance (PV) offers plenty of opportunities for career development in pharmaceutical industry. With increased number of drugs and biologics entering the market and enhanced drugs safety regulatory framework, need for skilled resources to carry out PV activities has gained importance. Increased drug safety awareness has also demanded robust yet cost-effective PV systems and operations. As a result of this, PV outsourcing has gained momentum, thus, increasing job opportunities. The PV market has recently seen an exponential growth. PV as a science is now well-established in the biopharmaceutical industry as well. A typical PV operation will have various functional units such as Individual Case Safety Report (ICSR) Processing, Medical Review, Literature Search and Review, Aggregate Report Preparation, Signal Detection, Pharmaco-epidemiology and Risk Management, Labelling, and Qualified Person for PV (QPPV or QP). Multiple other interface functions support and empower PV functional units or vice versa. Any aspiring PV professional is required to possess both technical and soft skills. Academically, the candidate should hold a degree in life science, nursing, pharmacy or medicine. A previous industry experience is of great value. Additionally, candidates should also possess essential soft skills. A career in PV is equally or more fulfilling than any other allied healthcare career because the work focused on patient safety involves collecting and analyzing safety data for a large number of medicinal products. This article aims to enlighten job aspirants regarding various aspects related to choosing and pursuing a career in PV.

Key words: Pharmacovigilance, drug industry, career choice, drug-related side effects and adverse reactions, pharmaceutical services

Introduction

The World Health Organization (WHO) defines PV as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.[1] In simple terms, PV involves a number of activities aimed at identifying risks associated with medicinal products and ensures that their harmful effects on patients are prevented or minimized. The reason for adopting PV by the pharmaceutical companies is because the majority of healthcare regulatory bodies around the globe such as Drugs Controller General of India (DCGI), United States Food and Drug Administration (US-FDA), The European Medicines Agency (EMA) have laid out regulations and directives on PV for pharmaceutical companies. Every pharmaceutical company developing or marketing a medicinal product is expected to comply with these PV regulations to ensure patient safety. Failing to comply with the regulations may have consequences including cancellation of the drug development program or marketing authorization and criminal proceedings against the company. Noncompliance will also damage the reputation and trust of the company.

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The importance of PV has gained attention over the years and stakeholder base is widening with many new pharmaceutical products added to the market each year. Historically, many drugs have been withdrawn from the market owing to their safety in the patient population because of which regulations around continuous benefit-risk monitoring of drugs are now tighter than ever. The growing biopharmaceutical industry offers plenty of opportunities for career development. These opportunities are spread across various segments of the industry such as manufacturing, research and development, information technology and bio-informatics, medical and regulatory affairs, clinical trial operations, sales and marketing, consulting, finance, quality control and assurance, PV, and few others. Of these, PV has gained importance over the past decade across the globe and continues to do so.

The unique nature of PV service involving both healthcare and informatics has provided plenty of career options for a large pool of talents, both fresh and experienced. The need for talented resources to proactively manage patient safety is increasing and there is a shortage of talent pool in PV market. A career in PV, hence, can be both rewarding and enriching in terms of exposure and experience. With more players entering into this job market coupled with increased need for a more strategically placed efficient systems and methodologies have made the job market more dynamic and demanding. This article aims to enlighten job aspirants regarding various aspects related to choosing PV as a career.

Core Pharmacovigilance Functions in the Industry and their Responsibilities

The PV is a specialty in the industry as along with the soft skills, it requires specific knowledge and skills related to pharmacology, pharmacotherapeutics,

Table 1: Pharmacovigilance functions and their responsibilities

Functional Unit	Key Responsibilities
ICSR Processing	• Collection and triage of ADR in safety database. • Perform duplicate check, data entry, QC • Data coding (AE and Drug coding), causality assessment, follow-up • Data reconciliation and expedited reporting
Literature Search and Review	• Identification of biomedical literature and lay press for safety surveillance • Literature review to identify AE and ADR for ICSR processing, signal detection, and aggregate report preparation
Medical Review	• Medical review of ICSRs, periodic reports, and adhoc reports • Medical review of signals and RMPs/REMS
Aggregate Report Preparation	• Preparation of PBRER, DSUR, and other periodic safety reports • Generation and review of line listings • Prepare adhoc reports as requested by HA
Signal Detection, Pharmaco-epidemiology, and Risk Management	• Screening of various data sources such as Clinical Trial and spontaneous reporting systems, literature, external databases, and others to identify signals through data mining • Signal validation, prioritization, and evaluation • Preparation of RMPs/REMS, communication with HA, follow-up on action items • Benefit-risk assessment in PBRERs, RMPs, and other reports • Safety communication
Labelling	• Creation and maintenance of the labels for company's products • Review of safety information document like CCDS and CCSI, country level labels, pack inserts, and patient information leaflets • Monitoring of safety labelling of products of other companies and implementation of health authority requests for safety-related labelling changes
QPPV or QP	• Oversight of company PV systems and processes • Overview of safety profile of the products and communicate with HA as required • Point of contact for HA with respect to company PV activities

Long forms: ADR-Adverse Drug Reactions, AE-Adverse Events, DSUR-Development Safety Update Report, CCDS-Company Core Data Sheet, CCSI-Company Core Safety Information, HA-Health Authorities, ICSR-Individual Case Safety Report, PBRER-Periodic Benefit Risk Evaluation Report, PV-Pharmacovigilance, QC-Quality Control, QPPV or PV-Qualified Person for Pharmacovigilance, REMS-Risk Evaluation and Mitigations Strategies, RMP-Risk management Plan.

pharmaco-epidemiology, PV methodologies, PV information sources, critical evaluation of biomedical literature, regulations, systems, and processes. Core PV functions in a pharmaceutical industry are listed in **Table 1**. The PV remains a specialized department within the research and development (R and D) operations of a pharmaceutical company and can be functioning within clinical research, regulatory affairs or medical affairs units or as a separate entity. When such an activity is outsourced to a third party, such as to a Contract Research Organization (CRO) or Business Processing Organization (BPO), the PV operations are considered as a separate arm of service delivery within the third party.

The operations typically begin with case handling process where the clinical trial adverse event (AE) and spontaneous adverse drug reaction (ADR) reports are received from various sources such as investigation sites, health care professionals, patients, general public, literature publications, and regulatory authorities. Many companies have set-up dedicated call centres called as medical information centres for the purpose of providing information regarding their pharmaceutical products. These centres also collect spontaneous ADR reports. The received AE or ADR reports are further processed through data entry, data coding, medical review, and quality control workflows using a dedicated safety system cum database. Some of these reports, commonly called as Individual Case Safety Report (ICSR) may qualify for expedited reporting to regulatory authority if they qualify the expedited reporting criteria stipulated in the guidelines.[2,3] As well, the data captured in the safety database are utilized for the purpose of signal detection, benefit-risk management, and periodic safety report writing. They are typically managed by separate functions outside the case handling function in the majority of the companies.

The PV operations also involve functions such as those involved in creating and developing Risk Management Plans (RMPs) and Risk Evaluation and Mitigation Strategy (REMS). The objective of RMP and REMS documents is to ensure the safety of the patients by providing detailed guidance on risks associated with the use of the medicines, monitoring, and interventions to minimize such risks. The only difference among these two documents is that REMS is required by the US-FDA, whereas RMP is specific to EMA.

An extended arm of PV operations could also involve teams supporting the drug label updates. The drug labels include EU summary of product characteristics (SPC), United States Package Insert (USPI), etc. Certain countries follow region or country specific label formats. The content of such labels is derived based on a company position document called Company Core Data Sheet (CCDS) and PV groups are responsible for providing up-to-date content with respect to safety data into the CCDS. The PV specialist and PV physicians routinely review drug labels and CCDS to ensure that most updated information related to product's safety data is included in them.

Interface functions with pharmacovigilance

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 (**Figure 1**).

Medical Information (MI) call centres typically handles queries related to medicinal products from various sources like patients and healthcare professionals. These centres manage inquiry receipt and processing of the requests. The MI staff may also receive ADR reports that are further processed into a safety database by the ICSR processing teams. Therefore, it is important that a proper workflow is established between MI and PV teams to process the received ADR in a timely fashion. Medical affairs group in a pharmaceutical company is comprised of licensed physicians responsible for various medico-marketing activities. Medical affairs team also reviews ICSRs, periodic safety reports as well as other safety documents from medical and clinical practice perspective. PV function works with medical affairs for various post authorization efficacy

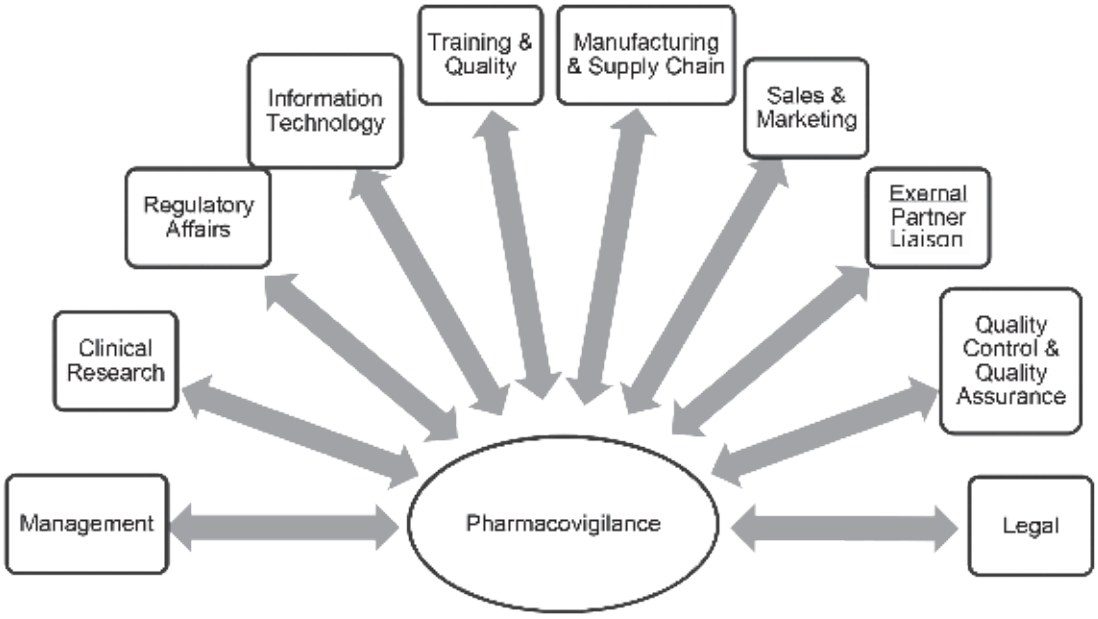

Figure 1: Pharmacovigilance Interface Functions

and safety studies, non-interventional studies and investigator-initiated studies. A close collaboration between medical affairs and PV is key because a medical review of the safety data is paramount before submission to health authorities. This ensures that an appropriate company comment is provided to the ICSRs as well as reviewing periodic safety reports.

The PV function is obligated to train all staff in the pharmaceutical company including sales and marketing staff to receive and report ADR reports to ensure 100% coverage of incoming safety reports. Healthcare professionals usually raise safety concerns associated with medications like ADR and product quality complaints to the sales and marketing teams as they are the primary contact points from pharmaceutical companies. The regulatory affairs team works very closely with the PV group since the former is the liaison between regulatory authorities and pharmaceutical company, and responsible for submission of the expedited and periodic safety reports to various regulatory agencies. The regulatory group works very closely with the PV during label revisions and renewal of product license in various countries. An effective collaborative strategy between these two groups ensures that the regulatory obligations are met consistently.

Another interface function that works closely with the PV function is the compliance and training group. This group plays an important part in a PV set-up since it ensures that the company is compliant with all legislations and guidelines in terms of its PV obligations and also in terms of providing required training and exposure to human resources working in various PV functions. The compliance teams support PV for quality management and assurance including audits and inspections. The staff working in compliance and training group are required to be aware of the PV domain expertise. Therefore, this group usually will have staff with required PV experience.

The role of Information Technology (IT) is inevitable in PV like any other function within the pharmaceutical industry to develop, deploy and maintain the PV systems like clinical and safety databases, drug and ADR dictionaries, tracking tools, and repositories. It certainly plays a significant role in ensuring all systems and tools utilized for PV delivery are established in cost-effective yet compliant manner. Guidelines such as 21 CFR Part

11 of the US FDA require that all computerized systems are compliant with established regulatory framework and IT teams play an important role in ensuring this.[4] Over the last few years, there has been a lot of investment in PV to bring in efficiency through automation. The need for cross-functional collaboration between IT and PV is increasing.

The legal team can have occasional engagement with the PV team for various reasons. Their involvement during processing of case reports arising from litigation and lawsuits is very predominant. Pharmaceutical companies often co-develop and co-market products with other companies. In the event of mergers and acquisitions, obligations associated with medicinal product licenses are transferred between companies. In all these types of collaborative work between pharmaceutical companies, the safety data exchange is dynamic and driven by safety data exchange agreements (SDEA). PV function works in close collaboration with the legal team to establish and maintain SDEA.

Pharmacovigilance as specialty in the pharmaceutical industry

The PV as a discipline is now well established in the biopharmaceutical industry. The majority of biopharmaceutical companies have either well-managed in-house PV department or partially/completely outsource such activities to a third party such as CRO or BPO. Achieving the required quality outcome during the conduct of PV activities by an organization is intrinsically related to the availability of a sufficient number of competent and appropriately qualified and trained personnel. The majority of workflow and capacity planning is dependent on qualified and trained human resources due to the fact that the safety data requires thorough assessment in the context of clinical practice and pharmacotherapy. This helps to draw a meaningful conclusion out and then submit this data in a pre-defined format for the purpose of regulatory reporting. Also, regulatory guidelines, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines require that the personnel involved in clinical research and PV activities are qualified by education training, and experience to perform his or her respective task(s).[5,6] Because many of the clinical research and PV operations are regularly subjected to audits and inspections, it is expected that the PV activities are conducted with integrity, high quality and compliance to meet the regulatory standards.

Growth of pharmacovigilance business

The PV market has seen an exponential growth in terms of volume and revenue over the last 6-7 years. The growth is accompanied by increased outsourcing of PV operations to CROs and BPOs, which are now representing half of the overall market share in drug safety.[7] A recent industry report forecasts that the PV market will exceed USD 8 billion by 2024 with Asia Pacific alone anticipated exceeding USD 2.4 billion by the same year.[8] Major players in the market are innovator and generic pharmaceutical companies, CROs, BPOs, and Knowledge Processing Organizations (KPOs). India, being the hub for many of these companies, the PV market is expected to reach USD 668 million by 2024. Increasing number of clinical studies following recent regulatory reforms along with the low operating cost of the region can be attributed to this growth in India.[9]

Skills for a successful career in pharmacovigilance

A successful career in PV requires a combination of both technical as well as soft skills. Organizations have put in place established hiring plans for various roles within PV and such plans require that the candidates meet these minimum requirements. The requirements increase with higher roles and such requirements are explicitly described by the company human resources (HR). Broadly, the requirements can be classified into three categories:

1) **Technical skills**

   Aspiring PV professionals are required to be familiar with the basics of medicinal products, health care, ADR and EU and Good Pharmacovigilance Practices (GVP). Globally there is a lack of specialized university certified academic courses in this area. There are few academic institutes that offer postgraduate courses in PV such as MSc in PV.[10,11,12] Few institutes offer training in PV through certain certificate or post-graduate diploma level programs that could be helpful for aspirants.[10,13,14]

The curriculum proposed by International Society of Pharmacovigilance (ISoP) and Uppsala Monitoring Centre (UMC) would guide the aspirants to develop required technical knowledge and skills to pursue PV career.[15] Although there is a preference for healthcare professionals in the pharmaceutical industry in general, candidates with a life sciences degree can get an entry-level job in PV. Hence, life science graduates with basic knowledge of PV with basic computer skills such MS Office can apply for a PV role. The current PV organizations employ staff with various academic backgrounds such as allopathic medicine, dentistry, nursing, Indian systems of medicine, pharmacy, and life sciences. The PV organizations recruit mainly graduates with a healthcare degree such as medicine or pharmacy due to the advantage that their academic curriculum which involves various courses related to PV like human anatomy and physiology, pharmacology, medicinal chemistry, pharmaceutics, jurisprudence, pharmacotherapeutics, good practices (Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and other GXPs). Regulatory authority in India require PV activities to be managed by medical or pharmacy graduates with relevant training and experience.[16] There are few organizations, predominantly CROs and BPOs who hire fresh talents from colleges as trainees and impart on the job training in PV and later be absorbed by the same organization based on their performance during the probationary period.

2) Soft skills

In addition to the required technical skills, certain soft skills play an important role in employability for a career in PV. A successful candidate attending an interview for any PV role has to exhibit competencies around the soft skills that can supplement the technical knowledge. These soft skills include, oral and written communication, attention to detail, organizational skills, presentation skills, faith and confidence, flexibility, up skilling ability, learning ability, and stability.

3) Skills to acquire for effective career enhancement

Companies invest a lot of time and resource in training their staff in soft skills. Very often these are inadequate for a person's overall career development. Self-development is an aspect that every professional is required to consider for a fruitful career in addition to existing training resources within an organization. The soft skills play an important part in successful business delivery, especially, when working in a CRO or BPO where multiple clients are involved. Efficient business delivery also depends on the innovation and management of the PV operations at all levels. In order to achieve this, it is imperative that the PV operations are led by strong leadership teams to ensure smooth delivery and keep the cost under control.

Apart from the aforementioned technical and soft skills, a successful career progression also depends on the continuous learning and development on the job. These skills help professionals to learn beyond the existing learning modules and continuously look for new ideas and technologies to be successful. These skills can be easily acquired and learned through self-motivation and practice (**Figure 2**).

Typical career ladder for prospective PV professionals

The career ladder for PV professionals varies between companies and regions and based on the scope of PV operations and organizational needs. However, in the majority of organizations, the career path starts with an Individual Contributor (IC) role and further progresses into management and leadership roles. The entry level job role may include that of a Drug Safety (DS) Coordinator or PV Coordinator role followed by DS/PV Associate and Senior PV/DS Associate role. A job title of PV/DS Scientist is also very common in the industry. As the career progresses, the employee may assume the role of a Project Lead/Team Lead and Project Manager/Team Manager. However, the actual job title would vary depending on the organizational HR policies. Each of the job roles may have its own ranking or level as assigned by the company HR

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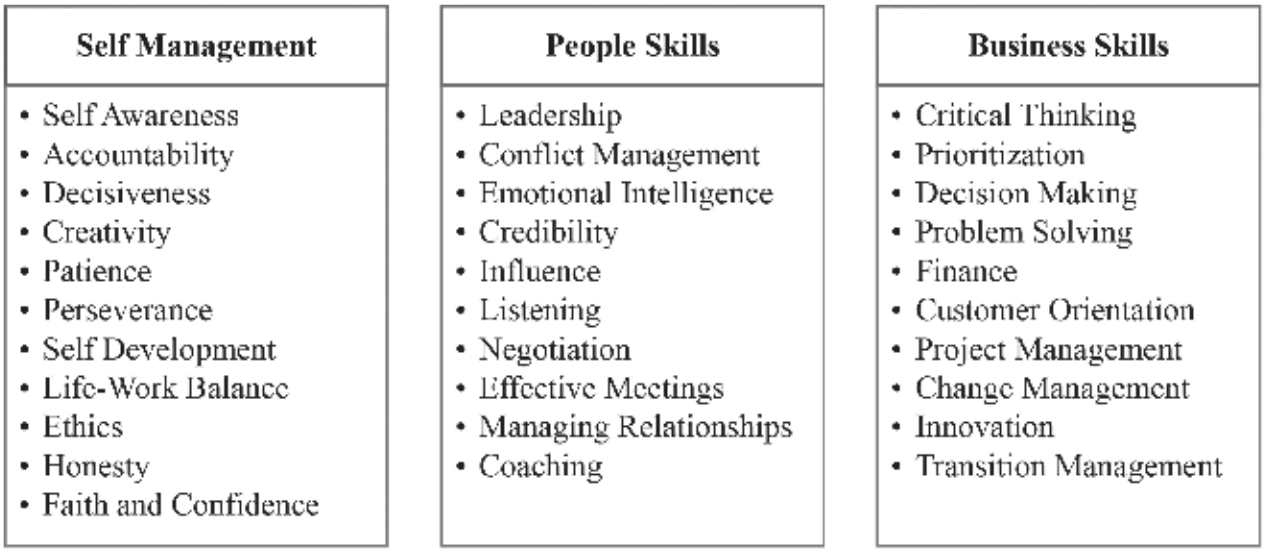

Figure 2: Soft skills required for a successful career in pharmacovigilance

policies and these may be either alphabetically or numerically ordered based on hierarchy.

- **Individual contributor roles:** The entry level job opportunity in the majority of the organizations would be that of an IC. The IC's role within an organization is to provide services based on the technical expertise that the individual has gained through education and training. These employees are either dedicated to a project if working in a pharmaceutical company or may work for multiple customers if working for a service provider such as CRO or BPO. They will deliver the core work in drug safety and gradually make into higher IC roles such as project lead or project manager (**Figure 3**). The employees will work only for the assigned technical tasks and would not usually take up any administrative, supervision or people management roles. At this role, the person will gain a lot of subject matter expertise with time and will be able to become a domain expert.
- **Management roles:** The management roles within a PV set-up either involve project management or people management or both. Basically, these roles will involve providing support and direction to the employees based on the organization's strategy and goals. The job description may involve, but not limited to, compensation and benefits, hiring, performance management, organization and people development, employee engagement, employee motivation, communication, administration, resources and operations management, budget and finance, and training. The managers are also expected to provide strategic thoughts to the growth of the organization through business growth and increased profitability. This is very crucial in the outsourcing business where cost-effectiveness and compliance are critical for success. Therefore, it is imperative that the managers are aware of both people management skills along with domain knowledge.

The PV organizations may either look at internal talents with required education and experience for managerial positions (internal vertical movement) or hire externally. Companies may consider the internal vertical movement to ensure that the candidate with an in-depth understanding of the organizational culture as well as basic understanding of the business delivery model would lead the functions. This is the reason that many companies invest a lot of resource and time in nurturing the internal talents and provide them training and exposure to become future leaders of their company. Such an approach will also ensure ranking equilibrium in the organization and increase the retention of key talents. Where required, companies would also reach

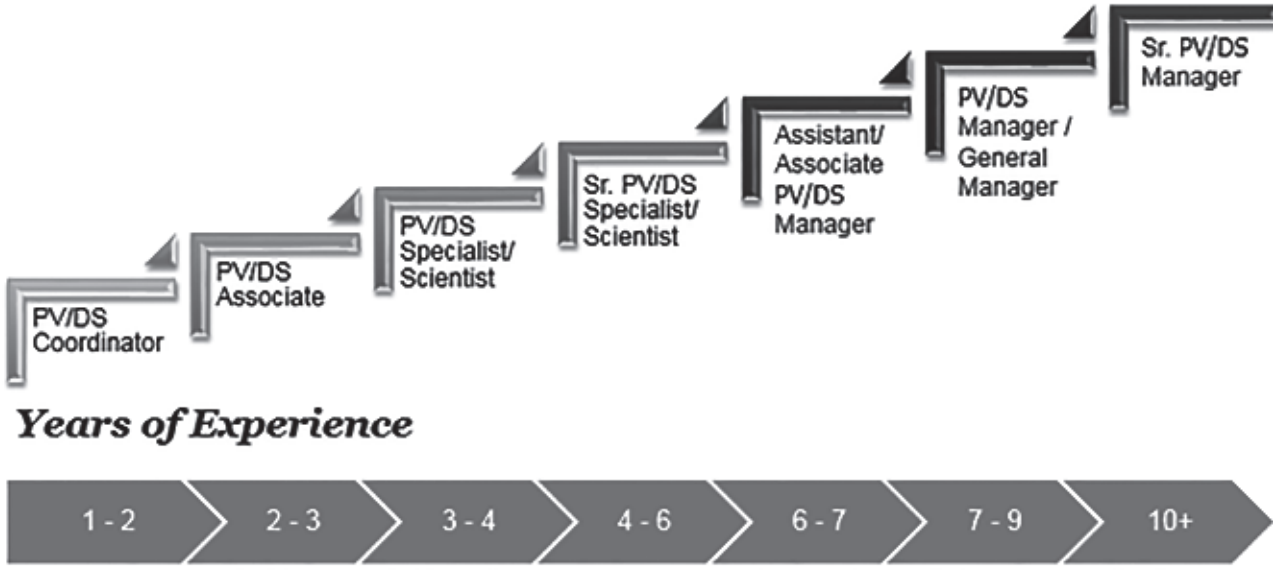

Figure 3: Typical Career Ladder in PV (Individual Contributor)

out to external market to hire management talents to suit the need especially for senior management and executive roles. Cross-functional hiring has also gained interest through lateral movement.

A typical entry level management position may include that of an Assistant Manager progressing into Associate Manager and Senior Manager. This is followed by 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 (**Figure 4**). Several roles are evolving towards 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 experts, and PV vendor management specialist.

Summary

The industry offers a wide variety of opportunities in PV for graduates and postgraduates in medicine, pharmacy, and life sciences in today's world. A career in PV is equally or more fulfilling than any other allied healthcare career because the work involves collecting and analyzing safety data for a large number of medicinal products aimed at patient safety. The candidates who pursue PV career should be passionate because the outcome of their work would have a social impact by minimizing or mitigating the medication-related harm and ensuring that patients receive medications which outweigh the benefits compared to risks. The jobs in the industry would require both technical and soft skills for a successful career development. There are plenty of career development opportunities once a person gets into the PV job through continued learning and development. The opportunities are spread across pharmaceutical companies as well as service providers such as CROs and BPOs.

The PV career opportunities continue to grow proportional to the growth of biopharmaceutical industry. Although the outsourcing of core PV services like ICSR processing has gained momentum over the last few years, the pharmaceutical companies are also looking at internal resource optimization and consolidation thereby keeping the opportunity open for PV growth. Outsourcing of niche and high-end work like signal detection and risk management has also seen a rapid growth. With increasing biopharmaceutical products in the market, continuously changing regulations around drug safety, rapidly fostering GVPs, and increased outsourcing of PV services, it is expected that there will be continuing demand for skilled PV human resources in the job market. Career development

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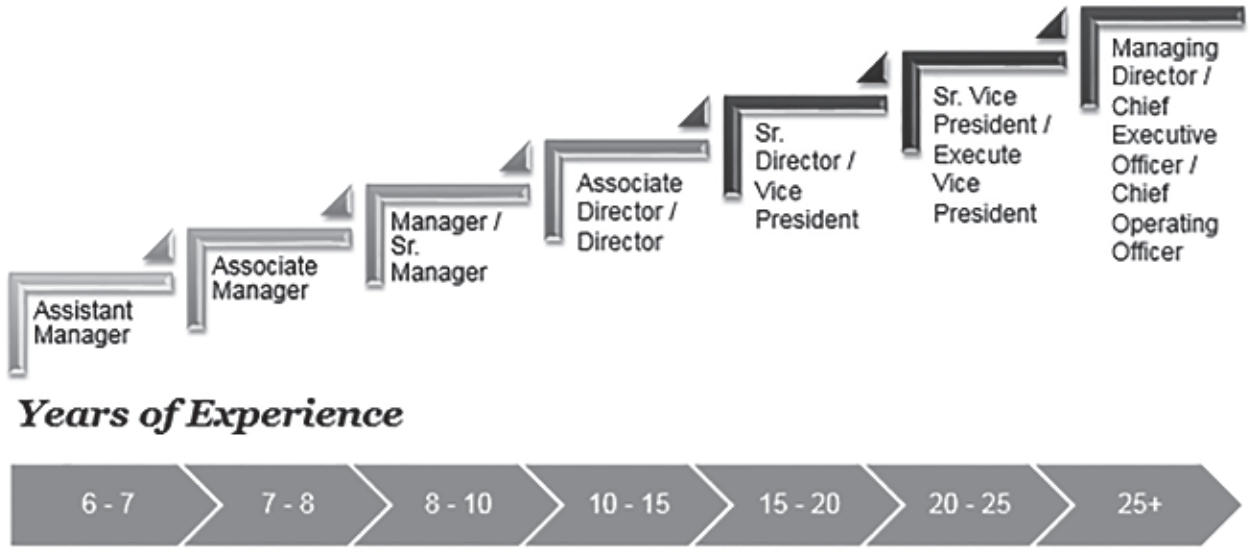

Figure 4: Typical Career Ladder in PV (Management Role)

in PV industry is driven by continuous self-development. The PV professionals should explore lateral and vertical growth, enrichment, realignment and transition opportunities for a successful career in the industry.

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