

## Pharmacovigilance Specialist

Reports to: Director, or Manager

### Main Duties

may vary from one company to another

- **Manages adverse events:** processes adverse-event case reports and conducts follow-up; notifies regulatory agencies and business partners accordingly; responds to requests from regulatory agencies; reviews scientific literature and bibliographic sources; helps draft and manage periodic safety-update reports; evaluates safety profiles; ensures document filing and archiving.
- **Involved in clinical-trial activities:** reviews the pharmacovigilance aspects of protocols and other documents; ensures management of adverse-event case reports; reconciles information in pharmacovigilance and clinical-research databases.
- **Contributes to ensure compliance of pharmacovigilance activities:** assures compliance of pharmacovigilance activities; conducts case reconciliation with concerned departments or business partners; takes part in audits and inspections.
- **Serves in an advisory capacity:** revises product monographs; drafts responses to pharmacovigilance requests from regulatory agencies; advises and informs health professionals about product safety; participates in the drafting and implementation of pharmacovigilance contracts and agreements.

### Evolution of the Profession

- Pharmacovigilance is the point of convergence between medical research, regulatory affairs, and marketing. Its role is increasingly important in an environment ever more sensitive to the concept of risk-benefit ratio and transparency of communications.
- One of the pharmaceutical industry's priority objectives is reducing the adverse events and side effects associated with incorrect drug use, resulting in the need for risk management and, therefore, to better identify, assess, and prevent risks.
- Increased company communications have an impact on the work performed by Pharmacovigilance Specialists, as they are required to verify or assist in the drafting of documents, articles, summaries, and presentations dealing with drug safety.

### Main responsibilities<sup>1</sup>

#### Management of Adverse Events

- Accurately evaluates cases for validity and consistency.
- Documents cases according to procedures.
- Accurately codes product-safety information and product-quality complaints.
- Appropriately assesses case severity in order to prioritize follow-up.
- Reviews data against source documents.
- Submits data in a timely manner.
- Properly assesses submission eligibility on a case-by-case basis as per the regulations.
- Diligently prepares and checks required documentation.
- Identifies appropriate regulatory agency directions and makes case referrals.
- Carefully reviews and documents regulatory-agency requests.
- Prepares responses based on requests.
- Prepares clear periodic reports.
- Diligently assesses product safety profiles.
- Recommends action based on identified risks.
- Helps draft safety-profile assessment reports.
- Files case reports according to appropriate archiving practices.

#### Involved in Clinical Study Activities

- Identifies the roles and accountabilities of participating clinical study resources.
- Thoroughly documents training available to concerned resources.
- Provides resources with relevant training on study protocol requirements.
- Plays an active role in reviewing contracts with investigators.
- Submits pharmacovigilance data in a timely manner.
- Verifies the risks listed in the investigator's brochure.
- Actively participates in the validation of study reports.
- Accurately assesses the seriousness of reported cases and maintains strict follow-up of treated cases.
- Verifies data quality against source documents.
- Compares information from the pharmacovigilance database with the clinical-research database.
- Ensures the accuracy of the information.
- Follows up on clarifications pertaining to case reports, if necessary.

### Best Practices

- Pharmacovigilance Specialists ensure that their knowledge of pharmacovigilance practices; existing legislation, regulations and guidelines; expertise in therapeutic products and areas; medical coding; safety-data administration through:
  - reading and analysis of product literature;
  - attending conferences and external training programs;
  - taking part in in-house training sessions and meetings.
- **Assurance of Pharmacovigilance Compliance**
  - Creates or adapts pharmacovigilance procedures based on overall or business-partner procedures and prevailing regulations.
  - Provides training to concerned persons based on the training plan.
  - Effectively manages training documentation.
  - Monitors pharmacovigilance procedures according to contracts, procedures, regulations, and directives.
  - Verifies data according to information sources prior to undertaking case reconciliation.
  - Properly reconciles cases and follows up on issues with concerned departments.
  - Plays an active role in the preparation, conduct, and monitoring of audits and inspections.
  - Archives documents according to prevailing standards.

<sup>1</sup> As per the company's mode of operations.

## Qualifications

### Pharmacovigilance Specialists have:

- A university degree in health sciences (bachelor's, or D.É.S.S. [Diplôme d'Études Supérieures Spécialisées], master's, doctorate), pharmacy, nursing, medicine, or a related discipline.
- Two to five years of relevant experience in pharmacovigilance, clinical research, or regulatory affairs. Other companies require three to five years of experience.

### Employers are seeking candidates who possess, among other skills, the following:

- Autonomy and a sense of responsibility.
- Analytical and synthesis skills.
- Ability to use simple language based on target audience.
- Ability to work on multiple projects simultaneously.
- Ability to work as part of a team.
- Ability to keep tight deadlines and work under pressure.
- Ability to inspire confidence and mutual respect.
- Excellent communication skills with different internal and external stakeholders.
- Fluency in English and French (spoken and written).
- Scientific expertise.
- Versatility.
- Meticulousness and attention to detail.
- Planning skills and organized work habits.

## Career-Path Options

With experience, depending on interests and training, Pharmacovigilance Specialists can aspire to, among other positions, the following:

- Senior Specialist.
- Project Leader.
- Manager.
- Director.
- Consultant.
- Trainer or Educator.

Competency	Behavioral Indicators
<p><b>Decision-Making</b> Ability to make sound judgments and properly assess situations.</p>	<ul style="list-style-type: none"> <li>• Evaluates the facts in order to make the best decisions.</li> <li>• Ensures management of proactive responses in dealings with regulatory authorities.</li> <li>• Makes realistic and appropriate decisions within a regulatory context.</li> </ul>
<p><b>Communication and Interpersonal Skills</b> Ability to build relationships of trust and demonstrate professional ethics.</p>	<ul style="list-style-type: none"> <li>• Demonstrates good interpersonal / listening skills and is accessible.</li> <li>• Adapts personal approach to individuals and situations.</li> <li>• Shows diplomacy, calm, and patience.</li> <li>• Communicates clearly and effectively and uses simple language to make information accessible to a wide audience.</li> <li>• Establishes and maintains fruitful interpersonal relationships.</li> <li>• Ensures the confidentiality of all aspects of work.</li> <li>• Drafts or reviews reports within prescribed time frames and in accordance with existing regulations.</li> </ul>
<p><b>Problem Solving</b> Ability to assess various situations and develop appropriate solutions.</p>	<ul style="list-style-type: none"> <li>• Assesses the urgency of situations.</li> <li>• Handles high-risk situations, recommends and implements solutions on a case-by-case basis.</li> <li>• Adopts a rigorous approach to problem solving within a regulatory context.</li> </ul>
<p><b>Advisory Role</b> Ability to assist concerned resources in pharmacovigilance matters.</p>	<ul style="list-style-type: none"> <li>• Revises product monographs.</li> <li>• Helps draft and implement pharmacovigilance contracts and agreements.</li> <li>• Helps draft responses to requests from pharmacovigilance regulatory agencies.</li> <li>• Advises and informs health professionals about product safety.</li> </ul>

Please refer to the *Pharmacovigilance Specialist's Analyse de profession\** and *Profil de compétences\** for all additional information.

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\* This document has not been translated yet.