

## 1 Overview

Encompasses the processing and monitoring of adverse event reports for investigational and marketed products following company Standard Operating Procedures to ensure compliance with worldwide safety regulations, corporate and regulatory guidance documents, and corporate policies.

## 2 Qualifications

- Associates degree, Bachelors degree or higher in Health/Biomedical Sciences related field or other relevant educational training
- For nurses (RN) and pharmacists (RPh), certification/licensure required

## 3 Salary Range

Permanent \$55,000 – \$110,000

## 4 Previous Positions

- Pharmacist

## 5 Industry Background

- Medical Information
- Pharmacist, Medical Doctor

## 6 Career Progression

- Senior Drug Safety Associate
- Manager/Sr. Manager, Drug Safety Operations
- Different therapeutic areas

## 7 Typical Responsibilities

- Evaluates adverse event reports, assesses regulatory status which is seriousness and expectedness/relatedness in order to prioritize workload.
- Processes adverse event reports from clinical trials and from marketing activities as per company Standard Operating Procedures and guidelines for maintaining regulatory compliance.
- Performs risk and quality function on adverse event reports including manual coding as needed.
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- May request Quality Assurance analysis on appropriate cases according to SOP.
- May determine need for and request follow-up using appropriate communication methods (eg. fax, email, telephone or site visit)
- Participates in team discussion for both processing and product knowledge.
- Prioritize workload for product and liaise with other Safety Associates to ensure timely processing.
- May determine the need for and request follow-up using appropriate communication methods (eg fax, email, telephone or site visit)
- May represent safety operations at clinical development meetings