	Job Description **Drug Safety Associate – Level 1 & Level 2 (PV Services)**

Preferred Education: Bachelor in Health Discipline

Preferred Experience: 1 - 2+ year's industry drug safety or clinical research experience.

Special knowledge needed: Medical terminology with knowledge of pathophysiology

Responsibilities:

- Receive, review and process Drug Safety information based on regulations and conventions
- Case creation
- Triage and prioritization
- Follow up for missing information
- Enter the source document information into safety database (e.g. Argus, ARISg)
- Data Entry of case administrative detail, patient, product, event, labeling, causality, lab tests etc.
- Medical coding (e.g. MedDRA and WHO-DD coding)
- Narrative preparation
- Quality Check of data (e.g. self, peer)
- Generate case reports (e.g. MedWatch, CIOMS, XML)
- Submission of Reports to Regulatory Authorities and Partners
- Literature Article Search and Assessment
- Maintain Periodic Reports submission calendar
- Collate information and author/review Period Reports
- Collate information for Signal Detection
- Perform administrative activities necessary for the job (e.g. Signing, Scanning and placing of source documents in database, update trackers, timesheet etc.)
- Manage workload under the direction of Team Lead
- Mentor Drug Safety Associates, interns/trainees
- Act as a Subject Matter Expert
- Comply with the processes and policies laid out for information security and responsible for using the organization's information assets in accordance with the Acceptable Use Policy in ISMS
- Notify the supervisor or Information Security officer of any security breaches/incidents.
- Any other responsibilities including cross-functional assignments delegated by the organization to fulfill business needs

Name:	Reporting Manager:
Signature:	Signature:
Date:	Date: