

Rockaway, NJ DRUG SAFETY DOCUMENTATION ADMINISTRATOR

This position is responsible to revise and maintain the document control system for WC Drug Safety Postmarketing Pharmacovigilance operations. This system ensures that pharmacovigilance documentation supporting marketed WC Company products is filed in a controlled fashion to provide an accurate and secure maintenance of source documentation to consistently meet FDA Regulations 21 CFR 314.80. This position prepares case folders for management of the initial adverse event case information, submission documents, evidence of correspondence, and subsequent follow up information and maintains the active files and archives case folders following periodic submissions. Tracks and reconciles case forwarding to Vendor for case processing and MedWatch preparation daily and weekly as necessary. This position will be responsible for the preparation of MedWatch submission letters, final preparation of Periodic Adverse Event Reports, licensing partner report sharing requirements and obtaining articles required for safety surveillance and maintenance of articles in electronic database.

About Warner Chilcott

Warner Chilcott is a leading specialty pharmaceutical company currently focused on the women's healthcare, gastroenterology, dermatology and urology segments of the U.S. and Western European pharmaceuticals market. It is a fully integrated company with internal resources dedicated to the development, manufacturing and promotion of its products. We have established strong franchises in women's healthcare and dermatology through our marketing techniques and specialty sales forces. We believe that our proven product development capabilities, coupled with our ability to execute acquisitions and inlicensing transactions and develop partnerships will enable us to sustain and grow our business.

The individual will be responsible for the following activities:

- Preparation and maintenance of adverse event case folders including initial case information, submission documents, evidence of correspondence, and subsequent follow up information daily
- Tracking of case forwarding to Vendor daily
- Reconciliation of Medical Affairs Tracking Tool (MATT) and Vendor Weekly Reports including verification of accuracy of including, but not limited to; initial receipt date, product, and Medical Information Worksheet (MIW) number, completion of Manufacturer Control Number field in MATT, and correspondence with Vendor regarding any discrepancies noted on a weekly basis
- Preparation of MedWatch submission letters, printing and closing expedited cases in pharmacovigilance database as needed
- Final preparation of Periodic Adverse Event Reports as needed

- Maintenance of submitted reports in Central File Room
- Performs activities related to licensing partner agreements including initial notification of receipt of adverse event followed by retrieval from pharmacovigilance database and submission of MedWatch / CIOMS to partner(s) as required, receipt and initiation of process for incoming cases from partners, and acknowledgement of receipt to partner(s) as required in a timely manner
- Obtains articles required for safety surveillance, distributes to Drug Safety Associate for review, files hard copy of article with review, maintains electronic database of articles
- Respond as appropriate to electronic mail addressed to Drug Safety, log contacts into MATT and forward for triage to Drug Safety Associate
- Development and/or revision of systems and procedures with Senior Manager, Drug Safety to ensure accurate and secure maintenance as well as timely retrieval of pharmacovigilance documentation
- Perform QC review of MATT entries as needed
- Any other duties as needed to support the business needs may be assigned.

Qualifications

- Associate degree in business related discipline
- 5 years related experience, including 3 to 5 years experience in the pharmaceutical industry
- Must have effective oral and written communication skills
- Must be fluent in Microsoft Office Suite (Word, Excel, PowerPoint)
- Knowledge of FDA 21 CFR Regulations for the postmarketing reporting of adverse events
- Ability to work effectively in a team environment and to establish and maintain cooperative working relationships
- Must be organized and capable to maintain complete and accurate records.
- Must be able to manage multiple projects simultaneously
- Must have a positive attitude, outstanding problem solving skills, excellent oral and written communication skills, and strong interpersonal skills.
- Must be able to handle changing priorities.

Candidates must be authorized to be employed in the United States. Candidates should be willing and able to travel as necessary. Candidates must be organized and have excellent oral presentation and communication skills. Candidates must also successfully pass a drug test and background check.

Warner Chilcott realizes that our success as an organization is dependant upon our people. We seek aggressive, success oriented and adaptable associates. Please apply at jobs@wcrx.com and reference "DocumentAdmin" in the subject.