



POST MARKET COMPLIANCE INVESTIGATOR III

Status: Full Time, Employee
Location: Miramar, Florida - USA
Work Status: Will *not* consider sponsorship for work authorization
Job Number: 2009-386

Summary:

Under limited supervision, this position completes product quality investigations as it relates to customer complaints and adverse events reported to the Post Market Compliance Department. The Post Market Investigator position requires the ability to handle variety of tasks, meet timelines, and maintain cross-functional interactions with laboratory, quality assurance, engineering and production departments as well as marketing clients.

Essential Job Functions: *This is not intended as a comprehensive list; it is intended to provide a representative summary of the major duties and responsibilities. Incumbent(s) may not be required to perform all duties listed, and, may be required to perform additional, position-specific tasks.*

- Initiates, completes, and manages the Investigation process for all customer complaints.
- Reviews and analyzes documents such as batch records, product release summaries, finished product material status, and sample submissions etc. to complete the investigation process.
- Concisely summarize the results of Investigation in writing.
- Perform data entry activities into the Customer Complaint Database (CCDB) as it pertains to the Investigation process.
- Escalate packaging complaints that require priority processing for Investigation.
- Monitor Investigation process as it relates to alert limits and trends.
- Maintain open communication with contractors and marketing clients.
- Responsible for the process of scanning and archiving closed complaints forwarded to appropriate marketing client(s).
- Responsible for the reporting of deliverables to Supervisor or Manager on a weekly basis to include the status of Investigations.
- Review and analyze reports from the CCDB for accuracy to support projects
- Ensure compliance to GMPs
- Perform special projects as directed by the Supervisor or Manager
- Provide training and mentoring to Post Market Investigator I and II colleagues
- Write/revise SOPs and/or Work Instructions (WI) relevant to the position's responsibilities.
- Represent Post Market Investigators on committees or meetings as needed.

Required Knowledge and Skills:

Knowledge of:

- FDA, cGMPs and SOPs regulations and guidelines related to evaluation and response to customer complaints and adverse reactions to pharmaceutical products.
- Ability to read and interpret documents such as safety rules, operating and maintenance instructions, and procedure manuals.
- Ability to write routine reports and correspondence.
- Ability to speak effectively before groups of customers, employees of organization.
- Current Company policies, practices and procedures, including safety rules and regulations.
- Pharmaceutical processes, principles, practices and their application
- Business English usage, spelling, grammar, and punctuation.
- Computer systems and software applications.

Skills In:

- Ability to add and subtract two digit numbers and to multiply and divide with 10's and 100's.
- Ability to perform these operations using units of American money and weight measurement, volume, and distance.
- Ability to apply common sense understanding to carry out instructions furnished in written, oral and diagram form.
- Ability to deal with problems involving several concrete variables in standardized situations.
- Communicating clearly and concisely, both orally and in writing.
- Establishing and maintaining cooperative working relationships with others.
- Strong organizational skills.
- Ensuring compliance with all Company policies and procedures, including safety rules and regulations.

Physical Requirements and Working Conditions:

Incumbents in this position are subject to extended periods of sitting, standing, and walking, vision to monitor, and moderate noise levels. Work is performed in an office environment.

Minimum Qualifications:

Bachelor's degree and 3 to 5 years related experience; or Associate's Degree or equivalent from a two-year College or Technical School and 5-7 years of experience, or equivalent combination of education and experience. Experience must be in customer complaints area in the pharmaceutical industry.

For consideration, submit resume to: careers@avevadds.com.

No phone calls please.

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