



SENIOR MANAGER, POST MARKET COMPLIANCE

Status: Full Time, Employee
Location: Miramar, Florida - USA
Work Status: Will *not* consider sponsorship for work authorization
Job Number: 2010-430

Summary:

Under general direction, responsible for management of post-market compliance reporting for Aveva's products from consumers, marketing partners, and other sources related to product quality complaints, adverse events (AEs), and medical or product quality inquiries. The Sr. Manager is responsible for all aspects of compliance with regulatory requirements for complaints, including ensuring AEs for Aveva products are reported to the Food and Drug Administration (FDA), Health Canada, and other Regulatory agencies as required.

The Sr. Manager is responsible for oversight of Pharmacovigilance (PV), including establishment of PV Agreements, the exchange and submission of AE reports and related reconciliation reports with partners per PV and/or Quality agreements, as well as with the safety reporting contractor and regulatory agencies.

The Sr. Manager is responsible for daily, weekly, and monthly tracking and trending reports of complaints and AEs to Aveva Management (Quality Council) and as appropriate, to partners/clients, and regulatory agencies. The Sr. Manager is responsible for the timely initiation and management of any multidisciplinary investigations required in support of complaints/AEs, maintaining required cycle times for and for ensuring a validated customer complaints database is maintained and upgraded in compliance with FDA rules, regulations, and expectation. The incumbent manages the Quality Systems metrics and trending project/Product Dashboard Program.

The Sr. Manager develops and implements functional standards for handling of complaints and AEs, ensures required standard operating procedures are written and followed, and keeps abreast of regulatory requirements in the US and countries where Aveva intends to offer products for sale.

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.*

- Manages the complaint handling AE reporting system, including interacting with management, partners, contractors, and regulatory agencies
- Writes procedures and reports, performs weekly, monthly, and other periodic exchanges per regulatory requirements and agreements to ensure compliance with reconciliation requirements for complaints and AEs
- Evaluates and approves complaint investigations; ensures multidisciplinary investigations are initiated and completed per requirements
- Analyzes data and reports trends in quality systems (including AEs and product complaints) to upper management at Aveva and Nitto Japan, as appropriate

- Responsible for timely submission of Periodic Reports, Annual Reports, and other submissions as assigned for Aveva-owned marketing applications to the appropriate regulatory agencies
- Participates in preparation and review of new and revised labeling with marketing partners, Quality Assurance and related disciplines
- Participate in inspections by regulatory agencies and auditors, can serve as primary contact or inspection team coordinator
- Trains and supervises RA PMC support staff

Required Knowledge and Skills:

Knowledge of:

- Adverse event reporting and submission requirements (US required, foreign desirable)
- GCPs, GMPs, GLPs, and post-market safety and surveillance compliance
- Various types of pharmaceutical product submission requirements
- Ability to communicate well in person and in writing with senior management and regulatory authorities.
- Knowledge of transdermals (desired)
- Management, supervision, leadership, training, recruiting, interviewing and selecting applicants in accordance with established employment practices and methods.
- Ability to apply advanced mathematical concepts and perform operations such as frequency distribution, analysis of variance, correlation techniques, and trend analysis.
- Computer literate in a Windows environment with the ability to use electronic mail system, the Internet and the Microsoft Office Suite including Excel, Word, and Power Point and, Access.

Skills in:

- Ability to identify the needs for growth and design necessary systems to ensure compliance with Regulatory requirements
- Competency in writing reports in the English language
- Strong organizational skills
- Ability to work with under minimal supervision and rely on experience and good judgment to plan and accomplish assigned goals.
- Able to manage multiple tasks simultaneously, be responsive and adaptable to project/task change based on business requirements
- Strong interpersonal skills to interface with many levels of an organization.
- Ability to perform tasks of substantial variety and complexity and to serve as a resource in the resolution of problems and issues
- Ability to adapt procedures, techniques, tools, materials, and/or equipment to meet special needs.
- Supervising, coordinating, delegating assignments, training, coaching and reviewing the work of assigned department personnel.

Physical Requirements and Working Conditions:

While performing the duties of this job, the employee is regularly required to sit; use hands to finger, handle, or feel and reach with hands and arms. The incumbent is frequently required to talk or hear and occasionally required to stand and walk. The incumbent must occasionally lift and/or move up to 10 pounds. Specific vision abilities required by this job include depth perception and ability to adjust focus.

Minimum Qualifications:

RN, BS or equivalent in a scientific/medical discipline from an accredited college or university, and a minimum of 8 years of biopharmaceutical experience in an FDA regulated environment, which includes at least two years of complaint unit management including adverse event reporting, or Masters degree plus minimum of 6 years experience. Experience in the pharmaceutical or other regulated industry and at least 2 years of previous supervisory experience required.

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

No phone calls please.

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