Complaint Investigator Resume

Job Objective

Accomplished Complaint Investigator searching for opportunity to put my skills and past experience to work to help company reach both short and long-term goals.

Highlights of Qualifications:

- Vast experience in complaint handling, reporting and trending
- Wide knowledge of FDA regulations, safety standards and regulatory compliance guidelines
- Familiarity with FDA 21 CFR 820.198, QSRs, ISO 9001 and other medical device regulations
- Proficient with Eclipse, Aria and 4DTC software
- · Exceptional ability to handle multiple tasks and conduct with accuracy and a high attention to detail
- Ability to train and mentor local staff on quality, regulatory regulations and compliance issues
- Strong ability to plan, schedule and prioritize own work routine to meet established schedule and support the activities of Q&R
- Excellent written, oral communication and interpersonal skills
- Proficient with computer and Microsoft Office

Professional Experience:

Complaint Investigator, August 2005 – Present Philips, Wilmington, NC

- Assigned investigative tasks to analyze root cause and resolution of identified complaints.
- Collaborated with the Engineering, QE and support departments (SCS/SDL) to complete complaint analysis and compile investigation results.
- Generated Medical Device Reports (MDRs) and Vigilance Reports.
- Analyzed complaint data monthly to identify new and systemic issues as necessary.
- Prepared responses to customers and field as necessary per process.
- Provided training and guidance on reporting regulations.

Complaint Investigator, May 2000 – July 2005 Medical Systems, Inc., Wilmington, NC

- Coordinated complaint data collection with customers, Application Specialists and local service personnel at technical investigation sites, as necessary.
- Collaborated closely with Help Desk to re-create customer problems as necessary during complaint investigations.
- Evaluated complaints to analyze whether an investigation is necessary and when appropriate, lead and participated in those complaint investigations.
- Followed up with customers to evaluate adverse events and acquired other pertinent clinical information, as needed.
- Performed peer reviews of complaint investigation documentation.

Education:

Bachelor's Degree in Business Administration, Oberlin College, Oberlin, OH

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