Complaint Investigator

Job Description

Amplion Clinical Communications, Inc. provides a communications system that empowers hospitals and their caregivers to deliver higher levels of patient care to patients. Through the nurse call system, Amplion provides caregivers with advanced methods to manage patient care requests, alarms and routine care tasks. As a result, caregiver teams become more organized and responsive, patients and families become confident of receiving quality care and management can access real-time data to take patient safety and satisfaction to new levels…while understanding clearly the clinical resources needed for quality care.

This position requires an experienced and knowledgeable Medical Device Complaint Investigator interested to join a team of technical, quality-focused colleagues.

We are at the forefront of using technology and interoperability to transform the healthcare clinical and patient experience. If you share our passion for making an impact through new ideas to address critical needs in the healthcare industry, join our team at Amplion.

Position Summary:

The Complaint Investigator will evaluate, investigate, and resolve complaints, initiate CAPAs, analyze complaint data, gather additional data as needed and provide feedback to the development and manufacturing teams on potential product improvements, product defects, and safety evaluations.

Key Responsibilities:

- Perform internal quality audit of complaint source records to determine if a complaint investigation is necessary
- Perform customer complaint investigations to determine root cause and appropriate CAPA
- Work with Process Owners and Complaint Investigators to ensure compliance to the complaint handling process
- Escalate any new, unknown risk or hazards for further evaluation and decisions
- Work with multidisciplinary and cross-functional teams to ensure the timely completion and closure of complaints
- Work closely with the Regulatory and Compliance Manager to ensure FDA compliance
- Create, document, and implement procedures
- Report process metrics relating to timeliness of complaint investigations and quality of complaint records
- Interpret and analyze statistical data to identify trends
- Other duties as required

Reports to: Regulatory and Compliance Manager

Position: Exempt

Qualifications and Skills:

- Bachelor's degree in a science-related field
- 2+ years' experience in an FDA-regulated environment
- Prefer at least 1 year of experience in a Quality Assurance Complaint Investigator role

- Working knowledge of medical device regulations, FDA Code of Federal Regulations (CFR), Title 21, Part 820, Quality System Regulation and 21 CFR 803, Medical Device Reporting
- An organized, analytical thinker with exceptional attention to detail
- An excellent communicator, both oral and written
- Experience with TrackWise
- Capable of interpreting data, identifying root causes and generating appropriate CAPAs
- Working knowledge of Windows
- Able to manage multiple projects and meet project deadlines

Physical Requirements & Environmental Conditions:

Employee is regularly required to talk or hear, sit, stand and utilize technology tools such as a laptop computer for extended periods of time. Specific vision abilities include close vision, and the ability to adjust focus. Work is performed in an office environment.

Travel Requirements:

- Travel Rate: Less than 10%

Benefits Package:

- Competitive Salary
- Company Health, Dental, and Vision Insurance
- 401(k) Match
- Short and Long-Term Disability
- Life Insurance
- Paid Time Off (PTO)