Document Control Manager

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 Document Control Manager 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 Document Control Manager will control and maintain records both within and outside the Quality System.

Key Responsibilities:

- Manage and Maintain document control activities per SOP and regulatory guidelines
- Develop and/or update workflows, policies and procedures to govern archival and record retention processes
- Ensure all approved documents are maintained throughout the document lifecycle
- Manage all controlled records both hard copy and electronic
- Maintain record retention library and secure access
- Provide leadership, direction and support to staff to ensure adherence to company quality standards
- Develop training material and deliver training on importance of document control
- 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 Document Management role
- Working knowledge of medical device regulations, FDA Code of Federal Regulations (CFR), Title 21, Part 820, Quality System Regulation
- An organized, analytical thinker with exceptional attention to detail
- An excellent communicator, both oral and written
- Experience with TrackWise
- 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
- 410K Match
- Short and Long-Term Disability
- Life Insurance
- Paid Time Off (PTO)