



Quality Associate July 2018

Description

HemoSonic, LLC is seeking a Quality Associate who will be responsible for reviewing manufacturing records for accuracy and completeness to ensure compliance as well as timely release. This position will also be responsible for assisting in document control activities.

The successful candidate will thrive in a small, fast-paced company environment and have experience in a regulated industry, preferably with *in vitro* diagnostics.

Key Attributes of the Successful Candidate:

- Strong organizational skills and attention to detail
- Excellent verbal/written communication and problem-solving skills
- Able to prioritize and manage multiple tasks with minimal direction

Key Responsibilities:

- Review batch records including but not limited to manufacturing batch records, packaging records, QA data, investigations, protocols, and other associated documentation to assure they are compliant with SOPs, Work Instructions, and cGMPs.
- Disposition finished product in accordance with SOPs and Work Instructions.
- Assist in document management via cataloguing, circulating and maintaining documents.
- Participate in the Nonconformance/Deviation, CAPA and Change Control systems with timely documentation and closure.
- Assist in maintaining the training tracking system/files and send out training update notices.
- Assist with maintenance of the Device History files and other quality system documents.

Key Knowledge and Skills Required:

- Working knowledge of current and applicable GMP regulations e.g.: 21 CFR Part 820/ ISO 13485.
- Working knowledge of Nonconformance/Deviation, CAPA and Change Control programs with experience in writing and reviewing of documentation for these processes.
- Ability to positively interact with internal associates to quickly and effectively resolve documentation related issues.
- Advanced computer skills (Excel, Power Point, MS Word, etc.)



Education and Experience Required:

- A minimum of a Bachelor's degree in technical field and 1-3 years of experience with laboratory or manufacturing quality assurance activities; or equivalent combination of education and experience.

The position is based in Durham, NC.

To apply, please email your cover letter, resume and salary requirements to:
careers@hemosonics.com

HemoSonics, LLC is an equal opportunity employer. All applicants will be considered for employment regardless of race, color, religion, sex, sexual orientation, gender identity, national origin, veteran or disability status.