



DOCUMENT CONTROL ASSOCIATE

Employment Type: Full-Time / Non-Exempt / Hourly
Department: Quality & Regulatory / #270
Effective: December, 2020

Position Summary:

Works under the direction of the Quality Assurance Manager. Responsible for document control duties including initiating change control, filing, scanning, batch record review and other document control related duties as requested.

Required Education, Experience and Skills:

Bachelor's Degree or equivalent preferred. Previous document control experience in diagnostic manufacturing preferred. Ability to read, write, and speak English and follow instructions. Good verbal and written communication skills required. Must be detailed orientated, organized and have the ability to learn processes quickly. Must be able to work independently and apply good judgement. Intermediate computer skills, including Microsoft Office (*Project, Word and Excel*) required and MasterControl experience preferred. Strong documentation skills and experience maintaining standard operating procedures is desirable. Experience with project management preferred.

Essential Functions/Major Responsibilities:

- Supports the overall quality management system, based on FDA and applicable international regulations.
- Supports Operations Department with Raw Material Specification (RMS), Work Instructions (WIs) and Standard Operation Procedures (SOPs) generation/maintenance.
- Responsible for creating and updating SOPs and work instructions related to the document control group.
- Responsible for assisting with the maintenance and organization of document control, including managing the final updates of documents before release and ensuring the completeness of documents submitted to MasterControl.
- Creation of certificates of analysis for outgoing products.
- Responsible for the review and approval of batch records.
- Assists with process improvement activity as required.
- Assists with Document Control support during regulatory inspections and quality system audits (ISO, FDA, internal audits) as needed.
- Responsible for compliance with the company's quality system requirements through training and adherence to policies, procedures, and processes.
- Responsible for the maintenance and organization of the document control department including all hard copy and electronic files.