



PRODUCTION INVESTIGATOR III

Status: Full Time, Employee
Location: Miramar, Florida - USA
Work Status: Will *not* consider sponsorship for work authorization
Job Number: 2010-400/401

Summary:

Under limited supervision, this position completes Production investigations as it relates to product quality. The Production Investigator position requires the ability to handle a variety of tasks, meet timelines, and maintain cross-functional interactions with Technical Services, Engineering, Quality Control and Quality Assurance,

Essential Job Functions: *This is not intended as a comprehensive list; it is intended to provide a representative summary of the major duties and responsibilities. Incumbents may not be required to perform all duties listed, and, may be required to perform additional, position-specific tasks.*

- Initiates, completes, and manages the Investigation process for all Production product quality deviations and customer complaints.
- Becomes familiar with company product line, production equipment, batch records and relevant SOP's.
- Reviews and analyzes documents and data such as batch records, lab testing, finished product material statuses to complete the investigation process.
- Serves as an investigation team leader into process failures and discrepancies to assess impact upon product quality and validation status.
- Recommends improvements in manufacturing and control systems including corrective and preventative actions (CAPA).
- Concisely summarizes the results of an Investigation in writing.
- The Investigator troubleshoots the production processes and identifies process improvement opportunities.
- Assists manufacturing in scale-up and manufacturing processes such as equipment selection, process start-up, troubleshooting, etc.
- Monitors the Investigation process as it relates to alert limits and trends.
- Ensures compliance with GMP's.
- Provides training and mentoring to supervisors and other colleagues performing simple investigations.
- Writes/revises SOPs relevant to the position's responsibilities.
- Performs special projects as directed by the Director of Production or Vice-President of Production.

Required Knowledge and Skills:

Knowledge of:

- Knowledge of Current Good Manufacturing Practices,(cGMPs), Food and Drug Administration (FDA), Drug Enforcement Administration(DEA), and other regulatory requirements.
- Pharmaceutical and Engineering principles applied to manufacturing processes including blending, coating and drying.

- Pharmaceutical quality control and manufacturing processes.
- Techniques of sampling, testing and measuring.
- Proficient in the use of mathematical and statistical computations.
- Proficient in the use of Statistical Process Control, Experimental Design and statistical software.
- Speak and write fluent English with a proficiency in technical writing for complex reports and regulatory documents.
- Personal computers and competent with Microsoft Office applications

Skills In:

- Analyzing and troubleshooting problems, identifying solutions and recommending and implementing methods, procedures, systems and/or techniques for resolution.
- Performing necessary projects, assignments to implement goals and objectives for effective, efficient and cost effective management of allocated resources.
- Functioning as an individual contributor, with minimal supervision.
- Ability to prepare all types of pharmaceutical documentation (batch records, SOPs, protocols, summary reports, etc.)
- Communicating effectively, both orally and in writing.
- Establishing and maintaining cooperative working relationships with those contacted (internal and external) in the course of work.
- Handling hazardous chemicals within established safety guidelines.
- Handling multiple projects and tasks.

Physical Requirements and Working Conditions:

Incumbents in this position are subject to extended periods of sitting, standing, and walking, vision to monitor, and moderate noise levels. Work is performed normally in an office environment.

Minimum Qualifications:

A Bachelor's degree in Engineering or Life Sciences from an accredited college or university and at least 5-8 years experience or a Master's degree and 3-5 years of experience in a cGMP regulated manufacturing environment or an equivalent combination of training and experience is required.

For consideration, submit resume to: careers@avevadds.com.

No phone calls please.

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