QA Technical Assurance Specialist

VistaPharm, Inc. - Largo, FL

Job Summary:

The QA Technical Assurance Specialist ensures compliance by authoring and/or reviewing the appropriate execution of Quality Assurance related documents including: Deviations, OOS investigations, CAPA and Change Controls. The incumbent, will also be responsible for reviewing other technical documents in support of Operations, Quality Assurance, Quality Control, validation and equipment qualification activities. Also responsible for working with company subject matter experts to write and edit technical documentation while ensuring compliance with applicable regulatory requirements.

Job Responsibilities:

- Review and approval of technical documents including: SOPs, validation and qualification documents (IQ/OQ/PQ/PPQ), specifications and change requests for facility, manufacturing, and laboratory.
- Primary contact for all Notice of Events (NOEs). Assess and classify NOE and ensure prompt initial product impact and scope.
- Primary quality contact for customer complaints/ notifications.
- Write investigations and gather information from internal and external sources in order to evaluate the impact of the occurrence, risk to future processes, root cause analysis, CAPA determination and effectiveness.
- Partner with subject matter experts to conduct investigations
- Ensure proper root cause analysis using various investigative techniques.
- Ensure each investigation is closed within the 30-day time frame and ensure extensions are filed as appropriate.
- Works cross-functionally in identifying appropriate corrective/preventative actions designed to mitigate quality deficiencies.
- Oversee the CAPA (corrective and preventative action) system and ensure timely closure and extension (if warranted).
- Develop, implement and monitor the CAPA effectiveness system.
- Develop and implement tracking mechanisms for investigations, CAPAs and other documents. Report metrics to Quality Council.
- Escalate potential quality issues to Sr. Management as appropriate.

Qualification and Requirements:

A Bachelor's Degree is required. A focus degree in Science or Engineering is preferred. 4+ years of pharmaceutical/FDA regulated facility or other GMP regulated environment.

Individual must demonstrate the following:

- Ability to read, analyze and interpret common scientific and technical documents.
- Strong written and verbal communication skills. A technical writing background is preferred.
- Proven investigational skills including prior experience using root cause analysis tools.
- Strong decision-making/analysis skills, problem-solving and Lean mindset.
- Thorough understanding of compliance requirements and ability to follow detailed written procedures.
- Ability to handle multiple, at times complex tasks and prioritize and adapt to business needs.
- Proficient in Microsoft Office Suite of programs (Word and Excel is required, Visio, Project, PowerPoint, and Access skills are preferred).
- As part of your job duties, travel between VistaPharm buildings is required on a routine basis.

Reporting Structure and Supervisory Responsibilities

- Reports to Quality Assurance Supervisor

Benefits & Compensation:

This position offers a competitive total compensation package, including health benefits (medical, dental, and vision), 401k with company match, life insurance, and paid vacation and personal time.