

Compliance Specialist

VistaPharm, Inc. - Largo, FL

Job Summary:

The incumbent will assure individual compliance with the FDA regulations, cGMP's and all other applicable international regulatory compliance requirements, applicable department programs, including training, documentation, standard operating procedures, and VistaPharm, Inc. policies and procedures.

Job Responsibilities:

- Assist in the coordination of the Quality Council Meetings. Gather metrics, prepare slide presentation and schedule meetings. Assist in the preparation of minutes and ensure follow-up actions are completed.
- Assist in the coordination of Escalated Quality Events meetings, including the preparation of minutes and follow-up on pending actions.
- Assist on activities related to any market actions, such as, Field Alert Reports, potential Recalls, or any other regulatory actions.
- Participate on internal audits to proactively identify compliance issues, and provide timely report findings.
- Assist in maintaining and managing processes for qualifications of VistaPharm suppliers.
- Assist in gathering supplier data to ensure suppliers meet all the Supplier Qualification Program requirements.
- Collect, review, and analyze data to write all the Annual Product Review reports within the established due date.
- Engage in External Audit Processes (Customers, Regulatory, Government Agencies, etc.)
- Follow up on internal and external corrective actions to ensure timely implementation and validate their effectiveness.
- Other duties as assigned by the Quality Management team.

Qualification and Requirements:

- BS In scientific discipline (chemistry, biology)
- Minimum of 3 years with direct exposure to or knowledge of pharmaceutical quality assurance control and regulatory affairs
- Experience implementing and maintaining quality systems
- Ability to write reports, conduct internal audits and support with external quality system audits
- Audit and regulatory experience preferred

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.