



Job Title: Analytical Data Reviewer (Part Time)

Location: Bridgewater, NJ

Description:

Solaris Pharma Corporation is a leading generic corporation with the vision of improving the patient's quality of life through development of niche pharmaceutical products. Solaris Pharma Corporation has a fully equipped Research & Development facility with expertise in the development of generic and specialty products. Solaris Pharma Corporation develops specialty dermatology products that have a relatively high barrier to entry due to manufacturing complexities and high-end clinical patient study demands. With a thorough knowledge of the development life cycle and well-trained, committed scientific personnel, Solaris Pharma Corporation has streamlined processes that are efficient in reducing development costs and shortening timelines, without compromise in quality.

Solaris Pharma Corporation is currently engaged in the development of several generic dermatology products and is committed to establish itself as a pacesetter in dermatology pharmaceuticals.

Solaris Pharma Corporation is seeking a: Analytical Data Reviewer available 16-24 hours per week.

Responsibilities:

- Auditing Analytical Data associated with research and development, method validation, raw materials, stability and drug product.
- Ensure test have been completed as per applicable method and/or standard operating procedure.
- Verify that all equipment used to perform testing is calibrated.
- Verify that all reagents and solutions used to perform testing are prepared correctly and within specification and/or solution stability where applicable.
- Verify associated calculations are correct.
- Obtain corrections and clarification where needed.
- Collaborate with laboratory personnel to ensure that data is reviewed in a timely manner.
- Author and review SOPs upon request as they relate to responsibilities.
- Support investigation of LIRs where applicable.
- Perform receipt/reconciliation of Analytical samples used for testing.
- Administrative duties as requested by Direct Manager.

Requirements:

- BS/BA degree in chemistry, biology, allied health, or chemical engineering
- At least 4 -7 years' experience in pharmaceutical industry and/or relative experience
- Experience with IC, IR, UV, HPLC and GC
- Experience performing analytical data review
- Previous Analytical laboratory/testing experience
- Experience performing batch record review a plus (not a requirement)
- Knowledge of cGMPs and GLPs
- ASQ or relevant certifications are a plus in lieu of experience
- Must be a collaborative self-starter
- Must be able to work independently and meet required time-lines
- Must be able to work in a fast pace environment
- Excellent communication/soft skills and the ability to negotiate
- Exhibits skills to think outside of the "box"
- Proactive and takes initiative in the absence of Direct Manager