Job Title: Quality Assurance (QA) Specialist

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: Quality Assurance (QA) Specialist.

Responsibilities:

- Perform Batch record Review of MBRs and PBRs associated with ANDA, Validation and Commercial product batches.
- Participate in Product Quality Complaint Review and processing
- Review Annual Product Reports provided by Contract Drug Manufacturing Organizations (CDMOs)
- Asist Sr. Manager of QA or Designee with Managing internal Quality Systems
- Asist with tracking investigations performed at third parties
- Maintain QA databases and Spreadsheets
- Review analytical and formulation data generated in-house
- Create and implement Standard Operating Procedures (SOPs) as they relate to Quality Systems and other technical areas with the assistance of SMEs
- Update specifications and COAs where applicable
- Generate COAs for the release of materials and finished product
- Initiate Change Controls
- Provide Support to Quality Management with regards to vendor management/management of 3rd party relationships
- Act as co-auditor during onsite audits of CDMOs
- Act as co-auditor during internal audits
- Asist with receipt of Finished Product (FP) samples and materials

- Perform issuance and administration of documentation required for routine business
- Perform Issuance and assignment of Laboratory notebooks
- Perform review and approval of laboratory equipment qualification and calibration reports
- Asist Quality Management or Designee with review and tracking of external change controls, complaints, compendia updates and updates to specification/methods/protocols
- Perform administrative task as required by the position noted and as requested by Quality Management
- Perform minimum task as described by the job description and as assigned by Quality Management
- Support Regulatory Authority Inspections

Requirements:

- BS/BA degree in chemistry, biology, allied health, or chemical engineering
- Advanced degree preferred in Sciences, Regulatory Affairs and/or Quality Assurance but not required
- At least 3 -7 years' experience in pharmaceutical industry and/or relative experience
- Knowledge of cGMPs and basic GLPs
- ASQ certifications are a plus in lieu of experience
- Experience performing analytical data review
- Previous Analytical laboratory/testing experience a plus
- 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
- Must be able to travel up-to 10% - 15% of the time upon request
- Must be able to lift at least 25 lbs.