Job Title: Quality Assurance – QA/QC GMP Manager/Supervisor

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/QC GMP Manager/Supervisor (Depending on experience).
Responsibilities:

- Asist the Associate Director of Quality or Designee in Implementing Quality Systems within the cGMP Laboratory and other areas as applicable
- Create and implement Standard Operating Procedures (SOPs) as they relate to Quality Systems and other technical areas with the assistance of SMEs
- Provide general oversite to the cGMP Laboratory
- Asist Laboratory personnel with Investigation of Laboratory Investigation Reports (LIRs)
- Perform review and approval of LIRs.
- Review analytical and formulation data where applicable.
- Perform review and approval of method validation protocols and reports related to test performed by internal and external laboratories
- Review method verification reports where applicable and documentation provided by Third Party laboratories
- Aid QC RD in the review of DMFs for updates as it related to designated projects
- Act as liaison for Safety program
- Manage Laboratory personnel and designated personnel training records
- Update specifications and COAs where applicable
- Initiate Change Controls where applicable
- Provide Support to Quality Management with regards to vendor management/management of 3rd party relationships
- Act as co-auditor during onsite Laboratory audits and/or audits of 3rd parties
- Asist with receipt of samples and materials
- Perform issuance and administration of documentation required for routine business

- Act as representative for QA as delegated during onsite meetings with Executive Management
- Perform Issuance and assignment of Laboratory notebooks
- Perform review and approval of laboratory equipment qualification and calibration reports
- Asist Associate Director of Quality with review and tracking of external change controls, complaints, compendia updates and updates to specification/methods/protocols
- Generate COAs for the release of materials and finished product where applicable
- Act as administrator for assignment of Lab IDs for electronic systems
- Perform administrative task as required by the position noted and as requested by Associate Director of Quality or Designee
- Perform minimum task as described by the job description and as assigned by the Associate Director of Quality or Designee
- Perform internal audit of cGMP Laboratories and systems
- 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 2 -8 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.