Job Title: R&D Program Manager

Location: Bridgewater, NJ

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 looking for a full time, Program Manager.**

Responsibilities:

- Development and management of strategic plans and initiatives to meet company goals
- Lead, coordinate and manage all aspects of company projects, including but not limited to preparing meeting agendas, meeting set up, recording meeting minutes, tracking action items, and coordinating external and internal team activities.
- Lead weekly cross-functional core team status meetings to: ensure stakeholder engagement; monitor project progress and minimize/remove barriers to successful execution.
- Identify critical areas that impact or may potentially impact the execution plans and escalate issues as necessary to senior leadership.
- Manage Solaris Pharma programs at CMOs/CROs and maintain good working and professional relationship to ensure successful timely execution of the programs.
- Maintain the time lines for the projects and establish tracking of project schedule/critical path activities and status reporting.
- Conduct risk assessments and collaborate with key stake holders to develop contingency plans via resource allocation to ensure projects are completed in a timely manner.
- Manage and resolve technical issues as they arise.
- Serve as operational lead and primary point of contact, for cross-functional teams.
- Develop and maintain project documentation using project management tools, such as MS Project, Smart sheets, and online software such as share point and drop box.

- Organize and review documents for regulatory submission. Thoroughly understand the regulatory documentation requirement for ANDA submission and manage submission timeline.
- Organize and lead the meetings to support deficiency responses to FDA. Maintain time line by preparing the action item tracker for responding to each deficiency, owners and due dates.
- Manage the budget and resources for both outsourced and internal activities.

Qualifications:

- BA or BS degree in science from accredited college or university, with a minimum of 3 years' experience in the generics pharmaceutical industry, with at least 2 years in Program (Project) Management.
- Prior experience in managing generic R&D projects from inception to product approval a plus
- Experience in cGMP pharmaceutical R&D and / or Manufacturing Operations a plus.
- Certification: PMP certification is a plus.
- Experience with working with third party CMOs on development and product launches.
- Experience with ANDA drug development.
- Strong analytical skills and business acumen specific to operational activities and product launches in generics.
- Cross functional collaboration skills with the ability to network with different functional areas and integrate cross functional deliverables.
- Proficiency in MS Office, MS Project/Smart Sheet, and SharePoint.
- Excellent interpersonal, collaboration and communication skills.