



Job Title: Regulatory Affairs Associate/Sr. Associate

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.

The Regulatory Affairs Associate will have hands on experience assisting with regulatory filings as necessary to market Solaris Pharma products. This is an entry level position with 2-3 years of experience, providing training towards full competency in Regulatory Affairs (RA). This position requires a basic understanding of the pharmaceutical industry, as well as a basic understanding of the regulatory submissions process. May perform some or all of the following functions, depending on specific assigned focus.

Summary:

Prepare and submit regulatory filing. Monitor and track information and requirement changes. Interact with regulatory agencies.

Responsibilities:

- Leads regulatory affairs projects to organize, analyze, identify, track and resolve submission and filing issues. Implements and designs systems and processes used to ensure completeness and accuracy of submissions, filings and tracking methods.
- Identifies issues or areas of concern. Determines and initiates required follow-up.
- Receives little supervision for most assignments. Receives general instructions for nonstandard analyses and projects. Data analysis is complex and requires input from multiple sources and innovative problem-solving. Interfaces to negotiate and exchange information with all levels of management.
- This position has no supervisory responsibility.

Levels:**Knowledge**

Complete understanding and wide application of technical principle, theories, and concepts in the field. General knowledge of other related disciplines.

Problem Solving

Provide technical solutions to a wide range of difficult problems. Solutions are imaginative, thorough, practicable, and consistent with organization objectives.

Discretion/Latitude

Works under only general direction. Independently determines and develops approach to solutions. Work is reviewed upon completion for adequacy in meeting objectives.

Impact

Contributes to the completion of specific programs and projects. Failure to obtain results or erroneous decisions or recommendations would typically result in serious program delays and considerable expenditure of resources.

Liaison

Frequent inter-organizational and outside customer contacts. Represents the organization in providing solutions to issues associated with specific projects.

Education and Experience

Bachelor's Degree and 1-3 years of related professional experience.

Competencies

- Attention to detail
- Computer knowledge
- Excellent oral and written communication skill
- Problem solving skills
- In-depth knowledge and understanding of regulatory requirements
- Excellent planning organization and project management skills