Associate Director of Formulation

Responsible for formulation development, technical transfer, scale-up and commercialization of generic products (Aseptic and Non-Aseptic dosage form including Gels, Ointments, Creams, Lotions, Solutions, Suspensions, Powder for suspension, Ophthalmic, Foams). Management of a dynamic and scientifically driven team, dedicated to the design, development, and characterization of generic drug product formulations. Design of protocols/processes which simplifies formulation/process development. Assisting in identifying new opportunities which addresses unmet clinical or market need with branded drugs. Determine feasibility of overcoming the technical challenges related to the new opportunities identified. Develop Product Development and Analytical Research and Method Development (ARMD) strategies in support of overall company strategy. Provide technical support (formulation/analytical) for meetings with the FDA. Lead opportunities that are identified through product development at Solaris Pharma laboratories and transfer the technical information to manufacturing site for exhibit/clinical batch and provide any assistance during batch manufacture Collaborate with Operations to ensure the successful scale-up of new formulations into commercial manufacturing Provide the necessary support required for regulatory filing with the FDA. Assist in responding to deficiencies from FDA. Support technical due diligence audits conducted by existing and potential partners. Serve as a resource of scientific and technical expertise across the organization. Represents the company in all related technical matters of high significance. Determines overall organizational structure and budget and allocates managerial responsibilities. Serve as a representative or lead on multidisciplinary teams, due diligence activities and alliance partner management efforts. Assisting in coaching, developing, and mentoring developing formulation scientists. Partner with senior leadership to manage budgets, resources, and timelines of drug product development projects. Ensure problems are resolved effectively and efficiently. Act as liaison between Company and Third Party (CROs, agencies, etc.) contacts. Ensure compliance with Company policies, cGMP (Good Manufacturing practice) GLP, GCP and FDA requirements. Must have at least a Master's degree in Pharmaceutical Manufacturing or Pharmaceutical Science and 48 months of experience as a Formulation Scientist or in a related role. Must have completed graduate level coursework in Good Manufacturing Practices in Pharma, Pharma Finishing and Packaging, and Validation and Regulatory Affairs in Pharma.

Job Location: Bridgewater, NJ.