**Job Title: Regulatory Affairs Associate - I**   
**Location: Somerset, NJ**

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| **Description:** Solaris Pharma Corporation is a leading specialty pharmaceutical company committed to the development and commercialization of high-quality, specialty pharmaceutical products. Solaris Pharma Corporation employs an experienced R&D and management team focused on right-first-time development while maintaining the highest quality standards. With a strong financial position and employee centric focus, the company strives to be a pacesetter in the specialty pharmaceutical market.  The Regulatory Affairs Associate – Must have hands on experience assisting with regulatory filings as necessary to market Solaris Pharma products. This is an entry level position with 1-2 years of experience, providing training towards full competence 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 filings.  **Responsibilities:**   * Prepare and submit high quality Generic Abbreviated New Drug Applications (ANDAs), Prior Approval Supplements (PAS), Changes Being Affected 30s (CBE-30s) and CBE - 0s. * Submit annual reports and periodic adverse drug experience reports. * Publish regulatory filings using eCTD software. * Prepare and review labeling documents for development and commercial products. * Assist in preparing and submitting controlled correspondences to the FDA. * Generate SPL (structured product labeling) using eCTD tool. * Work directly with development partners, Contract Manufacturing Organizations (CMOs) and contract regulatory service providers to obtain documents for regulatory submissions. * Assist in reviewing change controls. * Track regulatory activities using project management tools such as MS Excel. * Other duties as assigned.   **Education and Experience**  A minimum of bachelor’s degree or higher in related field and 1-2 years of related professional experience.  **Competencies**   * Attention to detail * Excellent oral and written communication skills * Computer knowledge * Proficiency with Microsoft Office * Proficiency with Adobe Acrobat * In-depth knowledge and understanding of regulatory requirements * Excellent planning organization and project management skills |