**Regulatory Affairs Manager/Senior Regulatory Associate**

This position will provide technical and regulatory support to API Suppliers and Customers as well as the SST Sales and Operations Departments.

**Responsibilities:**

* Respond to regulatory and technical requests from Customers and Suppliers
* Respond to internal regulatory and technical requests from within SST
* Handle and document Customer complaints, investigations and return of product
* Resolve Customer specification and analytical method issues
* Assist Customers with NDA/ANDA filings
* Review of US DMF amendments, annual reports, deficiency responses and providing feedback to DMF holders (Suppliers).
* Provide guidance on filing mechanisms to customers for post approval changes to processes, specifications, analytical methods, container closure, etc.
* Manage GDUFA Self-ID, Facility fees, DMF fees and Establishment Registration, etc. by Suppliers to ensure compliance with GDUFA regulations
* Manage applicable federal and states licenses, permits and applications
* Conduct internal audits to ensure compliance with SST’s GMP related SOPs
* Write, review and revise Regulatory SOP’s and procedures
* Coach and mentor junior Regulatory colleagues
* Other duties, as assigned, or as business needs require

**Requirements:**

* A BS or graduate degree in Chemistry or related field with 5-7 years of experience in similar position is preferred
* Strong technical knowledge and through understanding of all FDA requirements pertaining to regulatory submissions
* Familiarity with ICH and FDA Guidance for Drug Substance and Drug Product regulations
* Effective verbal and written communication skills
* Proficiency in Computers and applications (e.g.: Word, Excel, etc.)
* A good understanding of laboratory, analytical and/or synthetic work; actual experience in API development/manufacturing is preferred