Sravani Ravipati
Email: sravaniravipati@gmail.com
Mobile: 646-787-6339

Summary

- 10+ years of relevant industry experience in Regulatory Affairs (CMC and Operations) with understanding current trends of FDA requirements.
- Strong background in ANDA/ 505(b)(2)/ IND/ CGT/ PFC submissions along with the post publishing activities like archiving and dispatching of the submissions.
- Expertise in drafting and review of CMC sections (Module 1, 2, 3 and 5) to ensure Regulatory compliance are met.
- Expertise in drafting controlled correspondences for pre-approval and post-approval submissions.
- Expertise in all publishing, verification, submission and lifecycle management of eCTD submissions.
- Experience working with software applications like PharmaReady, eCTDManager, Omnicia, Citrix Workspace, Veeva Vault, SDMS, EDMS, Documentum, Trackwise, Smartsheets, Docuproof.
- Experience in reviewing regulatory documents through a strategic lens and provide feedback to functional teams to ensure the documents will meet Agency expectations and established guidelines.
- Performed as a main point of contact with FDA for exchange of communications throughout product lifecycle.
- Experience working with cross functional teams like Project Management, R&D, Quality Assurance to ensure timely submission of documents to Regulatory Agency.
- Result-oriented with focus on continuous improvement in quality and regulatory compliance.

Work Experience

Breckenridge Pharmaceutical Inc. (Remote) **January 2024 – Present**
Regulatory Affairs Consultant

- Plan, coordinate, author, review and publish ANDAs, Amendments, Supplements, Annual Reports, DSURs and other life cycle management activities.
- Review labeling artworks and perform Docuproof for package inserts for assigned projects.
- Plan the project by understanding client needs, manage project deliverables and provide solutions as needed.
- Work with cross-functional teams to track and follow outstanding documentation, coordinate on project status and report to stakeholders.
- Identify, communicate and escalate potential regulatory issues and propose mitigation.
- Assist in maintain regulatory trackers and perform miscellaneous tasks assigned by upper management.

Fresenius Kabi USA LLC (Remote) **June 2023 – June 2024**
Regulatory Affairs Consultant

- Preparation and submission of ANDAs, 505(b)(2), Amendments, Supplements and Annual Reports.
- Critically review CMC documentation intended for submission to the FDA for consistency to relevant FDA guidelines.
- Work with project management, development, and commercial teams and lead regulatory activities associated with planning, authoring, compiling and submitting high-quality regulatory submissions to the FDA within predetermined timelines.
- Update management of significant regulatory issues that affect assigned products.
- Ensure that regulatory files and data systems are maintained and in compliance with related work instructions and regulations.

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Eugia US LLC (f/k/a AuroMedics), NJ **June 2019 – October 2022**
Manager, Regulatory Affairs

- Represented as an US Agent for Eugia's foreign establishments (injectables).
- Perform peer review of ANDAs/ INDs/ 505(b)(2)/ Amendments/ Supplements/ Annual Reports for completeness and accuracy.
- Effective communication with FDA RPMs (Regulatory Project Managers) to clarify any issues related to the applications and to obtain the status of pending submissions.
- Receive and manage all FDA communications for the foreign establishments.
- Prepare and submit controlled correspondences to OGD and CDER.
- Draft Pre-ANDA/ Pre-IND, Mid-Cycle Assessment, Post Complete Response meeting requests.
- Track key internal meetings and maintain the tracking list of all regulatory activities and submissions.
- Track new approvals and guidance updates and circulate to teams.
- Communicating regulatory strategy, key issues and remediation activities needed throughout the product life cycle, to project teams and appropriate management levels.
- Responsible to ensure regulatory commitments are met for assigned projects.
- Review and Archive of Labeling for commercial products and perform due diligence of third party acquired ANDAs/ NDAs.
- Author and review Regulatory Affairs SOPs. Assign and maintain NDC list.
- Responsible for sourcing competitor and innovator samples from vendors for foreign establishments.
- Assist QA in timely release of incoming shipments.

Solaris Pharma Corp., NJ. **November 2016 – June 2019**
Senior Associate, Regulatory Affairs

- Author and submit Abbreviated New Drug Applications (ANDAs) submissions for Food and Drug Administration.
- Author and perform timely submission of amendments to deficiencies (labeling, CMC and Clinical) and information requests for ANDAs.
- Author and submit PFC (Pre-Submission Facility Correspondence) and CGT (Competitive Generic Therapy) submissions for priority ANDA applications.
- Coordinate with Clinical Research Organizations for Bio-equivalence studies and compile Module 5 section for submissions.
- Coordinated submission work with cross-functional teams in gathering submission documents, communicated submission issues and publishing status.
- Prepares and updates the road map for each assigned product with committed timeliness by each department.
- Liaison with project management team for requesting documents and maintaining timelines for ANDA submissions.
- Advise on the development of regulatory documentation that meets relevant regulatory requirements and ensure that the documentation meets the FDA requirements.
- Tracks the committed timeliness and follows up with the internal departments proactively for required documents.
- Organizes and maintains submission components associated with a regulatory submission electronically.
- Responsible for providing summary review documents to R&D for formulation design.

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NATCO Pharma Ltd. **September 2012 – August 2015**
Regulatory Affairs Associate

- Compile and submit ANDAs in eCTD and NeeS submissions.
- Prepared, reviewed & submitted new registration, re-registration and variation dossiers to all LATAM, MENA, ASEAN, ROW and CIS Countries.
- Review documents for legibility, format, completeness and accuracy (pagination, spelling and grammar) according to electronic submission standards.
- Monitoring changes in eCTD regulatory submissions environment and procedures and implement new eCTD guidance as required.
- Coordinate with different levels of teams within the organisation (formulation development, Analytical development, Quality Control, Quality Assurance and Manufacturing) to obtain all the CMC documents required for Initial submission.
- Co-ordination with legal and marketing department for Manufacturing Licenses, GMP certificates, free sale certificates, certificate of pharmaceutical product (COPP) wholesale license etc.
- Prepare finished product monograph/summary of product characteristics, patient information leaflet, product labelling.
- Perform literature searches/analyses to address specific regulatory questions or issues as per company objectives by working with other departments.
- Tracking and timely follow-up for all internal and external regulatory activities.

Education

JNTU, India
Masters in pharmacy (Pharmaceutics) 2010 – 2012

RGUHS, India
Bachelor of Pharmacy 2005 – 2009