Regulatory Associate – Regulatory Affairs

Responsibilities:

- Authors and prepares original IND and amendments
- Provide Regulatory support for assigned products and CMC development projects
- Execute CMC strategy and provide regulatory support and input.
- Maintain approved INDs in compliance with FDA regulations; prepare annual report submission packages
- Work with stakeholders to collate data and information required for CMC submissions, including responses to queries from FDA/Health Authorities
- Review supporting product CMC documentation; Applies knowledge of regulatory requirements to the review of scientific documentation
- Provide regulatory support to the Quality Assurance team with Change Controls; reviewing change control requests for completeness and accuracy; assess impact of change; track info required for annual reporting.
- Deliver projects and other initiatives to progress current product portfolio; provide regulatory direction and support to stakeholders under the supervision of senior regulatory staff
- Other duties, as assigned, or as business needs require.

Qualifications:

- BS in Natural Sciences required
- An understanding of drug development with 3-5 years in the biopharmaceutical industry
- A minimum of 1 year of relevant Regulatory work experience required
- Strong knowledge in analytical QC testing of biologics or experience in biological products industry is highly preferred
- High attention to detail and strong organization skills
- Must be able to work to agreed deadlines and take ownership for highlighting potential delaying factors promptly to line management.
- Must have excellent written, verbal communication skills
- Demonstrates knowledge of GMPs, FDA requirements and guidance documents pertaining to submission of CMC regulatory documents; GCP knowledge, clinical development, and clinical trial processes is a plus
- Understanding of IND, BLA, and eCTD dossier component requirements is preferred

Project Manager – Program Management

RESPONSIBILITIES

The Associate Director, Program Management, will serve as a cross-functional Project Manager, accountable for supporting drug development team(s), with one or more programs in development. He or she will utilize a variety of project management tools to help enable high-performing cross-functional teams.

The AD, Program Management provides project management support to the team and works closely with the SVP, Clinical Operations, Chief Medical Officer, Functional Leads / Department Heads and other key stakeholders. The AD, Program Management helps to ensure optimal execution against agreed plans and consistency with established company goals and objectives. The role requires a broad understanding of oncology drug development (Clinical, Regulatory, Manufacturing, etc.). Responsibilities include creating and maintaining integrated cross-functional project plans / timelines (e.g., MS Project Plans), preparing agendas and minutes, contributing to development of core documents, and ensuring effective communication between the teams and management. The AD, Program Management will also have a key role in the portfolio management process. Advaxis is a flat organization; the AD, Program Management will have an opportunity to contribute to strategic planning in addition to their hands-on project management duties.

Project / Program Management

- Support multi-disciplinary project teams to ensure successful implementation, management and completion of development program.
- Develop project milestones and deliverables; prepare reports that summarize key progress and issues on development programs across departments and divisions, including preparation of background documents and presentations to senior management.
- Develop and maintain detailed MS Project Timelines / Gantt charts
- Provide project management oversight and support in key areas, such as Risk
- Management and Communication Planning
- Leverage Metrics and Key Performance Indicators as appropriate to help ensure execution
- Lead / facilitate efficient and effective team meetings
- Serve as critical escalation point across functions
- Provide support to SVP, CMO, Clinical Operations and Finance Dept. for development and maintenance of program budgets (e.g., forecasting)
- May be asked to serve as primary contact for alliance partner(s)

EXPERIENCE

- A minimum of 10-15 years of experience in pharmaceutical drug development or related role/expertise (biotech preferred) with at least 1-3 years of experience in a management role.
- Significant cross functional experience in drug development; preferably strong oncology experience
- Direct experience project managing INDs, NDAs, BLAs preferred
- Experience with a biologic investigational product or cellular therapeutic is a plus
- Demonstrated ability to work effectively and accomplish goals in team settings.
- Ability to quickly gain an understanding of the overall drug/vaccine development process and key functions involved.
- Ability to relate project details to larger corporate strategies to provide context to teams.
- Effective interpersonal skills; able to establish good working relationships and collaborate with networks of employees of all levels; able to foster cooperation in others; creative problem-solver.
- Very effective communicator; oral and written.
- Knows when and how to speak up and appropriately raise issues to team and to management.
- Keeps both team members, departmental colleagues and management fully apprised of project / initiative status and issues.
- Diplomatic, decisive, straightforward, and honest.
- Ability to delegate work effectively and hold others accountable for deliverables.
- Experience working in a small, fast-paced environment.
- Able to work collaboratively with others both internally and externally.
- Ability to adjust altitude; executing on hands on tasks while being mindful of the "big picture".
- Level will be based on experience.

EDUCATION

Minimum of a bachelor's degree in Medicine, Pharmacy or Life Sciences.

SPECIALIZED KNOWLEDGE, LICENSES, CERTIFICATIONS

PMP certification is a plus.

This position is office-based in Princeton, NJ. Travel may be required, with less than 10% expected.

Director – Quality

RESPONSIBILITIES

- The Director of Quality directs and develops the Quality operations at Advaxis ensuring compliance with company directives and government regulations; and, to lead the site's interface with regulatory authorities governing the manufacture of biological drug products. This position ensures that all products are manufactured, tested, stored and distributed in accordance with regulatory and company standards, guides, and procedures and meet the requirements of applicable regulatory agencies. This position also oversees and audits programs to assure compliance with all principles of current Good Manufacturing Practices. This position must comply with all environmental health and safety regulations and the current Good Manufacturing Practices required by the job function. This position ensures quality and compliance oversight of new product introduced to the site.
- Manage the performance and development of 1-5 direct reports.
- Directs all aspects of site quality programs, systems, operations and compliance activities, including, Quality Control, Compliance, Quality Assurance, and Quality Engineering.
- Ensures that appropriate GMP Quality Systems are in place, both through review and approval of procedures and shop floor presence, as required, and that adequate documentation exists to support and drive compliance.
- Ensures that deviations from procedures and specifications are investigated, resolved and documented; that corrective/preventative actions are identified and implemented to avoid the occurrence/recurrence of deviations and that no materials are released before the completion of the investigation.
- Interfaces with Regulatory Agencies (FDA, EMA and foreign regulatory agencies) as necessary, leads site regulatory inspections. Interfaces directly with suppliers and customers, as well as Manufacturing and supply chain management.
- Notifies the appropriate levels of management of significant quality issues immediately.
- Ensures that all departments have knowledge regarding the roles, responsibilities and authority of the Quality Unit.
- Ensures an effective process/system for disposition of raw materials, API's, packaging and labeling materials and the involvement in the decision for Bulk Drug Substance & Product and Personalized Drug Product disposition.
- Chair the site Quality Council in conjunction with the Head of CMC operations, and anticipates regulatory trend and establishes systems to adhere to GMP compliance for the site.
- Monitor implementation plans for any new Quality Policies, Directives and associated impact assessments and verify compliance with Advaxis Policies and Guidelines.
- Ensures that all incoming personnel have adequate training, education, and experience to perform their GMP related job functions effectively.

- Ensure the appropriate information to and obtain the Qualified Person's approval as required by the specific European Union (EU) regulatory authorities is provided
- Ensure that all equipment qualification protocols and reports, process, product and computer systems validation protocols and reports, change control documentation, redressing / reprocessing / rework operations, Investigation reports related to manufacturing process and microbiology laboratory, and Annual
- Product Quality Review (APQR's) elements are revised and approved.
- Ensures that all current vendors are qualified and conduct audits of approved Third Party Manufacturers and other vendors at defined frequencies as part of the vendor monitoring process as part of the Supplier Management Program.
- Ensure manages the product complaints that include performing complaint investigations in a timely manner, instituting corrective actions where appropriate and identifying product complaint trends.
- Exercise sound and phase appropriate judgment in making decisions and recommendations within generally defined practices and policies and senior management when necessary. Works on abstract problems across functional areas of the business. Identified and evaluates fundamental issues for major functional areas through assessment of tangible variables.
- Ensures that qualification/calibration of laboratory equipment is conducted following applicable procedures.
- Ensures budget development and the preparation of periodic projections of spending against budgets; and manages and controls departmental spending.
- Direct involvement in securing regulatory filings of a facility or process and supports product submission documentation.

EXPERIENCE

- A minimum of 10 (ten) years of progressive managerial experience within the quality control and quality assurance and/or regulatory in a biopharmaceutical industry.
- Excellent verbal, written and presentation skills and have the ability to deal effectively with all levels of management.
- Proven ability to lead and motivate employees in all operational areas of the Company.
- Team oriented with excellent interpersonal skills.
- Able to establish and manage priorities according to the business needs.
- Ability to plan and conduct projects within a multi-disciplinary environment, inquisitive, research oriented individual - but practical, with an ample sense for innovation.
- Effectively manage cultural and operational differences.
- General knowledge and understanding of the clinical development lifecycle.
- Extensive knowledge and experience in pharmaceutical/health care operations, manufacturing, pharmaceutical/health care technology, quality control testing and federal/International regulations are essential for appropriate decision-making ability and representation to regulatory agencies.

- Proficient in cGMP's and FDA and EMA regulations and requirements.
- Experience in supporting quality and compliance for Phase I-III clinical and commercial operations.
- Experience working with third party contract development, manufacturing and/or testing organizations.
- Particularly experienced with resolving complex quality and CMO issues, as well as corrective and preventive actions identification to resolve non-conformances/trends.

EDUCATION

Bachelor's degree in a scientific discipline required.
Advanced degree in a scientific or management discipline preferred.
ASQ, certification preferred.

ADVAXIS
IMMUNOTHERAPIES

We offer a highly competitive benefits package to include, medical, dental, vision, life insurance, and 401k.

Our company provides equal employment opportunities to all employees and employment applicants without regard to unlawful considerations of race, religion, creed, color, national origin, sex, sexual orientation, gender identity, age, ancestry, medical condition or disability, marital or veteran status or any other classification protected by applicable local, state or federal laws.

Applicants can apply to: careers@advaxis.com