

Associate Director Project Management

The WhiteOak Group, Inc (WGI) is an innovative drug development company specialized in nucleic acid therapeutics. Our research and development team is characterized by a spirit of excellence and thorough understanding of the scientific, technical, and regulatory requirements of complex drug development. We strive to provide comprehensive, integrated, efficient, and custom-tailored project management by leveraging our global network of service providers and subject matter experts.

Qualifications

- Bachelor's degree in Biology, Chemistry, Pharmaceutical Science, or related scientific discipline with 5+ years of relevant experience. Or M.S. degree in Biology, Chemistry, Pharmaceutical Science, or related scientific discipline with 3+ years of relevant experience. Or Ph.D. degree in Biology, Chemistry, Pharmaceutical Science, or related scientific discipline with 1+ years of relevant experience.
- 1+ year of US regulatory experience and/or quality assurance experience, preferably in the pharmaceutical industry. Excellent potential candidate without experience but with strong interest in regulatory affairs will also be considered.
- 1+ year of project management experience, preferably in the pharmaceutical industry.
- Prior experience in clinical trials, oncology, gene therapy, and/or complex parenteral drug products such as liposomes, nanoparticles, or microspheres is a plus.
- The candidate must possess excellent English oral and written communication skills; additional fluency in Chinese (Mandarin) is a plus.
- Must be willing to travel domestically and internationally up to 15% of the time

Responsibilities

The **Associate Director Project Management** will apply his or her expertise in scientific principles, regulatory affairs, and project management to mobilize innovator drug programs. Key responsibilities of the full-time position based in Rockville, MD include, but are not limited to:

- Provide leadership to the team and functional areas to anticipate and identify complex project issues.
- Coordinate communications between development teams, management, vendors, and stakeholders.
- Provide oversight on internal R&D program and contracted research to ensure scientific rigor and regulatory compliance in study design/execution, records management, data reporting, etc.
- Prepare and execute project plan; monitor and control progress, ensuring appropriate resource allocation and quality of manufactured deliverables within the approved budget and timeline.
- Support to prepare, review, and revise Meeting Request, Meeting Briefing Package, Investigator's Brochure, DMF, IND, NDA, ANDA, annual report, warning letter response, and other regulatory documents for submission to the US FDA to ensure compliance with applicable regulations and guidance.
- Serve as a resource for colleagues in areas of expertise and develop employee training program.
- Conduct literature review, data interpretation, risk assessment, and gap analysis to prepare technical reports for project meetings, conference presentations, investor due diligence, etc.
- Address challenges in development in an efficient and comprehensive manner.
- Represent WGI at national and international conferences, client visits, and FDA meetings.
- Participate in career development and networking opportunities.
- Publish white papers, peer-reviewed manuscripts, promotional literature, etc.