Position Summary
The position will report to the Managing Director and will be expected to direct and perform preformulation/formulation development functions for University of Iowa Pharmaceuticals. Primary responsibilities for the Preformulation and Formulation Development Director will include client engagement and outreach, performance and management of formulation development activities, management and fulfillment of contract obligations, and composing technical reports. Qualified candidates may be eligible for an adjunct teaching appointment within the College of Pharmacy undergraduate, professional and graduate programs.

Key Areas of Responsibility

Analysis and Development
• Establish and manage multiple research projects/programs.
• Manage research projects, support and conduct complex research, and direct all phases of the project and client services.
• Collaborate and interact with scientists, chemists and manufacturing personnel, plan and execute the generation, characterization and analysis of pharmaceutical materials.
• Collect and interpret experimental data to guide subsequent experiments aimed at pharmaceutical product and process development.
• Develop formulations and processes suitable for manufacturing clinical trial supplies, in co-operation with internal manufacturing and analytical research groups.
• May develop new methodology and techniques related to the area of research.
• May perform complex statistical analysis of data using advanced statistical methods.

Compliance
• Assure safety and compliance with required organization and regulatory policies for laboratory activities, respond to compliance and safety violations.
• Responsible for the appearance, function, maintenance, and compliance of the group’s equipment and physical space.
• Responsible for staff compliance with UI policies and procedures.
• Develop written operating procedures; provide employee training and maintain written documentation of equipment training.

Leadership
• Build capability and direct the preformulation and formulation laboratory.
• Manage the operational, fiscal and HR/staffing activities for the laboratory.
• Direct complex processes, external relationship development, and project leadership.
• Lead projects and personnel to facilitate smooth and methodical progression of projects.
• Collaborate and interact with collegiate faculty, particularly in the division of Pharmaceutics and Translational Therapeutics (PTT) to advance research and development projects within University of Iowa Development Consortium (UIPDC).

Human Resources
• Collaborate with human resources personnel to hire new staff.
• Lead Human Resource functions, including interviewing, selection, training, performance review, salary determination, promotion and disciplinary action, conduct and/or provide input in annual staff performance reviews.
• Design and evaluate training techniques and procedures needed to execute development projects.
• Oversee written documentation of employee training, as required.

Financial Responsibility
• Oversee the planning and preparation of budgets. Perform cost analysis and set prices.
• Develop and implement organizational goals including revenue generation targets, in collaboration with the Managing Director.
• Engage with existing and potential clients; respond to requests for work proposals, produce work proposals and quotes to seek contracts for UIP and UIPDC, and produce monthly client invoices.

Universal Competencies of the Position

Collaboration/Positive Impact (Expert/Leader)
Ability to work with a variety of individuals and groups in a constructive and civil manner while appreciating the unique contribution of individuals from varied cultures, race, creed, color, national origin, age, sex, disability, sexual orientation, and gender identity.

Service Excellence/Customer Focus (Expert/Leader)
Ability to meet or exceed customer service needs and expectations and provide excellent service in a direct or indirect manner. Ability to effectively transmit and interpret information through appropriate communication with internal and external customers.

Diversity, Equity and Inclusion (Expert/Leader)
Ability to work with individuals and groups in a constructive and respectful manner while appreciating the unique contribution of an inclusive workforce that brings together the talents of people across multiple identities (race, creed, color, religion, national origins, age, sex, pregnancy, disability, veteran status, sexual orientation, gender identity, or associational preferences).

Technical Competencies

Research and Analysis (Expert/Leader)
• Mentors others in research analysis for a range of situations.
• Assumes leadership role in producing research results within the organization.
• Maintains and enhances current research analysis regulations and procedures.
• Promotes an organization's research analysis performance and validity.
• Develops and shapes new research analysis methodologies and technologies.
Predicts future trends and directions of research analysis.

**Laboratory Testing (Expert/Leader)**
- Designs standard procedures to ensure the accuracy and timeliness of laboratory testing.
- Advocates the design of advanced equipment and methodologies for laboratory testing.
- Elaborates on prior experiences with legal and safety issues for effective laboratory testing.
- Leads in the establishment of best practices for laboratory testing.
- Monitors industry trends and direction for laboratory testing.
- Generalizes on past and future innovations of laboratory testing.

**Pharmaceutical Development Documentation (Expert/Leader)**
- Consults on documenting development procedures.
- Updates internal standards and procedures for writing and publishing documents.
- Develops pro forma templates that could be used as a basis for creating documents.
- Leads discussions on the differences in documentation styles for diverse fields.
- Establishes case studies to understand the differences between well-written and poorly-written documentation.
- Authors development documents; uses them as examples for others to follow.

**Research Safety (Expert/Leader)**
- Consults with others on policies, standards and emergency preparedness activities to improve research safety.
- Develops or enhances operational practices intended to improve or maintain research safety; advocates for safe equipment.
- Establishes and deploys policies and procedures related to the safety of employees, students, research subjects and the environment.
- Remains current with new industry specific standards and guidelines.
- Cites extensive experience in responding to research safety issues in a variety of situations.
- Develops or updates as necessary training and fire safety and emergency management plans.

**REQUIRED QUALIFICATIONS:**

**Education:**
Doctorate degree in Pharmaceutics, Chemistry, or Chemical Engineering or equivalent combination of relevant education and experience.

**Experience:**
Minimum five (5) years’ industry experience in preformulation/formulation development functions to include:
- Demonstrated ability to apply scientific principles to preformulation/formulation development of pharmaceutical dosage forms.
- Demonstrated experience within industry independently leading pharmaceutical product development activities.
- Working knowledge of cGMPs, including CMC regulatory information required for INDs/NDAs/ANDAs with respect to API, preformulation, formulation, analytical methods, and
dosage form manufacturing processes.
- Knowledge of requirements to safely work with Safebridge 3 compounds or equivalent.
- Demonstrated ability to work collaboratively in diverse environments.
- Excellent written and oral communication skills.

**DESIRABLE QUALIFICATIONS:**
- Expertise in the development of freeze-dried formulations for small molecules and biologicals.
- Expertise in addressing solubility and bioavailability issues in the development for oral or parenteral pharmaceutical products.
- Expertise in characterization of pharmaceutical materials and an understanding of material properties and their influence on product quality.
- Expertise in developing analytical methods to assess product stability
- Working knowledge of statistics relevant to pharmaceutical product development.
- Record of publications and presentations describing investigations focused on preformulation/formulation activities.
- Demonstrated leadership roles in academic, industrial, or professional organizations.