Position: Associate Director – Analytical

TARIS Biomedical is a unique therapeutically-focused urology company developing drug-device combination products for the treatment of genitourinary diseases. The individual will be responsible for supporting development activities such as analytical method transfer, test method development, product testing and phase appropriate validation. This hands-on individual will report to the Head of Product Development and will lead activities related to analytical methods in a collaborative environment. This position is responsible for leading development, validation of late-stage methods (post -IND), including transfer as needed, to support development of drug-device combination products to NDA/MAA/or other marketing applications. Key responsibilities include identifying and implementing tests needed to fully characterize the physical, chemical and microbiological properties of pharmaceutical materials (Drug Substances, Drug Products, Excipients, Key Intermediates and Device) and their performance. By providing methods, data, and subject matter expertise, this position will play a key role in Drug and Device development, manufacturing process development, stability evaluation, packaging material selection, and the identification of appropriate storage conditions and expiry dating. The individual may manage the work internally at Taris, as well at external service providers to ensure that the goals of the project teams are met in a timely, cost-sensitive, and phase-appropriate fashion. The incumbent is responsible to develop and align analytical development activities with company goals to effectively carry out the work in a R&D/GMP/ISO compliant quality standard as warranted.

Primary responsibilities include but are not limited to the following:

- Lead the overall scientific, technical and operational efforts of Analytical Development with delivery of methods, data, and process knowledge needed to meet Taris project milestones as well as associated regulatory requirements. This includes the design of protocols as well as execution and reporting of data.
- Lead the effort to recommend standards and specifications for late stage drug products under development and ensures the delivery of high quality CMC sections of IND/CTA/NDA filings. Addresses quality-related inquiries from regulatory agencies to support clinical trial and commercial marketing applications.
- Sets a high compliance standard and ensures that systems and resources are in place to ensure the activities of the laboratories are conducted in compliance with relevant Regulatory Standards (e.g. GXP, OSHA)
- Work closely with outside vendors and internal resources to support analytical activities. Provide analytical representation/expertise to CMC/project teams and other task forces as appropriate. Facilitates teamwork and coordinates execution of plans with key stakeholders. Allocates resources and ensures tracking and follow-up as necessary. Ensures the department works as a

development partner with collaborators and teams and facilitates the interpretation of data and the development of process knowledge to contribute to team and company goals.

- Maintains productive cross-functional communications with Product Development, Quality Assurance and Regulatory Affairs as needed to ensure understanding of needs, proper prioritization and the timely delivery of product knowledge, customer-oriented data and documentation. Regularly exchanges ideas and information to develop effective plans and strategies to meet business needs. Establishes effective partnerships/relationships through collaboration, expertise in current and future analytical technologies, and seamless transfer of information. Understands needs and considers external customers and/or internal clients in decisions and actions. Encourages and supports collaboration across departments and takes actions that are best for Taris.
- Creates an impactful vision for the late stage analytical function and communicates a supporting strategy to align people, resources and management at CROs or other partner organizations as needed. Delivers results with the proper blend of scientific rigor, development phase-appropriateness, and business acumen. Strives for continuous improvement.

Skills:

- Encourages new ideas and processes, and encourages new approaches.
- Promotes a culture of technical excellence, multidisciplinary problem solving, teamwork, consistency, flexibility, execution, quality and effective communication.
- Influences and impacts others through building and maintaining strong networks that are leveraged to obtain critical information and accomplish objectives.
- Anticipates needs, assesses and manages risks and organizational dynamics as well as their implications.
- Expert at planning, including the building of various options to meet Analytical Development project goals that achieve different balances of speed, cost, and risk. Able to envision, articulate, and deliver on a scenario that achieves the balance required by the project team.
- Recognizes and resolve issues across organizational boundaries.

Qualifications and experience:

- Scientific knowledge and experience in late stage analytical drug development of oral solid dosage forms and parenterals for small molecules. Experience with medical devices highly desirable.
- Experience in managing and mentoring analytical chemists internally and at

CMO's

- Intellectual curiosity, attention to detail and a team-oriented work approach
- Experience with analytical methods for solid dosage form testing and extractables and leachables. Experience with Quality by design and statistical software packages preferred.
- Excellent leadership and problem-solving skills
- Thorough knowledge of cGMP/GLPs in the pharmaceutical industry. ISO/CE marking experience is a plus.
- Excellent written and communication skills to effectively represent the analytical issues with internal project and CMC teams, external contract organizations and senior management.
- Degree in a relevant technical discipline (Chemistry, Biochemistry) or related field: Minimum requirements are as follows:
    - BS: 15 plus years of relevant industry experience
    - Master's: 10 plus years of relevant industry experience
    - PhD: 8 plus years of relevant industry experience

To apply, please send your CV to careers@tarisbio.com