TRACON Pharmaceuticals
Job Description

Job Title: Director, Analytical Development
Department: Product Development
Reports To: Senior Vice President of Product Development
Location: San Diego, California
Date: 25 March 2015

Who We Are
TRACON Pharmaceuticals, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, age-related macular degeneration, or AMD, and fibrotic diseases. We are a leader in the field of endoglin biology and are using our expertise to develop antibodies that bind to the endoglin receptor. Our lead product candidate, TRC105, is in Phase 2 clinical trials and is an anti-endoglin antibody that is being developed for the treatment of multiple solid tumor types in combination with inhibitors of the vascular endothelial growth factor, or VEGF, pathway. TRACON outsources manufacturing and has engaged top quality Contract Manufacturing Organizations (CMOs) to perform analytical testing. More information about TRACON can be found at www.traconpharma.com.

The Opportunity
TRACON is seeking an experienced professional who will join the Product Development group and play a key leadership role in advancing TRACON’s analytical development as a critical part of the late-stage development and commercialization of TRC105. The Director of Analytical Development will lead the analytical activities at TRACON, from analytical development, overseeing GMP testing, to validation and transfer of analytical technologies. The Director will provide strategic vision, scientific leadership and direction to the Product Development team. The Director will work closely with the CMOs and ensure strong alignment with other functional groups at TRACON.

Job Responsibilities

- Works with TRACON’s global CMO network to ensure appropriate analytical technologies are used in the development and GMP testing of Tracon’s clinical drug candidates
- Represents TRACON in project team meetings with the CMOs
- Plans, coordinates, and directs programs for analytical GMP testing in support of GMP manufacturing
- Reviews, tracks and trends all analytical testing including GMP release and stability data
- Leads analytical investigations as required
• Oversees bioassay development and validation
• Manages analytical method transfer activities
• Oversees validation of the analytical methods
• Works with the project team to design and implement comparability strategies
• Authors analytical sections of regulatory documents
• Stays current with current industry standards, new trends, technologies and technical developments and all applicable regulations

Who You Are

• Minimum education and experience: Bachelor of Science (BS) in life sciences with minimum 12 years of experience in GMP laboratory setting or Ph.D. with 8+ years of experience in GMP laboratory
• The candidate must have experience with standard biologics analytical tests, preferably for monoclonal antibodies. This experience should include early to late-stage clinical development and cGMP commercial manufacturing
• Experience in the assessment of technical data is required in order to provide technical reviews for historical manufacturing and stability data, documents and regulatory submissions
• Demonstrated leadership is a must, ideally 10+ years leading teams/departments responsible for analytical development activities
• Must have strong knowledge of global regulatory environment. Experience with writing IND’s and BLA’s is a plus
• Demonstrated ability to manage scientifically and operationally complex programs and to balance the strategic needs of the program with tactical day-to-day activities

TRACON is an equal opportunity employer & prohibits unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital and veteran status.