

Position: **Clinical Operations & Project Team Leader:**

About **NeuroRx**

NeuroRx is a clinical stage, small molecule pharmaceutical company developing novel therapeutics for the treatment of central nervous system disorders. The company is built upon 30 years of basic science and clinical expertise in understanding the role of the brain's N-methyl-D-aspartate (NMDA) receptor in regulating human thought processes in general and in regulating depression and suicidality in specific.

Every day in the United States we lose 100 individuals or more to suicide. About ½ of these may be related to bipolar depression.

The company's lead clinical program is a sequential combination therapy for the Treatment of Severe Bipolar Depression associated with Acute Suicidal Ideation and Behavior. In its 2b/3 study for NRX-101, treatment is initiated with a single infusion of NRX-100 (ketamine), an FDA-approved anesthetic, followed by approximately six weeks of daily oral NRX-101. NRX-101 is a proprietary, oral fixed-dose combination capsule containing two FDA-approved drugs: D-cycloserine, an NMDA receptor modulator; and Lurasidone, a 5-HT_{2a} receptor antagonist. It is being developed under a 505(b)(2)-development path.

On November 9th NeuroRx received Breakthrough Therapy Designation by the US FDA for NRX-101, after having already been granted a SPA for our P2b/3 program, as well as Fast Track designation, and a Biomarker Letter of Support.

Characterized by a deep commitment to patients, we dare to try what others have not. Our nimble corporate team is composed of highly seasoned leaders that are "hands-on", and excited about working at all levels to make a difference. This is what has allowed us to reach this exciting stage in the short time since our founding.

CLINICAL OPERATIONS & PROJECT TEAM LEADER

POSITION: Full time

COMPENSATION: Competitive, based on experience & track record, includes equity

LOCATION: Site based in Radnor, Pennsylvania

OTHER: Must be legally able to work in the USA.

ROLE DESCRIPTION:

Position: **Clinical Operations & Project Team Leader:**

You are an experienced "hands-on" clinical operations professional, that knows what it takes to execute a mid to late stage psychiatry trial. You know how to manage CRO's, sites, and have the budgeting and project management skills to smoothly run the process. You will lead the clinical implementation of all of our projects and provide integrative leadership, analytical, planning and lead the implementation of what needs to get done across our functions (Clinical Operations, Clinical, CMC, Regulatory, Finance, Commercial, Vendors, CRO's) ensuring that we deliver with quality, on time, and within budget. Our P2b/3 SPA study of ~150 patients is the only study required for approval for our first indication. Therefore this role requires an experienced "hands-on" clinical operations professional that is excited about working at all levels.

- Leads the clinical operations implementation for our clinical development programs - though an experienced leader - s/he is a hands-on executive. (e.g. site qualification & initiation, contract negotiations, budgeting, working with the sites and CRO's deliver on commitments)
- Site selection and feasibility assessments, initiation; in collaboration with CRO's
- Develops and manages the overall project & development plan for our clinical programs, instilling accountability, enthusiasm and commitment across all internal team members and the external partner organizations (CRO's, contractors, suppliers, etc.)
- Accountable for creating and meeting critical timelines, budgets, and objectives, proactively identifying project risks and mitigation strategies
- Runs key cross-functional meetings, consolidates functional inputs to develop an integrated project schedule, resource plan, and budget.
- Drives and manages the analytics & reporting for key work streams, including weekly cross-functional team meetings (status reports, minutes)
- Monitors critical timelines and goals, proactively managing to potential hurdles, assuring that functions stay on track and budget; develops dashboards, meeting minutes that effectively communicate the status of the program and associated risks. (e.g. drug supply, ancillary supportive clinical studies, regulatory milestones)
- Prepares and, in collaboration with senior leaders, enables milestone review meetings, generating relevant scenarios, strategies, recommendations, etc.
- Efficiently plans and implements key meetings including Investigator meetings, DSMB meetings, Ad Board meetings and supports team members in implementing select activities.

REQUIREMENTS:

- 10+ years of relevant drug development clinical operations (director or senior director), project management and functional experience (of which at least 5 years of clinical operations experience) in mid / late stage clinical development experiences,
- Strong preference for experiences in smaller pharmaceutical firms,

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- Psychiatry experience - strong plus,
- Passionate about patient safety with a focus on quality. Recognizes that patients are at the center of everything we do.
- Passionate about succeeding as a team to deliver life saving treatments,
- “Planner and Doer” mentality, flexible mindset
- “Can Do” attitude. Resilient in overcoming adversity, and uncertainty. *NeuroRx is doing what others have not done.* Works with and influences across all levels
- Strong organizational & communications skills, coupled with appropriate sense of urgency
- Skilled in the use project management tools and using these to inform working team members and executive leadership (e.g. MS Project, etc.)
- Demonstrated ability to create solid documentation in platforms (e.g. Box / Dropbox), making them accessible to teams
- Knowledge of key regulatory elements & requirements along the development path
- Ability to work individually and in small teams with limited resources, flexible, innovative mindset
- Demonstrated impact through influence skills, for internal and external stakeholders

Academic:

- MS in Sciences / Mgmt., with a preference for advanced degrees MBA, Ph.D., etc.