JOB DESCRIPTION

Job Title:	Head of Clinical Assays
Department:	Research & Development
Reporting To:	Chief Scientific Officer
Hours of Work:	Full time (37.5 hrs/wk)

Main Purpose of Role
Lead a small team responsible for generating biomarker and activity data from clinical trial samples and providing strategic input into translational approaches for PsiOxus' candidates.

Role Responsibilities
Overall The role with involve three main components: 1. Coordinating sample testing at external contract testing organizations (CTO's). 2. Managing small team of scientists focused on assay development and non-GLP testing of clinical samples to provide exploratory endpoint data. 3. Analysis and reporting of data, written and verbal, including providing strategic input to translational activities.
Key Activities will include, but are not limited to: **<u>Interactions with CTO's:</u>** • Identification and selection of suitable organizations; • Acting as technical representative for site audits; • Assay transfer and trouble-shooting; • Establish and maintain close and effective communication links with key contacts; • Use the latter to manage activities and timely delivery; • Cover assay development and CTO engagement for any required *in vitro* GLP toxicology studies; **<u>Data Analysis and Reporting</u>** • Use of suitable software to analyse, tabulate and graphically represent assay data; • Interpret and draw conclusions from the data, and communicate these effectively in presentational and/or written formats as needed; • Develop hypotheses based on the data and broader knowledge (internal and literature) to help guide further analyses and/or guide future studies; • Write and review appropriate sections of regulatory documents (e.g. IB, CSR, agency briefing documents etc);

Line Management and Broader Team Activities:

- Line manage and develop the capabilities of team members;
- Integrate activities of the team within the broader remit of the research group, including flexibly helping to resource non-clinical assay work as/when required;
- Establish close and effective working relationships both within the Research team and with the Development organization, particularly the Director of Translational Medicine and members of the clinical and quality teams;
- Use assay data and other experience to provide strategic input into translational and other research activities;
- Adopt a "one science team" approach to all activities, and participate in guiding and helping the broader research team to achieve its goals.

Candidate Profile

Candidates should have a minimum of 5 years of *relevant* experience post PhD (8 years if no PhD or equivalent), at least partly within the Biotech/Pharma industry, with the following further requirements:

Technical Experience

- Experience of outsourcing to contract laboratories, including management and auditing;
- Understanding of laboratory requirements to meet quality guidelines / regulations as part of sampling and testing in a clinical trial;
- Strong experience using relevant data analysis & graphical software packages (e.g. JUMP, PRISM, Excel) together with a good knowledge of statistics;
- Validation of assays as suitable for analysis of samples in a clinical trial.

Scientific Background

- Experience of assay development and use in a clinical immunology or oncology setting, preferably immune-oncology is preferred;
- Experience of the following assay approaches would also be beneficial: immunoassays, qPCR/RT-qPCR, flow cytometry, gene expression (mRNA) profiling, immunohistochemistry.

Management Experience

- Proven ability to manage and mentor staff, both as direct reports and in a matrixed project team setting;
- Demonstrated ability to work effectively in a dynamic and flexible corporate scientific environment.

Personal Abilities and Traits

- Highly motivated with an excellent team-based approach.
- Thrives in a flexible, team-focused scientific environment.
- A highly effective communicator, both orally and in writing.
- Advanced problem-solving abilities.