Clinical Program Director - Assignment No.: P4-341

THE COMPANY

International Pharma / Biotech company.

THE POSITION

The Clinical Program Director will have the global responsibility for the clinical part including clinical pharmacology aspects of a development project and the execution of the clinical program. The Clinical Program Director has to design and conduct a state-of-the-art clinical program with regard to medical scientific quality and budget aspects.

Responsibilities will also include but are not limited to the following:

- Develop, maintain, and execute Clinical Development Plan phases 1-3b together with Clinical Development Team within the agreed timelines and budget. Develop phase 3b and strategic Phase 4 trial program (e.g. registration trials in specific regions or impacting global profiling or label) together with Commercial and execute trials and other duties, as assigned
- Ensure the medical/scientific coherence and quality of clinical development programs
- Manage resources, incl. CROs, to successfully complete clinical projects
- Lead to the conceptualization and development of protocols, Clinical Trial Reports, and regulatory documents in collaboration with other team members
- Ensure the study-related safety of the subjects in the clinical trials through appropriate medical monitoring of studies on an ongoing basis
- Drive and coordinate the clinical part of the submission process in cooperation with Regulatory Affairs
- Present the clinical development program internally or to an external audience (e.g. investigators, experts), where appropriate
- Build and maintain appropriate external network of investigators and experts
- Provide medical input to preclinical projects

THE CANDIDATE

- MD with experience in Oncology (from clinics and/or biopharmaceutical industry)
- Several years experience in clinical development in the Biopharmaceutical industry and conduct of clinical trials ideally in the field of Oncology
- Experience in project management of multiple clinical trials, incl. budget responsibility
- Experience in authoring or significantly contributing to scientific communication materials documents (e.g. Clinical Development Plan, study protocols/amendments, abstracts, manuscripts, posters, regulatory documents and submissions)

TERMS AND CONDITIONS

- Prospect for promotion to VP Clinical Development
- An attractive package commensurate with experience