PCI Biotech's mission is to improve the lives of cancer patients, by developing and commercialising products based on the company's innovative PhotoChemical Internalisation (PCI) platform technology.

PCI is applied to three distinct anticancer paradigms: fima*CHEM* (enhancement of chemotherapeutics for localised cancer treatment), fima*VACC* (T-cell induction technology for therapeutic vaccination), and fima*NAC* (nucleic acid therapeutics delivery). The fima*CHEM* programme is nearing commercialisation, consisting of a pivotal clinical study with registration intent in bile duct cancer; the fima*VACC* programme has successfully completed a phase I in healthy volunteers; and the collaborative fima*NAC* programme is in preclinical stage with established research collaborations with several key players in the field.

PCI Biotech is a clinical stage biopharmaceutical company headquartered in Oslo, Norway. The company is listed on the Oslo Stock Exchange under the ticker PCIB.

For further information – visit: www.pcibiotech.com

Clinical Project Director

PCI Biotech is seeking an experienced clinical project director for its fima*CHEM* programme.

We are looking to strengthen our team with an operational clinical study leader that is an excellent planner, coordinator, and communicator and can balance easily between delegation and operational work. We look for passion for clinical development and extensive experience in clinical trial operation.

As a clinical project director, you will have a wide range of responsibilities. Primarily, you will be responsible for leading the clinical study team and oversee the study CRO to achieve successful execution of the global pivotal clinical RELEASE study.

Job responsibilities:

- Provides project oversight and leadership for clinical deliverables:
  - Plans and leads execution of the day to day activities for the monitoring of a clinical study
  - Takes the initiative to make things happen and leads and supports the clinical team and the CRO to ensure success according to time, quality and budget parameters
  - Communicates consistently with the clinical team and the CRO providing project objectives, expectations and status updates
  - Works with the clinical team and the CRO to set priorities
  - Ensures effective communication plans are in place for the clinical team and the CRO
  - Ensures effective escalation plans are in place for the study
  - Works with the clinical team and the CRO to facilitate cross functional communication for proactive problem-solving during the study
  - Monitors the quality of clinical deliverables and addresses quality matters
  - Identifies opportunities to improve training, execution and quality control

    - Liaises with relevant staff and CRO to provide data on clinical operations performance metrics and project status metrics
    - Works with the relevant staff and CRO to identify data related matters and risks to clinical activities; develops contingency and mitigation plans to minimize risks
- Quality Development
    - Creates and maintains, in collaboration with the CRO, project specific plans, documents and tools for the study
    - Analyses data related to sites activation, monitoring, data retrieval and close out to identify issues and risks to clinical deliverables; develops contingency and mitigation plans to minimize risks; communicates risks & mitigation strategies
    - Ensures all trial information is submitted, approved and filed in accordance with the trial protocol, local regulations, ICH-GCP and any other processes or procedures governing the clinical trial
    - Reviews filing of Essential Documents in the electronic Trial Master File to ensure sponsor and investigator obligations are being met and are in compliance with applicable local regulatory requirements and ICH guidelines

To be considered for this role you will meet the following criteria:

- Excellent leadership, team-working and communication skills
- A proven track record of 7+ years of Pharmaceutical/CRO experience in international clinical trial management
- Experience as clinical study team leader in oncology therapeutic area
- Experience in managing CROs and other external clinical study stakeholders
- Thorough understanding of GCP/ICH requirements

Location and reporting line
The position is up to full time and will be based at the company's headquarter in Oslo. Flexibility with regard to working hours and travel is required. The position is currently reporting to the CMO.

Remuneration
PCI Biotech offers a challenging and exciting role in one of Norway's most innovative pharmaceutical companies. The company offers a remuneration package including base salary, performance bonus and share options.

Please send your application to post@pcibiotech.com within 18 October 2020.

Contact person:
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PCI Biotech
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