

PDC*line Pharma (<u>www.pdc-line-pharma.com</u>) is a clinical-stage spin-off of the French Blood Bank (EFS), that develops a new class of potent and off-the-shelf therapeutic cancer vaccines based on a proprietary cell line of Plasmacytoid Dendritic Cells (PDC*line).

Based on a robust preclinical package and a first-in-human Phase Ib in melanoma, PDC*line Pharma has initiated a clinical development in lung cancer with a new candidate (PDC*lung) and neoantigens (PDC*neo).

PDC*line Pharma comprises a team of 27 persons based in Belgium (Liège, headquarters) and France (Grenoble). The company has raised nearly €52 million in non-dilutive equity. The last round of the financing has been led by the Asian leading Venture Capital company KIP (Korean Investment Partners).

In order to strengthen its team located in Liege (Belgium), we are actively looking for several

QA and logistics assistant

In relation to the activities carried out by PDC*line Pharma, the person occupying the position of QA and logistics assistant has the following responsibilities:

- Participate to the development and maintenance of the Quality Management System at PDC*line Pharma;
- Ensure strict application of cGMP requirements during QC analysis of investigational medicinal products batches;
- Communicate with PDC*line Pharma other teams and/or suppliers for quality and logistics purposes;
- Identify, write and review SOPs and other type of QMS documents;
- Review and approval of master batch record and completed batch record in SmartReg;
- Manage the internal and the external distribution of PDC*line Pharma's QMS documents;
- Support the Quality Manager in the process of Batch Release;
- Support the continuous improvement of PDC*line Pharma QMS;
- Manage OOS, Deviation CAPA and Change Control;
- Assist in carrying out internal quality audits on PDC*line Pharma process and QMS;
- Perform investigation, corrective action and follow up on received complaints;
- Participate in annual quality reviews;
- Participate in audits organized by the competent authorities;
- Participate in the management of suppliers and subcontractors (selection, qualification and complaints);
- Assist in carrying out external quality audits of suppliers and subcontractors
- Ensure the organization of staff training, provide training related to quality system and verify its correct implementation;
- Manage the identification, IQ/OQ, maintenance, qualification and cleaning of equipment;

- Maintain up-to-date the equipment database;
- Review material specifications and monitor storage conditions for materials;
- Manage secondary and tertiary packaging requests for our experimental drug with our subcontractor, ensure follow-up and verify documentation;
- Manage requests for preparation of sample collection kits, organize their preparation, ensure follow-up and verify documentation;
- Coordinate all transport of the experimental drug, collection kits and samples with the logistics companies subcontracting to PDC*line Pharma;
- Collect and verify documentation relating to all transport, including verifications of related quality criteria;
- Ensure the technical follow-up of the invoicing of our logistics providers;
- Update logistics tools such as tracking log, calendar, ...;
- Write and review Quality System procedures in relation to logistics activities.
- Meet defined timelines and execution of tasks according to quality and logistics priorities
- Ensure additional missions in the field of her/his skills

The position of QA and logistics assistant requires the following skills:

- Scientific higher education;
- Further training and experience in quality management;
- Experience in the biopharmaceutical sector;
- Knowledge of quality tools;
- Knowledge of GMP guidelines;
- Knowledge of the activities of PDC*line;
- Knowledge of English (comprehension of English text).
- Good organization and communication skills

We offer :

- A diversified position with responsibilities within a fast-growing start-up.
- The opportunity to join a human-sized, dynamic and professional environment.
- A permanent contract and an attractive salary package in line with your experience.

Interested?

Please apply by sending your CV and cover letter via e-mail to the attention of Valérie Donolato - HR&Admin (v.donolato@pdc-line-pharma.com).

Your application will be treated as confidential.