

Open position : Quality system manager

DNAlytics at a glance

DNAlytics develops and markets precision medicine solutions based on a data mining platform. The development of such solutions consists in identifying new sets of biological markers and predictive models for medical decision support (diagnosis, prognosis or treatment response) and building the necessary software to make these solutions effective. The company's mission is to improve patients' health, healthcare systems sustainability and industry products positioning. DNAlytics's vision is to see its solution implemented in routine care at an international scale.

DNAlytics has been the first company to market a **data-driven** precision medicine solution in rheumatology in Europe. It has been awarded several prestigious prizes from entities such as IBM, Microsoft, the MIT or the European Union. DNAlytics also has an excellent track record of working for international customers.



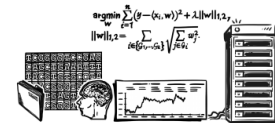
DNAlytics has product lines in **oncology** and **rheumatology**. Since its onset in 2012, it has also conducted a consulting activity in the field of data mining for pharma, biotech and IVD companies as well as academia. **This activity is mainly a scouting activity for new product leads and ensures regular revenues as well.**



Colonokit, a diagnostic solution in Oncology



Rheumakit, a diagnostic solution in Rheumatology



Data mining consultancy services

Open position as Quality manager.

Starting from 2017, DNAlytics dynamic 6-people team will grow to rapidly reach 10 people, and up to 40 in 2022. The team will be reinforced in highly multi-disciplinary skills. We are looking for motivated and highly competent colleagues to join us and complete the team in terms of data scientists and IT profiles, business development capacity (link with KOLs, out-licensing and partnerships, reimbursement, sales), quality management, and operations. Most positions are intended to be based mainly in our headquarters at Louvain-la-Neuve, Belgium.

In that context, we are currently looking for an experienced collaborator to **maintain and develop the quality system of the company, from day-to-day processes to CE-marking of precision medicine products**. This position is part of the operations team of DNAlytics, under the supervision of the top management, and interacting with the whole company.

Responsibilities:

1. Quality system management
2. Responsible of CE-IVD marking of in vitro diagnostic products
3. Act as the company's Data Privacy Officer

interact with public health authorities and/or notified bodies.

5. Execute supplier audits.
6. Remain up-to-date with the regulatory standards
7. As Data Privacy Officer, contribute, namely with Data Scientists, IT manager and Software Developer, to the implementation of the GDPR (General Data Protection Regulation) from the European Union. In that context, contacts will be made namely with the Belgian Privacy Commission.

Tasks:

1. As Quality System Manager, develop and maintain the current quality system (close to ISO13485 standard).
2. Support regulatory inspections
3. Develop and maintain the CE-IVD dossiers (technical documentation, risk management, scientific and clinical evidences) of the products of the company (RheumaKit, ColonoKit) and to do so, collaborate namely with Data Scientists, Lab Managers, Operations Manager.
4. Implement the new IVD regulation from the European Union, and when needed,

Diploma's / degrees:

Master Degree in Pharmacy, Engineering, Bio-engineering, Management sciences or equivalent.

Experiences:

- Prior experience in Quality Management and in similar position(s) is required
- Prior experience with IVD products or at least Medical Devices is a plus.
- Demonstrated ability to conduct audits or being audited is a plus.
- Prior experience with IT-based lifescience products is a plus.

Other skills:

Languages:

- Fluent oral/written English required ;
- Fluent oral/written French desirable ;
- Other languages are a plus.

Computer.

- (Libre/Open) Office softwares (word, excel, ...)
- Simple use of Linux/Unix systems is a plus.

Other:

- Knowledge of International Standards as well as IVD regulatory landscape (EU, US,...), and if not, of Medical Devices.
- Communication skills
- Show good team spirit but sufficiently autonomous to evolve in a dynamic startup

To join DNalytics and to know more about these positions, go to <http://dnalytics.com/corporate/careers/> or contact careers@dnalytics.com