Biomapas is a functional and full outsourcing solution provider to the global life science industry, with key expertise in Clinical Trials, Regulatory Affairs and Pharmacovigilance. With headquarter in Lithuania and offices in Switzerland, Russia, Georgia, Ukraine, Poland and Sweden, Biomapas operations are spread over 4 continents, concentrated in Europe, Russia and former CIS region.

Biomapas is looking for a **Quality Assurance Director** to join leading position and strengthen our further development and expansion of overall company activities globally.

Directly reporting to: Chief Executive Officer.

Key areas of responsibility

- Developing and implementing company's quality assurance and management strategy according to the best global standards;
- Overseeing all quality assurance efforts within organization;
- Maintaining and improving quality management system;
- Ensuring GCP audit revenues plan execution;
- Consulting company's employees regarding all quality related questions.

Main tasks and activities

- To continuously develop, execute and adjust quality assurance and management strategy;
- To maintain and ensure continuing improvement of determined quality policy and quality management system in the company;
- To ensure ongoing interaction with the management team and periodic management review meetings;
- To ensure that clinical operations, pharmacovigilance, regulatory affairs processes conform to the applicable regulations, GCP, GVP and other applicable practice guidelines, ISO 9001 and ISO13485 standards requirements;
- To ensure the development of external GCP/GVP audits, MAH's quality management system development and oversight, and GCP training services to the clients;
- To define and ensure implementation of Quality Assurance Department objectives;
- To establish and implement quality and performance metrics and analysis methods in collaboration with heads of departments;
- To coordinate the establishment of selected electronic QMS;
- To oversee and ensure compliance with QMS documentation and local and international requirements and standards;
- To host second, third party audits or regulatory inspections in the company and oversee the implementation of corrective and preventive actions plans after the audits;
- To participate in the training process of the staff by preparing and presenting quality and legal requirements relevant trainings;
- To participate in other activities related to quality management system improvement.

Requirements

- Minimum 10 years of relevant executive quality management experience in B2B environment;
- Minimum 5 years of experience in managing and leading teams;
- Experience in strategic development and execution of quality management system;
- Experience in a clinical, regulatory affairs or pharmacovigilance service provider environment;
- Deep knowledge of GCP, GVP, ISO 9001 and ISO 13485 standards;
- Experience in operations with any electronic QMS;
- Superior presentation, written and oral communication skills;
- Ability to lead/supervise activities in a high-pressure, fast paced and changing environment to ensure objectives are met in a timely manner;
- Excellent command of written and spoken English.

Additional assets

- Life science or business management background is a benefit;
- Prove of GxP (GCP, GVP, GLP, GDP) trainings is a benefit;
- Ability to travel periodically.

In Biomapas, you will find a supportive work environment with a guarantee for professional and personal development, as well as competitive salary and benefits and many more initiatives that will make your daily office life comfortable.

Will be waiting to receive your CV and motivation letter to **HR@biomapas.com**

In case you would like to get more information – please do not hesitate to contact Raimonda Klimiene, HR and Training manager by **+370 69 815 736**.

Be kindly informed that only selected candidates will be contacted.

Abbreviations

GCP – Good clinical practice
GDP – Good distribution practice
GLP – Good laboratory practice
GVP – Good pharmacovigilance practice
MAH – Marketing authorization holder
QMS – Quality management system