Quality Assurance Officer (GMP) **Job Summary:**

We are looking to employ a Quality Assurance Officer to provide support for the Quality department within the company. The company operates a cGMP Quality Management System which ensures compliance with the necessary legislation for EU and US Gene Therapy Products

Job Description:

We are seeking to recruit a Quality Assurance Officer for our ongoing GMP QA activities.

The QA officer will report to the QA Director,

The successful candidate will:

- Review and manage documents including but not limited to standard Operating Procedures (SOPs), batch records, production material specifications, to ensure compliance with company policies, practices and relevant standards and guidelines
- Write, implement, review and maintain SOPs, policies and other documentation for QA activities
- Review and approve key quality documents including Incident Reports, Change Controls, CAPA and Risk Assessments
- Perform data review audits (Batch Production Records, Validation Documents and Development Documentation, Quality Control Data as required)
- Support the Qualified Person and Quality Director in the definition and maintenance of the annual internal and external audit programs.
- Perform and review internal and external audits to determine compliance with GMP and identify areas for improvement
- Review and approve suppliers / service providers
- Support the Quality Director with customer audits and regulatory inspections
- Maintain and deliver training in quality related topics to personnel
- Perform tasks as reasonably expected by the Quality Director
- Act as deputy for the quality assurance Director as required including in appropriate meetings/ forums and presentation of quality reports/issues.

Skills/Experience Required:

The successful candidate will have:

- At least 2 years' experience in a relevant area of activity (eg pharmaceutical industry)
- Communication, interpersonal and motivational skills
- Ability to take decisions, to analyze information in a logical manner and to prepare coherent investigative and/or technical reports
- A clear understanding of GMP, regulatory and accreditation systems and quality management

Delphi Genetics SA
Rue Antoine de Saint-Exupéry 5
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NACE code : 72110
NAICS code : 541711

- Competent in computer packages including Microsoft Office and an electronic quality management package

Behavioral Competencies:

This is an exciting role and the successful candidate will be able to demonstrate the following behavioral competencies:

- Emotional resilience and an ability to work under pressure with a "can do attitude".
- Ability to process a high volume of planned and un-planned work effectively
- The ability to multitask and manage time effectively to ensure all work streams are managed
- A determination to continually develop and improve our processes.
- Effective communicator with the ability to build strong working relationships
- The ability to provide constructive feedback for issues affecting Quality
- Keen to learn and share knowledge with the whole team
- A team player with the ability to work unsupervised
- Conscientious and takes personal responsibility for own actions and behaviors
- Understands the needs of the customers and responds accordingly to deliver excellent customer service

Offer:

- A diversified function within a developing society.
- The opportunity to join a human-sized, dynamic and professional environment.
- A training course from the start and throughout your evolution.
- A contract of indefinite duration accompanied by an attractive salary package.

Interested in Joining us, send your application to Charline Savels: csavels@delphigenetics.com

Your application and related information will remain strictly confidential

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