Position Description:
Quality Assurance Associate

CLINUVEL

POSITION DETAILS:

Title	Quality Assurance Associate
Reporting	Head of Quality and Drug Safety
Location	Wesley House, Bull Hill, Leatherhead, Surrey KT227AH
Hours	8.30am – 5.00pm, Monday to Friday
Travel	Some overseas travel may be required

***Primary Objective*:** support the quality department in the maintenance, management and development of the Company's quality management system.

Main Interfaces:
Internal: Quality Assurance Associate, Head of Quality and Drug Safety, General Manager, Liaison Managers, Senior Regulatory Affairs Manager (Europe)

External: Service providers

Key Result Areas

- Maintain and improve of existing quality processes to ensure continuously appropriate/compliant operation of quality processes
- Work closely with other departments to facilitate actions and maintain compliance to the current systems for change controls, CAPA, deviations, complaints, internal GxP audit observation follow up
- Carrying out investigation of GxP non-compliances and/or customer product quality complaints
- Utilise quality tools and techniques to perform and document full root cause investigations, to evaluate and resolve quality issues, and to enhance continuous improvement
- Aid with development of corrective and preventive actions plans and implement these within a given timescale to eliminate the root cause of a non-conformance
- Update, maintain and improve quality management system process documents and documentation
- Perform data analyses, prepare quality trend/metrics, and report results to internal interested parties
- Creation and control of product specifications
- Carrying out PQRs (product quality reviews) as required

Skills/Abilities

- Experience with GMP and GDP Operational Quality Systems for Commercial Drug Product
- Distribution Supply Chain Operations experience
- Relevant experience in a pharmaceutical or other life science organisation
- Experience in utilising of quality System processes (such as, Audit, Deviations, CAPA, Change Control)
- Good experience of articulating and implementing SOPs & quality documents
- Ability to clearly and concisely communicate technical information
- Studious, active mind, willing to acquire knowledge
- Ability to research, analyse and report independently across a breadth of topics
- Excellent administrative and people skills
- Ability to work under pressure
- Flexibility to adjust course when required
- Ability to work autonomously and prioritise workflow
- Flexible approach to working hours where needed

Desirable candidates will possess:

- Experience managing communications projects (graphics, online, video etc) and creative contractors;
- An eye for detail
- An ability to work independently and at distance where necessary
- An inquisitive mind, unafraid of scientific information or new concepts
- Hold a Degree in a relevant Scientific discipline
- Excellent communication and organisational skills, with a versatile approach
- Native or flawless English, with knowledge of other European languages (particularly German/ French/Italian) an advantage.

The Quality Assurance Associate provides support to all functions within the Quality department. With a solid foundation in QA, they are expected to be flexible and nimble in their role to manage short- and long-term projects as well as dealing with day-to-day QA tasks. The Quality Assurance Associate will interact closely with the pharmacovigilance and regulatory departments and all GMP/GDP service providers to ensure the required post-approval compliance level is achieved and maintained.

The role will be office based in Leatherhead, Surrey; some European travel may be required. Working across the global business as part of a high-performing team there is an expectation of out-of-hours flexibility to deliver on projects. Salary commensurate with experience.