Role Profile/ Job Specification

Role Title:	Senior QC Analyst
Reports to:	Quality Control Manager
Responsible for (number of staff if appropriate):	None
Hours pw and details of shift requirements if appropriate :	37.5 hours per week. Site based role
Department/ Company:	Quality Control/ Eaststone Ltd

The Company:

Walkboost Ltd was established in 2003 and consists of 3 Pharmaceutical companies. In total Walkboost Group has c100 staff.
Maxearn Ltd is a parallel import company; Quadrant Pharmaceuticals Limited is a licensing company; Eaststone Ltd is a specials manufacturing company.

Brief Role Description:

To undertake all Quality Control duties to support the sites operations along with the documenting and reporting of work conducted. Responsible for undertaking of QC analysis, method development and validation. Finished products, Raw materials and Stability trials analysis.
Provide support to the wider Quality Department and Eaststone as a whole if and when required

Key Responsibilities :

- Plan and schedule work to meet KPIs
- Perform method development, verification / validation of existing and new products.
- Carry out analysis of finished products, in-process samples, raw materials using QC validated methods. Generate validation protocols and write technical reports for method validations and stability trials.
- Conduct checks on data to ensure quality and consistency of data, ensure protocols and validations comply with ICH
- Production support in terms of QC release of raw materials, primary packaging, and finished products, as well as any non-routine investigations.
- Write and review QC procedures as subject matter expert.
- Maintain all equipment calibration and carry out performance maintenance of equipment.
- Ensure that the procedures relating to the calibration of analytical systems are adhered to and that accurate records of these calibrations are maintained.
- Carry out equipment\instrument troubleshooting in particular HPLC.

- Generate or update local procedure (SOP and guideline).
- Conduct a full investigation and document as per MHRA OOS guidelines in case of an analytical/lab out of specifications results.
- All QC staff member are expected to undertake any additional duties on line Managers or Departmental Manages discretion.
- Support deviations, CAPA, change control, complaints and recalls
- Providing auditing support.
- Ensuring targets are met and our company's strategy is achieved through consistent development and coaching of staff.
  Train new staff as and when required.
- Developing colleagues within their roles and providing appropriate training, allowing both departments to operate more efficiently and effectively
- Undertaking relevant project work as required, involving continuous improvement of QC systems and processes.

Key outcomes:

- Analyse all Finished Product batch samples within 2 days of receipt.
- All Raw Material analysis and document collation to be completed within 2 days of receipt.
- All stability trial samples to be analysed on time within the allowed time window time points.
- Stability trial trending to be performed on monthly basis.
- Quality Control metrics to be trended on monthly basis.
- Working closely with the team to ensure compliance to GMP and procedures.
- All assigned tasks completed in a timely manner.
- Assigned databases and quality control metrics must be in an inspection ready state always.

Competency requirements for the role - Refer to Walkboost Competency framework
Core competencies:

- Customer and Quality Focus
- Personal Integrity
- Drive and resilience
- Team working
- Developing self and others

Person specification :	
Qualifications: **Essential**	**Desirable**
• Scientific Degree (Preferably in an analytical chemistry or chemistry discipline)	• Second degree in Pharmaceutical science
Skills/ knowledge **Essential**	**Desirable**
• Good knowledge of analytical instrumentation and troubleshooting. • Good team, interpersonal skills, and communication skills. • Good organisational and time management skills. • Ability to work successfully as part of a team or using own initiative, sharing knowledge, collaborating with and supporting colleagues. • Motivated, results and delivery focused with a commitment to quality of work. • Flexible in approach and adaptable to change. • Proficient in Word, Excel, PowerPoint.	• Multi product analysis experience in a pharmaceutical environment is ideal. • Understanding of Regulatory Affairs and GMP compliance guidelines. • Good problem management skills - focus on finding the right solutions and problem solving. .
Experience : **Essential**	**Desirable**
• 5 years' experience in analysis of multi dose products • Experience in testing all dosage forms • Undertaking stability trails, testing and reporting.	Understanding of regulatory framework for testing specials products.

This job description indicates in general terms, the type and level of work to be undertaken as well as the typical responsibilities of employees. The company reserves the right to make reasonable amendments to this description as required.

You are also required to undertake any other duties within your capabilities as may be reasonably required.