**Role Profile/ Job Specification**

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| **Role Title:** | QA Officer |
| **Reports to:** | Head of Quality |
| **Responsible for (number of staff if appropriate):** | N/A |
| **Hours pw and details of shift requirements if appropriate:** | Full-Time, 37.5hours, Monday to Friday |
| **Department/ Company:** | Quality Assurance – Eaststone Specials |

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| **The Company:****Walkboost Ltd** was established in 2003 and consists of **3 Pharmaceutical companies**; all the companies are based in Bolton. In total Walkboost Group has c110 staff.**Maxearn Ltd** is a parallel import company; **Quadrant Pharmaceuticals Limited** is a licensing company; **Eaststone Ltd** is a Specials manufacturing company. Our Quality team has seen vast improvement with a re-structure, creating additional roles and further training. We strive for excellence and ensure compliance is always maintained. We welcome candidates who are willing to learn, bring their own ideas and ensure they can work as part of the wider quality team for the end goal of patient safety. |
| **Brief Role Description:**To undertake Quality Assurance duties to support the sites operations along with the documenting and reporting of work conducted. Support in tasks such BMR Generation, Final Release, Quality Management System Activities, ensuring compliance with GMP/GDP and Home Office Regulations. |

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| **Key Responsibilities:*** Batch release of manufactured Specials products and Release of Third-Party Specials or Special Obtained Products
* Line Clearance duties within the cleanroom e.g. weight, product and cleaning checks.
* Managing documentation system in Manufacturing Area, and reporting/recording deviations, errors monitoring, fails, reworks and other non-compliance (change controls, unplanned deviations)
* Assisting in the generation or review of SOPs and other documents.
* Providing technical expertise to support the customers and answering queries and product investigations
* Coordinate and resolve immediate/urgent customer complaints, ensuring prompt responses/ resolution
* Participate in the internal audit programme to ensure continued GMP compliance of all site activities
* Liaise with suppliers in order to obtain documents needed for internal Quality Approval
* Utilise scientific resources in order to work on improving quality of products and services
* To maintain personal training folder in an auditable state
* To undertake any task required by your Line manager, and for which you have received full training and or an explanation has been provided and understood
* Advise on the manufacturing of new Special products and liaise with the R&D team
* Coordinate import of Special products including documentation and requirements for imported products from EU and non-EU member countries
* Respond to external and internal medicines information requests
* To establish a log/database and a procedure/process for responding to medicines information
* To maintain and update the log of queries/ update established database
* Operate CAPA system, recording out of specification and deviation events etc
* Support in environmental monitoring activities of the unit
* Maintaining quality documentation system
* Support in validating equipment
* Participate in the internal audit program to ensure continued GMP compliance of all site activities.
* Assist in the generation or review of other technical documents, qualification documentation, validation documentation
* Liaise with suppliers in order to obtain documents needed for Internal Quality Approval
* Participate in quality improvement initiatives
* All training for the activities mentioned will be provided internally/externally
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| **Key outcomes:*** Working closely with the team to ensure compliance to GMDP and procedures.
* All assigned tasks completed in a timely manner.
* Support in ensuring the QMS must be in an inspection ready state always.
* PQRs, SOPs, validations should be under control and up to date.
* Customer complaints, incidents managed pro-actively in a timely manner.
* Cleaning verification and environmental monitoring schedule adhered to and outcomes/ actions monitored.
* SOPs and quality related documentation reviewed and updated in a timely manner.
* Enquiries, supplier approval and technical agreement systems should be up to date.
* Ensuring all Eaststone products released are manufactured according to the product specifications and in compliance with GMP guidelines.
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| **Competency requirements for the role :** **Core competencies:*** Customer Focus
* Personal Integrity
* Drive and resilience
* Team working
* Developing self and others
* Analysing & Decision Making (2)
* Managing Performance (1)
* Managing Change (2)
* Communicating with Impact (2)

**Job Knowledge and Qualifications:*** Educated to Degree level of a Scientific Background
* Must possess computer proficiency skills, Microsoft packages such as Word, Excel, Power Point and Outlook (Intermediate to Advanced)
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| **Person specification:**  |
| **Qualifications:****Essential** | **Desirable** |
| * N/A
 | * Degree/Higher education
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| **Skills/ knowledge****Essential** | **Desirable** |
| * Operating a personal computer and standard office equipment
* Knowledge of using Microsoft Packages (Word/Excel/PowerPoint/Outlook)
* Excellent written and verbal communication skills
* 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.
* Takes ownership and actively looks for personal learning and development opportunities.
* Flexible in approach and adaptable to change.
 | * Understanding of Regulatory Affairs and GMP compliance guidelines.
* Good problem management skills - focus on finding the right solutions and problem solving.
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| **Experience:****Essential** | **Desirable** |
| * Minimum 2 years GMP experience
* Experience working in GMP/GDP regulated environment
 | * Knowledge and experience of EU GMP and MHRA/FDA regulations and audits.
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| **Other:****Essential** | **Desirable** |
| * Able to work as part of a team, and as an individual
* Working in a fast-paced environment whilst adhering to strict deadlines
* Knowledge of Health & Safety in a GMP environment
* Computer literate
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| **Prepared by: O Sattar** | **Date: 13SEP2021** |

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.