

Discovermore

Head of Quality Assurance

Department: QA
Hours per week: 37.5
Basis: Permanent

Job Purpose

The Head of Quality Assurance is responsible for leading the business' strategic approach to Quality Assurance.

Working as a key member of the Senior Quality Leadership Team, they will own and drive the site quality improvement agenda.

Key Responsibilities

- Defines and drives the vision and strategy for the site QA function
- Accountable for the performance of the Quality Assurance function; responsible for setting the quality standards, targets, measures, and has oversight for the provision of the metrics
- Responsible for ensuring all products, processes and operations within the Worthing site are fit for purpose, adhere to relevant regulatory requirements and match the Company's marketing commitments
- Accountable for ensuring that the function signs off accurate and fit for purpose Deviation/Complaint investigations to identify root cause and establish appropriate actions
- Ensure the PQS meets the requirements of the licences, and current standards, legislation and guidance and directs the site in the use of the PQS and where required supports the development and implementation of the electronic QMS
- Leading Quality Council and Change Management forums, and (where required) escalation of adverse trends/metrics/performance to the Executive
- Drive ownership for delivered quality and compliance and ensures all QA processes are lean and efficient through use of performance management tools
- Lead role in support of audits/inspections by customers, internal auditors and external regulatory bodies. Ensure the QA function and site is continually inspection ready and supports development of site CAPA and responses
- Review and approval of reports, procedures, policies, critical and major non-conformances, complaints (etc) as required and determines the acceptability of data
- Support reviews / compilation of reports in support of PQR's, MAA or BLA
- Lead the Quality Assurance teams, ensuring high levels of team and personal engagement and leading the teams through change

Knowledge, Experience & Skills Required

- Substantial experience leading teams in an Operational Quality environment (of which a significant amount should include managing QA teams)
- Experience of fronting multiple Health Authority inspections and internal audits
- Demonstrates foundational knowledge and understanding of current UK and EU GMP standards and regulations
- Practical experience preferably from aseptic manufacturing, in a management role
- Strong people focussed manager with leadership, coaching and influencing capability
- Able to advise and act on complex quality issues – e.g. business processes, root cause analysis, document control and traceability

If you are interested in this role,
a job description is available on request.

Please send all applications to:
careers@allergytherapeutics.com

**Allergy
Therapeutics**