Job Description & Person Profile

QA Manager

Department: Quality

Reporting to: Head of Quality

Senior Manager: Head of Quality

Job Purpose:

To lead and manage the operational performance of the Quality Assurance (QA) function, ensuring the successful delivery of business strategies and objectives, whilst adhering to regulatory compliance and achieving commercial success.

To ensure the efficient and effective day to day running of the QA function and to act as the primary contact for QA related queries.

To perform batch release of 'specials' products as required.

Responsibilities:

- Implementing the departmental strategy, to ensure that it meets the business requirements and customer deliverables, as well as ensuring the departmental performance against goals.
- Leading, managing and developing the QA function, ensuring the efficient and effective use of resources.
- Identifying, implementing and monitoring departmental Key Performance Indicators (KPIs) in line with business objectives.
- Liaising regularly with all managers to ensure consistency of service delivery across the business, in line with agreed business objectives.
- Challenging existing methods and presenting alternatives, continually improving internal systems.
- Overseeing the departmental workload, ensuring that all QA activities are performed in accordance with Good Manufacturing Practice (GMP), the Quality standards and in support of customer service.
- Assessing and making decisions relating to Quality, GMP and Good Distribution Practice (GDP) related issues.
- Acting as the Responsible Person on the Wholesale Dealers licence.
- Acting as the primary contact for QA related queries.
- Batch release of 'specials'.
- Reviewing, approving and authorising new formulations and product labels.
- Writing, reviewing and approving Quality documentation, including validation protocols, change controls, GMP deviations, technical agreements, periodic reviews, risk assessments, internal and external audit reports and Quality reports.
- Involvement with technical customer queries and product investigations.
- Responding to enquiries in a timely manner, giving advice on Quality requirements in order to maintain the company's reputation for customer service and technical acumen.
- Ensuring that the company complies with current and future GMP legislation.
- Participating in MHRA inspections, Home Office inspections, third party inspections and self inspections.
- Participating in self inspections and quality audits of suppliers.
- Providing and presenting quality metrics to the monthly quality review meeting.

- Ensuring safe working practices in accordance with HASAWA and COSHH.
- Acting as Regulatory Manager for Controlled Drugs (CDs) and Regulatory Manager/Responsible Person for Precursor Chemicals.
- Overseeing all operations involving CDs and ensuring compliance with the Misuse of Drugs Act 1971, Misuse of Drugs Regulations 2001 and Safe Custody Regulations 1973.
- Writing, reviewing, amending, approving and implementing Standard Operating Procedures (SOPs), ensuring regulatory compliance in conjunction with being 'fit for purpose' operationally and commercially.
- Managing, motivating and mentoring the QA team.
- Leading by example at all times, providing support, encouragement and help where needed to other members of the QA team.
- Developing personal development plans for the QA team.
- Dealing with day to day departmental staff matters and all related administration (e.g. 1:1s, holiday requests, and return to work meetings).
- Delivering on the job staff training, as and when required.
- Managing, preparing and justifying the departmental budget.
- Liaising with the QA team regarding all none budgeted costs and Capex requirements.
- Promoting the business e.g. attendance at conferences, presentations to external parties, etc.
- Keeping up to date with all legislative and industry guidance/best practice and advising management of key changes.
- Managing and implementing projects, both within the department and across the business.
- Ensuring good relations and communications with all members of the team and responding politely and in a timely fashion to internal and external customers.
- Working with all members of staff to maintain and develop the positive progressive culture within The Specials Laboratory.
- Observing and complying with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).
- Observing and complying with company Health and Safety Policies.
- Observing and complying with company Standard Operating Procedures (SOPs).
- Undertaking any other duties, either for this department or any other department within the business, which may be requested by the Line Manager, for which training and/or an explanation has been provided and understood.

Person Profile:

- Essential Requirements:
  - Pharmacy degree.
  - Impressive, demonstrable track record and skills/experience gained within a similar position(s), at a similar level.
  - Good understanding of the pharmaceutical market, including the unlicensed medicines sector.
  - Wide knowledge of products and processes used in the manufacture of unlicensed medicines.
  - Good IT skills e.g. Microsoft Office (Word, Excel and Outlook).
  - Strong leadership/team management skills and experience.
  - Credible and confident communicator (written and verbal) at all levels.

- Strategic thinker with the ability to influence at a senior level.
- Highly customer focused and passionate about delivering excellent customer service.
- Commercially astute.
- Strong analytical and problem solving ability.
- Good project management skills.
- Excellent presentation skills (written and verbal).
- Hands on approach, with a 'can do' attitude.
- First class planning, organisational and time management skills.
- Excellent attention to detail, with the ability to work accurately in a busy and demanding environment.
- Ability to achieve and maintain high standards.
- Self motivated, with the ability to work proactively using own initiative.
- Committed to learning and development.
- Enhanced Criminal Records Bureau (CRB) Disclosure (in relation to CDs).

Training:

You will receive on the job training and other specific training, as agreed and required.