

# Job Description & Person Profile

## Head of Quality

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**Department:** Quality

**Reporting to:** Managing Director

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### Job Purpose:

To lead and manage the strategic and operational performance of the Quality department, ensuring the successful delivery of business strategy, Key Performance Indicators (KPIs) and objectives, whilst adhering to regulatory compliance and achieving commercial success.

To ensure the efficient and effective day to day running of the department.

### Responsibilities:

- Developing and implementing the Quality department's strategy, to ensure it meets the business requirements and customer deliverables, as well as ensuring the departmental performance against goals.
- Implementing and monitoring all Quality Assurance systems to ensure compliance with EU Commission Directive 2003/94/EC, covering GMP for medicinal products for human use and investigational medicinal products (IMPs) for human use.
- Implementing and maintaining a Quality Risk Management system to ensure that risks are adequately controlled in accordance with current requirements (EU GMP Part III Q9).
- Acting as the main point of contact on all Quality matters, internally and externally.
- Coordinating MHRA inspections, Home Office inspections, Pharmacy inspections and internal inspections.
- Maintaining MHRA authorisations, including submission of variations (named on licences as responsible for Quality Control).
- Ensuring regulatory compliance with TSL MHRA licences (e.g. Assembly, Specials, Vet Specials, Wholesale).
- Ensuring regulatory compliance with TSL Home Office licence.
- Maintaining and improving departmental operational performance, to meet the requirements of regulatory authorities, company Standard Operating Procedures (SOPs) and external and internal customers, with respect to quality, service, lead time and cost.
- Ensuring the development of departmental SOPs (writing, revising and approving), ensuring regulatory compliance in conjunction with being 'fit for purpose' operationally and commercially.
- Ensuring that all activities are performed in accordance with GMP, company SOPs and Health and Safety policies.
- Ensuring that there is an audit programme in place which is communicated to Operations.
- Ensuring that the supplier and subcontractor audits are performed and reported as scheduled.
- Ensuring that there is a self inspection programme in place which is communicated to Operations to meet the requirements of EU GMP.
- Managing all validation activities, including validation strategy and approval of protocols and reports.
- Maintaining an awareness of new and proposed legislation that impacts the business and communicating any changes to the Senior Management Team (SMT).
- Ensuring the availability of adequate competent resources to carry out the review and approval batch documentation in accordance with in house and GMP requirements.
- Ensuring sufficient QP resource to provide QP certification for commercial and clinical trial products.

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- Preparing, reviewing and approving Technical and Quality Agreements.
- Ensuring appropriate investigation of discrepancies, errors, complaints, failures or adverse events requiring documented review and action (if necessary, interrupting processes causing material to be quarantined or placed on hold until matters are resolved).
- Leading customer and regulatory audits/inspections, as required.
- Ensuring that the Quality department meets or improves on budget, cost, volume and efficiency targets (KPIs) in line with business objectives.
- High level resource planning.
- Providing direction and guidance to the Quality team.
- Managing, motivating, coaching and mentoring direct reports, to higher levels of management capability.
- Identifying and developing the Quality team structure.
- Preparing and justifying the Quality department's budget.
- 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 GMP and 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:
  - Scientific degree (ideally pharmacy, pharmaceutical sciences, chemistry or related).
  - Eligible to be a Qualified Person in accordance with directive EC/2001/83.
  - 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.
  - 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.
  - Commercially astute.
  - Strong analytical and problem solving ability.
  - Excellent project management skills.
  - First class presentation skills (written and verbal).
  - Hands-on approach, with a 'can do' attitude.

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- First class organisational skills.
- Ability to prioritise, demonstrating good time management skills.
- Excellent attention to detail, with the ability to work accurately in a busy and demanding environment.
- Self motivated, with the ability to work proactively using own initiative.
- Committed to learning and development.
- Highly Desirable:
  - Good IT skills e.g. Microsoft Office (Word, Excel and Outlook).

### **Training:**

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