Protak Scientific Limited
Luminox House Holmethorpe Avenue
Redhill | Surrey | UK | RH1 2NL

+44 (1737) 924 900
info@protakscientific.com

Quality Systems Manager – Job Description

Protak Scientific

We are the world exclusive manufacturer of Enzymatic Biological Indicators (EI's) for rapid decontamination process validation for the pharmaceutical and healthcare sectors. Having invested multimillions into product development and global introduction, we are now rapidly growing and see significant growth. We already hold ISO9001 registration and have developed a substantial QMS. Due to changes within the company we have a need to appoint a highly experienced Quality Systems Manager.

Definition:

Responsible for developing the Quality strategy, policies, processes, standards and systems for Protak and its supply chain to operate within. This will include auditing to ensure compliance, both internally and externally as needed. To lead Protak and our products to successful registration for ISO13485 and applicable registrations globally.

Overall Purpose of the Role:

Develop and sustain the Quality Management System in line with the required industry standards (including: ISO9001, ISO13485), accreditation requirements and business requirements across the organisation through existing and new procedures. Regulate, control and improve the quality of all processes throughout the business and the final product. Manage the audit program to ensure that all nonconformities raised from certification bodies, customers or against suppliers during audits are effectively corrected and independently verified. Embed a culture of continuous improvement throughout the company. Lead the team to achieve quality management system targets for customers and business goals.

Key Responsibilities:

Strategy and Development

- Contribute to the creation and implementation of best practice Quality strategy, policies, processes and procedures to aid and improve operational performance.
- Lead and manage certification for ISO 13485.
- Contribute to new business initiatives and projects and review and communicate the impact on Quality Management Systems (QMS).

General and Task Management

- Develop the Quality Management Systems strategy and the management arrangements for key milestones, demonstrating solid progress against plans and objectives.
- Manage all external registration requirements to ensure they are met. Liaise with external bodies on all matters relating to registration. Maintain and improve, in line with business needs.
- Implement all relevant procedures described in the Quality Management System (QMS).
- Ensure that all in-house systems and procedures are updated, revised and modified to meet the needs of external certification bodies whilst ensuring simplicity and understanding for their use.
- Update quality documentation and communicate to carry forward lessons learned from quality concerns.

Protak Scientific Limited
Luminox House Holmethorpe Avenue
Redhill | Surrey | UK | RH1 2NL

+44 (1737) 924 900
info@protakscientific.com

- Ensure that all necessary systems and procedures are in place to satisfy all customer requirements and audits.
- Introduce new systems and procedures where appropriate.
- Train others in all aspects of the quality system and application of procedures.
- Undertake regular internal/external process audits of the QMS.
- Ensure corrective actions are undertaken to address non conformities found.
- Verify and ensure timely closure of non-conformities.
- Provide detailed analysis of the QMS KPIs to senior management.
- Ensure ongoing compliance with the Quality Management System (ISO9001).
- Lead Protak Quality Committee meetings ensuring all aspects of the QMS are discussed and any actions are driven to satisfactory completion.
- Identify business improvement opportunities within the organisation.
- Ensure KPIs are met by working to the overall plan, including management of, and reporting.
- Report on achievement of targets and identify any actions required.
- Ensure that the function operates in accordance with any health, safety and environmental policies and procedures to ensure the safety and wellbeing of staff and visitors.
- Embed and ensure suitable risk management processes are in place for the business.

People Management

- Motivate and coach the team to operational success, both in terms of quality delivery and customer satisfaction.
- Monitor the completion of tasks and ensure good performance and record on appropriate systems.
- Consistently promote high standards through personal example and roll out through the team so that each member of the team understands the standards and behaviours expected of them in relation to Quality.
- Review, implement and update company records e.g. training matrices, performance reviews, risk assessments.
- Communicate KPIs from the strategic management plan so that each employee is aware and motivated to be successful.
- Responsible for achieving budget and forecast.
- Relationship Management.
- Develop and maintain strong relationships with internal and external stakeholders to ensure optimal Quality performance.
- Work collaboratively, negotiate and engage with key stakeholders to facilitate delivery and compliance with the Quality strategy.
- Liaise and communicate with other departments, customers, suppliers and other service providers.
- Work as part of the Management team to share ideas and improve operation, recommending, supporting and implementing continuous improvement activities and process and procedure improvements to optimise results and improve quality of delivery, in line with quality standards requirements delivery in line with Company and Customer requirements.
- Communicate with personnel at all levels, internally and externally to Protak, in relation to Quality matters.

PROTAK SCIENTIFIC

Protak Scientific Limited
Luminox House Holmethorpe Avenue
Redhill | Surrey | UK | RH1 2NL

+44 (1737) 924 900
info@protakscientific.com

Self-Management:

- Comply with the Health, Safety and Environmental Policies.
- Proactively contribute to creating a good team atmosphere.
- Anticipates and overcomes obstacles.
- Makes useful links to arrive at insightful plans and solutions.
- Embraces personal challenge.
- Confident, rounded thinking.
- Takes ownership for team cohesion and team development.
- Is self aware.
- Is resilient, optimistic and open to change.
- Has a collaborative approach to others.
- A self-starter, motivated and able to positively motivate others.
- Focused, target driven with a positive, can-do attitude.

Skills and Attributes:

- Excellent influencing skills ensuring content of discussions are factual, thoughtful and conclusion/resolution based.
- Excellent interpersonal skills.
- Ability to manage a variety of cross-functional team members.
- Excellent written, verbal and presentation skills.
- Excellent organisational and follow-up skills.
- Competent in problem solving, team building, planning and decision making.
- Commercially aware.

Qualifications and Experience Levels:

- Relevant pharmaceutical related degree is preferred, or HND, BTec Professional Level 5 Award or equivalent NVQ Level 5 qualifications.
- Significant experience in an aseptic pharmaceutical production / manufacturing environment is key.
- Experience of H_2O_2 gaseous decontamination processes advantageous and desirable.
- Strong knowledge of Pharmaceutical manufacturing/Medial device quality management.
- Experience in conducting QMS related audits. ISO 9001 Lead Auditor Training accreditation Advantageous and desirable.
- Previous experience and involvement in Regulatory Audit control processes (facilitation, hosting and presenting).
- Experience of dealing with customers and suppliers.