Quality Coordinator
Job Description

- Reporting to: Senior Operations Manager
- Ideal start date: September 2021
- Place of work: Office and home based with occasional travel to supplier sites
- Hours: Full or part time. Minimum 3 days per week
- Salary: Circa £35,000 (part-time pro rata)

Overview
Lightpoint Medical is an innovate medical device company dedicated to improving health outcomes for cancer patients through image-guided surgery. The company's products address the pressing medical need for better tools to detect cancer during surgery in order to improve clinical outcomes and reduce healthcare costs. At Lightpoint Medical we're building a world-class team to transform the practice of cancer surgery. We hire dedicated people who want to make a meaningful impact. If you think this is you, join us now.

Lightpoint Medical is recruiting a Quality Coordinator to play a key role in the company's development plans. This will be a full or part-time role, depending on the right candidate.

Reporting to the Head of Operations, the objective of this role is to deliver the Quality agenda for the company, maintain and improve the company quality management system and work closely with the Regulatory Compliance manager covering and maintaining the RA/QA system in accordance with the latest relevant product industry standards.

Key responsibilities will be to maintain the company QMS through effective CAPA management, administer key meetings such as the Management Review and Quality Check-in, conduct internal and supplier audits, participate in external audits, conduct KPI reporting and ensure all training records are maintained and up-to-date. Improve awareness, visibility, and communication on quality initiatives to support assigned quality goals and priorities.

Role Responsibilities:

- Maintain the company QMS, ensure that it is kept up-to-date
- Support the management representative and hold quality review meetings for the management team
- Maintain the QMS in compliance with all relevant regulatory requirements and standards identified as a requirement for the company.
- Managing the CAPA process within the business to ensure that non-conformities are documented, investigated and appropriate action is implemented to prevent recurrence
- Carrying out internal audits and help to identify and implement improvements to the QMS.
- Participate in external audits to maintain the company's relevant certifications and liaise with notified body and regulatory authorities as required.
- Report KPI on current QA and related activities, the effectiveness of the QMS and identify areas for improvement.
- Liaise with appropriate departments in order to implement new and revise to existing procedures.

- Provide training sessions in policies, processes and procedure as required.
- Perform continuous improvement projects, from concept stages to implementation.
- Act as a leader in bringing the 'culture of quality' into medical device development.
- Supply chain quality management; ensuring that all key suppliers are assessed before commencement of supply and, where necessary, carrying out audits prior to use and on a regular ongoing basis to safeguard the quality of purchased materials

Skills experience should include:

- Proficient working to quality management systems ISO 13485 and FDA 21CFR part 820 and part 11.
- Demonstrable knowledge in MDD, IVFDD and MDR.
- Medical Device industry experience, preferably in manufacturing and development of electro-mechanical devices with software.
- Have excellent written and oral communications skills to communicate clearly and effectively with third parties, regulatory authorities and management.
- Proven strengths in attention to detail, analytical ability, understanding and interpreting regulations.
- Ability to plan, prioritise and work in a team.
- An understanding of current EU medical device regulations.
- You will be process driven with a can-do approach to find fitting and effective solutions to move projects forward.

Education and Experience required as a Minimum:
Degree or equivalent.

Reporting Structure:
The Quality Coordinator will report to the Senior Operations Manager.