Job Description
Junior Regulatory Coordinator

- Full-time, permanent position
- Office based in Chesham
- Reporting to Regulatory Compliance Manager
- Salary range: £25,000 - £30,000

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 trailblazing professionals who want to make a meaningful impact. If you think this is you, join us now.

Lightpoint Medical is recruiting a Junior Regulatory Coordinator to play a key role in the company's product development plans.

Reporting to the Regulatory Compliance Manager, the objective of this role is to work closely with the Regulatory Compliance Manager and Quality Coordinator covering and maintaining the RA/QA system in accordance with the latest relevant product industry standards and assisting in the registration of devices with worldwide regulatory and legislative bodies. In addition, working with the Product Development team to perform testing of the systems produced and bring the technical and regulatory documentation through the development process and baseline it in the technical file.

Key responsibilities will be to support the Regulatory Compliance Manager to build the regulatory pathway for individual products and to perform testing on those products, as part of the validation process.

Role Responsibilities:

- Support the Regulatory Compliance Manager to ensure that existing product documentation is maintained and kept up-to-date.
- Prepare reports on product performance in the market including adverse events and produce Post Market Surveillance statistics.
- Set, communicate and train regulatory standards in the company in support of the Regulatory Compliance Manager.
- Maintain product Technical Files, including updating in line with engineering changes and annual reviews. Effectively prepare submissions and regulatory documents.
- Update project documentation registers and work with engineers to ensure documentation is completed/updated.
- Support the Product Development manager in producing product test strategies.
- Create and execute test plans and scripts on the systems being built.

- Research into UKAS accredited laboratories / affiliates to conduct validation testing such as regulatory type testing.
- Work with the Quality Manager, to ensure the company working practices and operating procedures are followed and updated as required.
- Be up to date with changing regulatory requirements and guidelines and update the company with these changes.
- Involvement in design reviews and audits and preparation of the presentations.
- Execute the validation testing of products in development.

Skills experience should include:

- Some experience in development and production test systems.
- Inquisitive, self-motivated and focused.
- Some experience in regulatory affairs or governance in a structured environment.
- An understanding of the full product lifecycle, with a focus on product development.
- Keen to learn, have a good eye for detail and good organisational skills.
- 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.
- Someone who wants to influence their own development.
- Looking for a company where they may broaden their experience and grow with the company.
- 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 Junior Regulatory Coordinator will report to the Regulatory Compliance Manager.

Lightpoint's close-knit and dedicated staff members are welcoming and friendly, and we offer a fast-paced yet flexible working environment. Staff benefits include performance-based tax-advantaged stock options, company pension with matched contributions, income protection and life insurance, annual healthy living allowance, generous holiday policy and flexible working hours.