## JOB PROFILE:

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| **INCUMBENT’S NAME** |  |
| **JOB TITLE** | Regulatory Affairs Specialist, United States, Canada and Mexico |
| **BUSINESS UNIT** | Rayner Surgical Inc. (RSI) |
| **LOCATION** | 100 Park Avenue, New York, NY 10017 |
| **REPORTS TO** | Director, North America |
| **RAYNER**  **KEY OBJECTIVES**  **PURPOSE OF JOB** | Rayner is a leading developer and manufacturer of ophthalmic implants and pharmaceuticals. It specialises in intraocular lenses (IOLs) and related products used in cataract surgery and refractive surgery. Since the development of the first IOL, Rayner has continuously pioneered IOL design with a goal to improve vision and restore sight worldwide. Today, Rayner’s mission remains to deliver innovative and clinically superior ophthalmic solutions that respond to the expectations of our global customers to improve sight and quality of life for their patients.  As a Regulatory Affairs Specialist for RSI, which in the US represents the interests of its sister company; Rayner Intraocular Lenses Limited (RIL), a UK based manufacturer of Class III medical devices, your primary responsibility will be developing, advising on and implementing regulatory and clinical strategic plans with view to meeting Rayner’s primary goal of registering new products on the US market. Secondary responsibilities will include Canada and Mexico.  The role holder will be responsible for providing US specific regulatory advice and support to RSI, RIL, and as required, to the wider Rayner Group and for maintaining and ensuring ongoing compliance with US, Canadian and Mexican regulatory requirements as these apply from time to time under medical device regulation in these jurisdictions. You will be expected to be familiar with the requirements and to ensure that all new and existing processes and procedures whether introduced by RSI or RIL comply with those of the FDA, Health Canada and COFEPRIS.  You will work closely with an established Regulatory Affairs team based in the UK and will be the subject expert within Rayner for your jurisdictions.  This is an excellent opportunity to join a highly innovative business as it builds towards a series of product launches and associated submissions, including IDE and clinical trial. This will be a busy and demanding role and you will be joining at the dynamic start-up in the US of a profitable UK Group with ambitious growth potential, particularly in the US. The right candidate, in what is considered to be a key appointment, will have an excellent opportunity to make a positive impact as the business continues to grow. |
| **KEY ACTIVITIES/**  **ACCOUNTABILITIES**  ***.*** | * To support Rayner in maintaining a state of preparedness for regular review of its Regulatory systems in the US, Canada and Mexico by competent authorities. To ensure ongoing compliance. * To provide expertise on regulatory processes with particular emphasis on those applicable to the US, Canada and Mexico and to be responsible for the regulatory strategy in these markets working closely with the Regulatory team at Rayner’s Group’s headquarters in the UK. * To evaluate risk and provide effective management of and regulatory support for preclinical studies, post market clinical follow-up and clinical studies. To liaise effectively with clinicians and key opinion leaders in the US who may be interested in conducting or engaged in studies of Rayner products. * To lead in the management and preparation of relevant submissions to the relevant authorities including the FDA, negotiating and interacting with those regulatory authorities, clinicians, distributors and other stakeholders to ensure timely submission and approval. * To ensure maintenance of the US, Canada and Mexico regulatory submissions calendar and database of specific product listings, registrations and approvals * To lead in regulatory projects for product development in the three markets and to ensure timely registration and compliance of devices marketed in them. * To work closely with the Regulatory team in the UK in general, and to ensure it has a US appropriate vigilance and post market surveillance systems in place and is maintaining compliance with regulatory and legal obligations with respect to patient safety, as these apply in the US, Canada and Mexico. * To establish and maintain within RSI, appropriate and required regulatory information systems such as technical documentation, quality records, routine reports and regulatory agency communications for regulatory activities. * To provide guidance on the regulations governing the advertisement of medical devices in all three jurisdictions, to review and sign off on advertising, promotional materials, packaging, website and booth materials and labelling to ensure territory specific compliance before release. * To provide regulatory input and appropriate follow-up support to inspections and audits by Notified Bodies and National Competent Authorities. * To keep up to date with developments in regulations and QMS requirements in the three jurisdictions and more generally as appropriate, and to take an active role in bringing relevant matters to the attention of RSI and RIL; to suggest, develop or arrange the development and provision of appropriate training in regulatory and quality assurance matters to US and non-US colleagues as requested or required. * To participate in product development teams and where appropriate to ensure US, Canadian and Mexican regulatory requirements are incorporated into the development process. |
| **KEY BEHAVIOURS & COMPETENCIES** | * Expert in US (Canadian and Mexican) Regulatory Affairs. Knowledge of FDA requirements as these apply to medical devices is essential. * A flexible and pragmatic problem solver. * Innovative and capable of creative and lateral thinking. * Reliable, self-motivated, capable of working without supervision on own initiative. * Ability to work under pressure. * Able to communicate clearly and effectively to fellow employees, external consultants, suppliers and advisers. * Able to understand and implement detailed instructions. * A flexible and pragmatic problem solver. * Able to work as part of a team and across multi-disciplinary teams in different jurisdictions on projects and to represent RSI in the regulatory arena when required. * Strong and confident user of MS Word and Excel. * Time management – able to manage multiple projects and multiple deadlines   ***Act in line with our Company Values:***   * **Ambition:** *We have the drive to continuously improve* * ***Integrity:*** *We are accountable for what we do acting ethically and in the best interests of our customers, patients and stakeholders* * ***Openness: –*** We positively consider new ideas and challenges * ***Respect: -*** We support each other and our customers to succeed |
| **KEY PERFORMANCE INDICATORS** | Based on annual performance objectives and reviews |
| **KEY RELATIONSHIPS** | **Internal:**   * UK based Regulatory Affairs team (Registrations, Vigilance and PMS, Pharmaceutical QARA) * R&D (primarily UK based) * Operations (UK based) * Finance (primarily UK based) * Legal (UK based) * Sales Group wide, US, UK etc * Marketing UK, US, Germany   **External:**   * Regulatory agencies * Notified bodies * National competent authorities * Clinicians * Agents and distributors * End users * Suppliers |

## CANDIDATE PROFILE:

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| **QUALIFICATIONS/ TRAINING** | **Essential:**   * Degree in Science/ Engineering or equivalent professional experience |
| **EXPERIENCE** | **Essential:**   * Proven FDA submissions and regulatory affairs experience * Investigational Device Exemption and regulatory support and submissions related to clinical trial of Class III medical devices * Direct experience of interaction with regulatory authorities (Notified Bodies, Competent Authorities, Government Agencies in North America) * Experience in management of complex medical device regulatory projects in the United States * Solid working knowledge of cGMP, FDA 21 CFR Part 820 Quality Systems Regulation and related regulations * Familiar with Quality System concepts, practices and procedures * Technically literate; from a science, clinical or engineering background * Ability to communicate effectively both in person and in writing * Willingness to engage in some travel particularly in the US and to Europe   **Desirable:**   * Health Canada and COFEPRIS registration submissions experience * Experience working across export markets and dealing with international distributors * Experience in Quality Management in a Regulated Environment |