Job Specification	
JOB TITLE	Regulatory Affairs Specialist
DEPARTMENT	Regulatory Affairs
LOCATION	Berlin
PURPOSE OF ROLE	The purpose of this role is to provide and maintain regulatory support, supply regulatory input and data and ensure compliance with standards and medical device regulations worldwide. This post includes the formal role of "Person Responsible for Regulatory Compliance" for Rayner Surgical GmbH as EU Importer and Authorised Representative for Rayner Intraocular Lenses Limited (as defined by Regulation EU 2017/745, Article 15.6).

KEY ACTIVITIES/ ACCOUNTABILITIES	• Carry out the duties of PRRC as defined in Article 15.6 of EU 2017/745
	• Carry out the duties of AR as defined in Article 14(2) of Directive 92/43/EEC, and Article 11 of Regulation (EU) 2017/745
	• Provide support for registration activity in your assigned geographic region(s) this includes (but is not limited to):
	  ○ Developing registration and launch plans with the regional sales managers to ensure that registration work is under control
	  ○ The preparation and submission of registration dossiers, and their submission and remediation.
	  ○ Establish and maintain regulatory information systems such as technical documentation, quality records, routine reports and regulatory agency communications
	  ○ Interpret existing and/or new regulatory requirements/guidelines and standards as they relate to company products and procedures
	• Ensure compliance to global regulatory requirements and company policies
	• Provide input to Company activities including the risk management process, process and procedure improvements, management review and support new product development activities
	• Review document and product changes for regulatory submission impact
	• Support equipment, system and process development in-house and with suppliers
	• Interface and co-ordinate with regulatory agencies; provide regulatory input and appropriate follow-up support to inspections and audits (e.g. FDA, Notified Bodies etc)
	• Participate on product development teams to ensure regulatory requirements are incorporated into the development process
	• All such other tasks as may be reasonably required to support the activities of the Regulatory Affairs department and the Company

COMPETENCIES	**1) Ambition:** *We have the drive to continuously improve* **2) Integrity:** *We are accountable for what we do acting ethically and in the best interests of our customers, patients and stakeholders* **3) Openness:** *We positively consider new ideas and challenges* **4) Respect:** *We support each other and our customers to succeed* **5) External Awareness:** *Understands and keeps up to date on local, national, and international policies and trends that affect the organization and shape stakeholders' views; is aware of the organisation's impact on the external environment.* **6) Adaptability:** *Adjusts to changing environments whilst maintaining effectiveness* **7) Communication:** *Communicates effectively, listens sensitively, adapts communication to audience and fosters effective communication with others* **8) Decisiveness:** *Makes well-informed, effective, and timely decisions, even when data are limited, or solutions produce unpleasant consequences; perceives the impact and implications of decisions.* **9) Teamwork:** *Contributes fully to the team effort and plays an integral part in the smooth running of teams without necessarily taking the lead* **10) Organisational Awareness:** *Demonstrates an understanding of underlying organisational issues*
PERSON SPECIFICATION	

QUALIFICATIONS/ TRAINING/ EXPERIENCE	**Essential**
	• Fluent in English and German sufficient to be able to provide responses to technical queries in either language to UK and German authorities/agencies (e.g. MHRA, BfArM).
	• 2-3 years' experience in a Regulatory role in a medical devices company – including direct interaction with regulatory authorities (Notified Bodies, Competent Authorities, Government Agencies etc.)
	• Either:
	  ○ a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;
	  ○ four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.
	• Familiar with Quality System concepts, practices and procedures (e.g. ISO 13485, MDSAP)
	• Familiar with the Medical Device Directive and Medical Device Regulation
	Desirable
	• Experience working across export markets and dealing with international distributors
	• Familiar with databases and business management systems (ERP)
	• Registration experience in non-EEA countries in Europe

Please apply by sending an up-to-date CV & covering email to recruitment@rayner.com