## JOB DESCRIPTION

**JOB SPECIFICATION**

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| **EMPLOYEE NAME** |  |
| **JOB TITLE** | QARA Manager – Pharmaceutical |
| **GRADE** | R3 |
| **DEPARTMENT** | RA |
| **LOCATION** | Worthing |
| **LINE MANAGER** | Head of Regulatory Affairs |
| **PURPOSE OF ROLE** | * This is a role with responsibility covering General Medicines (prescription) products, working on Life Cycle Management (renewals/variations) in the European markets, with opportunities to learn/support Pre-Approval applications (includes Clinical Trial Applications).
* Key Objectives
	+ Ensure that the company systems support and maintain compliance with GDP
	+ Ensure all product dossiers are created and maintained
	+ Project lead on Falsified Medicines Directive
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| **KEY ACTIVITIES/****ACCOUNTABILITIES** | Key Activities:* Ensure all GDP activities are fully compliant with regulations and Wholesaler dealing licence is retained.
* Undertake the role of Responsible Person (RP) as defined by the guidelines on GDP practice of medicinal products (2013/C 343/01)
* To ensure that the operations team fully support the wider business through organising resources and processes and the quality of medicines and medical devices are supplied.
* Ensure Rayner Pharmaceuticals is fully compliant with all relevant EU, FDA, and National Quality regulations. These include ECGMP Directive (2003/94/EC), the related EEC-GMP-Guide (Eudralex Volume IV) as well as all appertaining EC guidelines and (ICH) as required.
* Keep the Leadership Team of Rayner informed of any supply or serious Quality or Safety issues.
* Lead due diligence for Rayner Pharmaceuticals on new product opportunities in the areas of Medical, Regulatory, and Quality and to provide support to the Leadership Team in other areas.
* Lead non-clinical product development activities for Rayner Pharmaceuticals.
* Manage medical affairs activities, including supervising our Pharmacovigilance consultant.
* Ensure regulatory filings and approvals delivered to agreed timescales.
* Manage third party vendor relationships in the Regulatory, Medical Affairs, Quality, and Pharmacovigilance areas.
* The ability to participate in some multi-day travel to key suppliers and professional meetings (in the UK and overseas)

Key AccountabilitiesInternal* Rayner Leadership Team
* Commercial and Marketing Departments
* Supply Chain Manager
* Regulatory Affairs and Quality Departments

External* Third Party Vendors and Consultants
* Regulatory Authorities
* Manufacturing Supply Chain Partners
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| **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. **Flexibility:** *Modifies his or her approach to achieve a goal. Is open to change and new information; rapidly adapts to new information, changing conditions, or unexpected obstacles.*
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. **Creativity and Innovation:** *Develops new insights into situations; questions conventional approaches; encourages new ideas and innovations; designs and implements new or cutting-edge programs/processes.*
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## PERSON SPECIFICATION

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| **QUALIFICATIONS/ TRAINING/ EXPERIENCE** | Essential:* Registered with MHRA as a Responsible Person for WDA(H)
* Life Science degree or equivalent professional qualification.
* Thorough understanding of the manufacture, testing and quality assurance of sterile products.
* Direct experience in a similar role, covering the creation, maintenance and submission of pharmaceutical registration documents.

Desirable:* Experience as a Quality System leader in the pharmaceutical industry.
* Demonstrable knowledge of the regulatory environment relating to the manufacture of sterile.
* Experience of sterile pharmaceutical products.
* Experience of ophthalmic products is desirable but not essential.
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