JOB DESCRIPTION	
JOB DESCRIPTION CREATION DATE	March 2021
POSITION:	**Quality Assurance Officer**
BUSINESS UNIT:	Pharma Services Ireland
LOCATION:	Dundalk, Ireland
REPORTING TO:	**Quality Assurance Team Leader**
RESPONSIBLE FOR (PEOPLE):	N/A

OVERALL ROLE OBJECTIVE:

To work as part of the Quality Assurance team at Almac Pharma Service's Ireland facility in Dundalk, Ireland. The post holder will support the Pharmaceutical Quality System (PQS) and verify the adherence of manufactured products for human use, in line with current Good Manufacturing Practice (cGMP).

JOB SPECIFIC RESPONSIBILITIES:

The following is a non-exhaustive list of responsibilities:

1. Utilise a broad understanding of cGMP to provide QA support, mentoring and coaching for Operations, Analytical, Logistics and Engineering departments to assure that activities are undertaken in compliance with cGMP and Almac procedures, as appropriate.

2. Provide quality assurance support/advice to operational departments in support of new and existing projects and products. This will involve interaction with internal and external customers to achieve required timelines while maintaining product quality and compliance.

3. Internal/external contact for queries related to product compliance and quality

4. Play an active part in the development of the Pharmaceutical Quality System (PQS) by constructively challenging deficiencies and inefficiencies.

5. Collate and review data to be used in reports, investigations, key performance indicators (KPIs) and other quality indicating metrics.

6. Conduct internal audits as per the approved schedule to detect process and procedural deficiencies. Support the affected areas to ensure appropriate corrective and preventive actions (CAPAs) are undertaken to correct any observations.

7. Assist and participate in audits of external suppliers, as well as assist in hosting customer and regulatory audits as required

8. Participate in the Supplier Management Process to assure that materials are appropriate for pharmaceutical manufacturing

9. Aid as necessary, the life cycle of PQS documentation, such as Deviations, Change Controls, Suspect Analytical Results, Risk Assessments, Technical Agreements, Procedures, Generation, approval and training of new/revised procedures etc.

10. Assist in the compilation and review of Product Quality Reviews/ Annual Product Reviews, as appropriate.

11. Undertake the review and approval (pre and post-execution) of Master Batch Records (MBRs) and any associated supporting documentation, (such as stability and validation documentation, generation/updating of supply chain maps, compliance dossiers etc), prior to final assessment by a Qualified Person (QP).

12. Communicate with internal and external stakeholders regarding projects, products, complaints and other quality related topics, building relationships and trust.

13. Monitor and contribute to GMP compliance and Quality of manufactured and released pharmaceutical products

14. Additional duties related to the assurance of GMP compliance and quality of manufactured and released pharmaceutical products, may also be assigned.

This role may occasionally require coverage beyond normal working hours and infrequent travel. It is a condition of employment that you would be able to fulfil these requirements.

QUALITY SPECIFIC RESPONSIBILITIES:

Almac Pharma Services' Quality Mission;
To operate within a quality excellence framework that is both efficient and effective and continually assures safe and efficacious product to the patient.

The post holder will, support the quality mission of the business by:

1. Ensuring exceptional and reliable quality in all aspects of work and recognising that quality determines the extent of success.

2. Engaging with the Pharmaceutical Quality System to ensure that quality records are completed accurately and proactively managed in line with committed timelines. Quality performance against set targets is a key goal and aligns with business objectives.

3. Actively contributing to the Quality Vision outlined by the Senior Management Team of reducing the gap between "where we are today" versus "where we want to be today".

GENERAL ROLE RESPONSIBILITIES:

Quality	Ensure GMP is adhered to in all areas of work.
Health & Safety	Understand Company's Health & Safety Policy and follow all company HSE procedures. Report all accidents or any unsafe conditions in the work place.
Training and Development	Ensure training has been received before undertaking specific duties and that all training is recorded in training records.
Human Resource Management	Adhere to all HR policies and procedures, to include all absence policies and procedures.
Communication	Communicate within your own department to ensure that all relevant information is forwarded to the appropriate personnel on a regular and timely basis. Provide regular updates to your line manager regarding progress on required duties and the status of any projects.
Equal Opportunities	Observe and adhere to the company's Equal Opportunities and Dignity at Work policies ensuring that a neutral and harmonious work environment is maintained in which bullying and/or harassment does not occur.
Core Competency Framework	Ensure that all job specific responsibilities relating to the overall role objective are carried out in accordance with the requirements outlined within the Almac core competency framework.

By signing this Job Description, I accept that I have received and read the Job Description and have accepted the responsibilities identified therein.	
EMPLOYEE'S SIGNATURE:	
PRINT NAME:	
DATE:	

This job description should not be regarded as conclusive or definitive. It is a guideline within which the individual jobholder works. It is not intended to be rigid or inflexible and may alter as the Company's strategic direction changes.

PERSON SPECIFICATION

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	ESSENTIAL REQUIREMENT	DESIRABLE REQUIREMENT	ASSESSMENT METHOD
QUALIFICATIONS	**Bachelor's degree (or equivalent) in a scientific or technical discipline or relevant equivalent experience in a GxP Quality Assurance role**		Application Form & Documentation
EXPERIENCE	Worked within a pharmaceutical / GxP environment in a Quality related role Writing and producing scientific reports	Demonstrated knowledge of / familiarity with packaging processes used across multiple dosage forms Management of electronic & physical documentation systems	Application Form & Interview
KEY SKILLS	Effective communication skills (both written and oral) Proficiency in the use of IT applications (Word, Excel, Outlook, Project, PowerPoint etc) Excellent attention to detail Proven ability to work effectively on own initiative as well as contributing to the team environment	Proven ability to plan and prioritise workload	Psychometric Testing and/or Interview

ALMAC CORE COMPETENCIES

COMPETENCY	BEHAVIOUR	ASSESSMENT METHOD
RESULTS DELIVERY	Delivers results on time, within constraints and in line with company policy and procedure and organisational strategy. Demonstrates a continuous drive for quality and a commitment to excellence.	Interview
PROACTIVE SOLUTIONS	Analyses and uses experience and logical methods to make sound decisions which solve difficult problems. Seeks practical/workable and innovative methods to deliver solutions.	Interview
LEADS BY EXAMPLE	Promotes a clear vision and mission. Acts as a positive role model for the organisation, fostering a climate of teamwork and development.	Interview
COMMUNICATION	Communicates clearly and effectively. Promotes the exchange of ideas and information across the organisation. Fosters dialogue to ensure everyone understands what is going on.	Interview
CUSTOMER FOCUS	Strives to exceed the expectations and requirements of internal and external customer; acts with customers in mind and values the importance of providing high-quality customer service.	Interview
JOB SPECIFIC KNOWLEDGE	Demonstrates required job knowledge and understanding to successfully and competently fulfill or exceed the requirements of their post. Follows correct procedures and guidelines (SOPs). Proactively demonstrates a desire to enhance and develop their job knowledge.	Interview