



JOB DESCRIPTION

JOB DESCRIPTION CREATION DATE:	March 2021
POSITION:	PS CR Product Quality Auditor
BUSINESS UNIT:	Almac Pharma Services
LOCATION:	Craigavon
REPORTING TO:	PS CR Product Quality Team Leader
RESPONSIBLE FOR (PEOPLE):	N/A

OVERALL ROLE OBJECTIVE:

The post holder will work as part of the Product Quality Team responsible for review of batch records prior to QP certification and release.

JOB SPECIFIC RESPONSIBILITIES:

1. Review of Pharma manufacturing and packaging batch records pertaining to commercial and clinical operations for GMP compliance.
2. Preparation of the batch disposition pack to support QP certification, including the appraisal of any deviations or changes impacting GMP compliance.
3. Support Product Quality department objectives in relation to the delivery of batches in line with OTIF timelines, including performing the associated electronic transactions required to generate KPI data.
4. Ensure customer requirements for batch release are met in relation to Promise Date, escalate any anticipated issues in meeting these timelines to the Product Quality Team Leader and log constraints as required.
5. Respond to queries from internal and external customers in an accurate, timely and professional manner.
6. Perform data verification for internal data repositories.
7. Additional duties related to the assurance of GMP compliance and quality of manufactured and released pharmaceutical products, may also be assigned.
8. Contribute to and support continuous improvement initiatives within the Product Quality department.
9. Conduct administrative duties associated with the position as necessary.

This role may require coverage beyond normal working hours as required. It is a condition of your employment that you are able to fulfil this requirement of the role.

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	5 GCSEs (or equivalent) at Grade C or above including English Language and Maths 3 'A' Levels (or equivalent)	Level 5 Qualification	Application Form & Documentation
EXPERIENCE	Previous experience working within an established Quality System (e.g. GMP, ISO)	Previous experience in review/auditing of GMP records Previous experience working within a pharmaceutical manufacturing environment	Application Form
KEY SKILLS	Effective communication skills (both written and oral) Proficiency in 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 effectively contributing to the team environment		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